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# **Towards a Framework Convention on Global Health: A Transformative Agenda for Global Health Justice<sup>†</sup>**

**Lawrence O. Gostin<sup>\*</sup> & Eric A. Friedman<sup>\*\*</sup>**

## **ABSTRACT:**

Global health inequities cause nearly 20 million deaths annually, mostly among the world's poor. Yet international law currently does little to reduce the massive inequalities that underlie these deaths. This Article offers the first systematic account of the goals and justifications, normative foundations, and potential construction of a proposed new global health treaty, a Framework Convention on Global Health (FCGH), grounded in the human right to health. Already endorsed by the United Nations Secretary-General, the FCGH would reimagine global governance for health, offering a new, post-Millennium Development Goals vision. A global coalition of civil society and academics has formed the Joint Action and Learning Initiative on National and Global Responsibilities for Health (JALI) to advance the FCGH.

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<sup>†</sup> Professor Lawrence O. Gostin and Mr. Eric A. Friedman are members of the Steering Committee of the Joint Action and Learning Initiative on National and Global Responsibilities for Health (JALI). JALI is an international campaign, comprised of civil society and academic leaders, from the global South and North, dedicated to establishing a Framework Convention on Global Health. This framework convention would serve as a historic, innovative treaty on global health equity. See JOINT ACTION AND LEARNING INITIATIVE ON NATIONAL AND GLOBAL RESPONSIBILITIES FOR HEALTH, <http://www.jalihealth.org> (last visited Nov. 29, 2012). This Article offers the first detailed account of the treaty's mission, norms, and processes, together with a systematic justification for a radically new form of global governance for health. The authors thank current and former members of the JALI Steering Committee: Adila Hassim (SECTION27, South Africa), Anand Grover (Lawyers Collective), Armando De Negri (World Social Forum on Health and Social Security, Brazil), Attiya Waris (University of Nairobi/Tax Justice Network), Devi Sridhar (Oxford University, United Kingdom), Gorik Ooms (Hélène De Beir Foundation, Belgium), Harald Siem (Norwegian Directorate of Health), Mark Heywood (SECTION27, South Africa), Mayowa Joel (Communication for Development Centre, Nigeria), Moses Mulumba (Center for Health, Human Rights and Development, Uganda), Shiba Phurailatpam (Asia Pacific Network of People Living with HIV/AIDS), Thomas Gebauer (Medico International, Germany), and Tim Evans (BRAC University, Bangladesh).

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## INTRODUCTION

Consider two children—one born in sub-Saharan Africa and the other in a developed region, such as Europe or North America. The African child is fifteen times more likely to die in her first five years of life. If she lives to childbearing age, she is nearly one-hundred times more likely to die in labor. Overall, she can expect to die twenty-six years earlier than a child born into a wealthy part of the world.<sup>1</sup> Collectively, the vast inequalities between richer and poorer countries as well as the inequalities among people within poorer countries translate into nearly 20 million deaths every year—and have for at least the past two decades. These disparities in health represent approximately one-third of global deaths, not including deaths related to inequalities within high-income countries.<sup>2</sup>

The persistence of such an unconscionable level of avoidable deaths reveals the single greatest gap in international law. In general, there is a dearth of international law addressing the most fundamental issue of life and death. Some international legal regimes, such as trade and investment treaties, negligibly influence or even harm health.<sup>3</sup> Others, such as environmental, refugee, and labor

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1 *Human Development Report 2011*, U.N. DEV. PROGRAMME 130 (2011), [http://hdr.undp.org/en/media/HDR\\_2011\\_EN\\_Complete.pdf](http://hdr.undp.org/en/media/HDR_2011_EN_Complete.pdf); *Levels & Trends in Child Mortality: Report 2012*, UNICEF 9 (2012), [http://www.unicef.org/media/files/UNICEF\\_2012\\_IGME\\_child\\_mortality\\_report.pdf](http://www.unicef.org/media/files/UNICEF_2012_IGME_child_mortality_report.pdf) (last visited Nov. 29, 2012); *Trends in Maternal Mortality: 1990 to 2010*, WORLD HEALTH ORG. 19 (2012), [http://whqlibdoc.who.int/publications/2012/9789241503631\\_eng.pdf](http://whqlibdoc.who.int/publications/2012/9789241503631_eng.pdf).

The life expectancy at birth in the 47 countries that score highest on the UNDP's Human Development Index is 80.0 years, compared to 54.4 years in sub-Saharan Africa. *Human Development Report*, *supra*.

2 Juan Garay, *Global Health (GH) = GH Equity = GH Justice = Global Social Justice: The Opportunities of Joining EU and US Forces Together*, NEWSL. EUR. UNION EXCELLENCE U.C. BERKELEY (Winter 2012), <http://eucenter.berkeley.edu/newsletter/winter12/garay.html>. The figure derives from the difference in death rates between high-income countries and other regions of the world.

3 See, e.g., Panel Report, *United States—Measures Affecting the Production and Sale of Clove Cigarettes*, WT/DS406/R (Sept. 2, 2011) (holding that the United States' ban on clove cigarettes violated the non-discrimination principle of article 2.1 of the Agreement on Technical Barriers to Trade, even though it was a valid public health measure). Tobacco industry giant Philip Morris, meanwhile, has brought separate suits against Uruguay and Australia under bilateral investment treaties. The company is claiming that Uruguay breached its obligations to protect Philip Morris' trademark rights under a bilateral investment treaty with Switzerland. Uruguayan regulations, implemented in 2009, require graphic warning labels that cover 80% of cigarette packages and limit the number of cigarette varieties a brand can sell. Meanwhile, Philip Morris asserts that Australia's new packaging legislation, requiring cigarettes to have graphic health warnings and standardized designs, breaches Australia's bilateral investment treaty with Hong Kong by expropriating company investments and intellectual property without compensation. *Philip Morris Brand Sàrl (Switz.), Philip Morris Prods. S.A. (Switz.) and Abal Hermanos S.A. (Uru.) v. Oriental Republic of Uru.*, ICSID Case No. ARB/10/7 (ongoing arbitration); *Bilateral Treatment Treaty Claim, Uruguay*, PHILIP MORRIS INT'L (Oct. 5, 2010), [http://www.pmi.com/eng/media\\_center/company\\_statements/Pages/uruguay\\_bit\\_claim.aspx](http://www.pmi.com/eng/media_center/company_statements/Pages/uruguay_bit_claim.aspx); *Philip Morris Sues Australia Over Cigarette Packaging*, BBC NEWS (Nov. 21, 2011), <http://www.bbc.co.uk/news/world-asia-15815311>;



law, improve health and save lives in less-developed countries, but their impact is marginal relative to the large magnitude of these deaths.

Several international law regimes, however, could play a greater role in combating health inequities. Humanitarian law espouses the chief goal of protecting the lives of non-combatants. Because most of today's wars occur in poorer countries, this body of law could reduce global health inequities. Recently enacted arms control treaties, such as the Mine Ban Treaty,<sup>4</sup> as well as treaties currently being negotiated, like the Arms Trade Treaty,<sup>5</sup> will prove most beneficial to developing countries. Nonetheless, humanitarian law does not impact global health inequities in most nations, which do not fall into the narrow set of countries facing large-scale armed conflict. And even within this limited set of countries, notoriously poor compliance with these international agreements limits the impact of humanitarian protection of non-combatants, such as can be witnessed in the genocide in Sudan, the massive shelling of civilians in Sri Lanka, or the violence of the Burmese military against ethnic minorities.<sup>6</sup>

The closest legal regime to addressing these health inequities is human rights law. Yet even this regime, which asserts the rights to health and an adequate standard of living, has yet to be adequately developed and enforced. As a result, it cannot easily translate its norms into wide-scale practices sufficient to avert the large numbers of deaths resulting from health inequities. Along with poor adherence, the fact that international action is only weakly addressed in human rights law poses a critical challenge for tackling these inequities.<sup>7</sup> Although this Article will later discuss the potential for human rights law to form the basis of a global health agreement to reduce health inequities, at present, it suffices to note that even the explicit commitment of human rights law to health

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Windsor Genova, *Philip Morris Files Arbitration Case Vs. Australia Over Plain-Packaging Law*, INT'L BUS. TIMES (Nov. 22, 2011).

4 Convention on the Prohibition of the Use, Stockpiling, Production and Transfer of Anti-Personnel Mines and on their Destruction, Sept. 18, 1997, 36 I.L.M. 1507 [hereinafter *Mine Ban Treaty*] (entered into force Mar. 1, 1999).

5 *Towards an Arms Trade Treaty*, U.N. OFFICE FOR DISARMAMENT AFFAIRS, <http://www.un.org/disarmament/convarms/ArmsTradeTreaty/> (last visited Dec. 1, 2011).

6 See, e.g., Lydia Polgreen, *U.N. Panel Says Sri Lanka Attacked Civilians Near End of War on Rebels*, N.Y. TIMES (Apr. 19, 2011), available at <http://www.nytimes.com/2011/04/19/world/asia/19lanka.html>; Marlise Simons et al., *Arrest Is Sought of Sudan Leader in Genocide Case*, N.Y. TIMES (July 15, 2008), <http://www.nytimes.com/2008/07/15/world/africa/15sudan.html>; Edward Wong, *An Ethnic War is Rekindled in Myanmar*, N.Y. TIMES (Jan. 20, 2012), <http://www.nytimes.com/2012/01/20/world/asia/ethnic-war-with-kachin-intensifies-in-myanmar-jeopardizing-united-states-ties.html>.

7 A group of human rights experts have sought to clarify extraterritorial obligations. *Maastricht Principles on Extraterritorial Obligations of States in the area of Economic, Social and Cultural Rights* (2011), [http://www.humanrights.ch/upload/pdf/120111\\_Maastricht\\_ETO\\_Principles\\_-\\_FINAL.pdf](http://www.humanrights.ch/upload/pdf/120111_Maastricht_ETO_Principles_-_FINAL.pdf) [hereinafter *Maastricht Principles*]. While an important advance, even these principles, interpreting existing law, provide little guidance on such critical questions of the level of international assistance states are obliged to provide.

is insufficient to prevent the majority of these avoidable deaths.

Very few international law regimes are directed primarily toward the main causes of avoidable sickness, injury, and premature death. The two major World Health Organization (WHO) treaties—the International Health Regulations (IHR)<sup>8</sup> and the Framework Convention on Tobacco Control (FCTC)<sup>9</sup>—have the potential to save millions of lives. The IHR is devoted to public health emergencies of international concern, such as a novel strand of influenza. This treaty, however, does not reach the major causes of illness and premature death, such as enduring infectious diseases (e.g., AIDS, malaria, and tuberculosis) or chronic non-communicable diseases (e.g., cancer, cardiovascular disease, diabetes, and respiratory disease). The FCTC's focus on tobacco use is certainly directed towards a major cause of preventable illnesses and death. Yet, it uniquely benefits from the nearly universal aversion to unethical tobacco company practices. Moreover, both treaties lack strong accountability regimes and robust mechanisms that would be necessary for effectively enhancing the capacities of developing countries to respond to public health emergencies and enforce tobacco control measures.

Aside from international health law, including the WHO's constitution, international regimes are remarkable primarily for their silence on matters of population health and safety. It is not that international law is powerless to improve human health and well-being. Wealthier countries with strong public health regulation have made considerable progress over the past several decades in reducing child and maternal mortality and combating AIDS and malaria.<sup>10</sup> Concerted national and international efforts have led to significant declines in maternal and child deaths and have brought life-saving medicine to millions of people living with HIV/AIDS.<sup>11</sup> These experiences confirm that societal action—either influenced or directed through law—can dramatically reduce illness, suffering, and premature death. International law has significant, yet largely untapped, potential to extend the benefits of good health to people in all countries, with dramatic improvements in health for those who live in the poorest countries and communities.

This Article offers an innovative framework for clarifying national and

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8 WHO, *Revision of the International Health Regulations*, WHA Doc. WHA58.3 (May 23, 2005).

9 WHO Framework Convention on Tobacco Control, Feb. 27, 2005, 2302 U.N.T.S. 166 [hereinafter F.C.T.C.], available at [http://www.who.int/fctc/signatories\\_parties/en/index.html](http://www.who.int/fctc/signatories_parties/en/index.html).

10 See generally LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT* (2d ed. 2008).

11 Maternal deaths fell from 543,000 in 1990 to 287,000 in 2010 and child deaths from 12 million in 1990 to 6.9 million in 2010. *Levels and Trends in Child Mortality*, *supra* note 1, at 9; *Trends in Maternal Mortality*, *supra* note 1, at 25. More than 8 million people in low- and middle-income countries were receiving AIDS treatment by the end of 2011. *Together We Will End AIDS*, UNAIDS 18 (2012), [http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/20120718\\_togetherwewillendaids\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/20120718_togetherwewillendaids_en.pdf).

global responsibilities to ensure the right to health by reducing global and national health inequities. It explains a proposal to codify these obligations and create accountability for their effective implementation by describing the potential for a new legal instrument--a Framework Convention on Global Health (FCGH).<sup>12</sup> Our goal is to show the potential of international law to markedly transform prospects for good health, particularly for the world's most disadvantaged people.

Part I begins by describing the major causes of injury, disease, and premature death and demonstrating their disproportionately high levels among the poor--both globally and nationally. Part II then discusses extant global health law and governance: the rules, norms, institutions, and processes that shape the health of the world's population. It explains why current global health governance is deeply inadequate to the task of resolving these inequities.<sup>13</sup> Section I.A lays out seven challenges of global governance for health that underlie this inadequacy. The main purpose of the FCGH would be to reshape global governance for health to redress the unequal burdens of suffering, disease, and early death among the world's poor.

Next, Part III argues that human rights law is the best conceptual and practical framework to underpin the international community's solution to these health inequities by reconceptualizing health aid as a protection of the essential human right, rather than the provision of charity. To be sure, human rights law has significant structural flaws. It lacks hard standards or effective compliance mechanisms and relies on the vague "progressive realization" principle behind socioeconomic rights.<sup>14</sup> Nevertheless, human rights law is uniquely positioned to

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12 In this Article, we develop the idea of a Framework Convention on Global Health (FCGH) originally proposed in 2008, discussing in detail the elements of such a treaty as well as its value to national and global health. See Lawrence O. Gostin, *Meeting Basic Survival Needs of The World's Least Healthy People: Toward a Framework Convention on Global Health*, 96 GEO L.J. 331 (2008) [hereinafter *Meeting Basic Survival Needs*]. Since 2010, the Joint Action and Learning Initiative on National and Global Responsibilities for Health (JALI) has advanced the Convention as a realistic global health strategy. See Lawrence O. Gostin et al., *The Joint Action and Learning Initiative: Towards a Global Agreement on National and Global Responsibilities for Health*, 8 PLOS MED. E1001031 (May 2011) [hereinafter *Joint Action and Learning Initiative*]; Lawrence O. Gostin et al., *The Joint Action and Learning Initiative on National and Global Responsibilities for Health*, World Health Report, WORLD HEALTH ORG. (2010), [http://www.who.int/entity/healthsystems/topics/financing/healthreport/JALI\\_No53.pdf](http://www.who.int/entity/healthsystems/topics/financing/healthreport/JALI_No53.pdf) [hereinafter *JALI World Health Report Background Paper*]; Lawrence O. Gostin et al., *National and Global Responsibilities for Health*, 88 BULL. WORLD HEALTH ORG. 719 (2010) [hereinafter *National and Global Responsibilities for Health*], available at <http://www.who.int/bulletin/volumes/88/10/10-082636/en/>; see also Lawrence O. Gostin, *Redressing the Unconscionable Health Gap: A Global Plan for Justice*, 4 HARV. L. & POL'Y REV. 271 (2010) (proposing a voluntary compact among states and partners in civil society, philanthropy, and business to reduce global health inequities).

13 See generally LAWRENCE O. GOSTIN, *GLOBAL HEALTH LAW: INTERNATIONAL LAW, GLOBAL INSTITUTIONS, AND WORLD HEALTH* (forthcoming 2013).

14 *JALI/Framework Convention on Global Health: Preliminary Answers to 5 Priority Questions*, JOINT ACTION & LEARNING INITIATIVE ON NAT'L & GLOBAL RESPS. FOR HEALTH (2012),

advance global health justice, given its universal acceptance, along with its emphasis on equality and accountability.

Part IV explores four fundamental questions to clarify national and international responsibilities under the human right to health and offers preliminary answers to these questions.<sup>15</sup> These questions define the future of global health:

(1) *What are the health services and goods guaranteed to every human being under the right to health?* We will argue that everyone is entitled to the conditions required to be healthy. This entails well-functioning health systems, underlying determinants of health such as nutritious food, clean water, and adequate sanitation, and broader socioeconomic determinants of health, such as employment and gender equity.

(2) *What do states owe for the health of their own populations?* States must allocate adequate funding to health. The critical question is how much. They must simultaneously maintain good governance and a focus on equity to ensure that these funds are used properly.

(3) *What responsibility do states have for improving the health of people beyond their borders?* We argue that general principles related to international cooperation and assistance must be more robust. More precise funding requirements should be based on a shared responsibility to achieving human rights and directly assuring everyone healthy conditions, with an emphasis on the least well-off. Beyond funding, states must articulate coherent policies regarding the right to health, such that actions outside the health sector do not undermine the right to health.

(4) *What kind of global governance mechanisms are required to guarantee that all states live up to their mutual responsibilities to provide health goods and services to all people?* Governance mechanisms will need to embody principles of the right to health, such as equity and accountability, while addressing problems such as poor coordination, unpredictable funding, lack of enforcement, and inadequate global health leadership in other legal regimes. We will propose some possibilities to overcome these challenges.

The answers to these four questions promise markedly improved health outcomes and reduced health inequalities, which will occur if all people enjoy the conditions required to be healthy. Such a world can be ours if states meet their responsibilities both to their own populations and to people beyond national borders, with governance structures designed to hold states accountable to meeting their responsibilities and facilitating their ability to do so. Finally, we explain the idea of the FCGH, showing how it could drive national and global

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<http://www.jalihealth.org/>.

<sup>15</sup> These questions were developed at a meeting in Oslo, Norway, in March 2010, hosted by the Norwegian Directorate of Health. At this meeting, JALI was formed and attendees were called to explore the idea of an FCGH.

policies with respect to these four questions. The Convention would establish the norms, monitoring, and accountability necessary to improve health for all and significantly narrow health inequities.

## I. THE IMPOVERISHED STATE OF WORLD HEALTH

Basic human needs continue to go unmet for the world's poorest people. In 2010, 780 million people lacked access to clean water and 2.5 billion people were without access to proper sanitation facilities, while approximately 870 million people faced chronic hunger.<sup>16</sup> Despite United Nations' Millennium Development Goal (MDG) pledges to enable more people to meet these basic needs, these statistics represent more hungry people than in the 1990 benchmark year of the MDGs. (Although, the proportion of people suffering from hunger has decreased very modestly.)<sup>17</sup>

Even with notable health improvements in a number of areas in the past several decades, deep inequities—unfair inequalities<sup>18</sup>—and millions of preventable deaths persist. The depth of inequity is two-fold, with overwhelming numbers of preventable deaths in poorer countries and the poor and marginalized within these countries suffering most. With the happenstance of one's birth still the greatest determinant of health, the current state of the world is one of deep global health injustice.

### A. Child and Maternal Health

Progress in reducing child and maternal deaths over the past decades has been significant. But with millions of preventable deaths that continue to occur annually—overwhelmingly in poorer countries—such progress is still deeply inadequate. Since 1970, the mortality rate for children under five has declined by

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16 *Progress on Drinking Water and Sanitation: 2012 Update*, WORLD HEALTH ORG. (2012), [http://www.who.int/water\\_sanitation\\_health/publications/2012/jmp\\_report/en/index.html](http://www.who.int/water_sanitation_health/publications/2012/jmp_report/en/index.html); *The State of Food Insecurity in the World 2012*, FOOD & AGRIC. ORG. (2012), <http://www.fao.org/docrep/016/i3027e/i3027e.pdf> (providing projects for 2010-2012).

17 In 1990-1992, the Millennium Development Goal on halving the proportion of people suffering from hunger by 2015 used the official baseline measurement of 828 million people suffering from hunger. U.N., *THE MILLENNIUM DEVELOPMENT GOALS REPORT 2011*, at 11 (2011), available at [http://www.un.org/millenniumgoals/11\\_MDG%20Report\\_EN.pdf](http://www.un.org/millenniumgoals/11_MDG%20Report_EN.pdf).

18 Health inequities are unfair differences in health. For example, some people have better health than others because of different socioeconomic positions. We use the term "inequity," rather than "inequality," because lack of full health equality might not be unfair. Consider, for instance, the case when hospitals are not as close to people in far-flung rural areas compared to those individuals who live in urban areas. Moreover, ending health disparities might not always be medically feasible. For example, there are differences in life expectancy for people born healthy compared to those born with certain severe genetic illnesses. For more on the meaning of health equity, see Paula Braveman & Sofia Gruskin, *Defining Equity in Health*, 57 J. EPIDEMIOLOGY & COMMUNITY HEALTH 254 (2003).

60%;<sup>19</sup> yet too many parents still grieve over undersized coffins. Nearly 7 million children under the age of five died in 2011, including almost 3 million in their first month of life.<sup>20</sup> There are gaping inequities: 33.9% of child mortality occurs in Southern Asia and 48.7% occurs in sub-Saharan Africa, while only 1.4% of deaths occur in high-income countries.<sup>21</sup> Relatively simple and inexpensive interventions such as child nutrition, clean water, basic medications and treatments, and vector control<sup>22</sup> would avert most of these deaths.

Like their children, mothers too face intolerable risks, including the risk of dying in childbirth. Maternal mortality has dropped, from 543,000 in 1990 to 287,000 in 2010. However, the improvements mask extreme variations across and within countries and regions. The overwhelming majority of these deaths—around 99%—occur in developing countries,<sup>23</sup> where there are vast inequalities of access to obstetric care within countries. In Southern Asia, for example, women in the top wealth quintile are almost five times more likely to be attended by a skilled health worker than women in the poorest quintile.<sup>24</sup>

The aggregate improvements are largely attributable to skilled childbirth attendants and emergency obstetric services; coverage has increased in many countries, thanks to growing funds and greater understanding of what it takes to save mothers' lives.<sup>25</sup> Skilled birth attendants with back-up care, as well as

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19 Julie Knoll Rajaratnam et al., *Neonatal, Postneonatal, Childhood, and Under-5 Mortality for 187 Countries, 1970-2010: A Systematic Analysis of Progress Towards Millennium Development Goal 4*, 375 LANCET 1988 (2010).

20 See *Levels and Trends in Child Mortality*, *supra* note 1, at 9 (reporting 6.9 million deaths of children under 5 in 2011); *id.* at 12 (reporting nearly 3.0 million neonatal deaths). Infections, complications from premature birth, and asphyxia are the main causes of death for children who die in their first month. Overall, infectious diseases, including pneumonia, diarrheal diseases, and malaria, are responsible for approximately two-thirds of deaths of children. Robert E. Black et al., *Global, Regional, and National Causes of Child Mortality in 2008: A Systematic Analysis*, 375 LANCET 1969 (2010).

21 See *Levels and Trends in Child Mortality*, *supra* note 1, at 10. Our use of country income groupings—high-, middle-, and low-income—is based on World Bank classifications. See *Country and Lending Groups*, WORLD BANK, <http://data.worldbank.org/about/country-classifications/country-and-lending-groups> (last visited Nov. 29, 2012).

22 Vector control refers to methods to reduce disease-carrying animals ("vectors"), such as mosquitoes.

23 *Trends in Maternal Mortality*, *supra* note 1, at 19. For every maternal death, approximately twenty to thirty women suffer severe complications from pregnancy and childbirth, including acute and long-term disabilities. *Safe Motherhood*, U.N.F.P.A., <http://www.unfpa.org/public/mothers/> (last visited Nov. 29, 2010) (reporting that "for every woman who dies, 20 or more experience serious complications"); *Constraints to Scaling Up and Costs*, WORLD HEALTH ORG. & WORLD BANK WORKING GROUP 1, at 11 (2009), [http://www.who.int/pmnch/media/membernews/2009/htltf\\_wg1\\_report\\_EN.pdf](http://www.who.int/pmnch/media/membernews/2009/htltf_wg1_report_EN.pdf) [hereinafter WORKING GROUP 1] ("For every woman who dies in childbirth, around 30 suffer short- or long-term consequences including a broad range of acute and long-term disabilities.").

24 *Progress for Children: Achieving the MDGs with Equity*, UNICEF 27 (2010), [http://www.unicef.org/publications/files/Progress\\_for\\_Children-No.9\\_EN\\_081710.pdf](http://www.unicef.org/publications/files/Progress_for_Children-No.9_EN_081710.pdf).

25 *Trends in Maternal Mortality*, *supra* note 1, at 27-28; *World Health Report 2005—Make*

inexpensive interventions such as the drug misoprostol, could prevent most of this death, disability, and suffering.

### *B. Infectious Diseases*

Infectious diseases continue to cause millions of deaths in developing countries, while also posing threats to every region of the world. More than 3 million people die annually from AIDS, tuberculosis, and malaria.<sup>26</sup> The global incidence of HIV is falling, and there have been real improvements in access to anti-retroviral therapy. More than 8 million people in developing countries were on anti-retroviral medication by the end of 2011.<sup>27</sup> Yet, nearly 7 million people in need of treatment were still not receiving it.<sup>28</sup> Moreover, for every person who enters treatment each year, nearly two become newly infected.<sup>29</sup>

Some of the greatest global health successes in recent years have been against malaria. According to the WHO, malaria deaths fell from 810,000 in 2004 to 655,000 in 2010,<sup>30</sup> with forty-three countries reducing disease incidence by more than half over the past decade.<sup>31</sup> Still, malaria persists as a leading cause of death for children in Africa.<sup>32</sup> Climate change, coupled with growing resistance to anti-malaria medications, pose major threats to sustaining progress over the long term, although a vaccine may be launched for children in Africa by 2015.<sup>33</sup>

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*Every Mother and Child Count*, WORLD HEALTH ORG. (2005), <http://www.who.int/whr/2005/en/index.html>.

<sup>26</sup> *The Global AIDS Epidemic – Key Facts*, UNAIDS 1 (2012), [http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/20121120\\_FactSheet\\_Global\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/20121120_FactSheet_Global_en.pdf) (reporting 1.7 million AIDS deaths in 2011); *Global Tuberculosis Report 2012*, WORLD HEALTH ORG. 17 (2012), [http://www.who.int/tb/publications/global\\_report/en/](http://www.who.int/tb/publications/global_report/en/) (reporting 990,000 tuberculosis deaths in 2011, excluding 430,000 deaths from tuberculosis among HIV-positive people, as these are classified among HIV/AIDS deaths); *World Malaria Report 2011*, WORLD HEALTH ORG. 74 (2011), [http://www.who.int/malaria/world\\_malaria\\_report\\_2011/en/index.html](http://www.who.int/malaria/world_malaria_report_2011/en/index.html) (reporting 655,000 malaria deaths in 2010).

<sup>27</sup> *Together We Will End AIDS*, *supra* note 11, at 18. The number of people in sub-Saharan Africa receiving anti-retroviral therapy to treat AIDS increased approximately 100-fold from 2000 through 2010. In 2000, about 50,000 people in sub-Saharan Africa were receiving anti-retroviral therapy. This number grew to 6.2 million by the end of 2011, including an increase of more than 1 million during 2011 alone. *Id.* at 20.

<sup>28</sup> *The Global AIDS Epidemic – Key Facts*, *supra* note 26, at 1.

<sup>29</sup> In 2011, 1.4 million additional people received AIDS treatment, compared to 2.5 million new HIV infections. *Id.*

<sup>30</sup> *World Malaria Report 2011*, *supra* note 26, at 74. A new study questions these figures, finding higher rates of malaria, particularly among older children and adults, with total malaria deaths peaking at 1.82 million in 2004 and then falling to 1.24 million in 2010. Christopher J.L. Murray et al., *Global Malaria Mortality Between 1980 and 2010: A Systematic Analysis*, 379 LANCET 413, 421 (2012).

<sup>31</sup> *World Malaria Report 2011*, *supra* note 26, at ix.

<sup>32</sup> *Id.* at 3 (stating that malaria causes 16% of deaths in children under five in Africa).

<sup>33</sup> Nicholas J. White, Editorial, *A Vaccine for Malaria*, 365 NEW ENG. J. MED 1926 (2011).

There also has been progress against tuberculosis (TB), with a 41% reduction in mortality since 1990. Still, 1.4 million people died from tuberculosis in 2011, including people infected with HIV.<sup>34</sup> Multi-drug-resistant (MDR) TB, especially in the former Soviet Union, and the particularly pernicious, extensively drug-resistant (XDR) TB threaten tuberculosis control.

Neglected tropical diseases (NTDs), meanwhile, are infectious diseases that thrive in impoverished settings. There are seventeen in all, including Chagas disease, trachoma, leprosy, schistosomiasis, lymphatic filariasis, and dengue. NTDs are often transmitted by insects or the eggs of worms and infect more than 1 billion people annually, killing more than half a million people each year.<sup>35</sup> Beyond early death, these diseases of poverty cause great pain and physical anguish, for example, when filarial worms cause disfiguring enlargement of the arms, legs, breasts, and genitals (elephantiasis), or river blindness leading to unbearable itching and loss of eyesight. Sufferers are often tormented by social stigmatization for the rest of their lives. Diseases of poverty exacerbate the cycle of poverty, decreasing earning capacity and economic productivity.<sup>36</sup>

In addition, emerging infectious diseases, such as SARS and novel influenza strains (e.g., H1N1 and H5N1), which are universally threatening, pose a disproportionate risk to people in developing countries. The health systems in poorer countries are least prepared to detect and contain these emerging health dangers. And absent a global agreement on sharing the vaccines and medications needed to prevent and treat them, people in developing countries are last in line for these essential medical technologies.<sup>37</sup>

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34 *Global Tuberculosis Report* 2012, *supra* note 26, at 17. This represents little change in the absolute number of deaths from tuberculosis since 1990. *See id.* at 12 fig. 2.4. There are 8.7 million new cases of tuberculosis in 2011, 85% of which were in Asia (56%) and Africa (29%). Global incident rates were steady during the 1990s, but began to fall in 2001. In absolute terms, while the number of new HIV infections had begun to fall since peaking in the early 2000s, today's annual incidence is still higher than in 1990. *Id.* at 9, 11, 12 fig. 2.4. HIV, which makes individuals susceptible to tuberculosis, factors heavily in the tuberculosis epidemic, particularly in sub-Saharan Africa, where in 2011, 39% of people with tuberculosis were co-infected with HIV. *Id.* at 11.

35 *Neglected Tropical Diseases, Hidden Successes, Emerging Opportunities*, WORLD HEALTH ORG. ii-iii (2009), [http://whqlibdoc.who.int/publications/2009/9789241598705\\_eng.pdf](http://whqlibdoc.who.int/publications/2009/9789241598705_eng.pdf).

36 *Neglected Diseases: The Diseases of Poverty*, PAN AM. HEALTH ORG., <http://www.paho.org/english/ad/dpc/cd/psit-nd-poster.pdf> (last visited Nov. 29, 2012); Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, *Mission to Uganda*, Comm'n on Human Rights, U.N. Doc. E/CN.4/2006/48/Add.2 (Jan. 19, 2006) (by Paul Hunt) (reporting that neglected tropical diseases "cause immense suffering and lifelong disabilities among the poorest populations ...[contributing] to the entrenched cycle of poverty, ill health, stigmatization and discrimination experienced by neglected populations").

37 The WHO's *Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits* offers some limited access to novel influenza vaccines. *Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*, WHA Doc. WHA64.5 (May 24, 2011) [hereinafter *Pandemic Influenza Preparedness Framework*], available at [http://apps.who.int/gb/ebwha/pdf\\_files/](http://apps.who.int/gb/ebwha/pdf_files/)



### C. Non-Communicable Diseases

The terrible toll of infectious diseases has overshadowed a fast growing rate of non-communicable diseases (NCDs), which are an even more substantial cause of morbidity and premature mortality in low-income and middle-income countries. NCDs include cardiovascular disease, stroke, cancer, diabetes, chronic respiratory diseases, and mental disabilities. Though often thought to primarily affect people in wealthy countries, recent statistics tell a different story. In 2005, 80% of deaths from NCDs occurred in developing countries.<sup>38</sup> The epidemiologic transition, from infections to non-communicable diseases as the greatest killers, is unmistakable. NCDs are on track to cause 70% of all deaths in developing countries by 2020.<sup>39</sup> The poor already die at higher rates than the wealthy—from cancer especially—due to vastly inferior early detection and treatment.<sup>40</sup>

These rising numbers have become too daunting and disconcerting to ignore. In September 2011, the United Nations General Assembly held a high-level summit,<sup>41</sup> adopting a Political Declaration on the Prevention and Control of NCDs.<sup>42</sup> This was only the second health issue that a high-level United Nations summit has addressed. The other was HIV/AIDS, where a 2001 summit transformed the global response to the AIDS pandemic. The NCD Summit, while vital in raising the political profile of NCDs, thus far has not mobilized a global response comparable to AIDS.

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WHA64/A64\_R5-en.pdf. However, it is a highly limited vehicle for sharing vaccines and essential medicines in a global health emergency. David P. Fidler & Lawrence O. Gostin, *The WHO Pandemic Influenza Preparedness Framework: A Milestone in Global Governance for Health*, 306 JAMA 200 (2011).

38 2008-2013 Action Plan for the Global Strategy for the Prevention and Control of Noncommunicable Diseases, WORLD HEALTH ORG. (2008), [http://whqlibdoc.who.int/publications/2009/9789241597418\\_eng.pdf](http://whqlibdoc.who.int/publications/2009/9789241597418_eng.pdf).

39 Abdesslam Boutayeb & Saber Boutayeb, *The Burden of Non Communicable Diseases in Developing Countries*, 4 INT'L J. FOR EQUITY IN HEALTH (2005), <http://www.equityhealthj.com/content/pdf/1475-9276-4-2.pdf>.

40 Tan Ee Lyn, *Developing Nations to Bear Cancer Brunt*, REUTERS (Aug. 19, 2010), <http://www.reuters.com/article/2010/08/19/us-cancer-preparedness-developing-idUSTRE6711GT20100819>. For example, more than 80% of the 274,000 annual cervical cancer deaths worldwide occur in developing countries. Dylan Neel, *An Exercise in Economics: Cervical Cancer Prevention in the Developing World*, HARV. COLLEGE GLOBAL HEALTH REV. (Nov. 15, 2011), <http://www.hcs.harvard.edu/hghr/online/cervical-cancer-prevention/>.

41 Kelly Morris, *UN Raises Priority of Non-Communicable Diseases*, 375 LANCET 1859 (2010).

42 Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, G.A. Res. 66/2, U.N. Doc. A/RES/66/2 [hereinafter Political Declaration on Non-communicable Diseases], available at [http://www.who.int/nmh/events/un\\_ncd\\_summit2011/political\\_declaration\\_en.pdf](http://www.who.int/nmh/events/un_ncd_summit2011/political_declaration_en.pdf).

### *D. Mental Disabilities*

One category of NCDs has been particularly marginalized: mental illness. This category of diseases was not even part of the agenda of the NCD Summit.<sup>43</sup> Yet unipolar depression alone was the third largest contributor to the global burden of disease in 2004,<sup>44</sup> and is expected to become the largest contributor to the global burden of disease by 2030.<sup>45</sup> Most of the burden of depression, bipolar disorder, schizophrenia, and other mental illnesses falls on people in low-income and lower-middle income countries, where nearly three-quarters of the global burden of psychiatric disorders is felt. More than 75% of people in developing countries have no access to mental health treatment, in part due to an extreme paucity of mental health workers.<sup>46</sup>

The human rights violations against persons with mental disabilities are historic and enduring. Under official state policy, mentally ill persons may be committed to isolated and abusive institutions, or they may lose civil and political rights such as voting, driving, and managing personal and financial affairs. Popular culture marginalizes the mentally ill through society's deep stigma, fear of dangerousness, and discrimination.<sup>47</sup>

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43 Priya Shetty, *Mental health a forgotten problem*, SciDEV.NET (Oct. 19, 2010), <http://www.scidev.net/en/opinions/biomed-analysis-mental-health-a-forgotten-problem-1.html>; Angelina Wilson & Emily Fisher, *The "Missing Story" on Mental Health during the UN-High Level Summit on Non-Communicable Diseases*, IUHPE STUDENT AND EARLY CAREER NETWORK (Nov. 2, 2012), <http://isecn.org/2011/11/02/the-missing-story-on-mental-health-during-the-un-high-level-summit-on-non-commuicable-diseases/>.

44 *The Global Burden of Disease: 2004 Update*, WORLD HEALTH ORG. 43 tbl. 12 (2008), [http://www.who.int/healthinfo/global\\_burden\\_disease/2004\\_report\\_update/en/index.html](http://www.who.int/healthinfo/global_burden_disease/2004_report_update/en/index.html).

45 *Depression: A Global Crisis*, WORLD FEDERATION FOR MENTAL HEALTH 14 (Oct. 10, 2012) available at <http://www.wfmh.org/2012DOCS/WMHDay%202012%20SMALL%20FILE%20FINAL.pdf>. Depression leads to approximately 1 million suicides annually. *Depression: Fact sheet No. 269*, WORLD HEALTH ORG. (Oct. 2012), <http://www.who.int/mediacentre/factsheets/fs369/en/index.html>.

46 MENTAL HEALTH GAP ACTION PROGRAMME, SCALING UP CARE FOR MENTAL, NEUROLOGICAL AND SUBSTANCE USE DISORDERS (2008); Diana Gregor, *Mental Illness as a Silent Predator in the Developing World*, MEDIAGLOBAL NEWS (Aug. 14, 2010), <http://www.mediaglobal.org/2011/03/15/mental-illness-as-a-silent-predator-in-the-developing-world/>.

47 Civil society and human rights courts have documented inhuman and degrading treatment in psychiatric institutions, prisons, homeless shelters, and even group homes. DISABILITY RIGHTS INTERNATIONAL, TORTURE NOT TREATMENT: ELECTRIC SHOCK AND LONG-TERM RESTRAINT IN THE UNITED STATES ON CHILDREN AND ADULTS WITH DISABILITIES AT THE JUDGE ROTENBERG CENTER (2010); Lance Gable & Lawrence O. Gostin, *Human Rights of Persons with Mental Disabilities: The European Convention of Human Rights*, in PRINCIPLES OF MENTAL HEALTH LAW AND POLICY 103 (Lawrence O. Gostin et al. eds., 2010); Lawrence O. Gostin, *'Old' and 'New' Institutions for Persons with Mental Illness: Treatment, Punishment, or Preventive Confinement?*, 122 PUB. HEALTH 906 (2008).

### *E. Injuries*

The health impact of injuries in developing countries is also frequently overlooked. More than 90% of deaths from unintentional injuries occur in low-income and middle-income countries.<sup>48</sup> Poverty heightens the risk of injury in myriad ways: for example, through unsafe working conditions, uncovered wells leading to drowning, the use of open fires for cooking, and the use of kerosene or paraffin lamps, which can easily be knocked over and ignited.<sup>49</sup> It also correlates with increased injuries resulting from poorly designed roads, defective motor vehicles, lack of safety equipment, inadequately enforced traffic safety laws, and chaotic traffic. Although low-income and middle-income countries have only 48% of the world's registered vehicles, they experience over 90% of traffic fatalities.<sup>50</sup> Injuries are a major public health problem, which are amenable to cost-effective prevention strategies given the resources and political will.

### *F. Climate Change*

Even as greenhouse gas emission levels are increasing to the point where 2010 emissions exceeded the worst-case scenario according to estimates made in 2007 by the Intergovernmental Panel on Climate Change,<sup>51</sup> climate change already exacts a grim toll. It causes 300,000 deaths annually<sup>52</sup> and is projected to substantially exacerbate health hazards in the coming decades. Although climate change will affect the entire world, it will impose vastly disproportionate burdens on low-income and middle-income countries.<sup>53</sup> Poorer countries are

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48 Robyn Norton et al., *Unintentional Injuries*, in DISEASE CONTROL PRIORITIES IN DEVELOPING COUNTRIES 737 (Dean T. Jamison et al. eds., 2006).

49 See, e.g., *Drowning: Fact sheet No. 347*, WORLD HEALTH ORG., (Oct. 2012) <http://www.who.int/mediacentre/factsheets/fs347/en/index.html> (stating that 96% of the 388,000 deaths in 2004 from drowning occur in low- and middle-income countries); *Stamping Out Tin Kerosene Lamps in Kenya*, TIEDMANN GLOBE. (Jan. 31, 2011), <http://tiedmannnglobe.com/blog/2011/1/31> (citing example of children dying in a fire in Kenya caused by a kerosene lamp).

50 WORLD HEALTH ORG., GLOBAL STATUS REPORT ON ROAD SAFETY: TIME FOR ACTION (2009). The cited statistics are based primarily on data from 2007.

51 *Greenhouse Gases Rise by Record Amount*, GUARDIAN (Nov. 4, 2011), <http://www.guardian.co.uk/environment/2011/nov/04/greenhouse-gases-rise-record-levels>.

52 John Vidal, *Global Warming Causes 300,000 Deaths a Year, Says Kofi Annan Thinktank*, GUARDIAN (May 29, 2009), <http://www.guardian.co.uk/environment/2009/may/29/1>. The WHO's estimate is more conservative. *Climate change and health: Fact sheet No. 266*, WORLD HEALTH ORG. (Oct. 2012), <http://www.who.int/mediacentre/factsheets/fs266/en/index.html> ("Global warming that has occurred since the 1970s caused over 140,000 excess deaths annually by the year 2004.").

53 *Climate Change: Impacts, Vulnerabilities and Adaptation in Developing Countries*, U.N. FRAMEWORK CONVENTION ON CLIMATE CHANGE (2007), <http://unfccc.int/resource/docs/publications/impacts.pdf>.

predominately located in warmer climates that will only become more extreme. Furthermore, lower-income countries have fewer resources with which to adapt to changing climatic conditions, such as by erecting flood barriers, sanitizing drinking water, and delivering emergency services.

As the climate changes and air temperatures rise, the intensity and range of climate-sensitive diseases, such as malaria and dengue, will increase. Changes to rain patterns, along with rising sea levels, will affect the supply of food and clean water, leading to increased hunger and waterborne diseases such as diarrhea and cholera. Extreme weather events will kill both directly and indirectly, by causing droughts and floods that destroy crops, reduce biodiversity, contaminate water sources, displace people, and expand habitats for mosquitoes. Models indicate that some of the world's poorest regions, in southern Africa and south Asia, will experience reductions of staple food crops of 10% to 30% by 2030.<sup>54</sup> Climate change will also degrade air quality and cause severe heat waves, contributing to cardiovascular and respiratory illnesses.<sup>55</sup> Further, the stress, trauma, and displacement wrought by climate change can lead to mental illness, particularly post-traumatic stress disorder, and may contribute to other mental illness and psychological suffering.<sup>56</sup>

### *G. National Health Disparities*

Aggregate figures of the disabilities, diseases, and early deaths that continue to burden the world's poorer regions should not mask the disparities within these regions, and the extra burdens faced by poor and other disadvantaged populations, such as indigenous peoples and persons with disabilities. In Nairobi, Kenya, for example, the death rate for children under five in the worst-off slums is many times the rate in the wealthiest neighborhoods.<sup>57</sup> In thirty-eight countries containing the highest levels of maternal mortality, more than 80% of women are attended by skilled health personnel, compared to a mere 30% for women in the poorest quintile.<sup>58</sup> The disparities are far worse in some countries.<sup>59</sup>

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54 *Climate Could Devastate Crops*, BBC NEWS (Jan. 31, 2008), <http://news.bbc.co.uk/2/hi/science/nature/7220807.stm>.

55 See *Redressing the Unconscionable Health Gap*, *supra* note 12, at 271–94.

56 Helen Louise Barry et al., *Climate Change and Mental Health: A Causal Pathways Framework*, 55 INT'L J. OF PUB. HEALTH 123 (2010).

57 Neil MacFarquhar, *Wider Disparity in Life Expectancy is Found Between Rich and Poor*, N.Y. TIMES (Oct. 17, 2008), [http://www.nytimes.com/2008/10/17/world/17briefs-WIDERDISPARI\\_BR.html](http://www.nytimes.com/2008/10/17/world/17briefs-WIDERDISPARI_BR.html); *World Health Report 2008 – Primary Health Care (Now More Than Ever)*, WORLD HEALTH ORG. (2008), <http://www.who.int/whr/2008/en/index.html> [hereinafter WORLD HEALTH REPORT 2008]. *Population and Health Dynamics in Nairobi's Informal Settlements*, AFR. POPULATION & HEALTH RES. CENTER (2002), <http://www.aphrc.org/insidepage/page.php?app=downloads&articleid=285>.

58 Zulfiqar A. Bhutta et al., *Countdown to 2015 Decade Report (2000–10): Taking Stock of Maternal, Newborn, and Child Survival*, 375 LANCET 2032, 2040 fig. 8 (2010) [hereinafter *Countdown to 2015 Decade Report*].

The yawning health gap, moreover, cannot be understood fully by using the over-simplified division of the world into the global rich and poor. In fact, more than one-third of the largest fortunes in the world are in low- and middle-income countries, with one-quarter of the world's billionaires in Brazil, Russia, India, and China.<sup>60</sup> In addition, even within wealthy states, dramatic health differences exist that are closely linked with degrees of social disadvantage. The poorest people in Europe and North America often have life expectancies similar to citizens of the least developed countries. A black unemployed youth in Baltimore, Maryland has a lifespan thirty-two years shorter than a white corporate lawyer.<sup>61</sup> Infants born to black women in Pittsburgh, Pennsylvania are five times more likely to die than infants born to white women.<sup>62</sup> Native Americans on the Pine Ridge Reservation in South Dakota have a life expectancy in the upper forties.<sup>63</sup>

Experiences in countries such as Brazil demonstrate that such inequalities are not inevitable. Brazil has overcome vast inequities to achieve near universal coverage of skilled birth attendants. Furthermore, the gap in Brazil between the prevalence of stunting among children in the richest and poorest quintiles shrank from 35-37% in 1989 to 5-7% in 2007.<sup>64</sup> Brazil's accomplishments, along with many other successes throughout the developing world, demonstrate that the extreme level of avoidable death and disease in developing countries is just that—avoidable. Effective interventions exist, but many of the world's poor cannot access them.

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59 In West and Central Africa, a woman in the top income quintile is three-and-a-half times more likely to have her birth attended by a skilled health worker than a woman in the lowest income quintile. In Nigeria, skilled health workers cover 84% of births for women in the highest quintile, compared to 12% for women in the lowest quintile. *Progress for Children: A Report Card for Maternal Mortality*, No. 7, UNICEF 16 (2008), [http://www.unicef.org/publications/files/Progress\\_for\\_Children-No.\\_7\\_Lo-Res\\_082008.pdf](http://www.unicef.org/publications/files/Progress_for_Children-No._7_Lo-Res_082008.pdf).

60 WalletPop Staff, *Forbes: The Richest People in the World 2011*, DAILYFINANCE (Mar. 9, 2011), <http://www.dailyfinance.com/2011/03/09/forbes-the-richest-people-in-the-world-2011/>. Among the top 100 wealthiest people on the 2011 *Forbes* list of the world's billionaires, 37 were from low- and middle-income countries, primarily from countries that the World Bank classifies as upper middle-income, namely Brazil (4), Chile (3), China (1), Colombia (2), Malaysia (2), Mexico (4), and Russia (13). Others were from India (4), Nigeria (1), and Ukraine (1). *The World's Billionaires*, FORBES (Mar. 9, 2011), <http://www.forbes.com/wealth/billionaires/list>; *World Bank List of Economies (Jul. 2011)*, WORLD BANK, <http://siteresources.worldbank.org/DATASATISTICS/Resources/CLASS.XLS> (last visited Dec. 5, 2012).

61 Vicente Navarro, *What We Mean by Social Determinants of Health*, 39 INT'L J. OF HEALTH SERVICES 423 (2009).

62 In Pittsburgh, infant mortality among African-Americans was 20.7 in 2009, compared to 4.0 for white infants. Timothy Williams, *Tackling High Infant Mortality Rates Among Blacks*, N.Y. TIMES, Oct. 14, 2011, at A10.

63 Nicholas D. Kristof, *Poverty's Poster Child*, N.Y. TIMES (May 9, 2012), <http://www.nytimes.com/2012/05/10/opinion/kristof-povertys-poster-child.html>.

64 *Countdown to 2015 Decade Report*, *supra* note 58, at 2040-41.

## II. PROSPECTS FOR A PERMANENT UNDERCLASS IN HEALTH: THE IMPERATIVES OF SUSTAINABLE FUNDING, GOOD GOVERNANCE, AND INTERNATIONAL LEGAL OBLIGATIONS

### *A. The Risk of a Persisting Global Health Underclass*

Progress over the past several decades demonstrates that the world has the collective knowledge to dramatically improve health, even in the poorest settings. What, then, is our fear? Why do we advance a new treaty and major innovations in how health is governed even as the world has mobilized to treat millions of people living with AIDS and some of the most egregious markers of health inequities are falling rapidly?

We do so because, despite real progress, we cannot be confident that current arrangements are attuned to global health justice. We have several abiding concerns that lead to the conclusion that the world must pave a new path towards global health justice.

First, even today's progress is unnecessarily slow, meaning millions of lives needlessly cut short and vast human potential lost. We will examine several reasons for this below. Important evidence of lost opportunities to save lives comes from the widely differing levels of progress across countries. Although progress in some countries has been impressive, populations in other countries suffer and die young, much as before. For example, while some countries are on track to achieve the MDGs on maternal<sup>65</sup> and child health,<sup>66</sup> others have made scant progress. National efforts towards universal access to AIDS treatment similarly vary.<sup>67</sup>

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65 Among countries on or nearly on track for achieving the maternal mortality target in the Millennium Development Goals are China (70% reduction in maternal mortality ratio from 1990 to 2010), Equatorial Guinea (81% reduction), Eritrea (73% reduction), and Vietnam (76% reduction). Among those that have experienced little or no progress from 1990 to 2008 are the Central African Republic (4% reduction), Kenya (9% decrease), Lesotho (19% increase), Somalia (15% increase), South Africa (21% increase), Sudan (27% decrease), Zambia (7% decrease), and Zimbabwe (28% increase). See TRENDS IN MATERNAL MORTALITY, *supra* note 1, at 37-45.

66 Countries in Asia making significant progress in reducing child mortality include China (where child mortality decreased from 39.6 out of 1,000 to 15.4 out of 1,000 from 1990 to 2010) and Vietnam (decrease of 46.3 out of 1,000 to 12.9 out of 1,000), with lesser improvements in Afghanistan (163.5 out of 1,000 to 121.3 out of 1,000) and Pakistan (113.3 out of 1,000 to 80.3 out of 1,000). Among countries in Southern and Central Africa with little or no progress in reducing child mortality during this timeframe were Equatorial Guinea (178.7 out of 1,000 to 180.1 out of 1,000), Congo (109.4 out of 1,000 to 107.5 out of 1,000), Swaziland (73.7 out of 1,000 to 101.2 out of 1,000), and Zimbabwe (73.3 out of 1,000 to 70.4 out of 1,000), with levels in many countries elsewhere in Africa remaining astronomical in 2010 (such as 168.7 out of 1,000 in Chad, 161.1 in Niger, and 157.0 out of 1,000 in Nigeria), even with reductions of the past decades. See Rajaratnam, *supra* note 19, at 1992-96.

67 Some countries, such as the Democratic Republic of Congo and Ukraine, provide antiretroviral therapy to less than 20% of their HIV-infected population in the most immediate need

This points to a second concern. Are we seeing the creation of a permanent global health underclass of poor and marginalized people? This could include both disadvantaged populations within better-off countries along with the vast majority of people in worse-off countries, those where factors such as poor governance, lack of political will, and inadequate funding threatens generations still to come with profound ill health. This health underclass might reside in any country, from the Native Americans of the Pine Ridge Reservation in the United States to slum dwellers, the rural poor, people with disabilities, and other disregarded people in the poorest—and wealthiest—countries of Africa. If even the richest countries have such pronounced health inequalities, will there persist into the indefinite future untold hundreds of millions of people whose broken lives are hidden behind significant aggregate improvements?

Several factors heighten the risk of long-persisting ill health for poor and marginalized populations. First, health improvements are often greater for wealthier than poor populations, as for child health. Second, inequality within countries is growing, exacerbating the levels and effects of health inequities.<sup>68</sup> Third, progress in some areas stands in sharp contrast to others. Maternal and child health are improving, but NCDs in developing countries are fast rising. Disproportionate burdens among the poor for this set of diseases risk replicating present inequities and becoming entrenched. Future threats present similar risks. Will another virus with the force of HIV emerge and again cause millions of deaths in the poorest parts of the world before an adequate global response? Will the pattern of death from a novel influenza virus replicate global and national inequities?

Meanwhile, present gains are not secure, with three global crises already beginning to bear down on us: climate change, food, and finance. Will climate change combined with growing global demand for food contribute to the type of jumps in food price we saw in 2007-2008,<sup>69</sup> only more frequently and persistently, with dire consequences? Will countries meet these new, complex health threats, or will the threats become a reality and further compound global health inequities?

The questions on present gains and further progress continue. Will there be

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of treatment, while coverage in Botswana and Rwanda, among others, exceeds 80%. *World AIDS Day Report*, UNAIDS 20 (2011), [http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2216\\_WorldAIDSday\\_report\\_2011\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2216_WorldAIDSday_report_2011_en.pdf).

68 See, *Born Equal: How Reducing Inequality Could Give Our Children a Better Future*, SAVE THE CHILDREN 15 (2012), [http://www.savethechildren.org.uk/sites/default/files/images/Born\\_Equal.pdf](http://www.savethechildren.org.uk/sites/default/files/images/Born_Equal.pdf) (reporting that across 32 countries surveyed, the gap between the richest and poorest children has grown by 35% since the 1990s).

69 FOOD & AGRIC. ORG., *supra* note 16, at 30 (arguing that increased food prices along with the economic downturn contributed to stalled progress in the fight against hunger); see Michael McCarthy, *Global Recession Halts Decades of Steady Progress in Reducing World Hunger*, INDEPENDENT (UK) (Oct. 9, 2012), <http://www.independent.co.uk/news/world/politics/global-recession-halts-decades-of-steady-progress-in-reducing-world-hunger-8204331.html>.

long-term economic retrenchment in wealthy countries struggling with debts and their own growing health care costs, reducing international funding to the poorest countries? Will inadequate funding for research and development mean that the world is ill-prepared to address drug resistance for diseases that are most prevalent among poorer populations?

Finally, we believe that global health has the opportunity to lead the way towards a more just world beyond health. Just as national health systems can either reflect and exacerbate or rebel against and begin to ameliorate inequities,<sup>70</sup> so too can the global health system. Achieving respect in the realm of health could help empower marginalized populations to effectively assert their rights in other spheres. Better health has very real benefits in other realms, such as education and economic well-being.<sup>71</sup> Moreover, enforceable guarantees of healthy conditions for all could be a step towards broad social protection that encompasses education, social security, and employment. Global health justice can be a foundation for greater global justice.

Present global governance for health, and the law that is its backbone, are inadequate, unable to expeditiously and permanently root out domestic and global health inequities. Global health justice remains in search of its own foundation.

### *B. Why Extant Global Health Law and Governance for Health Are Insufficient for Global Health Justice*

The scope of global health law remains far too narrow to effectively respond to global health inequities. Binding global health law is scarce. Along with the first global health treaty—the WHO Constitution—global health is populated by three major multilateral treaties: (1) two sets of international regulations binding on all WHO members:<sup>72</sup> the WHO Regulations No. 1 Regarding Nomenclature with Respect to Diseases and Causes of Death (the Nomenclature Rule) and the

70 See Lynn P. Freedman et al., *Who's Got the Power? Transforming Health Systems for Women and Children*, U.N. MILLENNIUM PROJECT (2005), [http://www.unmillenniumproject.org/reports/tf\\_health.htm](http://www.unmillenniumproject.org/reports/tf_health.htm).

71 See, *Strategic Implications of Global Health*, U.S. NAT'L INTELLIGENCE COUNCIL 10, 23–24 (2008), [http://kmsl.isn.ethz.ch/serviceengine/Files/ISN/95395/ipublicationdocument\\_singledocument/a028363c-5843-4c3f-b34a-c4f245faaefb/en/ICA\\_Global\\_Health\\_2008.pdf](http://kmsl.isn.ethz.ch/serviceengine/Files/ISN/95395/ipublicationdocument_singledocument/a028363c-5843-4c3f-b34a-c4f245faaefb/en/ICA_Global_Health_2008.pdf) (connections between health and education, such as the effects of malnutrition on intelligence and poor reproductive health care for girls and the ability to attend school). Another link is that poor health can keep children out of school. Meanwhile, health expenditures thrust 100 million people into poverty every year. *The World Health Report - Health Systems Financing: The Path to Universal Coverage*, WORLD HEALTH ORG. 5 (2010), <http://www.who.int/whr/2010/en/index.html> [hereinafter *World Health Report* 2010].

72 Under the WHO Constitution, regulations within the scope of Article 21 are binding on all WHO members unless they inform the WHO Director-General within a limited period of time that they reject them. WHO CONST. arts. 21–22, Apr. 7, 1948, available at <http://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf>.



International Health Regulations (IHR); and (2) the first public health convention under article 19 of the WHO Constitution: the Framework Convention on Tobacco Control.<sup>73</sup> Binding global health law also encompasses certain stipulations found in other areas of law, such as the right to health and its accompanying obligations, which we discuss below.<sup>74</sup>

The IHR and FCTC demonstrate the potential impact of binding global health law. An independent review found that the “IHR helped make the world better prepared to cope with public-health emergencies.”<sup>75</sup> Meanwhile, the FCTC has demonstrated great potential for addressing this major preventable cause of premature death. More than 60% of the seventy-two states party to the FCTC for more than five years have increased tobacco taxes and expanded smoke-free public places since ratifying the Convention. Measures that at least one-third of these seventy-two countries have taken include strengthening tobacco product health warnings, protecting public health policies against tobacco industry interference, and prohibiting tobacco industry advertising, promotion, and sponsorship.<sup>76</sup>

International health law demonstrates the potential of hard law to improve global health outcomes. Yet, existing treaties are deeply inadequate for the potent task of reducing global health disparities. The WHO’s review of the IHR also found that there were significant shortcomings in its first test. The 2009 H1N1 influenza pandemic demonstrated that the IHR alone were insufficient to enable the world to effectively respond to a severe pandemic. The IHR and FCTC are flawed because many of their norms lack enforceable standards, they have no concrete accountability provisions, and their norms fail to ensure that developing countries gain the scientific, legal, and technical capacity to safeguard their own population’s health, as well as contribute meaningfully to global health.<sup>77</sup>

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73 *Id.* at arts. 19, 21; WHO, *Revision of the International Health Regulations*, WHA58.3 (May 23, 2005); F.C.T.C., *supra* note 9; see Final Act of the International Health Conference (Arrangement concluded by the Governments represented at the Conference and Protocol concerning the Office international d’hygiène publique) (New York, 22 July 1946) 9 U.N.S.T. 3, *entered into force* 20 Oct. 1947 (dissolving the Office International d’Hygiène Publique, whose functions were integrated into the newly established WHO); see also Agreement on the Establishment of the International Vaccine Institute (New York, 28 October 1996) 1979 U.N.T.S. 199, *entered into force* 29 May 1997.

74 International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200A (XXI), U.N. Doc. A/6316 (1966), [hereinafter ICESCR] *available at* <http://www1.umn.edu/humanrts/instrree/b2esc.htm>.

75 WHO, *Implementation of the International Health Regulations (2005): Report of the Review Committee on the Functioning of the International Health Regulations (2005) in Relation to Pandemic (H1N1) 2009* W.H.A. Doc. A64/10 (May 5, 2011).

76 *Global Implementation of the WHO Framework Convention on Tobacco Control – Progress Note*, WORLD HEALTH ORG. (Sept. 2011), [http://www.who.int/fctc/reporting/Progress\\_note\\_September2011.pdf](http://www.who.int/fctc/reporting/Progress_note_September2011.pdf).

77 WORLD HEALTH ORGANIZATION, *supra* note 75, at 13 (observing that many countries lack the core capacities to detect and respond to potential threats, are not on track to develop these

Perhaps more importantly, these treaties address singular areas of global health—health security from diseases of international health importance (the IHR) and tobacco prevention and control (the FCTC). Neither treaty purports to deal with key determinants of health such as socioeconomic status, sanitation and hygiene, vector abatement, climate change, food security, and as behavioral lifestyles (e.g., nutrition and physical activity) leading to chronic diseases. Nor do they build stronger sustainable health systems or ensure access to essential vaccines and medicines.

Non-binding global health instruments, or “soft law,” are more abundant, including codes (e.g., the Global Code of Practice on the International Recruitment of Health Personnel),<sup>78</sup> declarations (e.g., the UN Millennium Declaration,<sup>79</sup> the Declaration of Commitment on HIV/AIDS,<sup>80</sup> the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases),<sup>81</sup> frameworks (e.g., the Pandemic Influenza Preparedness Framework)<sup>82</sup> and strategies (e.g., WHO’s Global Strategy on Diet, Physical Activity and Health).<sup>83</sup>

These instruments are more comprehensive. Yet by their non-binding nature, the possibilities of enforcement and accountability measures are more limited. Moreover, the precision of their norms and responsibilities varies considerably, they rarely include the specific accountability mechanisms, and even the corpus of these instruments includes significant gaps, such as an effective system to share vaccines with poorer countries in the event of a pandemic disease outbreak.<sup>84</sup> In short, while an important part of global health

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capacities by the 2012 deadline, and that the lack of enforceable sanctions is “the most important structural shortcoming of the IHR”); Heather Wipfli et al., *Achieving the Framework Convention on Tobacco Control’s Potential by Investing in National Capacity*, 13 TOBACCO CONTROL 433 (2004) (observing that lack of national capacity is a major barrier to implementing the Framework Convention on Tobacco Control and that funding is required to build capacity); *Campaign for Tobacco-Free Kids Promotes WHO International Treaty on Tobacco Control: Grant Report*, CAMPAIGN FOR KIDS FREE TOBACCO (2007), available at <http://www.rwjf.org/reports/grr/042060.htm> (observing that only four of the key measures contained in the Framework Convention on Tobacco Control are obligatory).

78 WHO GLOBAL CODE OF PRACTICE ON THE INTERNATIONAL RECRUITMENT OF HEALTH PERSONNEL, WHA Doc. WHA63-16 (May 21, 2010), [hereinafter CODE OF PRACTICE] available at [http://apps.who.int/gb/ebwha/pdf\\_files/WHA63/A63\\_R16-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R16-en.pdf).

79 U.N. Millennium Declaration, G.A. Res. 55/2, U.N. Doc. A/RES/55/2 (Sept. 8, 2000) [hereinafter U.N. MILLENNIUM DECLARATION], available at <http://www.un.org/millennium/declaration/ares552e.htm> (including health and other areas of development, as well as other areas including human rights, peace, and the environment).

80 Declaration of Commitment on HIV/AIDS, G.A. Res. S-26/2, U.N. Doc. A/RES/S-26/2 (June 27, 2001), available at <http://www.un.org/ga/aids/docs/aress262.pdf>.

81 *Political Declaration on Non-communicable Diseases*, *supra* note 42.

82 Pandemic Influenza Preparedness Framework, *supra* note 37.

83 See WHA 51.17, available at [http://apps.who.int/gb/ebwha/pdf\\_files/WHA57/A57\\_R17-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA57/A57_R17-en.pdf) (last visited Jan. 16, 2013).

84 The Pandemic Influenza Preparedness Framework takes initial, though insufficient, steps in

law, particularly for establishing norms, these instruments have not been and will not be sufficient for global health justice. A firmer foundation in health law is needed.

Today's shortcomings in global governance for health and persisting inequities demonstrate the insufficiency of current global health law. The world has witnessed a dramatic rise in interest and funding in global health on the part of governments, non-governmental organizations, philanthropists, volunteers, and businesses, often through public-private partnerships.<sup>85</sup> Yet this unprecedented engagement, despite admirable achievements, has not fundamentally changed the reality for the world's least healthy people. Nor has it significantly closed the health gap between the rich and poor.

A global governance structure—and the laws the underpin it—that can at last make “health for all” a reality will have to respond to at least seven “grand challenges” in global health:

### *1. Insufficient and Unpredictable Funding*

Despite significant growth in domestic and international health investments over the past decade, funding remains insufficient, with risks to future health financing. From 2000 to 2009, per capita government health spending in sub-Saharan Africa more than doubled, from an average of \$15 to \$41 per capita.<sup>86</sup> International health assistance increased from less than \$6 billion annually in the early 1990s to \$10.5 billion in 2000, and climbed to nearly \$26.9 billion in 2010. In addition, official development assistance for water and sanitation reached \$5.6 billion in 2009.<sup>87</sup>

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this direction. See Pandemic Influenza Preparedness Framework, *supra* note 37.

85 See Gill Walt et al., *Mapping the Global Health Architecture*, in MAKING SENSE OF GLOBAL HEALTH GOVERNANCE: A POLICY PERSPECTIVE 47-71 (in Kent Buse et al. eds., 2009); Mark Dybul et al., *Reshaping Global Health*, 173 POL'Y REV. (2012), <http://www.hoover.org/publications/policy-review/article/118116>.

86 These figures are in nominal dollars and include on-budget external assistance. *World Health Statistics 2012*, WORLD HEALTH ORG.133 (2012), [http://www.who.int/gho/publications/world\\_health\\_statistics/EN\\_WHS2012\\_Full.pdf](http://www.who.int/gho/publications/world_health_statistics/EN_WHS2012_Full.pdf).

87 Christopher J.L. Murray et al., *Development Assistance for Health: Trends and Prospects*, 378 LANCET 8, 8-10 (2011) [hereinafter *Development Assistance for Health*]; *Financing Global Health 2010: Development Assistance and Country Spending in Economic Uncertainty*, INST. FOR HEALTH METRICS & EVALUATION (2010), [http://www.healthmetricsandevaluation.org/publications/policy-report/financing\\_global\\_health\\_2010\\_IHME](http://www.healthmetricsandevaluation.org/publications/policy-report/financing_global_health_2010_IHME); Jen Kates et al., *Donor Funding for Health in Low- and Middle-Income Countries, 2001-2009*, KAISER FAMILY FOUND. (2011), <http://www.kff.org/globalhealth/upload/7679-05.pdf>. The international health assistance figures of less than \$6 billion, \$10.5 billion, and \$26.9 billion in 2008 include funding from governments, multilateral agencies, foundations, and NGOs incorporated in the United States and cover HIV/AIDS, tuberculosis, malaria, non-communicable diseases, maternal, newborn, child health, and health sector support. The \$5.6 billion in health assistance for water and sanitation in 2009 includes only government and multilateral agency funding.

Even these funding increases are inadequate, however. The \$41 per capita of government spending in sub-Saharan Africa—and only half that level in South East Asia<sup>88</sup>—is well below the minimum \$60 per capita that WHO estimates that low-income countries require by 2015 to ensure their populations key health interventions. On average, forty-nine low-income countries would have required \$44 per capita spending in 2009 to be on track for near universal access to these interventions by 2015, but thirty-one of them were spending less than \$35 per capita.<sup>89</sup>

Moreover, the upward trajectory of health investments, particularly international assistance, is under severe threat due to the global financial crisis. Austerity has become the order of the day, with high debts in European countries and the United States leading to budget constraints, which promise to continue for many years,<sup>90</sup> that are already affecting international assistance. In 2011, official development assistance fell for the first time since 1997, with pressures to limit international assistance budgets likely to continue.<sup>91</sup> This follows slowed growth from 2008 through 2010.<sup>92</sup> Consequences in the health arena have included the Global Fund canceling a funding round and many billions of dollars lower U.S. investments in global health than the Obama Administration had planned.<sup>93</sup>

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88 Government spending on health in South East Asia is the lowest in the world. It increased as a percent of total government expenditure from 4.4% in 2000 to 4.9% in 2009, and from \$6 per capita to \$19 per capita during the same time period. See *World Health Statistics 2012*, *supra* note 86, at 142–43.

89 *World Health Report 2010*, *supra* note 71, at 22–23; see WORKING GROUP 1, *supra* note 23. In practice, more than \$60 on average would be required. The minimum requirement estimates assume, counterfactually, highly efficient spending. It also covers only identified priority interventions, even as actual government health spending extends beyond these interventions.

90 An agreement of all European Members, except the United Kingdom, regarding strict European enforcement debt limits will further pressure budgets and motivate cuts, including in international assistance. Stephen Erlanger & Stephen Castle, *German Vision Prevails as Leaders Agree on Fiscal Pact*, N.Y. TIMES, Dec. 10, 2011, <http://www.nytimes.com/2011/12/10/business/global/european-leaders-agree-on-fiscal-treaty.html?>. Meanwhile, a painfully slow economic recovery underway in the United States, combined with a political consensus on the need to cut the deficit, threatens U.S. global health funding for years to come.

91 *Development: Aid To Developing Countries Falls Because Of Global Recession*, ORG. OF ECON. CO-OPERATION & DEV., DEV. CO-OPERATION DIRECTORATE (Apr. 4, 2012), <http://www.oecd.org/dac/aidstatistics/developmentaidtodevelopingcountriesfallsbecauseofglobalrecession.htm>. To take one health example, international funding for HIV “had been largely stable between 2008 and 2011.” *Together We Will End AIDS*, *supra*, note 11, at 104.

92 Katherine Leach-Kemon et al., *The Global Financial Crisis Has Led to a Slowdown in Growth of Funding to Improve Health in Many Developing Countries*, 31 HEALTH AFF. 1, 3 (2012) (noting that international health assistance jumped by 17% from 2007 to 2008, but that over the next several years assistance increased by only 4% annually).

93 Shortfalls in contributions to the Global Fund led it to cancel a funding round in 2011 after having initially launched the round, an unprecedented step *Modification of Grant Renewals and Transition to New Funding*, GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS & MALARIA (Nov. 21–22, 2011), [http://www.theglobalfund.org/documents/board/25/BM25\\_DecisionPoints\\_Report\\_en/](http://www.theglobalfund.org/documents/board/25/BM25_DecisionPoints_Report_en/).

Although the financial crisis emerged largely from the dishonest and irresponsible practices of the financial industry in the North, economies of the global South are directly affected. The financial crisis has reduced demand for products in the global South and reduced foreign investment. Even as African countries recover from the initial downturn, continued slow or no growth in wealthier countries threatens economic growth—and hence domestic health spending—in Africa.<sup>94</sup> Foreign direct investment declined sharply in Africa from 2008 to 2010.<sup>95</sup>

The threats to economic growth have special importance, because the past decade has demonstrated that under existing governance arrangements, the primary source of increased health funding and international assistance is economic growth, not greater allocation to health. Despite a pledge by all African countries to spend at least 15% of their budgets in the health sector, on average they increased their investments in the sector from 8.2% to only 9.4% of their budgets from 2000 to 2009.<sup>96</sup> Turning to international assistance, the proportion of gross national income (GNI) that members of the Organization for Economic Co-operation and Development (OECD) allocated to ODA in 2010 (0.32% GNI)<sup>97</sup> is essentially the same as it was in 1970 (0.33% GNP)—the year that wealthy countries pledged to spend 0.7% GNP on ODA.<sup>98</sup>

International health assistance can be volatile, as levels depend on annual appropriation cycles and the political party in power. Funders may switch from

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The Global Fund established a Transitional Funding Mechanism to continue to fund essential prevention, care, and treatment activities to current grantees. *Id.* The United States is well behind the pace set in the spending targets of the President's Global Health Initiative, originally planned at \$63 billion from 2009 through 2014. SUSAN B. EPSTEIN ET AL., CONG. RES. SERV., R41905, STATE, FOREIGN OPERATIONS, AND RELATED PROGRAMS: FY2012 BUDGET AND APPROPRIATIONS 8 (July 7, 2011), available at <http://fpc.state.gov/documents/organization/169056.pdf>; Laurie Garrett, *The U.S. Global Health Initiative is Dead: Long Live the U.S. Global Health Initiative!*, LAURIE GARRET BLOG, (July 2012), <http://www.lauriegarrett.com/index.php/en/blog/The%20U.S.%20Global%20Health%20Initiative%20is%20Dead:%20Long%20Live%20the%20U.S.%20Global%20Health%20Initiative!/>.

94 *Macroeconomic Prospects*, AFR. ECON. OUTLOOK, <http://www.africaneconomicoutlook.org/en/outlook/forecast/> (last visited Nov. 29, 2012).

95 AFR. DEV. BANK, *Africa's Performance & Mid-Term Prospects*, 1 AFRICA EMERGING ISSUES 13 (Nov. 2011), <http://www.afdb.org/fileadmin/uploads/afdb/Documents/Publications/Africa%20Emerging%20Issues%20Series.pdf>. A 1% decrease in GDP across countries of the Organization for Economic Cooperation and Development (OECD) could lead Africa's export earnings to fall by 9%. *Id.*

96 *World Health Statistics 2012*, *supra* note 86, at 142.

97 *Development Aid Reaches an Historic High in 2010*, ORG. OF ECON. CO-OPERATION DEV. [http://www.oecd.org/document/35/0,3746,en\\_2649\\_34447\\_47515235\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/35/0,3746,en_2649_34447_47515235_1_1_1_1,00.html) (last visited Nov. 29, 2012).

98 HELMUT FÜHRER, *THE STORY OF OFFICIAL DEVELOPMENT ASSISTANCE* (1994). For a historical perspective on foreign assistance, see Anup Shah, *Foreign Aid for Development Assistance*, GLOBAL ISSUES (April 8, 2012), <http://www.globalissues.org/article/35/foreign-aid-development-assistance>.

one health issue to another, or one sector to another (e.g., health to education), and funding grants may come to an end with no strategy for transition. This makes it difficult for countries to fully benefit from assistance. They may have to choose between developing programs for which long-term funding is insecure—with the risk that life-saving programs will be terminated—or passing up on funds that might be available. Countries may be particularly wary of investing in recurrent spending, such as health worker salaries, despite the need.<sup>99</sup>

Too frequently geopolitical interests drive development assistance, leading to a misalignment of spending compared to need (e.g., U.S. investments in Iraq and Afghanistan). Certain countries become donor favorites (e.g., Uganda, Rwanda, Zambia),<sup>100</sup> while others are orphaned (e.g., Central African Republic).<sup>101</sup> In addition, shifting priorities of wealthy countries can undermine country ownership, neglect basic needs, and enable diseases to resurge.

Funding also needs to be well-spent. There are growing efficiencies in some areas, notably AIDS, with funds able to stretch further. However, 20-40% of health spending is wasted, with even higher levels being wasted in poorer countries.<sup>102</sup> Among the factors that conspire against available funds yielding health benefits include the next two challenges: poor coordination among health actors and lack of accountability.

## 2. *The Lack of Collaboration and Coordination Among Multiple Players*

Today's global health discourse is dominated by terms such as "fragmentation" and "duplication," with a proliferation of actors, pictorially represented as an incomprehensible, tangled web of agencies and programs. Such complexity reduces the efficiency of health spending, at times even pitting international actors and local service providers against each other. Multiple systems are duplicative (e.g., an HIV drug supply chain alongside a national drug distribution system) and the high transaction costs of fragmentation consume health ministry resources, as ministries compile an endless series of reports for an array of partners. Partners often poorly coordinate among themselves, and often do not align their funding and programs with national strategies. They may fail to collaborate with health ministries, and even to inform health ministries of all of their activities. Furthermore, more generous compensation in partner

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99 JALI World Health Report Background Paper, *supra* note 12.

100 Nirmala Ravishankar et al., *Financing of Global Health: Tracking Development Assistance for Health from 1990 to 2007*, 373 LANCET 2113, 2122 (2009); *Development Assistance for Health*, *supra* note 87.

101 *Central African Republic – The Forgotten Country*, MERLIN (May 15, 2012), <http://www.merlin.org.uk/central-african-republic-forgotten-country> (last visited Nov. 29, 2012).

102 *World Health Report 2010*, *supra* note 71, at 71-72; *Investing in Health for Africa: The Case for Strengthening Systems for Better Health Outcomes*, HARMONIZATION FOR HEALTH IN AFRICA 4 (2011), [http://www.who.int/pmnch/media/membernews/2011/investing\\_health\\_africa\\_eng.pdf](http://www.who.int/pmnch/media/membernews/2011/investing_health_africa_eng.pdf).

organizations can draw the most qualified people away from health ministries.

The proliferation of uncoordinated actors poses significant challenges to the stewardship role of ministries of health and misses opportunities for collaboration and synergy. A new global governance structure will need a simplified architecture that translates into a more coherent and manageable picture at the country level, with relationships rooted in collaboration that harmonizes global health actions and aligns with national strategies.<sup>103</sup>

### *3. The Need for Accountability, Transparency, Monitoring, and Enforcement*

Basic principles of good governance are required at all levels: subnational, national, and international. Yet the global health field is marked by a paucity of detailed targets with concrete plans to achieve them, along with a lack of accountability. There is insufficient transparency among states and international organizations, and inadequate monitoring and evaluation of health initiatives. Meanwhile, global health funding and activities are, in practice, voluntary, with few mechanisms to ensure compliance.

Global health mechanisms have also proven inadequate to support effective health spending nationally and locally. From continued inefficient spending (e.g., vehicles for health ministries, ineffective short-term trainings) and over-spending (e.g., non-competitive tenders) to outright corruption—much less inappropriate medical care, such as unnecessary prescriptions and the overuse of injections—global mechanisms also fail to sufficiently support transparency and other accountability strategies at local and national levels, such as civil society advocacy. An effective global health architecture would include the following: (1) clear targets to improve the public's health and reduce health inequities; (2) benchmarks and indicators of success that are rigorously monitored; (3) incentives and enforcement mechanisms to ensure compliance; and (4) civil society engagement, virtual and in-person interactive forums, and publicly provided reasons for decisions to improve transparency.

It is not merely that there is too little money, too much of which is spent inefficiently, and too often in the dark. The funds that countries do invest in health largely neglect particularly important health needs. This is the subject of the next two challenges.

### *4. The Neglect of Essential Health Needs and Health System Strengthening*

Far-reaching health benefits would come from meeting such timeless human health needs as clean water, adequate nutrition, sanitation, sewage, and tobacco

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<sup>103</sup> *The Paris Declaration on Aid Effectiveness: Ownership, Harmonisation, Alignment, Results and Mutual Accountability*, ORG. OF ECON. CO-OPERATION & DEV. (2005), <http://www.oecd.org/dataoecd/30/63/43911948.pdf> [hereinafter *Paris Declaration*].

control, and abating disease vectors such as mosquitoes and rodents, and from developing health systems that equitably and efficiently deliver known, effective health interventions. A heightened global priority toward meeting these human needs would more effectively reduce the diseases and injuries that are responsible for most of the world's suffering, morbidity, and premature mortality.

Yet despite their demonstrable value in improving public health, basic needs have been largely overlooked—although this is beginning to change with a new focus on health system strengthening, including by mechanisms such as the Global Fund, with its primary mission still focused on AIDS, tuberculosis, and malaria.<sup>104</sup> Currently, though, there is no major funder that prioritizes resources for prevention, primary care, and access to essential medicines. Reforming the global health architecture would end this neglect.

### 5. *The Neglect of Vital Health Research and Development*

Also inadequately reflected in global governance for health is the need for research and development, both for diseases that are most prevalent among poorer countries and populations and diseases common globally, but with specific research and development needs for developing countries. With beneficiaries who have little money, companies lack the financial incentives to produce medicines and vaccines for these populations.<sup>105</sup> Pressing needs include new diagnostic tools and therapies for tuberculosis and treatments for neglected tropical diseases.<sup>106</sup> A prominent working group convened by WHO, the Consultative Expert Working Group, estimated that public funding on this research and development should double, with countries spending at least 0.01% of their GNP.<sup>107</sup>

There are nascent efforts to address this research gap, such as GAVI's Advanced Market Commitment, which spurred development and increased production of the pneumococcal vaccine (protecting against pneumonia).<sup>108</sup> The International Finance Facility for Immunization frontloads funds for GAVI

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104 The Global Fund now encourages interventions to improve maternal and child health and to strengthen health systems, but only if sufficiently connected to improving AIDS, tuberculosis, or malaria outcomes. Eric A. Friedman, *Guide to Using Round 10 of the Global Fund to Fight AIDS, Tuberculosis and Malaria to Support Health Systems Strengthening*, PHYSICIANS HUMAN RIGHTS (2010), [https://s3.amazonaws.com/PHR\\_other/round10-gf-hss-guide.pdf](https://s3.amazonaws.com/PHR_other/round10-gf-hss-guide.pdf).

105 *Financing and Coordination, Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination*, CONSULTATIVE EXPERT WORKING GROUP ON RESEARCH & DEV. (2012), [http://www.who.int/phi/CEWG\\_Report\\_5\\_April\\_2012.pdf](http://www.who.int/phi/CEWG_Report_5_April_2012.pdf) [hereinafter CONSULTATIVE EXPERT WORKING GROUP].

106 *Id.* at 25–26.

107 *Id.* at 83–84.

108 *How the Pneumococcal AMC Works*, GAVI ALLIANCE, <http://www.gavialliance.org/funding/pneumococcal-amc/how-the-pneumococcal-amc-works/> (last visited Nov. 29, 2012).



through bond sales to allow GAVI to commit to vaccine purchases at scale, helping to assure vaccine manufacturers that they will have a market.<sup>109</sup> Other possibilities, such as a Health Impact Fund to stimulate investment in diseases that cause the highest levels of morbidity and mortality,<sup>110</sup> are on the table. Recognizing the extent of the continued deficit, the Consultative Expert Working Group has proposed a new treaty on research and development.<sup>111</sup>

### 6. *The Lack of Global Health Leadership*

Underlying many of these challenges is a lack of global health leadership. Such leadership is required to mobilize, coordinate, and focus a large and diverse set of actors around a clear mission, common objectives, effective approaches, sustained action, and mutual accountability. It is needed to ensure that all health actors have—and have the power to act on—the best available scientific information to ensure that they can have the greatest impact on health. Moreover, global health leadership must ensure a focus on equity in national and international health policies and regimes by enhancing the understanding of national leaders on which policies can have the greatest impact on public health and by focusing on the importance of addressing health inequities.<sup>112</sup>

The WHO has the unique authority and legitimacy to assume this role, but it is experiencing a crisis of leadership.<sup>113</sup> Also, the Organization has proved reluctant to exercise its broad normative powers.<sup>114</sup> More importantly, however, the WHO controls little more than 30% of its own budget, with most resources going to what donors want rather than what the WHO requires,<sup>115</sup> restricting its

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109 *About IFFIm: Overview*, INT'L FIN. FACILITY FOR IMMUNISATION, <http://www.iffim.org/about/overview/> (last visited Nov. 29, 2012); *Why Immunization?*, INT'L FIN. FACILITY FOR IMMUNISATION, <http://www.iffim.org/about/why-immunisation/> (last visited Nov. 29, 2012).

110 HEALTH IMPACT FUND, <http://healthimpactfund.org/> (last visited Nov. 29, 2012).

111 CONSULTATIVE EXPERT WORKING GROUP, *supra* note 105, at 120–24.

112 For instance, laws that criminalize homosexual behavior keep men who have sex with men away from the public health system. When their health problems go unaddressed, along with harming their own health, the impact can be more broadly felt, such as leading HIV to spread into the population more generally. To take another example, failure to address the affordability of medicines can contribute to individuals' inability to complete medicine regimens, leading to drug resistance.

113 Devi Sridhar & Lawrence O. Gostin, *Reforming the World Health Organization*, 305 JAMA 1585 (2011).

114 See RICHARD DODGSON ET AL., GLOBAL HEALTH GOVERNANCE: A CONCEPTUAL REVIEW (2002); David P. Fidler, *The Future of the World Health Organization: What Role for International Law?* 31 VAND. J. OF TRANSNAT'L L. 1079 (1998); Allyn Taylor, *Making the World Health Organization Work: A Legal Framework for Universal Access to the Conditions for Health*, 18 AM. J.L. & MED. 301 (1992).

115 Assessed contributions edged up from 21% of WHO's 2010-2011 budget to 24% of its 2012-2013 budget. The remaining contributions are voluntary. Most voluntary contributions are earmarked, though a small portion is highly flexible. In the 2012-2013 budget, assessed contributions and highly flexible voluntary contributions together comprised 34% of WHO's

ability to direct and coordinate the global health agenda. Meanwhile, WHO's member states have failed to act as though they have a stake in the Organization's success, leading to a major deficit and staff-cutting in 2011.<sup>116</sup> Without leadership, the response to global health challenges has been *ad hoc* and fragmented. Furthermore, without a global health advocate, other regimes, such as intellectual property and world trade, have dominated when they have been at odds with global health concerns.

### *7. The Need for Health and Human Rights Leaders To Influence Multiple Global Sectors To Promote Health*

However effective the direct instruments of global health may be, such as global health treaties and funding mechanisms, they are alone insufficient to fully address the demands of global governance for health. International legal regimes outside of health can powerfully affect, for better or worse, human health. Health leadership in these regimes is often either absent or insufficient, or simply overwhelmed by more powerful interests.<sup>117</sup> Health and human rights leaders must be empowered to influence these sectors, including intellectual property rules that reduce access to essential medicines and vaccines; trade and restrictive macroeconomic policies that limit government revenue and hence ability to invest in health; agricultural policies such as subsidies that promote unhealthy foods and biofuel production targets that impact global food markets; and energy policies, including subsidies, targets, and investments, that will exacerbate climate change, with its numerous adverse effects on health. Trade and investment treaties may undermine state power to enact rigorous tobacco control

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budget. *Medium-Term Strategic Plan 2008–2013 and Proposed Programme Budget 2012–2013*, WORLD HEALTH ORG. 14–15 (Apr. 4, 2011), [http://apps.who.int/gb/ebwha/pdf\\_files/WHA64/A64\\_7-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_7-en.pdf).

<sup>116</sup> Facing a \$300 million deficit, WHO cut headquarters staff by over 10% in 2011. Stephanie Nebehay & Barbara Lewis, *WHO Slashes Budget, Jobs in New Era of Austerity*, REUTERS (May 19, 2011), <http://www.reuters.com/article/2011/05/19/us-who-idUSTRE74I5I320110519>; see also *WHO in Overhaul as Body Faces Losses*, NEW AGE (S. Afr.) (May 16, 2011), [http://www.thenewage.co.za/18030-1020-53-WHO\\_in\\_overhaul\\_as\\_body\\_faces\\_losses](http://www.thenewage.co.za/18030-1020-53-WHO_in_overhaul_as_body_faces_losses).

<sup>117</sup> For example, despite the risk that overly protective intellectual property regimes will increase the price of medicines, putting even essential medicines out of reach of people in poorer countries, many bilateral and regional free trade agreements include higher levels of protection—so-called “TRIPS-plus” provisions—than required by the World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). See, e.g., James Harrison, *Trade Agreements, Intellectual Property and Access to Essential Medicines: What Future Role for the Right to Health?*, in GLOBAL GOVERNANCE OF HIV/AIDS (Obijiofor Aginam et al., eds., 2011); *All Costs, No Benefits: How TRIPS-Plus Intellectual Property Rules in the US-Jordan FTA Affect Access to Medicines*, OXFAM 2 (2007), <http://www.scribd.com/doc/52829094/All-Costs-No-Benefits-How-TRIPS-plus-intellectual-property-rules-in-the-US-Jordan-FTA-affect-access-to-medicines> (noting that TRIP-plus provisions of the United States-Jordan Free Trade Agreement have contributed to the 20% rise in the price of medicines in Jordan since 2001).

laws as required under the FCTC. Domestic workforce policies and international recruitment can accelerate the migration of trained doctors, nurses, and pharmacists out of developing countries already experiencing serious health worker shortages.

Health and human rights leaders will need to collaborate and take an active role in transforming sectors that adversely affect health and human rights, and those that need to be strengthened in their protection for health and human rights. Along with working to affect regimes on an individual basis, they should work to develop a hierarchy of rules that uniformly give priority to health and human rights. Otherwise, a narrow focus on a global health regime, without a positive influence on potentially competing regimes, will not result in global health justice.

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Global governance for health, therefore, is characterized by struggling leadership, inadequate and volatile funding, poor coordination, neglected priorities, little accountability, and insufficient intersectoral influence. This is hardly a recipe for a breakthrough in health equity. Yet, it is entirely possible to dramatically improve the world's health and reduce health inequalities with modest investments and smart, proven policies.

Thus far, the international community has only taken halting steps in the right direction. The Monterrey Consensus,<sup>118</sup> Paris Declaration on Aid Effectiveness, the Accra Agenda for Action,<sup>119</sup> and the Busan Partnership Agreement<sup>120</sup> established a new paradigm that became quickly accepted in principle. This paradigm advocates targets and indicators of success to establish benchmarks to enhance accountability,<sup>121</sup> harmonization among partners to improve coordination, alignment with country strategies to enable greater country ownership and reduce burdens on national policymakers, longer-term and more predictable international assistance, engagement with multiple stakeholders in civil society, and mutual accountability among development partners to better clarify mutual responsibilities.

Yet efforts to implement these principles have had setbacks. Consider the International Health Partnership and related initiatives (IHP+)—a partnership launched in 2007 consisting of most developed countries (with the notable

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118 International Conference on Financing for Development, Monterrey, Mex., Mar. 18-22, 2002, *Monterrey Consensus on Financing for Development*, U.N. Doc. A/CONF.198/11 (2003), available at <http://www.un.org/esa/ffd/monterrey/MonterreyConsensus.pdf>.

119 *Paris Declaration*, *supra* note 103.

120 *Busan Partnership for Effective Development Co-operation*, ORG. OF ECON. CO-OPERATION & DEV. (2011), <http://www.oecd.org/dataoecd/54/15/49650173.pdf> [hereinafter *Busan Partnership Agreement*].

121 For indicators and targets, see *Paris Declaration*, *supra* note 103, at 9–11.

exceptions of the United States and Japan) and by late 2012, thirty-one developing countries, primarily in Africa.<sup>122</sup> IHP+ has had successes in several areas as it has sought to put these principles into practice, including high-level alignment of partner plans with country plans, increased civil society involvement, and more timely disbursements of partner funding commitments. Yet progress has been decidedly mixed. While “[i]mportant progress has been made toward country ownership of development assistance . . . Development Partners as a whole have to date not realized the ‘step change’ in aid effectiveness that” the IHP+ originally envisioned.<sup>123</sup> Only three of twelve IHP+ targets were met. Evidence did not permit meaningful evaluation of the nature of civil society participation, which is particularly critical to ensure that countries are meeting the needs of marginalized populations and to hold governments accountable.<sup>124</sup>

The Global Fund embodies several key principles of good global governance. It is driven by country demand and receives multi-year funding proposals from Country Coordinating Mechanisms (CCMs), whose members include government officials—often from multiple sectors—civil society, development partners, and the private sector.<sup>125</sup> Civil society from developed and developing countries, governments from the North and South, foundations, the private sector, and most significantly a community delegation sit as equals on the Global Fund Board. Transparent in its programs in each country, the Fund also incorporates robust, independent measures to counter corruption.

Yet the purely voluntary funding scheme has caused the Global Fund to fall well short of its needs,<sup>126</sup> forcing it to delay grants, limit support to middle-income countries, slow its pace of new funding and, most dramatically, cancel its

122 *IHPA+ Partners*, INT’L HEALTH PARTNERSHIP & RELATED INITIATIVES, <http://www.internationalhealthpartnership.net/en/partners> (last visited Nov. 29, 2012).

123 *Progress in the International Health Partnership & Related Initiatives (IHP+): 2012 Annual Performance Report*, IHP+ RESULTS ii (2012), [http://ihpresults.burgercom.co.za/wp-content/uploads/2012/10/IHP\\_English.pdf](http://ihpresults.burgercom.co.za/wp-content/uploads/2012/10/IHP_English.pdf).

124 *Id.*

125 *Country Coordinating Mechanisms*, GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS & MALARIA, <http://www.theglobalfund.org/en/ccm/> (last visited Dec. 5, 2012). During its first decade, grant periods were five years, though under a revised funding model, standard grants will last three years, though with some flexibility. *See also* GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS & MALARIA, TWENTY-EIGHTH BOARD MEETING (Nov. 14-15, 2012), *available at* [http://www.theglobalfund.org/documents/board/28/BM28\\_DecisionPoints\\_Report\\_en/](http://www.theglobalfund.org/documents/board/28/BM28_DecisionPoints_Report_en/).

126 At the United Nations Millennium Development Goals Summit in September 2010, countries committed to provide “adequate funding” for the Global Fund. Yet at the Global Fund’s three-year replenishment conference the following month, the Fund received only \$11.7 billion in pledges, even as it had established a minimum need of \$13 billion, with a goal of \$20 billion. *Keeping the Promise: United to Achieve the Millennium Development Goals*, G.A. Res. 65/1, U.N. Doc. A/RES/65/1 (Sept. 22, 2010), *available at* <http://www.un.org/en/mdg/summit2010/pdf/mdg%20outcome%20document.pdf>. Donald G. McNeil Jr., *Global Fight Against AIDS Falters as Pledges Fail to Reach Goal of \$13 Billion*, N.Y. TIMES (Oct. 6, 2010), *available at* <http://www.nytimes.com/2010/10/06/world/africa/06aids.html>.

2011 round of funding. Beyond funding, whether non-governmental members are recognized and empowered to act as equal partners on CCMs—critical to ensuring that the proposals build civil society capabilities, address the needs of marginalized populations, and are sufficiently ambitious—varies significantly among countries.<sup>127</sup> Meanwhile, the Global Fund captures only a slice of health need, though with its support for health systems strengthening and, indirectly, improving maternal and child health, it is seeking to more fully align with the MDGs and country needs.<sup>128</sup>

In what could have been path-breaking progress on global health accountability, new global funding for maternal and child health has come with commitments to improved accountability. In 2011, the Commission on Information and Accountability for Women's and Children's Health laid out a strategy to enhance accountability in women's and children's health.<sup>129</sup> Its recommendations on strengthening health information systems and common indicators, regular reporting on spending and connections to results, improved oversight and transparency, and inclusive national accountability mechanisms are all important, deserve support, and provide standards that should extend throughout global health. The Commission also recognized the vast potential of information and communications technology to enhance information sharing and accountability. Yet the Commission had little new to offer.

Deep reductions in health inequities will require stronger global governance for health than this. Governance must be capable of ensuring that principles captured in the Paris Declaration and its successors are fully implemented. Moreover, it must go beyond these principles to better address the overall volume of health financing, equity, and underlying and deeper socioeconomic determinants of health. Far stronger forms of accountability are still required, as is true global health leadership. Global health law could play a role in all of these areas, yet its scope—particularly in legally binding form—remains narrow. Global health law has demonstrated its potential, yet remains highly

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127 *CCM Advocacy Report: Making Global Fund Country Coordinating Mechanisms Work Through Full Engagement of Civil Society*, INT'L TREATMENT PREPAREDNESS COAL. (2008), <http://www.rapnap.org/resources/docs/CCM%20Advo%20Rpt/pdf>.

128 GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS & MALARIA, TWENTY-SECOND BOARD MEETING (Dec. 13-15, 2010), *available at* [http://www.theglobalfund.org/documents/board/22/BM22\\_DecisionPoints\\_Report\\_en/](http://www.theglobalfund.org/documents/board/22/BM22_DecisionPoints_Report_en/); GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS & MALARIA, SIXTEENTH BOARD MEETING (Nov. 12-13, 2007), *available at* [http://www.theglobalfund.org/documents/board/16/BM16\\_BoardMeeting\\_Decisions\\_en/](http://www.theglobalfund.org/documents/board/16/BM16_BoardMeeting_Decisions_en/).

129 COMMISSION ON INFORMATION & ACCOUNTABILITY FOR WOMEN'S AND CHILDREN'S HEALTH, KEEPING PROMISES, MEASURING RESULTS (2011), *available at* [http://www.everywomaneverychild.org/images/content/files/accountability\\_commission/final\\_report/Final\\_EN\\_Web.pdf](http://www.everywomaneverychild.org/images/content/files/accountability_commission/final_report/Final_EN_Web.pdf). Missing were recommendations for incentives or sanctions that might encourage compliance. The Commission also failed to articulate a recommendation for local accountability mechanisms, building skills among, and ensuring the resources for, civil society and communities to hold their own governments to account—codifying commitments to open the potential for judicial enforcement or other strategies that could help fundamentally improve accountability.

underdeveloped.

A broad, cross-cutting treaty specifically targeted to the major determinants of health—the FCGH—could be at the heart of further developing global health law and reorganizing global governance for health to dramatically reduce global health inequities.

Before proceeding to the four questions whose answers we believe should provide the foundation for the evolution of global health law in general, and an FCGH in particular, we set out the moral and legal underpinning of our approach: that the concept of health aid as charity should be jettisoned in favor of a justice-based commitment to mutual responsibility beyond state borders. Shared national and global responsibilities, social justice, and the right to health form the normative perspective that would properly guide global governance for health.

### III. RECONCEPTUALIZING “HEALTH AID”: FROM CHARITY TO HUMAN RIGHTS<sup>130</sup>

Often tied to the concept of global health is that of health assistance provided by the affluent to the poor in a donor-recipient relationship as a form of charity—a concept we will refer to as “Health Aid.” Framing the global health endeavor as Health Aid is fundamentally flawed,<sup>131</sup> as it implies that the world is divided between donors and countries in need. This is too simplistic. Collaboration among countries, both as neighbors and across continents, is also about responding to health risks together and collaboratively building the knowledge, skills, and systems to respond to them—whether through South-South partnerships, gaining access to essential vaccines and medicines, or demanding fair distribution of scarce life-saving technologies. New social, economic, and political alignments are evident, for example, in the emerging health leadership of countries such as Brazil, India, Mexico, and Thailand.<sup>132</sup>

Likewise, the concept of “aid” both presupposes and imposes an inherently unequal relationship, where one side is a benefactor and the other a dependent. This leads affluent states and other donors to believe that they are giving “charity,” which means that financial contributions and programs are largely at their discretion. It also means that donors decide the amount and objectives of global health initiatives. The level of financial assistance, as a result, is not predictable, scalable to needs, or sustainable in the long term. These features of

130 This discussion draws heavily from *JALI World Health Report Background Paper*, *supra* note 12.

131 See, e.g., Gorik Ooms & Wim Van Damme, *Impossible to ‘Wean’ When More Aid is Needed*, 86 BULL. WORLD HEALTH ORG. 893 (Nov 2008); Gorik Ooms et al., *Financing the Millennium Development Goals for Health and Beyond: Sustaining the ‘Big Push’*, GLOBALIZATION & HEALTH (2010), <http://www.globalizationandhealth.com/content/6/1/17>.

132 Jennifer P. Ruger & Nora Y. Ng, *Emerging and Transitioning Countries’ Role in Global Health*, 3 ST. LOUIS U. J. HEALTH L. & POL’Y 253 (2010) (describing the role of the “BRIC” nations—Brazil, Russia, India, and China—in global health, as the givers and recipients of aid).

Health Aid could, in turn, mean that host countries do not accept full responsibility for their inhabitants' health, as they can blame donors for shortcomings.

Conceptualizing international assistance as "aid" masks the deeper truth that human health is a globally shared responsibility, reflecting common risks and vulnerabilities.<sup>133</sup> An obligation of health justice is that it demands a fair contribution from everyone, North and South. Global governance for health must be seen as a partnership—a direction that is now gaining broad international agreement<sup>134</sup>—with financial and technical assistance understood as an integral component of the common goal of improving global health and reducing health inequalities.

#### *A. A Shared Obligation: The Right to Health and Reinforcing Frameworks*

The right to the highest attainable standard of health ("right to health")<sup>135</sup> is the most important health-related international legal obligation for all countries. What makes the right to health a compelling framework for holding states accountable is that it has wide international acceptance as binding law. States have recognized the centrality of human rights to their mission, declaring through the United Nations, "[h]uman rights and fundamental freedoms are the birthright of all human beings; their protection and promotion is the first responsibility of Governments."<sup>136</sup>

What does the right to health entail? The most authoritative interpretation, which has since been built upon by a series of reports by the United Nations Special Rapporteurs on the right to health and supplemented by decisions of national courts, comes from General Comment 14 of the United Nations

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133 From infectious diseases that do not respect national borders, to cultural influences and trade that bear much responsibility for the growth of NCDs in developing countries, diseases and their determinants are increasingly globalized. Moreover, the contribution of health to other realms of life, such as education and economic productivity, affect countries' economic growth and the skills of its people in ways that benefit all. Health technologies and strategies developed as solutions in lower-income countries can provide lessons and approaches to better health care in wealthier countries. On this last point, see NIGEL CRISP, *TURNING THE WORLD UPSIDE DOWN – THE SEARCH FOR GLOBAL HEALTH IN THE 21ST CENTURY* (2010).

134 For example, the fourth of the first series of high-level global forums on aid effectiveness, in Busan, South Korea, in 2011, issued a declaration not about "aid effectiveness," like the landmark Paris Declaration that emerged from a 2005 meeting, but was about "development cooperation." The language changed from that of aid and assistance to partnership and cooperation. See *Paris Declaration*, *supra* note 103; *Busan Partnership Agreement*, *supra* note 120.

135 The full formulation of this right in one of the foundational human rights treaties, the International Covenant on Economic, Social and Cultural Rights is "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." ICESCR, *supra*, note 74, at art. 12.

136 World Conference on Human Rights, June 14-25, 1993, *Vienna Declaration*, ¶ 1, U.N. Doc. A/CONF.157/24 (June 19, 1993) [hereinafter *Vienna Declaration*], available at <http://www2.ohchr.org/english/law/vienna.htm>.

Committee on Economic, Social and Cultural Rights (CESCR).<sup>137</sup> As the General Comment explains, the right to health in international law covers both health care and the underlying determinants of health. It contains four “interrelated and essential elements,” requiring that health goods, services, and facilities be available and accessible to everyone (including being affordable and geographically accessible), acceptable (including culturally), and of good quality. States must respect, protect, and fulfill the right to health.<sup>138</sup> That is, states must refrain from interfering with individuals’ abilities to realize this right—for example, discrimination in access to health services is forbidden—and they must protect people from violations of this right by third parties and actively ensure the full realization of this right.<sup>139</sup>

Although the right to health offers a critical framework for national and global responsibilities for health, it also suffers from four limitations: First, the right to health contains broad aspirations, failing to structure obligations with sufficient detail to render them susceptible to rigorous monitoring and enforcement. Second, the oversight body—the CESCR—has possessed few enforcement powers beyond reviewing state reports on treaty implementation and making recommendations. Third, the ICESCR requires states to deliver on the convention’s promises “progressively,” rather than immediately, leading to a

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137 Among the special rapporteur reports are: Special Rapporteur of the Commission on Human Rights on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, *Report*, U.N. Economic and Social Council, U.N. Doc. E/CN.4/2005/51 (Feb. 11, 2005) (by Paul Hunt), available at [http://www.ifhro.org/images/stories/ifhro/documents\\_UN\\_special\\_rapporteur/3\\_4\\_4.pdf](http://www.ifhro.org/images/stories/ifhro/documents_UN_special_rapporteur/3_4_4.pdf); Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, *Promotion and Protection of all Human Rights, Civil, Political, Economic and Cultural Rights*, U.N. Economic and Social Council, U.N. Doc. A/HRC/7/11 (Jan. 31, 2008) (by Paul Hunt), available at [http://www.ifhro.org/images/stories/ifhro/documents\\_UN\\_special\\_rapporteur/3\\_4\\_2.pdf](http://www.ifhro.org/images/stories/ifhro/documents_UN_special_rapporteur/3_4_2.pdf); Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, *The Right to Health, transmitted by Note of the Secretary-General*, U.N. Doc. A/64/263 (Aug. 11, 2008) (by Paul Hunt), available at [http://www.ifhro.org/images/stories/ifhro/documents\\_UN\\_special\\_rapporteur/3\\_4\\_8.pdf](http://www.ifhro.org/images/stories/ifhro/documents_UN_special_rapporteur/3_4_8.pdf).

The CESCR will soon have additional opportunities to interpret the right to health and other economic, social, and cultural rights. In December 2008, the UN General Assembly adopted the Optional Protocol to the ICESCR, which will allow individuals and groups to file complaints (“communications”) regarding violation of their rights under the ICESCR. Upon ratification of a tenth state in early 2013, the Optional Protocol will enter force in May 2013. Optional Protocol to the International Covenant on Economic, Social and Cultural Rights, G.A. Res. 63/117, U.N. Doc. A/RES/63/117 (2008), available at <http://www1.umn.edu/humanrts/instree/opt-prot08.html>; Press Release, UN Office of the High Commissioner for Human Rights, Pillay Welcomes Major Breakthrough Enabling Individual Complaints on Economic, Social and Cultural Rights (Feb. 6, 2013), available at <http://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=12968&LangID=E>.

138 *General Comment No. 14, The Right to the Highest Attainable Standard of Health*, U.N. Comm. on Econ., Soc. & Cultural Rights, U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000), available at <http://www1.umn.edu/humanrts/gencomm/escgencom14.htm> [hereinafter *General Comment 14*].

139 *Id.*



staggered and uncertain path toward full realization. Fourth, the legal duty falls primarily on the state (not the international community) to provide health services to its own people, even if the state has few resources and limited capacity.

Yet these four structural limitations in the right to health framework can be overcome. The CESCR can develop clear and enforceable standards and press states harder toward implementation. In May 2013, the Optional Protocol to the ICESCR will enter force with respect to parties that have ratified the Protocol, enabling the CESCR to receive individual and group communications on violations and to issue its views and recommendations on these complaints, and to urge interim measures. The duty to “progressively” realize the right to health could be interpreted to require states to meet precise indicators or benchmarks of tangible progress. The ICESCR’s text itself requires states “to take steps” immediately to achieve “the full realization” of the right to health. The CESCR affirms that states must “move as expeditiously and effectively as possible towards that goal.”<sup>140</sup> As we will discuss more below, an FCGH could further clarify ambiguities and respond to limitations.

The all-important capacity problem can be overcome through the treaty’s insistence that states use “the maximum of [their own] available resources,” and that the international community provide “assistance and co-operation, especially economic and technical.”<sup>141</sup> As General Comment 14 explains, “If resource constraints render it impossible for a State to comply fully with its Covenant obligations, it has the burden of justifying that every effort has nevertheless been made to use all available resources at its disposal in order to satisfy, as a matter of priority, [its obligations].”<sup>142</sup> Taken together, the United Nations Charter, established principles of international law, and the Covenant itself hold that “international cooperation for development and thus for the realization of economic, social and cultural rights is an obligation of all States. It is particularly incumbent upon those States which are in a position to assist others.”<sup>143</sup> General Comment 14 states that international assistance is necessary to “enable developing countries to fulfill their core [obligations],” including immediate assurance of essential primary health care for all.<sup>144</sup> Still, like other aspects of the

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140 *General Comment No. 3, The Nature of States Parties' Obligations*, U.N. Comm. on Econ., Soc. & Cultural Rights, U.N. Doc. E/1991/23 (Dec. 14, 1990), available at <http://www1.umn.edu/humanrts/gencomm/epcomm3.htm> [hereinafter *General Comment 3*].

141 ICESCR, *supra* note 74, at art. 2(1). Scholars have made efforts to come to terms with the overly vague and difficult to measure obligations. See, e.g., RADHIKA BALAKRISHNAN ET AL., MAXIMUM AVAILABLE RESOURCES AND HUMAN RIGHTS: ANALYTICAL REPORT (2011), <http://www.cwgl.rutgers.edu/economic-a-social-rights/380-maximum-available-resources-a-human-rights-analytical-report-> [hereinafter MAXIMUM AVAILABLE RESOURCES]. These are among the ICESCR limitations to which an FCGH would respond.

142 *General Comment 14, supra* note 138.

143 *General Comment 3, supra* note 140.

144 *General Comment 14, supra* note 138.

right, the ICESCR and General Comment provide little guidance on what maximum available resources entail and the extent and nature of assistance and cooperation required.

The right to health—and related entitlements such as the right to food, clean water, and adequate sanitation—continues to evolve and gain international acceptance.<sup>145</sup> Meanwhile, several other emerging paradigms join the human rights framework in recognizing global health as a shared responsibility, a partnership, and a priority that requires the cooperation of all countries. These complementary and mutually reinforcing approaches include health as a fundamental aspect of human security<sup>146</sup> as well as health as a global public good.<sup>147</sup> Unlike the right to health, these two frameworks do not have the force of law, but they have gained international acceptance. With human rights benefiting from both widespread acceptance and firm legal grounding, even with their limitations, they are a powerful platform upon which to base a new framework on shared global responsibility for health.

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145 The Human Right to Water and Sanitation, G.A. Res. 64/292, U.N. Doc. A/RES/64/292 (July 28, 2010); The Human Rights to Safe Drinking Water and Sanitation, G.A. Res. 16/2, U.N. Doc. A/HRC/RES/16/2 (Mar. 24, 2011); The Right to Food, G.A. Res. 65/220, U.N. Doc. A/RES/65/220 (Dec. 21, 2010); The Right to Food, G.A. Res. 16/27, U.N. Doc. A/HRC/RES/16/27 (Mar. 25, 2011).

146 The concept of human security extends the notion of security far beyond traditional national security interests. The high-level Commission on Human Security, commissioned by the government of Japan, defined human security to mean “to protect the vital core of all human lives in ways that enhance human freedoms and human fulfillment,” including by protecting fundamental freedoms and “creating political, social, environmental, economic, military and cultural systems that together give people the building blocks of survival, livelihood and dignity.” *Human Security Now*, COMM’N ON HUMAN SEC. iv (2003), [http://www.policyinnovations.org/ideas/policy\\_library/data/01077/\\_res/id=sa\\_File1/](http://www.policyinnovations.org/ideas/policy_library/data/01077/_res/id=sa_File1/). “Good health is both essential and instrumental to achieving human security.” *Id.* at 96.

147 Public goods traditionally share the features of being non-rivalrous (once supplied to one person, the good can be supplied to all other people at no extra cost) and non-excludable (once the good is supplied to one person, it is impossible to exclude other people from the benefits of the good). Technically health does not share these features. For example, it is possible to supply one person with medicine, but not another, while supplying medicine to another person will have an additional cost. However, the collective action required to achieve global health, as well as its considerable positive externalities, such as preventing the spread of communicable disease and improving economic growth, has led scholars to apply this term to global health, or at least aspects of it. See *Global Public Goods*, WORLD HEALTH ORG., <http://www.who.int/trade/glossary/story041/en/index.html> (last visited Dec. 6, 2012); Richard D. Smith & Landis MacKellar, *Global Public Goods and the Global Health Agenda: Problems, Priorities and Potential*, 3 GLOBALIZATION & HEALTH (2007), <http://www.globalizationandhealth.com/content/3/1/9>.

## IV. FOUR DEFINING QUESTIONS FOR THE FUTURE OF THE WORLD'S HEALTH

*A. The Four Questions*

Having explained the moral and legal underpinnings of our approach, we now sketch preliminary answers to four questions that, taken together, are critically important for the future of global health.<sup>148</sup> The questions are designed to point the way towards global governance structures that will significantly advance global health equity while directly confronting issues of responsibility to underlie those structures.

These questions, which seek to clarify national and international responsibilities towards vital goals rooted in human rights and the governance required to effectuate these responsibilities, may also be instructive for other legal regimes. For example, how should institutions and processes that bear on food production be structured to ensure food security for all, and what responsibilities do countries hold for achieving this goal, both with respect to their own populations and with respect to the global population? One may ask similar questions about meeting everyone's right to education and to social security.<sup>149</sup>

*1. What are the health services and goods guaranteed to every human being under the right to health?*

Our first foundational challenge is to specify the essential health services and goods that make up the core obligations under the right to health. Answers on this front could guide national efforts to provide universal health coverage. Universal health coverage has become a clearly enunciated aim of an increasing number of countries, with some, such as Thailand and Brazil, making significant progress.<sup>150</sup> The international community, led by the WHO, has revived the goal of universal health coverage established in the 1978 Alma-Ata Declaration on

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<sup>148</sup> See *Joint Action and Learning Initiative*, *supra* note 12; *National and Global Responsibilities for Health*, *supra* note 12.

<sup>149</sup> For more on an emerging approach to meet the right to social security by developing a social protection floor, see INT'L LABOUR OFFICE & WORLD HEALTH ORG., SOCIAL PROTECTION FLOOR INITIATIVE (2010), available at <http://www.issa.int/content/download/136762/2785842/file/2social%20protection%20floor%20initiative.pdf>; Nicola Liebert, *No Justice Without Social Protection: What Can International Development Cooperation Do To Make the Social Protection Floor Initiative Work?*, DIALOGUE ON GLOBALIZATION (Sept. 2011), [library.fes.de/pdf-files/iez/08519.pdf](http://library.fes.de/pdf-files/iez/08519.pdf).

<sup>150</sup> Kannika Damrongplasit & Glenn A. Melnick, *Early Results from Thailand's 30 Baht Health Reform: Something to Smile About*, 28 HEALTH AFF. W457 (2009); Claudia Jurberg & Gary Humphreys, *Brazil's March Towards Universal Coverage*, 88 BULL. WORLD HEALTH ORG. 641, 646-47 (2010).

primary health care.<sup>151</sup>

A World Health Assembly resolution defined universal coverage “as access to key promotive, preventive, curative and rehabilitative health interventions for all at an affordable cost.”<sup>152</sup> Clarifying the health services and goods to which everyone is entitled will help define those “key” health interventions and give greater substance to a state’s core duty to meet the health needs of its inhabitants. Answers will also help assess the minimum extent to which affluent states should enhance the capacities of low-income and middle-income countries.

The WHO describes universal health coverage as a multi-dimensional, progressive process that entails increasing the proportion of the population served, the level of services, and the proportion of health costs covered by prepaid pooled funds.<sup>153</sup> The core human rights principle of equal access requires states to prioritize covering 100% of their populations. Although 100% coverage of all health services will not be possible immediately, full coverage of “key” health interventions should be an initial benchmark towards universal coverage.

The right to health framework militates against a narrow definition of “key” services. Rather, key services should encompass adequate health systems and services, including essential medicines, vaccines, and the fundamental human needs that are core to the mission of public health and incorporate the “underlying determinants of health” to which all people have a right under the

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151 The 1978 Alma-Ata Declaration set the goal of “the attainment by all peoples of the world by the year 2000 of a level of health that will permit them to lead a socially and economically productive life,” with primary health care “key to obtaining this target.” Declaration of Alma-Ata, Int’l Convention on Primary Health Care, Alma-Ata, USSR, art. 5 (Sept. 6-12, 1978), *available at* [http://www.who.int/publications/almaata\\_declaration\\_en.pdf](http://www.who.int/publications/almaata_declaration_en.pdf). Thirty years later, WHO’s World Health Report refocused global attention on primary health care, while WHO’s 2010 World Health Report focused directly on universal health coverage. *See World Health Report 2008, supra* note 57; *World Health Report 2010, supra* note 71. A 2005 World Health Assembly resolution urged member states “to plan the transition to universal coverage of their citizens.” WHO, Revision of the International Health Regulations, WHA Doc. WHA58.3 ¶ 1(4) (May 23, 2005), [http://apps.who.int/gb/ebwha/pdf\\_files/WHA58-REC1/english/Resolutions.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA58-REC1/english/Resolutions.pdf). The G8 has acknowledged “the goal of universal access to health services, especially primary health care.” Group of Eight, Responsibility Leadership for a Sustainable Future, L’Aquila Summit (Italy), July 8, 2009, at ¶ 121, <http://www.g8.utoronto.ca/summit/2009laquila/2009-declaration.html>. The African Union’s health strategy for 2007-2015 frames universal access as “the rallying point of the response to all health challenges.” African Union, *Africa Health Strategy 2007-2015*, CAMH/MIN/5(III), 3rd Session of the African Union Conference of Ministers of Health, Johannesburg, South Africa, Apr. 9-13, 2007, at 20, *available at* [http://www.africa-union.org/root/UA/Conferences/2007/avril/SA/9-13%20avr/doc/en/SA/AFRICA\\_HEALTH\\_STRATEGY.pdf](http://www.africa-union.org/root/UA/Conferences/2007/avril/SA/9-13%20avr/doc/en/SA/AFRICA_HEALTH_STRATEGY.pdf). In December 2012, the United Nations General Assembly passed a resolution endorsing universal health coverage. Global Health and Foreign Policy, U.N. General Assembly Res. 67/81, U.N. Doc. A/RES/67/81 (Dec. 12, 2012), *available at* [http://www.un.org/ga/search/view\\_doc.asp?symbol=A/67/L.36](http://www.un.org/ga/search/view_doc.asp?symbol=A/67/L.36).

152 *Social Health Insurance: Sustainable Health Financing, Universal Coverage & Social Health Insurance - Report by the Secretariat, Fifty-Eighth World Health Assembly*, WORLD HEALTH ORG. (2005) [hereinafter *Sustainable Health Financing, Universal Coverage & Social Health Insurance*].

153 *See World Health Report 2010, supra* note 71.

right to health.<sup>154</sup> “Assuring” for everyone these “conditions in which people can be healthy”<sup>155</sup> will go far towards achieving health equity.

The WHO sets out essential building blocks of a well-functioning health system: health services, health workforce, health information, medical products and technologies, a financing system that raises sufficient funds for health and assures access, and leadership and governance.<sup>156</sup> Health systems should ensure basic health care (e.g., primary, emergency, specialized care for acute and chronic diseases and injuries), including essential medicines,<sup>157</sup> and public health services (e.g., surveillance, laboratories, and response) for all inhabitants.

As critical as effective health systems are, people who cannot access nutritious food, whose water contains harmful bacteria, and whose lungs are smothered by pollution and tobacco smoke do not live in conditions that are conducive to good health. People must be ensured the underlying determinants of health and the closely linked ends of a traditional public health strategy, which are vital to maintaining and restoring human capability and functioning. These include adequate sanitation and potable water, clean air, nutritious food, decent housing, vector control, and tobacco and alcohol reduction.<sup>158</sup>

These health goods and services will vary by country in their details and should be determined with input from the public to ensure that they are appropriately adapted to country circumstances and to what people themselves see as their health needs and priorities. Whatever the precise health goods and services to which everyone is most immediately entitled under the right to health, states have an obligation to progressively and continually build upon that level, to more fully realize the right to health. States, even wealthy ones, will need to continue to progress towards universal health coverage, as even wealthy countries do not cover the entire range of services that could improve people’s health. They, too, have scope for more fully realizing the right to health. Yet even a core set of essential goods and services—well within the capacity of countries to provide under a framework of mutual responsibility—could greatly improve

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154 *General Comment 14*, *supra* note 138, at ¶ 11.

155 The Institute of Medicine of the United States National Academies “defines the mission of public health as fulfilling society’s interest in assuring conditions in which people can be healthy.” *The Future of Public Health*, INST. OF MED. 140 (1988), <http://www.iom.edu/Reports/1988/The-Future-of-Public-Health.aspx>.

156 *Everybody’s Business: Strengthening Health Systems to Improve Health Outcomes: WHO’s Framework for Action*, WORLD HEALTH ORG. (2007), [http://www.who.int/healthsystems/strategy/everybodys\\_business.pdf](http://www.who.int/healthsystems/strategy/everybodys_business.pdf).

157 WHO has developed a Model List of Essential Medicines, which include “the most efficacious, safe and cost-effective medicines for priority conditions.” WORLD HEALTH ORG., *THE SELECTION AND USE OF ESSENTIAL MEDICINES - WHO TECHNICAL REPORT SERIES NO. 920* (2010); see also *WHO Model List of Essential Medicines*, WORLD HEALTH ORG. <http://www.who.int/medicines/publications/essentialmedicines/en/> (last visited Dec. 5, 2012).

158 Lawrence O. Gostin, *Meeting the Survival Needs of the World’s Least Healthy People: A Proposed Model for Global Health Governance*, 298 JAMA 225 (2007).

the lives of a vast number of people.

Healthy conditions require even more, though. If all people are to be assured conditions in which they can be healthy, conditions requisite for a functioning, and indeed flourishing, life,<sup>159</sup> even what we have proposed thus far is insufficient. For example, a woman who is abused by her husband and lacks the educational and economic wherewithal to leave him and support herself and her children, or confidence in a justice system to protect her and prosecute him, still lives in unhealthy conditions even if she lives in a community with an effective health system, clean air, and clean water. The male clerk in the civil service in the United Kingdom in the 1960s would seem to have lived in the conditions required for good health—good health care through National Health Services, the water and food and other necessities readily available in one of the world's wealthiest countries. Yet, this clerk was four times more likely to die over a twenty-five year period than a colleague at the top of the civil service hierarchy.<sup>160</sup> Something needed for health was missing.

What people further require for good health are the broader social and economic determinants of health: gender equity, employment, education, effective justice systems that would have prevented the violence or enabled the woman to escape it, and the reduced stress and greater control over their lives that differentiated the lives of men at the top and bottom of the British civil service hierarchy. Achieving these ends requires healthy living conditions, from early childhood development to social security later in life, and overcoming the inequities in income, power, and other resources.<sup>161</sup>

The relative nature of many of these, such as greater equality and less stress, prevents them from being conceived of in a set of goods and services guaranteed to all people, like medicine, a health professional at the ready, or even clean air and nutritious food. In addition, goals like access to education and to fair employment belong to a mission that is much broader than improving health alone.

Yet health equity cannot be achieved without addressing these factors. Not only do the least affluent among us suffer the worst health, but wherever people live, the lower a person's socioeconomic status, the worse their health. As the WHO Commission on Social Determinants of Health stated, "Social injustice is killing people on a grand scale."<sup>162</sup> A single treaty focused on global health cannot be expected to solve these problems—to achieve not only greater health

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159 AMARTYA SEN, *DEVELOPMENT AS FREEDOM* (1999); JENNIFER P. RUGER, *HEALTH AND SOCIAL JUSTICE* (2010).

160 MICHAEL MARMOT, *THE STATUS SYNDROME: HOW SOCIAL STANDING AFFECTS OUR HEALTH AND LONGEVITY* 38-39 (2004).

161 See COMMISSION ON SOCIAL DETERMINANTS OF HEALTH, *CLOSING THE GAP IN A GENERATION: HEALTH EQUITY THROUGH ACTION ON THE SOCIAL DETERMINANTS OF HEALTH* (2008), available at: [http://whqlibdoc.who.int/publications/2008/9789241563703\\_eng.pdf](http://whqlibdoc.who.int/publications/2008/9789241563703_eng.pdf).

162 *Id.* at 26.

justice, but also a state of global social justice. At the same time, to succeed, an effort to secure global health justice must influence these other spheres of life.

## 2. What do states owe for the health of their own populations?

As the member states of the United Nations have themselves recognized, “[h]uman rights and fundamental freedoms are the birthright of all human beings; their protection and promotion is the first responsibility of Governments.”<sup>163</sup> Individual states hold primary responsibility to ensure the right to health of their inhabitants. Under the right to health, states are obliged to use the maximum of their available resources to fund and ensure the delivery of all the essential goods and services guaranteed to every human being, and to progressively achieve the highest attainable standard of health. These resources are not limited to financial resources; they also include human resources and information.<sup>164</sup> Some of these resources entail their own obligations, such as not blocking people’s access to health information.<sup>165</sup> Yet sufficient funding is a basic precondition for ensuring people the health services to which they have a right. States must provide adequate funding within their capacity.

Yet many states fail to do so. Despite the undoubted need for expanded health services, developing country health expenditures as a proportion of total government spending are significantly lower than the global average (<10% compared with >14%).<sup>166</sup> This low spending comes even as African heads of state pledged in the 2001 Abuja Declaration to commit at least 15% of their government budgets to the health sector<sup>167</sup>—a pledge reaffirmed at their 2010 summit.<sup>168</sup> At the present rate of increase (from 2000 to 2009), it will not be until 2044—more than four decades after the Abuja Declaration—that average health sector spending among African countries will reach the 15% target.<sup>169</sup> Health spending in South East Asia, both in absolute terms and relative to government

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163 *Vienna Declaration*, *supra* note 136, at ¶ 1.

164 Robert E. Robertson, *Measuring State Compliance with the Obligation to Devote the “Maximum Available Resources” to Realizing Economic, Social, and Cultural Rights*, 16 HUMAN RIGHTS QUARTERLY 693 (1994).

165 See *General Comment 14*, *supra* note 138, at ¶ 34.

166 See *World Health Statistics 2012*, *supra* note 86, at 142.

167 Organisation of African Unity, *Abuja Declaration on HIV/AIDS, Tuberculosis and Other Related Infectious Diseases*, OAU/SPS/ABUJA/3, 36th Ordinary Session, Abuja, Nigeria, Apr. 26-27, 2001, at 26, available at [http://www.un.org/ga/aids/pdf/abuja\\_declaration.pdf](http://www.un.org/ga/aids/pdf/abuja_declaration.pdf).

168 African Union, *Actions on Maternal, Newborn and Child Health and Development in Africa by 2015*, Assembly/AU/Dec.1 (XV), 15th Ordinary Session, Kampala, Uganda, July 25-27, 2010, at 1, available at [http://www.unfpa.org/webdav/site/global/shared/documents/news/2010/kampala\\_au\\_assembly\\_dec.pdf](http://www.unfpa.org/webdav/site/global/shared/documents/news/2010/kampala_au_assembly_dec.pdf).

169 African countries will need to spend, on average, an additional 5.4% of their budgets on the health sector to reach 15%, building on the increase from 8.2% in 2000 to 9.6% in 2009. See *World Health Statistics 2012*, *supra* note 86, at 142. At the current pace of a 1.4% increase every nine years, it will be 35 years after 2009 before the average reaches 15%.

budgets, is even lower.<sup>170</sup>

States' own health spending is influenced by foreign assistance, which accounts for 15% of total health expenditures in low-income countries on average, and can be as high as two-thirds in some low-income countries. Developing countries often reduce their domestic health spending in response to increasing international assistance—the so-called “substitution effect.”<sup>171</sup> It matters a great deal, of course, the purpose for which domestic health spending is being diverted. Non-health sector expenditures such as agriculture, education, or social security can improve health. Expenditures on infrastructure such as roads or electricity may similarly improve well-being.<sup>172</sup> Yet some governments will use these funds for purposes much less likely to improve health, such as the police or military, or might waste precious resources through corruption or inefficiency.

It is unrealistic to expect that affluent states will carry out their responsibilities efficiently if lower-income states do not provide necessary resources for health within their own economic constraints. Wealthier states may well ask themselves why they should assist countries in meeting their needs if these countries are unwilling to take the measures necessary to help themselves. A firm and realized commitment on the part of lower-income countries to make a clearly defined effort, consistent with their human rights obligations, could convince wealthier countries to accept their mutual responsibilities.

Regardless of whether 15% of government spending on that sector is the most appropriate funding target for health, the multi-sector dimensions of health will require additional government spending. African states again have been in the lead of establishing their own targets, even if they often fall well short of meeting them. They have committed to allocate at least 10% of their national budgets for agricultural development,<sup>173</sup> and thirty-two African countries set a target, framed as an aspiration, for public sector budget allocations for sanitation and hygiene programs to reach at least 0.5% of gross domestic product.<sup>174</sup>

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170 Government spending on health in South East Asia is the lowest of any region in the world. It increased as a percent of total government expenditure from 4.4% in 2000 to 4.9% in 2009 and from \$6 per capita to \$19 per capita during the same timespan. See WORLD HEALTH STATISTICS 2012, *supra* note 86, at 142.

171 See Chunling Lu et al., *Public Financing of Health in Developing Countries: a Cross-National Systematic Analysis*, 375 LANCET 1375 (2010).

172 Due to the increased access they provide to health services, greater road density in Africa is significantly associated with lower child and maternal mortality and greater access to improved sanitary facilities. Melina R. Platas, *Africa's Health Tragedy? Ethnic Diversity and Health Outcomes* (Working Group on African Political Economy, Working Paper, Dec. 5, 2010), available at [http://www.sscnet.ucla.edu/polisci/wgape/papers/19\\_Platas.pdf](http://www.sscnet.ucla.edu/polisci/wgape/papers/19_Platas.pdf).

173 African Union, *Maputo Declaration on Agriculture and Food Security in Africa*, 2nd Ordinary Session, Maputo, Mozambique, July 10–12, 2003, at 2, available at <http://www.nepad.org/system/files/Maputo%20Declaration.pdf>.

174 Second African Conference on Sanitation and Hygiene, *The eThekweni Declaration and*



A government's fidelity to the maximum available resources requirement raises the question of what resources are available. What revenue is available to the treasury? A certain level of effort, especially through progressive taxation policies and efficient tax collection, is necessary to increase the resources available. It will be difficult for national tax policies in the poorest states to generate government revenue above 20% of the gross national income (GNI).<sup>175</sup> States that rely heavily on royalties, taxes, and fees from natural resources must ensure that they are receiving a fair deal, while also being careful stewards of these funds.

The tax system is particularly critical. Evidence shows a strong positive correlation between the human development index and the proportion of GNI available for government investments through tax revenue.<sup>176</sup> That is, governments that are effective at collecting taxes are also more effective at meeting their people's needs. Yet only a handful of African countries have achieved the 20% level of tax revenue.<sup>177</sup> Countries should also use other levers to increase their resources, including actively seeking international support and through monetary policy.<sup>178</sup>

As we have emphasized, money alone will not ensure good health. Achieving the "highest attainable standard of . . . health" requires that the money is well spent, and policies are properly conceived and effectively implemented. Too often, this is not the case. Health sector corruption is a significant problem in some developing countries. According to a World Bank survey of twenty-two developing countries, health was one of the most corrupt sectors.<sup>179</sup> Health sector corruption includes bribes and kickbacks, drug diversion from the public sector to the private market, informal payments to providers, accreditation and licensing bribes, and professional absenteeism.<sup>180</sup> Foreign aid, in particular, is considered "ripe territory for corruption" because it theoretically permits "rent-seeking"

*AfricaSan Action Plan*, (2008), available at <http://www.wsp.org/wsp/sites/wsp.org/files/publications/cThekwiniAfricaSan.pdf>.

<sup>175</sup> George J. Schieber et al., *Financing Global Health: Mission Unaccomplished*, 26 HEALTH AFF. 921, 921-34 (2007).

<sup>176</sup> Attiya Waris & Matti Kohonen, Building Taxation to Build Millennium Development Goals in Africa: PowerPoint Presentation at the Go4Health meeting, Entebbe Uganda (September 18-19, 2012).

<sup>177</sup> *Id.*

<sup>178</sup> MAXIMUM AVAILABLE RESOURCES, *supra* note 141.

<sup>179</sup> *Corruption in the Health Sector: Causes and Consequences*, ANTI-CORRUPTION RESOURCE CTR., <http://www.u4.no/themes/health/causesandconsequences.cfm> (last visited Dec. 5, 2012); Maureen Lewis, Corruption and Health in Developing and Transition Economies: PowerPoint Presentation, available at <http://www1.worldbank.org/publicsector/anticorrupt/IACC/HealthCorruption.ppt> (last visited Dec. 9, 2012).

<sup>180</sup> For more on health sector corruption in developing countries, see Maureen Lewis, *Center for Global Development Brief: Tackling Healthcare Corruption and Governance Woes in Developing Countries* (2006), CTR. FOR GLOBAL DEV. [http://www.cgdev.org/files/7732\\_file\\_GovernanceCorruption.pdf](http://www.cgdev.org/files/7732_file_GovernanceCorruption.pdf).

behavior.<sup>181</sup> In other words, local officials can profit from foreign aid, which is often allocated to governments with substantial discretion and—at least historically—little accountability. A vicious cycle of corruption related to foreign assistance can occur, as corrupt countries tend to perform poorly and therefore increasingly depend on aid.<sup>182</sup>

This is not to say that funds are never well spent. To the contrary, the health improvements over the past decades, including the impact of PEPFAR and other global health programs, demonstrate that health investments can and often do lead to better health outcomes. It also obscures tremendous differences across countries. Yet corruption, mismanagement, and inefficiencies do mean that in many countries, health funding could go much further towards improving health outcomes if countries, and the health sector in particular, were better governed.

Along with funding then, states have a responsibility to govern well. The concept of “good governance” sets consistent standards for national management of economic and social resources for development:

Those who exercise authority to expend resources and make policy have a duty of *stewardship*—a personal responsibility to act on behalf, and in the interests of, those whom they serve. Sound governance is *honest*, in that it avoids corruption, such as public officials seeking personal gain or diverting funds from their intended purposes. It is *transparent*, in that institutional processes and decisionmaking are open and comprehensible to the people. It is *deliberative*, in that government engages stakeholders and the public in a meaningful way, giving them the right to provide genuine input into policy formation and implementation. Good governance is also *accountable*, in that leaders give reasons for decisions and assume responsibility for successes or failures, and the public has the opportunity to disagree with and change the direction of policies. Good governance enables states to formulate and implement sound policies, manage resources efficiently, and provide effective services.<sup>183</sup>

In addition, drawing on the right to health principles of equal and non-

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181 Jakob Svensson, *Foreign Aid and Rent-Seeking*, 51 J. INT’L ECON. 437 (2000).

182 JOSE TAVARES, DOES FOREIGN AID CORRUPT? (2001).

183 JALI World Health Report Background Paper, *supra* note 12, at 25; *see also, e.g., What Is Good Governance?*, U.N. ECON. & SOC. COMM’N IN ASIA & THE PACIFIC, <http://www.unescap.org/pdd/prs/ProjectActivities/Ongoing/gg/governance.asp> (last visited Dec. 5, 2012); WORLD BANK, MANAGING DEVELOPMENT: THE GOVERNANCE DIMENSION: A DISCUSSION PAPER (1991), *available at* [http://www-wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/2006/03/07/000090341\\_20060307104630/Rendered/PDF/34899.pdf](http://www-wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/2006/03/07/000090341_20060307104630/Rendered/PDF/34899.pdf).

discriminatory access and of equitable distribution,<sup>184</sup> a state should fairly and efficiently distribute health goods and services for its entire population. This requires paying special attention to the needs of the most disadvantaged in society such as those who are poor, minorities, women, children, and people with a physical or mental disability. It requires that health services are accessible and acceptable irrespective of socioeconomic status, language, culture, religion, or locality (e.g., rural or urban), and that states take special measures to ensure that those who would otherwise experience the least healthy conditions fully enjoy the conditions needed for health.

### *3. What responsibility do states have for improving the health of people beyond their borders?*

The duty of states is not limited only to their own people, but extends to advancing the right to health in other states as well. In our globalized world, health is a matter of common threats, most notably through the spread of infectious diseases, where insufficiently addressed health concerns abroad may harm the health of a state's own population. Beyond this, however, each state has a deeper responsibility to promote the global achievement of all human rights, even as different states will have vastly different capacities to promote human rights abroad.

We recognize that this expansive understanding of state responsibility will not be without controversy, and a fuller discussion could fill reams of paper drawing on centuries of theories of justice. Such a discussion is outside our scope. Here, let us suffice with several observations about why we take this stance, focusing on this responsibility as it relates to health.

First, this is a necessary position if we are to resolve today's global health inequities. These inequities are unacceptable and must be eliminated—a person's life chances should not depend on the happenstance of birth, and will require international action. The underlying premise that human rights are founded on, the "inherent dignity . . . of all members of the human family,"<sup>185</sup> is held by each individual, and is not subject to national borders. The proposition of a shared responsibility on achieving the right to health and other rights is now widely

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184 The core obligations include "[t]o ensure equitable distribution of all health facilities, goods and services." *General Comment 14*, *supra* note 138, ¶ 43(a). General Comment 14 emphasizes vulnerable and marginalized populations throughout. *See, e.g., id.* ¶ 43(f) (including that, as part of the core obligation to develop a national public health strategy, such strategies "shall give particular attention to all vulnerable or marginalized groups"); *id.* ¶ 12(b) (including that, as part of the requirement to non-discrimination, "health facilities, goods and services must be accessible to all, especially the most vulnerable or marginalized sections of the population, in law and in fact").

185 Universal Declaration of Human Rights, G.A. Res. 217 (III) A, U.N. Doc A/RES/217(111) at pmbl. (Dec. 10, 1948), *available at* <http://www1.umn.edu/humanrts/instreet/bludhr.htm>.

accepted and is reflected in the “international cooperation and assistance” obligations of the ICESCR, the pledge to cooperate with the United Nations in achieving “universal observance” of human rights,<sup>186</sup> and the shared responsibility inherent to the MDGs. A paradigm shift towards a notion of shared responsibilities is underway, even as the next, critical step of turning this principle into specific responsibilities remains.

Second, in our globalized world, we are interdependent, where many of our actions affect health in other countries. These include direct effects, such as trade agreements that may limit access to medicines, agricultural subsidies that reduce incomes and the ability of families in poorer countries to afford nutritious food, and greenhouse gas emissions that lead to climate change. They also include less direct effects, such as decisions of individual consumers that can support exploitative or fair agricultural and industrial practices abroad, and how wealthier countries manage their economies, affecting demand for imports, with implications for economic growth and health budgets in other parts of the world. Policies and practices of wealthier nations have contributed to the ill health in poorer countries, creating a responsibility for the wealthier nations to rectify national misdeeds. From colonialism to World Bank and International Monetary Fund structural adjustment programs,<sup>187</sup> and irresponsible loans followed by requiring debt repayments that often exceeded health budgets,<sup>188</sup> policies of wealthier nations have caused considerable damage. Countries that today bear the greatest burden of disease have incurred harms both to health directly and to broader national capacities.

Finally, to protect the health of their own populations, countries will need to protect health and strengthen health systems abroad. This is most directly the case for infectious diseases that, if not contained in one country, can spread to

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186 U.N. CHARTER art. 55 (“The United Nations shall promote . . . (c) universal respect for, and observance of, human rights and fundamental freedoms for all.”); *see also* U.N. Millennium Declaration, *supra* note 82, ¶ 2. (world leaders affirming that “we have a collective responsibility to uphold the principles of human dignity, equality and equity at the global level.”). In addition, while focused on other human rights violations, namely the types of mass atrocities that underlying crimes against humanity, war, and genocide, the international community has now adopted a “responsibility to protect.” Under this responsibility, states agree to the need for collective action where “national authorities are manifestly failing to protect their populations from genocide, war crimes, ethnic cleansing and crimes against humanity.” 2005 World Summit Outcome, G.A. Res. 60/1, U.N. Doc. A/RES/60/1 (Sept. 16, 2005).

187 For example, African countries implementing structural adjustment programs cut health spending by 50%, as the Economic Commission for Africa reported in 1989. Mohammed Nuruzzaman, *The World Bank, Health Policy Reforms and the Poor*, 37 J. CONTEMP. ASIA 59 (2007); *see also* Jennifer Prah Ruger, *The Changing Role of the World Bank in Global Health*, 95 AM. J. PUBLIC HEALTH 60 (2005).

188 Robin Stott, *The World Bank: Friend or Foe to the Poor?*, 318 BRIT. MED. J. 822 (1999); Eric A. Friedman, *An Action Plan to Prevent Brain Drain: Building Equitable Health Systems in Africa*, PHYSICIANS FOR HUMAN RIGHTS 30 (2004), [https://s3.amazonaws.com/PHR\\_Reports/Africa-prevent-brain-drain-report-2004.pdf](https://s3.amazonaws.com/PHR_Reports/Africa-prevent-brain-drain-report-2004.pdf).

another. The less capable a country is of containing a disease, the more likely it will spread to other countries and affect the right to health of another country's population. This is also the case with respect to drug resistance. If countries with heavy burdens of tuberculosis were able to ensure prompt, effective treatment for everyone affected with tuberculosis, multiple-drug resistant and extremely drug resistant tuberculosis would not be the global health threats that they are today.

Yet even if we can agree on the need—and responsibility—for collective action to address global health challenges including our foremost concern of health inequities, a harder question remains to be answered: Exactly what are these responsibilities? One, is financing. To what extent are states, particularly wealthier ones, responsible for the provision of health-related goods and services to residents of other countries? Even recognizing transnational obligations, the questions remain, which states have duties, to whom, and for what?<sup>189</sup>

Despite the conceptual complexity, it is imperative to find innovative ways for holding richer states accountable for a certain level of international assistance. Unfortunately, a tremendous burden of avoidable morbidity and premature mortality rests on those who have the least capacity to adequately respond to it. As described above, earlier WHO estimates suggest that a basic set of health sector services costs a minimum of \$60 per person annually. If states were to generate 20% of GNI as government revenue and allocate 15% of their government revenue to the health sector, then they would be able to spend 3% of their GNI on the health sector.<sup>190</sup> Thus, in general, only states with a GNI of more than \$2,000 per person per year have the domestic capacity to develop health systems able to provide essential health goods and services.<sup>191</sup>

The \$60 estimate is a figure that will vary by country because of differences in purchasing power and in epidemiologies, geographies, and priorities. We question this figure because it includes only a limited number of services for non-communicable diseases.<sup>192</sup> More significantly, it does not include the underlying determinants of health such as nutritious food, much less broader socioeconomic determinants of health. Even leaving aside these limitations, even if states with a GDP per capita of \$2,000 had the capacity, using only internal resources, to provide everyone the health goods and services to which all people are entitled, billions of people would go without. More than one-third of the world's people

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189 NORMAN DANIELS, *JUST HEALTH: MEETING HEALTH NEEDS FAIRLY* (2008).

190 Gorik Ooms & Rachel Hammonds, *Taking up Daniels' Challenge: The Case for Global Health Justice*, 12 HEALTH & HUMAN RTS. 29 (2010), available at <http://www.hhrjournal.org/index.php/hhr/article/view/201/307>. If the government's revenue is 20% of GNI, 15% of this (i.e., the health sector share) is 3% of GNI. For government spending to be \$60 per capita, total GNI must be \$2,000 per capita ( $X * 3\% = \$60$ ).

191 *Id.*

192 See also Bellagio JALI meeting report, JALI 18 (2012), <http://www.jalihealth.org/documents/Bellagio%20report%205-3-12.pdf> (suggesting higher spending needs).

live in countries with the per capita GDP below \$2,000.<sup>193</sup> These countries, and we expect others, will require external support to provide their entire populations essential health goods and services.

The Commission on Macroeconomics and Health calculated that affluent states would need to devote approximately 0.1% of GNI to international development assistance for the health sector.<sup>194</sup> Other data suggest that a similar,<sup>195</sup> or somewhat higher, proportion of GNI may be necessary.<sup>196</sup> In 2008,

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193 Ooms & Hammonds, *supra* note 192, at 37. For most countries, GNI per capita is very similar to GDP per capita. For example, India GDP per capita in 2011 was \$1,489, while its GNI per capita the same year was \$1,410. *GDP per capita (current US\$)*, WORLD BANK, <http://data.worldbank.org/indicator/NY.GDP.PCAP.CD> (last visited Feb. 20, 2013); *Gross national income per capita 2011, Atlas method and PPP*, WORLD BANK, <http://databank.worldbank.org/databank/download/GNIPC.pdf> (last visited Feb. 20, 2013).

194 WHO COMMISSION ON MACROECONOMICS AND HEALTH, *MACROECONOMICS AND HEALTH: INVESTING IN HEALTH FOR ECONOMIC DEVELOPMENT* (2001). While international assistance for health has fallen short of the Commission's recommendations, domestic health spending in developing countries has, overall, been higher than the Commission believed necessary. The Commission called for national health spending to increase by \$23 billion by 2007. In fact, from 1995 to 2006, developing countries' health spending increased from \$128 billion to \$241 billion (in 2006 dollars). See Pamela Das & Udani Samarasekera, *The Commission on Macroeconomics and Health: 10 years on*, 378 LANCET 1907 (2011); *Financing Global Health 2010: Development Assistance and Country Spending in Economic Uncertainty*, INST. FOR HEALTH METRICS AND EVALUATION 45–47 (2010), [http://www.healthmetricsandevaluation.org/publications/policy-report/financing\\_global\\_health\\_2010\\_IHME](http://www.healthmetricsandevaluation.org/publications/policy-report/financing_global_health_2010_IHME). However, as a percentage of GNI, developing countries have a mixed record with respect to the Commission's recommendation of increasing health spending as a percentage of GDP by 1% by 2007 and 2% by 2015. For example, it increased from 5.5% to 6.5% of GDP in Africa from 2000 to 2009, while during those years, it only edged up in South East Asia from 3.7% to 3.8% of GDP. *Id.*; *World Health Statistics 2012*, *supra* note 86, at 142. This suggests that the increased funding was more related to strong economic growth than to increased prioritization of funding for health. Most significantly, despite increased domestic health spending and genuine advances in health outcomes, the immense inequities we have described remain.

195 The MDG Africa Steering Group estimated that by 2010, Africa required an annual \$28 billion in external assistance for health care to meet the MDGs on maternal and child health and major diseases. MDG AFRICA STEERING GROUP, *ACHIEVING THE MILLENNIUM DEVELOPMENT GOALS IN AFRICA: RECOMMENDATIONS OF THE MDG AFRICA STEERING GROUP* (2008). At present, wealthy countries spend approximately 48% of their health assistance in sub-Saharan Africa (based on 2009 data). See KATES ET AL., *supra* note 86, at 6. To the extent that this reflects an appropriate regional distribution of health assistance, and not accounting for inflation or currency fluctuations, this suggests a global health assistance requirement of \$58 billion in 2010 (\$28 billion being 48% of \$58 billion). This is approximately 0.13% of high-income country GNI, based on a total \$43.4 trillion GNI for high-income countries in 2010. *Gross National Income 2010, Atlas Method*, WORLD BANK, <http://siteresources.worldbank.org/DATASTATISTICS/Resources/GNI.pdf> (last visited Dec. 5, 2012).

196 Another perspective on the figures from the MDG Africa Steering Group raises the possibility that a higher percentage of GNI might be required for health care. According to their calculations, the \$28 billion represented 39% of Africa's total MDG-related external assistance requirement. This is considerably higher than the 19% of MDG-related development assistance that would be used for health care if wealthy countries dedicated only 0.1% GNI towards health assistance out of a total of 0.54% GNI needed to meet the MDGs, according to calculations of the

Official Development Assistance (ODA) for health care from traditional donor countries—members of the Development Assistance Committee of the OECD—was slightly below 0.05% GNI, or less than half of what is likely required.<sup>197</sup>

Consequently, if low-income and middle-income countries are to afford their inhabitants a reasonable standard of health services, wealthier states will have to ensure financing that is predictable, sustainable, and scalable to needs. The High Level Taskforce on Innovative International Financing for Health Systems reported in 2009 that in order to achieve the MDGs and scale up essential health services, health spending (from all sources) in forty-nine low-income countries alone had to increase from \$31 billion to \$67-76 billion annually by 2015, which was \$10 billion more than existing commitments. Even this recommended level of funding largely excludes basic human needs such as clean water and adequate sanitation and hygiene.<sup>198</sup> However, the world is not on track to meet these and other funding requirements. Moreover, in the aftermath of the present global financial downturn, prospects for future growth in international health assistance appear grim.

The volume of international financial responsibility for global health certainly matters, but is not the only financing concern. Another is the long-term reliability of international funding. We have described harm that this lack of sustained, predicable funding entails, from health programs terminated to health workers not hired.<sup>199</sup>

Financial assistance not based on an understanding of mutual responsibility, and unreliable in the long run, is therefore an inefficient expenditure of resources,

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United Nations Millennium Project. *Investing in Development: A Practical Plan to Achieve the Millennium Development Goals*, U.N. MILLENNIUM PROJECT (2005), <http://www.unmillenniumproject.org/reports/fullreport.htm>.

<sup>197</sup> Official development assistance for health was \$17.2 billion in 2009, excluding water and sanitation, which were not part of the estimate from the Commission on Macroeconomics and Health (nor were included in the \$28 billion required from external sources to reach the health MDGs in Africa as estimated by the MDG Africa Steering Group). Total official development assistance (ODA) in 2009 was \$135.1 billion. Kates et al., *supra* note 86, at 6, 4. According to the OECD, which reports lower levels of total ODA (\$119.8 billion in 2009), OECD's Development Assistance Committee members spent 0.31% of their GNI on ODA in 2009. *Development Aid Rose in 2009 and Most Donors Will Meet 2010 Aid Targets*, ORG. FOR ECON. COOPERATION & DEV. (Apr. 4, 2010), [http://www.oecd.org/document/0,3746,en\\_2649\\_34447\\_44981579\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/0,3746,en_2649_34447_44981579_1_1_1_1,00.html) (last visited Dec. 5, 2012). The difference in total ODA is that the OECD figures provide net ODA (deducting loan repayments) while the Kaiser Family Foundation reports gross ODA (without deducting loan repayments). Using the proportion of ODA that went to health based on the Kaiser Family Foundation report (12.7%), the \$17.2 billion for health care was approximately 0.04% of GNI ( $0.127 \times 0.31$ ) for these countries.

<sup>198</sup> *More Money for Health, and More Health for the Money*, TASKFORCE ON INNOVATIVE INT'L FIN. FOR HEALTH SYSTEMS (2009), [http://www.who.int/tobacco/economics/en\\_tfi\\_economics\\_final\\_task\\_force\\_report.pdf](http://www.who.int/tobacco/economics/en_tfi_economics_final_task_force_report.pdf). The essential health services would cover "a broad set of interventions that address the main causes of burden of disease." They would cost \$8,000-10,000 per death averted. *Id.* at 22.

<sup>199</sup> See *Paris Declaration*, *supra* note 103 and accompanying text.

as it is limited in its ability to improve the provision of health-related goods and services. This alone should be sufficient reason to consider a global agreement on norms that clarify national and the global responsibilities for health, transforming ineffective short-term financial assistance into effective sustained funding.

International responsibility extends well beyond financing, as a range of policies, statutes, and bilateral or multilateral treaties outside the health sector have a considerable impact on health. As we have explained, states and multilateral organizations adopt policies that often impede, rather than facilitate, health among the world's poor.<sup>200</sup> Yet as part of their international human rights obligations, states must respect the right to health in other countries.<sup>201</sup> As the United Nations Special Rapporteur on the right to health observed, in the context of massive shortages of health workers facing many poorer countries, developed countries have certain obligations:

[D]eveloped countries should respect the right to health in developing countries . . . If a developed country actively recruits health professionals from a developing country that is suffering from a shortage of health professionals in such a manner that . . . reduces the developing country's capacity to fulfill the right to health obligations that it owes its citizens, the developed country is *prima facie* in breach of its human rights responsibility of international assistance and cooperation.<sup>202</sup>

These obligations extend to the full range of regimes that affect health, with immense implications, as with climate change. They also encompass how countries engage through the international organizations in which they are members.<sup>203</sup>

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200 See IHPA, *supra* note 122 and accompanying text.

201 See *Maastricht Principles*, *supra* note 7, at 4 ("States must desist from acts and omissions that create a real risk of nullifying or impairing the enjoyment of economic, social and cultural rights extraterritorially. The responsibility of States is engaged where such nullification or impairment is a foreseeable result of their conduct. Uncertainty about potential impacts does not constitute justification for such conduct.")

202 Special Rapporteur of the Commission on Human Rights on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, *The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, transmitted by Note of the Secretary-General, at ¶ 61, U.N. Doc. A/60/348 (Sept. 12, 2005) (by Paul Hunt), available at [http://www.ifhro.org/images/stories/ifhro/documents\\_UN\\_special\\_rapporteur/3\\_4\\_11.pdf](http://www.ifhro.org/images/stories/ifhro/documents_UN_special_rapporteur/3_4_11.pdf).

203 See *General Comment 14*, *supra* note 138, at ¶ 39.



*4. What kind of global governance mechanisms are required to ensure that all states live up to their mutual responsibilities to provide health goods and services to all people?*

A paradigm shift to genuine mutual responsibility for global health grounded in the right to health will require more than an agreed set of responsibilities and principles. It will also require constructing a more forceful, purposeful, efficient, and accountable set of institutions and arrangements. Global governance for health equity would include clearly defined legal obligations on national and domestic health financing for health and its determinants to ensure sustained, sufficient, and predictable funding—including the funds and the research and development needed to better meet today's health needs and prepare for tomorrow's. It would be directed towards national health strategies, while ensuring their quality. It would expand the agenda of global health from today's important, but overly narrow, focus on health care. This expanded agenda would include the full scope of disease and ill health and the conditions required for good health, including strong medical care systems and underlying determinants of health such as nutritious food and clean water, while linking to the broader social and economic determinants of health.

A shared sense of purpose and priorities, and greater coordination, should complement, not supplant, the benefits that come from a proliferation of global health actors. These include civil society, with its ability to reach and represent disadvantaged populations, to advocate, and to hold governments accountable; the private sector, with its ability to develop new medical technologies, market safer foods, and create safer and healthier workplaces; and foundations and philanthropists, with their ability and willingness to fund imaginative approaches to improving global health and meeting unmet needs. Public-private partnerships based on and organized around a shared respect for human rights and health for all will be vital to success in these challenges.

Global governance for health equity will overcome structural issues such as weak leadership and lack of accountability. The WHO would be empowered. Heightened accountability would come from clearer delineations of responsibility, benchmarks and targeting, newly imagined incentives and sanctions, and, above all, effective structures at local and national levels and strengthened civil society and communities. In addition, legal reforms would ensure an elevated place for health in other international regimes, including clear stipulations against undermining the right to health.

At every stage, global governance would be directed towards equity. Funding must take into account obstacles that keep poor and other marginalized populations from health care, from out-of-pocket payments for health to transportation costs. Governance structures and health institutions will need to directly incorporate the voices of these communities. Even as policies emanate

from regimes outside of health, health leaders must exert their influence against oppressive policies that discriminate against women and contribute to marginalization and undermine health. Researchers and innovators will need to ask whether their health technologies will work for the poorest among us. Health strategies will need to incorporate policies to meet the needs of poorer populations, as countries end policies that obstruct their needs. Finally, systems of accountability will need to find ways, beginning, but not ending, with incorporating poorer and marginalized populations into their procedures and at the top of their concerns, to transform the global health system into one that turns traditional power dynamics upside down, with the greatest, not least, accountability to those who have the least political power and suffer the worst health.

An initiative to fill international law's most significant gap, however difficult, is possible. We now propose specific elements of an FCGH. The treaty would be designed along the four dimensions discussed above. It would create standards on the universal conditions required for good health, clarify national and global responsibilities towards securing these conditions and the right to health more broadly, and structure a system of global governance for health that could effectively and efficiently effectuate these responsibilities. A worldwide civil society and academic-led initiative launched in 2010—the Joint Action and Learning Initiative on National and Global Responsibilities for Health (JALI)—is campaigning for an FCGH, conducting research, and launching an inclusive dialogue to further develop the Convention.<sup>204</sup>

#### V. A FRAMEWORK CONVENTION / PROTOCOL APPROACH TO GLOBAL HEALTH

In April 2011, the United Nations Secretary-General Ban Ki-moon asked political leaders to make a pledge:

[C]ommit to global solidarity, built on the tenets of shared responsibility, true national ownership and mutual accountability. . . . Let the AIDS response be a beacon of global solidarity for health as a human right and set the stage for a future United Nations Framework Convention on Global Health.<sup>205</sup>

204 See, e.g., *Submission to Rio+20: Outcome Document*, JOINT ACTION AND LEARNING INITIATIVE ON NATIONAL AND GLOBAL HEALTH RESPONSIBILITIES (Nov. 1, 2011), <http://www.uncsd2012.org/rio20/index.php?page=view&type=510&nr=279&menu=20>. For more information about JALI, please see JALI's website: JALI, <http://www.jalihealth.org> (last visited Dec. 9, 2012).

205 U.N. Secretary-General, *Uniting for Universal Access: Towards Zero New HIV Infections, Zero Discrimination and Zero AIDS-Related Deaths: Rep. of the Secretary-General*, ¶ 73, U.N. Doc A/65/797 (Mar. 2011), available at [http://www.unaids.org/en/media/unaids/contentassets/documents/document/2011/A-65-797\\_English.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/document/2011/A-65-797_English.pdf).

First proposed in 2008,<sup>206</sup> a framework convention/protocol approach to global health, using a bottom-up inclusive process, would accomplish the following: (1) set globally-applicable norms and priorities for health systems and essential human needs; (2) afford countries flexibility to meet domestic needs and take “ownership” of national policies and programs; (3) establish a sustainable funding mechanism or framework scalable to needs; (4) effectively govern the proliferating number of actors and activities in a crowded global health landscape; (5) create methods for holding state and non-state actors accountable to their obligations under the right to health, including for monitoring progress and achieving compliance with the FCGH itself; and (6) devise a process for the international community to establish further commitments beyond those in the initial Convention.

#### *A. Normative Standards and Priorities*

The central objective of the FCGH is to improve health for all, with particular attention to the least advantaged populations, thus seeking major reductions in health inequities within and among states. Any legal intervention with this avowed aim can succeed only if it addresses the full gamut of major determinants of health, including such broader social determinants such as employment, education, a healthy environment, and gender equity.

The entire scope of this task is more than any one treaty can be expected to accomplish, but the FCGH may be a milestone along the way to full health equity. It could firmly establish universal health coverage as a central goal of the post-MDG global health agenda and develop a normative framework for ensuring everyone effective, accessible health systems and a broad array of public health services. Furthermore, it could help ensure that countries have at least basic frameworks in place to address broader health determinants, building on the Rio Political Declaration on Social Determinants of Health of 2011.<sup>207</sup>

The treaty would ensure universal conditions for good health that extend far beyond universal health coverage as defined by WHO,<sup>208</sup> embracing not only health systems, but also underlying determinants of health. The treaty could delineate critical capacities and policies in each of the six health system building blocks that the WHO has identified along with commitments for shared national and global efforts to develop these capacities and support these policies. For example, it could build on the WHO Global Code of Practice on the International

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<sup>206</sup> See *Meeting Basic Survival Needs*, *supra* note 12.

<sup>207</sup> WHO, *Rio Political Declaration on Social Determinants of Health* (Oct. 21, 2011), [hereinafter WHO RIO POLITICAL DECLARATION], available at [http://www.who.int/sdhconference/declaration/Rio\\_political\\_declaration.pdf](http://www.who.int/sdhconference/declaration/Rio_political_declaration.pdf).

<sup>208</sup> See *Sustainable Health Financing, Universal Coverage & Social Health Insurance*, *supra* note 152.

Recruitment of Health Personnel, including by turning guidance against actively recruiting health workers from countries facing critical health personnel shortages into binding law.<sup>209</sup> It could delineate types of services that health systems must be able to provide, especially to ensure that potentially politically contentious services (e.g., comprehensive reproductive health care), traditionally neglected services (e.g., mental health care), services that are particularly prevalent among poor or other marginalized populations (e.g., neglected tropical diseases), and critically needed, but more expensive, services (e.g., AIDS treatment, including for children) are provided.

Further, the FCGH could specify a minimal proportion of national health costs covered by prepaid pooled funds, ensuring that out-of-pocket expenses do not exclude equal access by the poor. This might entail WHO's estimate of the level of prepaid pooled funds required or higher levels, with commensurate reductions in overall out-of-pocket spending.<sup>210</sup> The proportion of health spending out-of-pocket and across socioeconomic groups could be a crucial indicator in monitoring progress on universal health coverage.

The FCGH would extend commitments of universal coverage to include underlying determinants of health, establish what these include, and operationalize both long-standing and existing human rights norms, including the rights to food, clean drinking water, sanitation, and established principles and priorities of public health by the United Nations General Assembly.<sup>211</sup>

Coverage must be effective. It is not enough that a well-equipped clinic is available if a person cannot afford transportation to reach it, or if women avoid it because they are mistreated. Nutritious food must come with the knowledge about what food is nutritious. For some of these underlying determinants of health, the FCGH could establish universal minimums based on the best scientific evidence, such as the minimum number of liters of clean drinking water that must be available to each person every day, and the minimum number of calories and vital nutrients. The treaty could set floors for the annual pace towards ensuring clean water, decent sanitation, and nutritious food for all. Tobacco control measures could build on and incorporate obligations from the Framework Convention on Tobacco Control, subjecting them to the rigorous compliance mechanisms envisaged for the FCGH. Policies in other areas, such as vector control, alcohol reduction, or diet and nutrition, could build on WHO global strategies or other authoritative sources.<sup>212</sup>

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209 CODE OF PRACTICE, *supra* note 78, at art. 5.1 ("Member States should discourage active recruitment of health personnel from developing countries facing critical shortages of health workers.").

210 The WHO reports that out-of-pocket expenses should not exceed 15-20% of total health spending to avoid forcing people into poverty. WORLD HEALTH REPORT 2010, *supra* note 71, at 98.

211 G.A. Res. 64/292, ¶ 3, U.N. Doc. A/RES/64/292 (Aug. 3, 2010).

212 See, e.g., *Strategy to Reduce the Harmful Use of Alcohol*, WORLD HEALTH ORG. (2008) [http://www.who.int/entity/substance\\_abuse/alcohol/englishfinal.pdf](http://www.who.int/entity/substance_abuse/alcohol/englishfinal.pdf); GLOBAL STRATEGY ON DIET,

Even this vision of universal coverage of effective health systems and the underlying determinants of health would be narrower than the full range of determinants of health, which would require a variety of additional social and economic levers, such as education, housing, employment, the environment, a social safety net, and greater income equality. Many of the deeper causes of ill health are addressed by, or require, entire legal regimes focusing on gender equality, unequal distribution of power and resources, and more. Still, the FCGH could offer pathways for addressing the broader socioeconomic determinants of health.

The treaty could require countries to develop comprehensive public health strategies that encompass social determinants of health identified in the FCGH, along with benchmarked actions plans, with associated budgets and timelines, to implement these strategies. The Convention itself, or a later protocol, could establish processes for monitoring progress on and encouraging international support for these plans. A protocol might also extend commitments on universal health coverage to a broader set of social services, establishing for everyone a social protection floor.<sup>213</sup> Similarly, the FCGH could both require countries to develop specific plans of action to ensure full health equity for women and require that these plans remove obstacles women and girls face to health systems and other determinants of health.

By establishing an agreed and obligatory roadmap to universal coverage, the treaty would help clarify, monitor, and incentivize compliance with the right to health, including specifying its core obligations<sup>214</sup> and elucidating its progressive realization requirement. An FCGH would set out principles, benchmarks, and processes for expanding the level of health services available to all under the human rights framework. The norms that the FCGH affirms or establishes in international law would range beyond universal health coverage. It would elevate the right of people to participate in health-related planning<sup>215</sup> to a clearly articulated and legally enforceable principle of the right to health.

Perhaps most significantly, the FCGH would firmly embed in binding international law not only non-discrimination, but also the more far-reaching concepts of equal access as an immediate obligation of the right to health. It would affirm that this obligation is both a shield against malfeasance and a sword to cut away at inequities—in access to health services and fundamental human needs and in securing broader determinants of health, such as employment and

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PHYSICAL ACTIVITY AND HEALTH, WORLD HEALTH ORG. (2004), [http://apps.who.int/gb/ebwha/pdf\\_files/WHA57/A57\\_R17-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA57/A57_R17-en.pdf).

<sup>213</sup> See *id.*

<sup>214</sup> *General Comment 14*, *supra* note 138, ¶ 43.

<sup>215</sup> *E.g.*, *id.* ¶ 11 (stating that an important aspect of the right to health is “participation of the population in all health-related decision-making at the community, national and international levels”); *id.* ¶ 43(f) (requiring a national public health strategy and plan of action to be developed “on the basis of a participatory and transparent process”).

healthy environments. It is not enough that states protect all of their inhabitants from policies and practices that would undermine the health status of certain groups. States must also take affirmative measures to improve health outcomes for population groups that are being left behind.

We turn now to the aspects of an FCGH required to realize this expansive vision of universal health coverage and to significantly advance the right to health. We discuss different targets that the FCGH could include, explain a process to balance global norms with country circumstances, and illustrate how an FCGH could mobilize the funding required for universal health coverage. We outline how an FCGH could promote the global governance for health required to organize a multiplicity of international organizations and NGOs towards a common purpose of universal health coverage, and to ensure that other international legal regimes do not detract from—but rather contribute to—the right to health. Finally, we offer ways in which an FCGH could promote accountability, from that of the local health services to state obligations under the FCGH.

### *B. Targets and Benchmarks*

Effective implementation of treaty obligations requires governments to set targets and benchmarks of success. Countries would establish strategies and targets that are ambitious, yet achievable and consistent with their overall approaches to strengthening their health system. Within the health areas and in accordance to standards set by the FCGH, including on the participatory approaches to translating the FCGH mandates into nationally appropriate, desirable, and effective approaches, countries themselves would define the interventions guaranteed to everyone. They would establish the health workforce targets and standards for developing their networks of health facilities required to achieve universal coverage. Equity targets, such as to reduce disparities between urban and rural areas and between the highest and lowest income quintiles, could guide priorities and strategies in health systems strengthening. Moreover, they would ensure that financing is neither an obstacle to access for the poorest segments of the population nor for people who are above the poverty line but still require substantial support to fully access health systems.

Countries typically already establish targets, timelines, and strategies in many of these areas. The difference now is that they must accord to certain standards and goals backed by the necessary resources—as well as the assurance of international support to achieve these goals. Similarly, the pathways to underlying determinants of health for everyone might be tailored to country circumstances, with targets, timelines, and strategies. Consider clean water and decent sanitation. A country where only 75% of the population has access to safe drinking water cannot be expected to achieve universal access to safe drinking water by the same year as a country where 98% of the population already has

such access. Conversely, it should not be acceptable for countries where coverage is already high to delay in achieving universal coverage until far poorer countries can achieve this goal.

Further, what precisely clean water and decent sanitation entail is not straightforward. The MDGs measure the proportion of the world's population with "improved" sources of water and sanitation.<sup>216</sup> Yet within these improved sources is a wide range of technologies, not all of which are equal in protecting health. Improved water sources range from a borehole or protected well that might be a kilometer away from a person's dwelling to clean water piped into one's home. Improved sanitation includes not only indoor toilets, but also pit latrines.<sup>217</sup> Different countries may establish varying timelines to provide universal access first to more modest "improved" sources of drinking water and sanitation, then to piped water and indoor toilets.

### *C. A Flexible and Inclusive Process*

A key strength of the Framework Convention/Protocol approach is that the treaty sets globally applicable norms that are needed in every society for good health and reduced inequalities, while launching an inclusive process for grassroots buy-in and specifically tailoring commitments to the specific national and local population health needs. Here is an illustration of how this bottom-up, inclusive process would operate.

The FCGH could include ambitious, yet achievable, global targets. These would be refined locally through participatory, equitable processes that adapt them to local circumstances and ensure national and community ownership.<sup>218</sup> This local tailoring should enhance accountability, as the targets will truly be the country's own, and not viewed as externally imposed. Country ownership should promote not only government buy-in, but also genuine national priorities for improved health. The nationally developed targets could be included in a treaty protocol, a later codification that could affirm international support for these targets, while also subjecting them to the various monitoring and compliance processes of the FCGH.

Civil society and community participation in developing the targets and the strategies to achieve them is a critical role that the FCGH should reinforce. Participation can occur through a variety of forums, from national health assemblies, community consultations, and online input, to being part of the teams that ultimately develop the targets and strategies.

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<sup>216</sup> *The Millennium Development Goals Report 2011*, UNITED NATIONS 53–55 (2011), [http://www.beta.undp.org/content/dam/undp/library/MDG/english/MDG\\_Report\\_2011\\_EN.pdf](http://www.beta.undp.org/content/dam/undp/library/MDG/english/MDG_Report_2011_EN.pdf).

<sup>217</sup> *Water Sanitation Health*, WORLD HEALTH ORG., <http://www.hho.int/water-sanitation-health/monitoring/jmp2012/key-terms/en/index.html> (last visited Dec. 1, 2012).

<sup>218</sup> See Jeff Waage et al., *The Millennium Development Goals: A Cross-Sectoral Analysis and Principles for Goal Setting After 2015*, 376 LANCET 991 (2010).

Community and civil society involvement will help push against political boundaries and ensure that targets are ambitious and tuned to the demands of equity and the highest attainable standard of health. Their participation may create the pressure or provide the public health rationale for reluctant governments to address politically sensitive issues in their targets and strategies, including the needs—and rights—of disfavored populations, such as sexual minorities and drug users. Moreover, NGOs and community groups may bring knowledge from within communities and share effective strategies to connect marginalized populations and people living in rural and slum regions with health services.

This inclusive, national process can also establish the health services guaranteed to everyone, based on general guidelines and minimum standards in the FCGH. This will ensure that these guarantees match local circumstances and priorities, while avoiding endless battles at the global level to come to agreement on a detailed list of requirements.

The FCGH's process also foresees protocols that could be used for agreements on issues that parties cannot resolve when negotiating the initial treaty, to address problems that arise during the course of treaty implementation, and to respond to changes in the global health environment. A protocol might include a more detailed financing framework, effectively encompass a proposed new treaty on health research and development, more fully address complexities of health worker migration, establish innovative financing mechanisms, and strengthen mechanisms to promote treaty compliance and right to health accountability. Protocols could include specific ways in which state parties will engage in other legal regimes to promote health, bring additional social health determinants within the treaty's scope, or link the FCGH to broader initiatives, such as ensuring a universal social protection floor.

They might be supplemented by amendments to the treaty, such as updated funding formulas and standards, to respond to changing costs, economic growth, and evolving scientific knowledge. The expectation of protocols will also help maintain a global focus and stimulate global discussion on health inequities.

#### *D. Sustainable Funding Scalable to Needs*

Although increased global health spending has not reduced the global health equity gap, it has contributed to significant progress against AIDS and other diseases and causes of death that have their greatest impact in the global South. Moreover, even while efficiencies can contribute significantly to “more health for the money,” “more money for health” is also required if global health inequities are to be significantly reduced.<sup>219</sup> The FCGH, therefore, would have to

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219 *More Money for Health, and More Health for the Money*, TASKFORCE ON INNOVATIVE INT'L FIN. FOR HEALTH SYS. (2009), [http://www.ausaid.gov.au/publications/Documents/more\\_](http://www.ausaid.gov.au/publications/Documents/more_)



include a financing framework with clear funding benchmarks for governments' domestic health spending and for international health funding commitments.

The urgency of a framework to secure adequate funding is especially great now, as major economies look for ways to cut budgets, particularly expenditures for foreign assistance. The framework will have to ensure adequate funding backed by mechanisms to hold all partners accountable, while achieving political buy-in and avoiding detrimental competition with other global financing demands, such as climate change mitigation and adaptation. This poses a particularly difficult challenge for any international law regime.

Innovative financing mechanisms, support for countries' efforts to increase tax collection and prevent tax avoidance and evasion, private financing, and other measures could supplement ordinary government funding. With some creativity and the fortitude to resist entrenched interests (e.g., beverage industry opposition to taxes on sugary drinks and financial industry opposition to financial transaction taxes), these mechanisms could raise substantial resources.

New forms of taxes and fees, such as those placed on unhealthy foods and on medical tourism, could be implemented domestically and raise additional funds.<sup>220</sup> Meanwhile, illicit capital flight from low- and middle-income countries has been estimated at more than \$850 billion in 2010, representing enormous losses in tax revenue; tax havens for wealthy individuals alone may cost low- and middle-income countries \$50 billion annually in lost tax revenue.<sup>221</sup> The FCGH could facilitate these taxes, fees, and enhanced tax collection, such as through establishing information sharing, capacity building, and international cooperation responsibilities. Or, going beyond this, the FCGH could include more precise commitments, such as requiring taxes on unhealthy foods, increased tobacco taxes, or other sources of revenue.

FCGH financing commitments and mechanisms would establish and put into effect an understanding that financial sustainability should encompass both domestic and international funds, based on national and global solidarity and the right to health.<sup>222</sup> International funding would be provided directly to countries or channeled through a common funding mechanism, such as a Global Fund for Health,<sup>223</sup> to best ensure country ownership and to simplify the landscape of health actors at the country level. It could be that only wealthier nations provide international financing. Alternatively, not unlike a highly progressive national

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money\_for\_health.pdf.

<sup>220</sup> See *World Health Report 2010*, *supra* note 71, at 29.

<sup>221</sup> Dev Kar & Sarah Freitas, *Illicit Financial Flows from Developing Countries: 2001-2010*, GLOBAL FINANCIAL INTEGRITY 9 (Dec. 2012), <http://iff.gfintegrity.org/iff2012/2012report.html>; *Why Do Tax and Capital Flight Matter for Health?*, ECON. GOVERNANCE FOR HEALTH (Apr. 1, 2009), <http://www.eg4health.org/get-informed/tax-capital-flight-and-health/>.

<sup>222</sup> See Ooms & Hammonds, *supra* note 186.

<sup>223</sup> Giorgio Cometto et al., *A Global Fund for the Health MDGs?*, 373 LANCET 1500 (2009); see Ooms et al., *supra* note 131.

system of social protection extended globally,<sup>224</sup> in line with the concept of global solidarity and to take into account the growing financial capacity of many developing countries, all countries would provide international health assistance, with levels based on economic capacity. Poorer countries would receive far more than they contribute, and wealthier countries would contribute far more than they receive. Particularly if wealthier countries continue to provide much of their assistance bilaterally, supplementary provisions may be necessary, such as to untie aid<sup>225</sup> and to encourage using local contractors and sources of technical expertise to make aid more efficient and effective.<sup>226</sup>

Much as the FCGH could encourage and facilitate innovative sources of domestic financing, it could also establish forms of innovative international financing for health, such as financial transaction taxes. One review found eleven operational and three proposed novel international funding mechanisms for global health (and another twelve operational or proposed mechanisms to stimulate innovation and fund global health research).<sup>227</sup> These mechanisms could provide predictable sources of health funding that are less dependent on state compliance to the FCGH. In addition, a trust fund or similar mechanism could guard against funding volatility. For example, if several countries are failing to meet their international financing responsibilities, funding formulas could automatically adjust so that other countries cover the difference, or innovative mechanisms could compensate through slightly higher fees or tax levels. Such an approach would need to be coupled with a treaty enforcement regime that effectively dissuades countries from being free riders, knowing that other sources of revenue will be found.

Any funding formula that the FCGH includes is unlikely to be nuanced enough to fully capture the many factors that go into determining whether a country is spending the maximum of its available resources,<sup>228</sup> particularly given that this requirement spans all economic and social rights and cannot be viewed in isolation from them. Thus, the requirements in the FCGH would not obviate the more general obligations of the ICECSR. They could establish, however, valuable benchmarks that serve as strong indicators of whether a country is meeting its obligation to spend “the maximum of its available resources.” The requirements in the FCGH would also provide far greater clarity on what the

224 Gorik Ooms, *From the Global AIDS Response Towards Global Health?* (Hélène de Beir Foundation and the International Civil Society Support Group, Working Paper, Jan. 2009), available at [http://photos.pih.org/inforesources/IHSJ\\_Stony\\_Point\\_Conference\\_2009/From\\_the\\_Global\\_AIDS\\_Response\\_towards\\_Global\\_Health\\_G.Ooms.pdf](http://photos.pih.org/inforesources/IHSJ_Stony_Point_Conference_2009/From_the_Global_AIDS_Response_towards_Global_Health_G.Ooms.pdf).

225 Tied aid is assistance that requires purchasing goods and services from the country providing the aid.

226 See Dybul et al., *supra* note 85.

227 Josh Michaud & Jen Kates, *Innovative Financing Mechanisms for Global Health: Overview & Considerations for U.S. Government Participation*, THE HENRY J. KAISER FAMILY FOUND. 11–12 (2011), <http://www.kff.org/globalhealth/upload/8247.pdf>.

228 MAXIMUM AVAILABLE RESOURCES, *supra* note 141.

ICESCR's obligation on international assistance entails, as well as the comparable obligation in the United Nations Charter.<sup>229</sup>

### *E. Global Governance for Health*

One of the greatest deficiencies in global governance for health today is the lack of coherence among a multiplicity of global health actors, as well as among the multiple international legal regimes that impact health outcomes. A key priority for an FCGH is to gain greater rationality and cooperation among all actors and regimes around the central value of the right to health. This requires resolving the fragmentation and poor coordination within the health sector and the tensions between health and other regimes.

The FCGH would empower host countries to take the lead in managing all funding and technical partners around a single national health strategy. The treaty could extend and strengthen present efforts, such as through the IHP+,<sup>230</sup> to align international funding with national health strategies. Ministries of health would be responsible for monitoring and evaluation frameworks by firmly embedding in international law the global health equivalent of the three ones (one national AIDS action framework used to coordinate the work of all partners, one national AIDS coordinating authority with a multi-sector mandate, and one agreed country monitoring and evaluation system).<sup>231</sup>

The FCGH could require international partners to report regularly on obstacles to adhering to these principles and to develop action plans to overcome them, to inform health ministries of any funding and programs outside the direct control of the ministries, and to contribute to a national map of health activities to avoid duplication and gaps in coverage. It could require that countries providing bilateral assistance channel a minimum and gradually increasing percentage of it to direct support for the national strategy. Alternatively, as part of a financing framework, the FCGH could specify the proportion of international support that should be directed to a Global Fund for Health, with its direct support for national strategies.

The FCGH could also insist that where national systems (e.g., supply chain, health information, and financial management) achieve a certain level of quality, international partners commit to using these systems rather than creating their

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229 Through article 56 of the United Nations Charter, states "pledge themselves to take joint and separate action in co-operation with the" United Nations to achieve "conditions of stability and well-being," including universal observance of human rights and fundamental freedoms. U.N. Charter arts. 55–56.

230 For more information on the International Health Partnership and related initiatives (IHP+), see INTERNATIONAL HEALTH PARTNERSHIP AND RELATED INITIATIVES, <http://www.internationalhealthpartnership.net/> (last visited Dec. 3, 2012).

231 "Three Ones" Key Principles UNAIDS, (2004), [http://data.unaids.org/UNA-docs/three-ones\\_keyprinciples\\_en.pdf](http://data.unaids.org/UNA-docs/three-ones_keyprinciples_en.pdf).

own parallel systems. One approach would be to build on the Joint Assessments of National Health Strategies and Plans (JANS) of the IHP+ process. Through JANS, the host government, civil society, and development partners collectively review national health strategies. Where the assessments give a quality stamp of approval on a national health system component, partners could agree to use these systems, while they could also agree to strengthen system components that remain inadequate.

The national strategy itself must be rooted in the right to health, developed through participatory processes and prioritizing such principles as equity and accountability. A focus on a government-led strategy should not preclude funding outside the strategy where it falls short with respect to the right to health, such as by failing to fully address the needs of marginalized populations. Similarly, additional funding to community-based and other civil society organizations might be required to bolster accountability. Funding outside the national strategy might also be appropriate in other limited circumstances, such as to non-state actors not adequately covered by the plan that are taking innovative approaches to meeting unmet health needs.

Although rationalization of health sector actors is important, so too is harmonizing widely diverse requirements in parallel international law regimes. The FCGH would have to seek greater consistency and priority for human health among non-health sectors, such as trade, environment, finance, and migration. It might provide that all clear conflicts that might arise between these regimes and the FCGH must be resolved in favor of the FCGH and the right to health. For example, a policy that another regime allowed or even encouraged that interferes with a country's capacity to ensure universal health coverage would be impermissible. Such a rule might not only alter the behavior of states under the FCGH, but could also begin to establish new norms applicable to all states. The FCGH could require countries to conduct national policy reviews to identify conflicts with the right to health and to reform policies inconsistent with the right. In addition, to ensure continued policy cohesion around the right to health, countries would conduct right to health assessments of planned policies and projects outside the health sector to ensure their consistency with the right to health.<sup>232</sup>

The FCGH could offer specific actions that countries should take in non-health realms and mechanisms to evaluate the adoption and effective implementation of these measures. For example, an FCGH could inform adaptation measures that will reduce the health impact of climate change, ensure that intellectual property agreements and laws do not interfere with public health,

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232 Eric A. Friedman & Lawrence O Gostin, *Pillars for progress on the right to health: Harnessing the potential of human rights through a Framework Convention on Global Health*, 14 HEALTH AND HUMAN RIGHTS 1, 4–5 (June 2012), available at <http://www.hhrjournal.org/index.php/hhr/article/view/483/740> [hereinafter *Pillars for Progress*].

and regulate “land grabs”—the large-scale foreign purchase of land in developing countries, which can threaten food security.<sup>233</sup> The FCGH may be able to manage potential resource competition among regimes, for example, if a Global Fund for Health and a Green Climate Fund were both mandated to raise some of their resources through financial transaction taxes.

Effective global governance for health requires institutional competence and leadership. Although it is currently going through a funding crisis of its own, WHO, with expanded capacities, would be placed at the center of global governance for health. The WHO has the institutional credibility to help ensure the priority of health in other regimes. The FCGH might include ways to formalize WHO’s role outside the health sector. It could establish a WHO-led coordinating body that comprised key international organizations, such as the World Trade Organization, World Bank, Food and Agriculture Organization, International Labour Organization, the United Nations Environment Programme, and United Nations Women. Civil society and representatives of marginalized communities would also participate. Such a body would develop and implement pathways for making health more prominent in multiple legal regimes and could help develop a protocol to codify such measures.

Along with placing WHO at the center of global governance for health, the FCGH could include other measures to enhance WHO’s leadership. It could commit states to increased unearmarked funding to WHO. The FCGH might even include steps to enhance civil society participation in WHO governance, from lowering the bar to NGO participation in the World Health Assembly to more far-reaching reforms.<sup>234</sup>

The FCGH should find ways to respond not only to regimes where health is not presently a central value, but also to non-state actors that can powerfully impact—both for better and for worse—the right to health. The private sector, for example, has a substantial effect on the health of populations, ranging from pharmaceuticals, food, beverages, alcohol, and tobacco to energy, mining, transportation, and labor practices. The treaty could define the responsibilities of states to effectively regulate transnational corporations as they relate to health and identify ways to incentivize compliance. By mediating their interactions with states, or international organizations, it could find innovative ways to more

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233 *Special Investigation Phase One: Understanding Land Investment Deals in Africa*, OAKLAND INST., <http://www.oaklandinstitute.org/special-investigation-understanding-land-investment-deals-africa> (last visited Dec. 9, 2012).

234 See Sridhar & Gostin, *supra* note 113. The potential for reforming the WHO through an FCGH would depend in part on whether the FCGH were to be adopted by the World Health Assembly or another forum, in particular, the United Nations General Assembly. For more on possibilities for greater civil society inclusion in WHO processes, see WHO, *WHO Reforms for a Healthy future: Report by the Director-General*, Doc. EBSS/2/2 (October 15, 2011), at ¶ 88-91; Gaudenz Silberschmidt, Don Matheson & Ilona Kickbusch, *Creating a Committee C of the World Health Assembly*, 371 LANCET 1483 (2008).

directly bring corporations under requirements of the right to health, even if they are not themselves party to the FCGH. The PIPF has found a way to create contractual corporate obligations, even though PIP only directly applies to states.<sup>235</sup>

#### *F. Accountability and Treaty Monitoring and Compliance*

Greater accountability must be at the heart of improved global governance for health and hence would be central to the FCGH, from government accountability for health services delivered to communities to accountability for their international obligations. To enhance accountability within countries, the FCGH could require countries to develop plans to combat corruption and poor accountability in the health sector. The FCGH could have several guidelines for what all states must include in these plans, such as local accountability mechanisms; rules on transparent procurement including through competitive bidding; and transparent reporting on funding allocations in health and related sectors, including the flow of these funds to particular programs and even specific projects, communities, and facilities.

As part, or instead, of a national strategy, the FCGH could also separately require these measures, including developing community-based strategies for monitoring and holding government responsible for local health services. These strategies might include community scorecards and functioning community health committees.<sup>236</sup> Countries could tailor their accountability strategies to incorporate solutions to other corruption concerns, such as through improved supervision, incentives to reduce health worker absenteeism, curtailing informal payments, and a computerized database of health workers to remove “ghost” workers from payrolls.<sup>237</sup>

An FCGH could establish additional national and local accountability processes, such as maternal and child mortality audits.<sup>238</sup> To ensure

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235 See Pandemic Influenza Preparedness Framework, *supra* note 37, at art. 5.4, Annex 2 (providing a Standard Model Transfer Agreement under which, through enforceable private contracts, vaccine or medical manufacturers that benefit from WHO’s virus sharing network would agree to donate a portion of the vaccines or medications to WHO).

236 For more on community scorecards see *Citizen Report Card and Community Score Card*, WORLD BANK, <http://go.worldbank.org/QFAVL64790> (last visited Nov. 29, 2012). Community-based monitoring, such as scorecards, can have a powerful impact on health outcomes. A study in Uganda attributed a one-third drop in child mortality in certain communities to use of scorecards and associated monitoring activities. See Martina Björkman & Jakob Svensson, *Power to the People: Evidence from a Randomized Field Experiment on Community-Based Monitoring in Uganda*, 124 Q. J. ECON. 735 (2009).

237 See Lewis, *supra* note 180, at 6–7.

238 Maternal, newborn, and child death audits are meant to capture the structural and systematic factors that must be addressed to reduce maternal, newborn, and child deaths. For more on these audits, see UN Special Rapporteur on Health, *Preliminary Note on the Mission to India, Addendum*, U.N. Doc. A/HRC/7/11/Add.4 (Feb. 29, 2008); *No Tally of the Anguish: Accountability*

accountability to poor, marginalized, and vulnerable populations, an FCGH could include targets, strategies, and mechanisms—or processes to develop them—to ensure an emphasis on equity and meeting the needs of these populations. These could encompass disaggregated data, funding, participation, and outreach. The FCGH could require states to assess stigma and discrimination in the health sector, implement strategies to reduce such attitudes and practices, and hold health workers accountable for mistreating patients.

The treaty could also provide new mechanisms and funding streams to support community-based and other civil society organizations that can hold their governments to account, as well as to ensure that health services reach even the poorest segments of the population. Furthermore, it could require health worker education on the right to health, including rights in the FCGH and national constitutions, and how people can claim these rights. Moreover, the treaty could establish commitments and monitoring mechanisms to ensure that health plans, policies, and programs emphasize the health needs of traditionally discriminated against and underserved populations—to ensure that government accountability for its human rights and other health obligations and policies extend to their entire populations.

The FCGH could establish a new right to health capacity-building mechanism to fund civil society organizations and community networks, expand public and health worker education on the right to health, educate policymakers on this right, and support other measures to strengthen accountability and national understanding of the right to health, what it entails, and what obligations and rights to entails.<sup>239</sup>

Accountability is closely linked to other aspects of good governance, such as transparency and deliberative, participatory processes. State parties to the FCGH could commit to transparent and competitive bidding for ministry of health contracts, making publicly available information on the private assets of health ministry officials, and publishing and providing directly to communities information on health service funding that their local health services should receive. Moreover, the FCGH could establish or require countries to establish processes that ensure civil society and community participation in planning, implementing, and evaluating local, national, and international partner-supported health plans, policies, and programs.

As with any treaty, an FCGH's success will depend on the difficult issue of compliance. States would regularly and transparently report on their compliance with the FCGH, including progress towards benchmarks. Civil

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in *Maternal Health Care in India*, HUMAN RIGHTS WATCH (2009), <http://www.hrw.org/en/reports/2009/10/08/no-tally-anguish-0>; South Africa Every Death Counts Writing Group, *Every Death Counts: Use of Mortality Audit Data for Decision Making To Save the Lives of Mothers, Babies, and Children in South Africa*, 371 LANCET 1293 (2008).

<sup>239</sup> *Pillars for Progress*, *supra* note 232, at 5.

society organizations and other non-state actors would be welcome to formally provide their own reports and data on state compliance, which would also be factored into determining state compliance, with states encouraged to include civil society in drafting their own formal reports. Through a process of peer review, neighboring states might also have a role in assessing compliance. To further ensure the credibility and effectiveness of the compliance regime, the FCGH might also include a proactive mechanism to investigate state compliance if states fail to adhere to reporting requirements.

Effective compliance for the FCGH should also include an innovative regime of incentives and sanctions. This regime could include certain forms of international support provided only to states meeting obligations, suspension of eligibility for WHO Executive Board membership or of other WHO rights, and encouraging or requiring state parties to grant national courts jurisdiction to hear cases brought by their populations involving FCGH violations. Any sanctions would have to be carefully designed to ensure that this treaty on the right to health does not inadvertently undermine that right by limiting international support to the populations that most need it.

## VI. THE PATH TOWARDS AN FCGH

Therefore, the architecture of a Framework Convention on Global Health would (1) encompass core normative standards for health systems and underlying determinants of health, while beginning to reach broader socioeconomic determinants as well, (2) facilitate an inclusive participatory process for norm development suited to national needs and priorities, (3) establish funding modalities to build capacity in low-income and middle-income countries to meet the broad health needs of their populations, (4) prioritize and incorporate the right to health in other legal regimes, (5) strengthen health monitoring and accountability at community, national, and global levels, and (6) ensure a priority to equity and the needs and rights of disadvantaged populations throughout.

### *A. Overcoming Resistance and Other Challenges*

The scope and ambition of such a treaty promises that achieving it will not be easy. Even some in civil society have asked whether such a treaty is truly needed, whether it is achievable, and, even if states adopt and ratify it, whether they will then follow through and implement it. Here we touch on these concerns.<sup>240</sup>

First, why promote a treaty? After all, the right to health that would be at the core of the FCGH is already contained in numerous treaties. Yet this fact has

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240 For additional discussion on these and other possible objections, see *Preliminary Answers to 5 Priority Questions on the Framework Convention on Global Health*, JALI (Feb. 2012), <http://jalihealth.org/>.



proven insufficient to resolve tremendous and persistent health inequities. The right to health requires far greater precision to clarify such central obligations as what entails the primary health care that is part of its core minimum obligations, the pace and nature of progressive realization, and what precisely counts as states' maximum available resources. Moreover, to resolve health inequities, the delineation of these responsibilities may have to extend beyond prevailing understandings, as with international cooperation and assistance, and cover areas and actors inadequately addressed, such as state responsibility vis-à-vis transnational corporations. Further, such key principles as equal access, equity (beyond the command of non-discrimination), and participation are poorly reflected in such central treaties as the ICESCR, being instead developed through non-binding mechanisms, including the CESCR and reports of the United Nations Special Rapporteur on the right to health.

Why, though, is binding law required? For even as non-binding agreements may form welcome stepping stones towards the FCGH, ultimately, a new legally binding agreement is needed, for at least three reasons, beyond the truism that creating binding law will create or clarify obligations that are decidedly not optional, as they should not be for a concern as grave as health inequities. First, at least in countries where rule of law prevails, a treaty will likely create a greater sense of internal commitment to the agreement's stipulations, thus encouraging compliance.

Second, a treaty opens up additional channels of accountability, including the courts, with their increasing importance in enforcing economic, social, and cultural rights. Wherever treaties are justiciable directly, or where incorporated into national law as treaty ratifiers would be obliged to do, the courts can be an avenue to force treaty compliance. Legally binding commitments, particularly those with the precision that an FCGH would include, will create a stronger foundation for civil society advocacy. They will also create additional incentives (e.g., assured levels of assistance) and sanctions (e.g., suspension of certain WHO privileges) for compliance.

Third, law is needed to respond to law. Regimes that can negatively impact health are themselves rooted in bilateral, regional, and global treaties. A legally binding treaty has a far greater chance of influencing the position of health within these regimes than a non-binding agreement.

Even accepting the importance of the FCGH, is it achievable? Would states agree to assume its obligations? Or would distrust between the global North and South, or the financial obligations—and indeed, good governance obligations thrust upon states where poor governance can be lucrative—prove too great obstacles?

States may well conclude that such a treaty is in their interest, as they recognize that with mutual responsibilities come benefits for all. Countries in the global South would benefit above all from improved health for their populations,

but also from greater respect from international partners for their strategies; more, and more predictable, international funding; and prioritization of health in other legal regimes where the health harms otherwise fall most on their populations. Strengthened accountability systems would give wealthier countries more confidence that their assistance is being well spent, while strengthened health systems in poorer countries will help protect their own populations from global public health threats. Domestic financing commitments should over time lead to decreased need for international assistance over time. Meanwhile, all countries—and people everywhere—would benefit from the positive effects of better health in other realms—including economic,<sup>241</sup> educational, environmental, and security—along with lessons on improving health that they may be able to adopt. In addition, all countries can know that, as with endorsing a human rights regime decades ago, they are taking a significant step forward in a historic venture to create a more just world.<sup>242</sup>

Still, the key to achieving an FCGH is likely to be political pressure. We view the campaign for an FCGH not as an independent movement directed at a single treaty, but rather as part of a process of building social movements around

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241 Economic benefits will be considerable. Health services contribute to increased productivity and other sources of economic growth, including by maintaining a healthy workforce and, over the longer-term, by contributing to children's education and healthy development. Under-nutrition alone can lower a country's GDP by 2%. Ban Ki-moon, U.N. Secretary-General, *Global Strategy for Women and Children's Health* 6 (2010), [http://www.who.int/pmnch/topics/maternal/20100914\\_gswch\\_en.pdf](http://www.who.int/pmnch/topics/maternal/20100914_gswch_en.pdf) (citing SUSAN HORTON ET AL., SCALING UP NUTRITION: WHAT WILL IT COST? (2010)). Meanwhile, 30-50% of economic growth in Asia from 1965 to 1990 has been attributed to improved reproductive health, reduced infant and child mortality, and reduced fertility. *Id.* (citing *Investing in Maternal, Newborn and Child Health – The Case for Asia and the Pacific*, WORLD HEALTH ORG. & THE P'SHIP FOR MATERNAL, NEWBORN, & CHILD HEALTH (2009), [http://www.who.int/pmnch/topics/economics/20090501\\_investinginnmch/en/index.html](http://www.who.int/pmnch/topics/economics/20090501_investinginnmch/en/index.html)).

HIV/AIDS slowed the rate of annual GDP growth across 33 countries in sub-Saharan Africa from 1992 through 2002 by an average of 1.1%. *HIV/AIDS and Work: Global Estimates, Impact and Response*, INT'L LABOUR OFFICE 77 (2004), [http://www.ilo.org/wcmsp5/groups/public/@ed\\_protect/@protrav/@ilo\\_aids/documents/publication/wcms\\_116379.pdf](http://www.ilo.org/wcmsp5/groups/public/@ed_protect/@protrav/@ilo_aids/documents/publication/wcms_116379.pdf). The World Bank found that, compared to maintaining 2005 levels of tuberculosis treatment in sub-Saharan Africa, scaling up tuberculosis treatment and control interventions through 2015, in-line with the Stop TB Partnership's Global Plan to Stop TB, would require an additional of \$10 billion, but would bring \$88 billion in economic benefits. Ramanan Laxminarayan et al., *Economic Benefits of Tuberculosis Control* 16–17 (World Bank Human Development Network Health, Nutrition & Population Team, Working Paper, Aug. 2007), available at <http://www.who.int/management/EconomicBenefitofTuberculosisControl.pdf>. More broadly, a year increase in life expectancy raises a country's per capita GDP by approximately 4%. David E. Bloom et al., *Health, Wealth, and Welfare*, in *HEALTH AND DEVELOPMENT: A COMPILATION OF ARTICLES FROM FINANCE & DEVELOPMENT* 10–15 (Jeremy Clift ed., 2004). Meanwhile, prevention and control measures frequently more than pay for themselves through averted treatment costs. For example, a dollar spent on family planning typically will save at least four dollars in treatment costs of pregnancy-related complications. See Ban Ki-moon, *supra* at 6 (citing Jennifer J. Frost et al., *The Impact of Publicly Funded Family Planning Clinic Services on Unintended Pregnancies and Government Cost Savings*, 19 J. HEALTH CARE FOR POOR & UNDERSERVED 778 (2008)).

242 See *Joint Action and Learning Initiative*, *supra* note 12, at 4.

the right to health. If an FCGH is achieved, although state recognition of their interests in such a treaty will be important, ultimately it will be possible because their people demand it. Such social mobilization will also be at the heart of ensuring treaty compliance, once states ratify it.

The treaty will face challenges beyond political resistance. One is ensuring that the treaty will in fact address the health priorities and favored solutions by the populations in the global South—along with marginalized communities in wealthier countries—whose right to health is today further from being fulfilled. JALI is committed to a broad, inclusive process in drafting a treaty, recognizing that the urgency of an FCGH must be balanced by a process that will ensure the treaty's strength and effectiveness.

JALI is steering this broad consensus process, with the intent of helping launch a broader International Campaign for a Framework Convention on Global Health, of which JALI will be one member of many. JALI places critical importance on an extensive, inclusive process of input, including through community, regional, and global consultations, online consultative processes, and targeted research. We invite readers to join JALI's efforts through <http://www.jalihealth.org>, and once it is underway, the broader campaign.

There will be substantive challenges in developing every aspect of the treaty. One such challenge will be defining financing obligations, which will need to encompass multiple sectors, not only health (also, for example, water and sanitation, and agriculture). Should each sector have a target, or should countries have considerable leeway in allocations across sectors? A cross-sector target might threaten accountability, but would include needed flexibility. For instance, while investments in agriculture will be critical for food security in some countries, agriculture may be negligible in other countries—or, in countries where tobacco is a major crop, ultimately harmful to health. How would different approaches affect accountability?

Further, should financing targets differ across countries at different income levels with respect to their own national health investments? For example, wealthier countries would likely need to spend a far lower percentage of their GNI on water and sanitation. And should all countries have international financing responsibilities, small as these might be for poorer countries, in the spirit of solidarity and shared responsibility? Or given the health needs of poorer countries, along with the possibility that they would simply get their contributions back through the international support they receive, should these contributions be limited to wealthy countries? What of the growing economic middle-income powers, such as the “BRICS” (Brazil, Russia, India, China, and South Africa)?

Few challenges will be greater than establishing an effective regime of incentives and sanctions to address failure to comply with treaty requirements, beyond several possibilities that we have described. We believe far stronger

sanctions could be justified given that the scale of death from a government's failure to meet its population's right to health can match or exceed that of the atrocities that may lead the UN Security Council to impose targeted sanctions, particularly asset freezes and travel bans, on abusive government officials. Yet even with strong social movements, the prospects of countries agreeing to the possibility of such sanctions would seem dim. Meanwhile, measures such as reduced international support where countries fail to meet their own responsibilities risks harming the health of the very populations who are in greatest need of such support, and whose health is already being harmed by their own government's failings—something that would be unacceptable in a global health treaty. One possibility would be to re-channel funding from governments to civil society organizations, but this would risk deepening duplication and fragmentation, one of the concerns the FCGH is meant to address. Another is to re-channel some funds—beyond additional funds that might already be provided through a right to health capacity-building mechanism—to support civil society organizations and social movements seeking to hold their governments accountable, though governments might respond by limiting foreign funding that NGOs can receive.

Yet there is a wealth of experience to build on, from existing commitments (e.g., the Abuja Declaration) to accountability mechanisms from the community level (e.g., community scorecards, budget transparency) to the global level (e.g., the WTO regime). The FCGH will be able to draw upon the best of other legal regimes, as well as innovative thinking. We are confident that a sufficiently extensive process of research and consultation will find the best solutions—even as sometimes, there will be no perfect solution.

### *B. Legal Pathways*

Several forums could be home to the FCGH. One is WHO, building on its success with the Framework Convention on Tobacco Control and utilizing WHO's underused, yet powerful, treaty-making powers through the World Health Assembly, WHO's governing body comprising all member states.<sup>243</sup> Given that one of the treaty's goals would be to strengthen global health leadership, particularly through WHO, and the treaty's subject matter, WHO would be a natural home for such a treaty. It would also mean that health ministers negotiate the treaty, desirable given the treaty's potential to significantly advance their own goals.

However, the scope of an FCGH—affecting regimes far beyond health—

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243 Under the WHO Constitution, a two-thirds vote of the World Health Assembly is required to adopt a convention. Member states of WHO are then required, within eighteen months, to either ratify the convention or inform the WHO Director-General why they have not (yet) accepted it. WHO Const., *supra* note 72, at arts. 19-20.

may make the United Nations the proper home. With the treaty's grounding in human rights, the UN Human Rights Council could draft the treaty in the first instance, before forwarding a draft treaty to the General Assembly for all UN members to consider. The Human Rights Council could include civil society in a working group that develops the treaty, as the Council's predecessor, the Human Rights Commission, did when drafting the Convention on the Rights of the Child.<sup>244</sup> Alternatively, the General Assembly could, in the first instance, designate a committee or working group of the full General Assembly to draft the treaty.

Another possibility would be to develop the treaty outside of either the United Nations or WHO, as was the case for the Land Mines Treaty.<sup>245</sup> Although the United Nations General Assembly endorsed the need for such a treaty and urged countries to ratify it once it was adopted,<sup>246</sup> and the treaty was intricately linked to the United Nations,<sup>247</sup> the process itself was atypical. In a rapid series of events known as the Ottawa Process, launched by fifty like-minded states in Ottawa in 1996, Austria drafted the treaty in close collaboration with the International Campaign to Ban Landmines and the International Committee of the Red Cross, with the treaty adopted in Oslo in September 1997, opened for signature in Ottawa in December 1997, and entering force in March 1999.<sup>248</sup>

Whatever the formal process, civil society must be at the heart of developing the FCGH to ensure that it captures the ambition required to resolve the immensity and complexity of the problem that it aims to address. Although traditionally states have initiated and negotiated treaties, recent history suggests that bottom-up processes are not only possible, but also increasingly necessary. Along with the central role of civil society in the Mine Ban Treaty and

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244 *United Nations Background Note: Children's Rights*, UNITED NATIONS (1995), <http://www.un.org/rights/dpi1765e.htm>; *Children's Rights History*, CHILDREN'S RIGHTS PORTAL, <http://childrensrightsportal.org/childrens-rights-history/> (last visited Nov. 29, 2012).

245 Mine Ban Treaty, *supra* note 4.

246 General and Complete Disarmament, U.N. General Assembly Res. 51/45, at S, U.N. Doc. A/RES/51/45 (1996), *available at* <http://www.un.org/depts/dhl/resguide/r51.htm> (international agreement banning anti-personnel landmines); General and Complete Disarmament, U.N. General Assembly Res. 52/38, at A, U.N. Doc. A/RES/52/38 (1999), *available at* <http://www.un.org/depts/dhl/resguide/r52.htm> (Convention on the Prohibition of the Use, Stockpiling, Production and Transfer of Anti-personnel Mines and on Their Destruction).

247 See Mine Ban Treaty, *supra* note 4, at art. 7 (requiring state reports to be filed with the U.N. Secretary-General); *id.* at art. 8 (allowing states to submit a Requests for Clarification regarding compliance to the U.N. Secretary-General); *id.* at art. 11 (empowering the U.N. Secretary-General to call special meetings of the state parties); *id.* at art. 12 (directing the U.N. Secretary-General to convene a review conference); *id.* at art. 21 (designating the U.N. Secretary-General as the treaty repository).

248 *Ban History*, INTERNATIONAL CAMPAIGN TO BAN LANDMINES, <http://www.icbl.org/index.php/icbl/Treaty/MBT/Ban-History> (last visited Nov. 29, 2012); *What is the Ottawa Process or the Mine Ban Treaty?*, UNITED STATES CAMPAIGN TO BAN LANDMINES, <http://www.uscbl.org/about-landmines/mine-ban-treaty/> (last visited Nov. 29, 2012).

Convention on the Rights of the Child, a coalition of NGOs proposed and successfully advocated for the Convention on the Rights of Persons with Disabilities.<sup>249</sup>

An FCGH will need to follow this pathway as well. Like these other treaties, the role of civil society will be central at all stages, from developing the concept and populating the treaty, to advocating for its adoption and ratification, to monitoring its implementation. The Framework Convention Tobacco Alliance, for example, has driven the implementation and expansion of the FCTC. As the overwhelming majority of deaths attributable to health inequities occur in the global South—even as health inequities kill in the global North as well—it is imperative that Southern civil society, along with states of the global South, drives this process.

## VII. CONCLUSION

Most people understand that the defining issues of our time—among them climate change, food security, and global health—demand collective action, normative standards, and compliance mechanisms. It is hard to envisage fundamental change without the force of international law.

This Article's goal is to advance the vital task of constructing the norms and processes of an FCGH. Ultimately, though, a broad coalition of leading states, civil society organizations, and academic institutions will have to develop the ideas. Without a bottom-up, inclusive process, a treaty of this breathtaking scope and historic impact could never succeed politically. What is most important in formulating a treaty that successfully responds to the imperatives of human rights and global justice is that it captures the views and aspirations of the people whose health is most imperiled under current governance arrangements.

With global health justice as a core principle, JALI will enable and prioritize input of the people who suffer most from today's national and global health inequities—marginalized communities, people who live in extreme poverty, women, persons with disabilities, and other disadvantaged populations. Although civil society participation is crucial, so too is input from communities; suggestions should come not from only organizations working to advance the public's health, but also the people living with AIDS, grassroots women's networks, indigenous communities, and others whose rights to health are most severely compromised under extant national and international regimes.

A far-reaching process of developing an FCGH is needed not only to ensure the strongest possible treaty, but also to develop a social movement behind it.

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249 *History*, UNCPR INDIA, <http://uncrpdindia.org/about/history/> (last visited Nov. 29, 2012); Janet E. Lord, *NGO Participation in Human Rights Law and Process: Latest Developments in the Effort to Develop an International Treaty on the Rights of People with Disabilities*, 10 ILSA J. INT'L & COMP. L. 311, 316-318 (2004).

FCGH advocates face overwhelming challenges in securing the treaty, with resistance likely from powerful governments and influential transnational corporations. As much as progressive government leadership will be needed to navigate the FCGH from the conceptual realm to binding international law, the treaty's adoption and widespread ratification will require pressure from below, in both the global South and North. With a purview that extends far beyond health care services, the social movement behind an FCGH—like the FCGH itself—will need to encompass not only more traditional health movements, but also other social movements that intersect with the right to health, such as the labor movement, movements around food security, the environment, and climate change, and movements for the rights of women, indigenous communities, and sexual minorities.

With fifty-four thousand deaths every day connected to global health inequities,<sup>250</sup> developing international legal solutions should become a global priority. The United Nations Secretary-General's call to action for a Framework Convention on Global Health will test the international community's oft-reiterated commitment to global health and human rights. The question remains: Are states prepared to take the bold steps necessary to silence the daily drumbeat of preventable illness, suffering, and early death?

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250 See Garay, *supra* note 2.

# The Origins of American Health Libertarianism

Lewis A. Grossman\*

## ABSTRACT:

This Article examines Americans' enduring demand for freedom of therapeutic choice as a popular constitutional movement originating in the United States' early years. In exploring extrajudicial advocacy for therapeutic choice between the American Revolution and the Civil War, this piece illustrates how multiple concepts of freedom in addition to bodily freedom bolstered the concept of a constitutional right to medical liberty.

There is a deep current of belief in the United States that people have a right to choose their preferred treatments without government interference. Modern American history has given rise to movements for access to abortion, life-ending drugs, unapproved cancer treatments, and medical marijuana. Recently, cries of "Death Panels" have routinely been directed against health care reform proposals that citizens believe would limit the products and procedures covered by government health insurance. Some of the most prominent contemporary struggles for health freedom have been waged in court. But other important recent battles for freedom of therapeutic choice have taken place in other forums, from legislative hearings to Food and Drug Administration advisory committee meetings to public demonstrations.

This attitude of therapeutic libertarianism is not new. Drawing mainly on primary historical sources, this Article examines arguments in favor of freedom of therapeutic choice voiced in antebellum America in the context of battles against state licensing regimes. After considering some anti-licensing arguments made before independence, it discusses the views and statements of Benjamin Rush, an influential founding father who was also the most prominent American physician of the early national period. The Article then analyzes the Jacksonian-era battle against medical licensing laws waged by the practitioners and supporters of a school of botanical medicine known as Thomsonianism. This triumphant struggle was waged in explicitly constitutional terms, even though it occurred entirely outside of the courts. The Thomsonian campaign thus offers one of the most striking examples of a successful popular constitutional movement in American history. This article shows that, at its origin, the American commitment to freedom of therapeutic choice was based on notions of

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not only bodily freedom, but also economic freedom, freedom of conscience, and freedom of inquiry. Finally, this Article considers ways in which this early history helps illuminate the nature of current struggles for freedom of therapeutic choice.

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## INTRODUCTION

An American editorialist, outraged by the government's intrusive meddling in health care, angrily contended that restrictions on freedom of medical choice were the product of an insidious conspiracy among elites both inside and outside the government. He argued that state interference in the therapeutic choices of citizens represented an unconstitutional violation of the people's most basic rights. The writer ominously declared, "The . . . duty demanded on a cargo of tea in '76, was of small importance, but . . . the principle it involved . . . turned the whole harbor of Boston into one . . . teapot." The writer warned the "demagogues" in the legislature "to remember that the blood of that tea party still lives and runs" in their constituents' veins. He sought the support of "every man . . . who does not wish to be trampled in the dust and deprived of his constitutional liberty."<sup>1</sup>

The column described above was not published in the twenty-first century, but rather appeared in an 1838 issue of the *Botanico-Medical Recorder*, a journal of alternative medicine. The author was almost certainly Alva Curtis, the leader of a group of botanical practitioners known as the "Independent Thomsonians."<sup>2</sup> Thomsonianism was a system of cure developed some thirty years earlier by a New Hampshire farmer and itinerant healer named Samuel Thomson. Shortly before writing this editorial, Curtis had engineered a factional split between his "Independents" and less compromising devotees of Thomson's original system.<sup>3</sup> Despite this development, Curtis remained committed to the core aspects of Thomsonian medicine.<sup>4</sup> In this column, he directed his fury at the Ohio Legislature's refusal to grant a charter to a medical school that he had recently established in Columbus with a curriculum based on Thomsonian principles.<sup>5</sup>

Curtis' rhetoric exemplifies an extraordinarily successful Thomsonian-led movement for medical freedom in antebellum America. The primary aim of this

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1 *Editorial*, 6 *BOTANICO-MEDICAL RECORDER* 24, Aug. 25, 1838, at 376. Alva Curtis served as both the editor and publisher of the *Botanico-Medical Recorder*, which until October 1937 was known as the *Thomsonian Recorder*. See also the newspaper excerpt—in a journal otherwise completely dedicated to botanical medicine—describing a visit to New York City by the last living participant in the Boston Tea Party. *The Only Survivor of the Boston Tea Party*, 3 *THOMSONIAN RECORDER* 368, 368 (1835).

2 See Alex Berman, *Neo-Thomsonianism in the United States*, 11 *J. HIST. MED. & ALLIED SCI.* 133, 138 (1956).

3 *Id.* at 134; JOHN S. HALLER JR., *THE PEOPLE'S DOCTORS: SAMUEL THOMSON AND THE AMERICAN BOTANICAL MOVEMENT 1790-1860*, at 98–99 (2000).

4 Berman, *supra* note 2, at 134.

5 A bill awarding the charter had died in December 1837 after the chairman of the relevant committee in the Ohio Senate—an orthodox doctor—had reported against it. Curtis' lobbying and public advocacy ultimately succeeded, however, and on March 6, 1839, the state legislature overwhelmingly passed a bill chartering the Botanico-Medical College of Ohio. HALLER, *THE PEOPLE'S DOCTORS*, *supra* note 3, at 98–99.

movement was the repeal of state medical licensing laws. According to the Thomsonians, these statutes represented an effort by the orthodox (or “regular”) medical profession to obtain a monopoly on the practice of medicine by effectively outlawing botanical and other alternative practice. In 1833, five years before the appearance of the editorial, medical freedom advocates had managed to erase a licensing requirement from Ohio’s statute books.<sup>6</sup> Curtis viewed the denial of the medical school charter as a revival of the plot to violate the freedom of unorthodox practitioners and their patients. These Ohio battles were just one front in a nationwide war for medical freedom waged by the Thomsonians and their supporters. Their overwhelming victory is reflected in the fact that between 1830 and the Civil War, the United States was transformed from a country that almost universally embraced some form of medical licensing to one in which this type of regulation was virtually nonexistent.

While this Article focuses on health libertarianism in the period between the American Revolution and the Civil War, my broader project seeks to demonstrate that struggles for freedom of therapeutic choice have recurred throughout American history. During the late nineteenth century, a second wave of medical licensing statutes provoked another outpouring of medical freedom-of-choice literature, written largely by drugless practitioners (such as mind-curers, Christian Scientists, and osteopaths) and their allies.<sup>7</sup> Unlike the antebellum medical licensing laws, these later statutes survived, buoyed by the Progressive Era’s embrace of the value of professional expertise. Nevertheless, the popular demand for freedom of therapeutic choice ensured that these laws were drafted, revised, interpreted, and enforced in a way that allowed alternative healers to continue to practice largely unimpeded.<sup>8</sup> Beginning around the turn of the twentieth century, popular movements also developed to resist more aggressive impositions of “state medicine,” such as mandatory vaccination laws and the proposed establishment of a National Department of Health, which was thought likely to be dominated by the orthodox medical establishment.<sup>9</sup>

Movements for freedom of therapeutic choice were largely—though not completely—dormant between the 1930s and the 1960s, a period characterized

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6 WILLIAM G. ROTHSTEIN, *AMERICAN PHYSICIANS IN THE NINETEENTH CENTURY: FROM SECTS TO SCIENCE* 75–76, 145–46 (1992).

7 See, e.g., Benjamin Orange Flower, *Restrictive Medical Legislation and the Public Weal*, 19 *ARENA* 781, 808 (1898); Clifford P. Smith, *Christian Science and Legislation*, 23 *CHRISTIAN SCI. J.* 407 (1905); Alexander Wilder, *Medical Liberty*, 2 *MIND* 193, 194–95 (1898). See generally Lewis A. Grossman, *You Can Choose Your Medicine: Freedom of Therapeutic Choice in American Law and History* (unpublished manuscript) (on file with author) (providing a complete examination of the struggle over medical licensing through the mid-1910s).

8 *Id.*

9 See MICHAEL WILLRICH, *POX: AN AMERICAN HISTORY* (2011); Stephen Petrino, *Medical Liberty: Drugless Healers Confront Allopathic Doctors, 1910-1931*, 29 *J. OF MED. HUMAN.* 205 (2008); Manfred Waserman, *The Quest for a National Health Department in the Progressive Era*, 49 *BULL. OF THE HIST. OF MED.* 353 (1975).

by an anomalously high level of popular confidence in American governmental, scientific, and medical institutions.<sup>10</sup> Since the 1970s, however, such movements have reemerged in force, focusing on access to particular products and procedures. In contrast to the earlier *extrajudicial* medical freedom movements, many of the most prominent modern fights over freedom of medical choice have been waged in court. Most famously, in *Roe v. Wade*, the United States Supreme Court held that the constitutional right to privacy includes a time-limited right to obtain an abortion.<sup>11</sup> Since then, the Supreme Court has also wrestled with issues concerning access to alternative medicines,<sup>12</sup> life-ending drugs,<sup>13</sup> and medical marijuana.<sup>14</sup> Moreover, in a widely followed 2007 case, the United States Court of Appeals for the D.C. Circuit, sitting *en banc*, held that terminally ill patients do not have a substantive due process right to purchase drugs not approved by the FDA.<sup>15</sup>

Legal scholars have devoted an enormous amount of attention to these cases adjudicating the limits of medical freedom. But focusing exclusively on modern judicial decisions provides a misleading portrait of the struggle for medical freedom in the United States. This court-centered approach implies that constitutional arguments for freedom of therapeutic choice are only as old as modern privacy jurisprudence and that courts are the exclusive forum for

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10 See John C. Burnham, *American Medicine's Golden Age: What Happened to It?*, 215 Sci. 1474 (1982); Allan Mazur, *Commentary: Opinion Poll Measurement of American Confidence in Science*, 6 Sci., Tech. & Human Values 16 (1981).

11 410 U.S. 113 (1973).

12 *United States v. Rutherford*, 442 U.S. 544 (1979) (holding that the Federal Food, Drug, and Cosmetic Act neither expressly nor impliedly provides an exemption to the new drug approval requirements for terminally ill patients). Earlier in this litigation, the United States District Court held that the FDA had infringed cancer patients' constitutionally protected privacy interests by denying them access to Laetrile, the drug at issue. *Rutherford v. United States*, 438 F. Supp. 1287, 1298-1301 (W.D. Okla. 1977). This constitutional question was not on review at the Supreme Court, and on remand, the Court of Appeals reversed the District Court's conclusion that the FDA had violated the patients' constitutional right to privacy. *Rutherford v. United States*, 616 F.2d 455 (10th Cir. 1980).

13 *Washington v. Glucksberg*, 521 U.S. 702 (1997) (rejecting substantive due process right to assisted suicide); *cf. Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261 (1990) (confirming substantive due process right of competent individuals to refuse unwanted medical treatment, but permitting procedural safeguards to ensure that decision by incompetent patient's surrogates reflects patient's wishes).

14 *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483 (2001) (denying the existence of a medical necessity exception to the federal Controlled Substances Act that would permit marijuana used for medical purposes); *cf. Gonzales v. Raich*, 545 U.S. 1 (2005) (ruling that under the Commerce Clause, the federal government could constitutionally enforce the Controlled Substances Act with respect to homegrown marijuana cultivated for personal medical purposes).

15 *Abigail Alliance v. Von Eschenbach*, 445 F.3d 470 (D.C. Cir. 2006), 495 F.3d 695 (D.C. Cir. 2007) (*en banc*), *cert denied*, 552 U.S. 1159 (2008). This *en banc* decision vacated an earlier ruling in which a D.C. Circuit panel voted, 2-1, that terminally ill patients do, under certain circumstances, have a substantive due process right to purchase potentially life-saving drugs. 445 F.3d 470.

constitutional struggles of this type. Focusing only on judicial opinions may also suggest that American demands for medical freedom are typically based solely on notions of bodily liberty and integrity. This Article's exploration of the extrajudicial history of American health libertarianism in the country's first century is intended to challenge these assumptions.

By reviewing the robust early arguments for medical freedom in the United States, I will establish that such advocacy has deep roots, predating any substantial treatment in the Supreme Court jurisprudence. I will also show how during the antebellum period, struggles for freedom of therapeutic choice were waged on explicitly constitutional grounds, even though they occurred almost entirely outside of court. Furthermore, I will demonstrate that in the country's early years, advocates of medical freedom grounded their claims not only in the now dominant arguments for bodily freedom, but also in assertions of economic freedom, freedom of inquiry, and freedom of conscience and religion.

I begin, in Part I of this Article, by providing the background information necessary to understand early American health libertarianism. Section I.A presents a preliminary introduction to the concept of popular constitutionalism and lays the foundation for exploring how antebellum medical freedom advocates exemplified this phenomenon. Section I.B then offers a brief introduction to both orthodox and unorthodox medical practice in the nation's early years. In Part II, I proceed to examine American health libertarianism in the period prior to 1820. Section II.A describes the rise of medical licensing during the nation's first decades—a development that forms the backdrop for the medical freedom arguments explored in the remainder of the Article. Section II.B then examines some of the earliest examples of American anti-licensing rhetoric. Section II.C discusses Benjamin Rush who, though probably the most prominent orthodox physician of the early national period, advanced fairly detailed arguments for medical freedom. Section II.D goes on to consider Rush's legacy to later advocates for freedom of therapeutic choice.

In Part III of the Article, I explore the period between 1820 and the Civil War, during which the battle against medical licensing became a popular constitutionalist movement led by the Thomsonians. Section III.A begins by describing the success of this struggle, as illustrated by the virtual disappearance of medical practice acts from the American legal landscape. Section III.B then offers important information about the Thomsonian movement itself. Section III.C situates the Thomsonians in the broader context of Jacksonian Democracy, the dominant political culture of the 1830s and 1840s. Section III.D goes on to demonstrate that the victorious antebellum fight against medical licensing was waged on explicitly constitutional terms, even though it occurred completely outside the courts. Section III.E analyzes the different strands of freedom rhetoric contained in the Thomsonian literature, including not only bodily freedom, but also economic freedom, freedom of inquiry, and freedom of conscience and

religion. Finally, Section III.F offers a detailed description of the anti-licensing campaign in New York to provide a concrete example of how the Thomsonians succeeded in erasing most medical practice acts from the country's statute books. I conclude the Article by briefly considering how this historical perspective can help us understand modern extrajudicial activism for medical freedom as part of a multidimensional popular constitutional movement.

## I. BACKGROUND

### *A. Popular Constitutionalism*

The story of the successful antebellum fight against medical licensing depicted in this Article supports the thesis that during this country's first seventy years or so, medical freedom advocates shaped certain aspects of constitutional meaning entirely outside the courts. This Article thus contributes to the literature on "popular constitutionalism."

Although the term "popular constitutionalism" appeared in the law review literature as early as 1984,<sup>16</sup> it emerged as a common label for a branch of constitutional studies in the late 1990s. In 1999, Douglas S. Reed, limning what he called a "theory of popular constitutionalism," drew on the work of a group of scholars who were "trying, in many different ways, to provide a theory of extrajudicial legal interpretation and mobilization."<sup>17</sup> One of the authors he discussed was Mark Tushnet, who earlier that year had published *Taking the Constitution Away from the Courts*, which would prove to be one of the seminal works of popular constitutionalist scholarship.<sup>18</sup> Tushnet's book distinguished between the "thick Constitution" and the "thin Constitution."<sup>19</sup> According to Tushnet, the former consists of the many detailed provisions of the U.S. Constitution setting forth and regulating the organization of the federal government. These provisions are rarely the source of widespread or impassioned public debate. The "thin Constitution," by contrast, consists of the fundamental principles of equality and liberty stated in the Declaration of Independence and the Constitution's preamble. Although the "thin Constitution" is reflected in the U.S. Constitution's specific rights-guaranteeing provisions, it is not identical to these provisions or what the Supreme Court has said about them. Rather, its meaning is contested and shaped by the people themselves in public, often political, venues outside the courts. Tushnet dubbed this model, which he

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16 Ronald K. L. Collins, *Foreword: Reliance on State Constitutions—Beyond the "New Federalism"*, 8 U. PUGET SOUND L. REV. vi, xi, xii, xxiii (1984).

17 Douglas S. Reed, *Popular Constitutionalism: Toward a Theory of State Constitutional Meanings*, 30 RUTGERS L. J. 871, 877 (1999).

18 MARK TUSHNET, *TAKING THE CONSTITUTION AWAY FROM THE COURTS* (1999).

19 *Id.* at 9–14.

presented as more aspirational than descriptive, “populist constitutionalism.”<sup>20</sup>

Tushnet’s “populist constitutionalism” and Reed’s “popular constitutionalism” were closely related concepts.<sup>21</sup> For whatever reason, the latter term captured the field. Since the turn of the century, “popular constitutionalism” has been a standard classification for the work of a diverse assortment of scholars, including Tushnet himself, who embrace the notion that the people, rather than judges, are the ultimate constitutional authority.<sup>22</sup> While some of these scholars, like Tushnet, take a primarily normative approach, others claim that popular constitutionalism is not only an ideal to strive for, but also is an accurate account of constitutional practice for much of U.S. history. Larry Kramer, for example, has asserted that popular constitutionalism thoroughly dominated American constitutional understanding in the country’s early years and remained an important strain of American constitutionalism until the 1980s, when judicial supremacy became a shared ideal across the political spectrum.<sup>23</sup>

The literature on popular constitutionalism emphasizes arenas outside the courts in which citizens have fought to shape constitutional meaning. Kramer, for example, describes various “extrajudicial” forums for popular constitutional lawmaking in U.S. history, including mobs, boycotts, rallies, petition drives, elections, and jury service.<sup>24</sup> This is not to say that all scholars of popular constitutionalism exclude courts from the scope of institutions subject to influence by social movements.<sup>25</sup> In fact, popular constitutionalists express a wide range of views regarding the optimal and actual function of the courts in constitutional interpretation.<sup>26</sup> But they all share a conviction that the

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20 See generally *id.*

21 The differences between Tushnet’s “populist constitutionalism” and Reed’s “popular constitutionalism” are rather vague. See Reed, *supra* note 17, at 879 n.14. Reed points out that they coined their terms simultaneously and independently. *Id.*

22 Some prominent examples of this growing body of literature include LARRY D. KRAMER, *THE PEOPLE THEMSELVES: POPULAR CONSTITUTIONALISM AND JUDICIAL REVIEW* (2005); Larry Alexander & Lawrence B. Solum, *Popular? Constitutionalism?*, 118 HARV. L. REV. 1594 (2005); William N. Eskridge, Jr., *Some Effects of Identity-Based Social Movements on Constitutional Law in the Twentieth Century*, 100 MICH. L. REV. 2062 (2002); Reva B. Siegel, *Constitutional Culture, Social Movement Conflict, and Constitutional Change: The Case of the de Facto ERA*, 94 CALIF. L. REV. 1323 (2006). See also *A Symposium on The People Themselves: Popular Constitutionalism and Judicial Review*, 81 CHI.-KENT L. REV. 809–1182 (2006).

23 KRAMER, *supra* note 22.

24 *Id.*

25 Reva Siegel, for example, has shown how the popular mobilization both supporting and opposing the unsuccessful Equal Rights Amendment in the 1970s shaped judges’ understanding of the constitutional doctrine of equal protection in a way that ultimately forged a “de facto” amendment reflected in court doctrine. Reva B. Siegel, *Constitutional Culture, Social Movement Conflict and Constitutional Change: The Case of the De Facto ERA*, 94 CALIF. L. REV. 1323 (2006).

26 James E. Fleming offers a typology dividing popular constitutionalism into five versions based primarily on their adherents’ attitudes toward judicial review and judicial supremacy. James E. Fleming, *Judicial Review Without Judicial Supremacy: Taking the Constitution Seriously*



construction of constitutional meaning cannot be fully understood through an exclusive focus on judges.<sup>27</sup>

The early nineteenth-century battle over medical licensing is an excellent example of American popular constitutionalism in action.<sup>28</sup> Furthermore, it offers an ideal opportunity to examine popular constitutionalism in an extrajudicial context, for courts simply did not play a part in the drama. Indeed, antebellum foes of medical licensing appear not to have even sought judicial review. As will be shown below, in Part III, they pursued their struggle, and achieved their victories, entirely through popular mobilization outside the courts.

### *B. Orthodox Medicine and Its Alternatives*

The medical freedom rhetoric examined by this Article cannot be fully comprehended without some background information on orthodox medicine in the late-eighteenth and early-nineteenth centuries.

Early American orthodox medicine was based almost completely on speculative deduction from the principle that good health was a balance of systemic forces in the body. From this perspective, illness was an imbalance characterized by excessive excitement or enfeeblement. “The fundamental

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*Outside the Courts*, 73 *FORDHAM L. REV.* 1377, 1379–80 (2005).

27 Fleming, with questionable justification, counts among the ranks of popular constitutionalists “departmentalists who are not populists”—scholars who focus on the role of legislatures and executives, alongside courts, in determining constitutional construction but who do not emphasize the role of citizens generally. *Id.* at 1379. Robert Post and Reva Siegel warn against such a fusion of departmentalism and popular constitutionalism, observing, “Most theorists of departmentalism situate their analysis in the context of separation of powers, rather than popular constitutionalism.” Robert Post & Reva Siegel, *Popular Constitutionalism, Departmentalism, and Judicial Supremacy*, 92 *CALIF. L. REV.* 1027, 1032 (2004).

28 Theodore W. Ruger makes points somewhat similar to mine in *Plural Constitutionalism and the Pathologies of American Health Care*, 120 *YALE L.J. ONLINE* 347 (2011), which includes a short discussion of the antebellum anti-licensing campaign. *Id.* at 354–56. In framing his argument regarding the existence of a “noncanonical” constitution that “prioritizes individual therapeutic choice,” *id.* at 348, 356, Ruger draws heavily on the framework of “large C” Constitutionalism versus “small c” constitutionalism set forth in WILLIAM N. ESKRIDGE & JOHN FEREJOHN, *A REPUBLIC OF STATUTES* (2010). In this formulation, “large C” Constitutionalism is based on the formal text of the Constitution and Supreme Court decisions interpreting this text, whereas “small c” constitutionalism is rooted in foundational commitments expressed through political activity and popular social movements. *Id.* at 1–24. As Eskridge and Ferejohn themselves remark, a parallel exists between their categories and Tushnet’s “thick Constitution” and “thin Constitution,” respectively. *Id.* at 60. My chief disagreement with Ruger is that he characterizes the antebellum arguments against medical licensing as being primarily “large C” ones, whereas in this Article I will show that “thin constitutional” arguments (parallel to “small c” arguments) were prevalent, and probably dominant, in the anti-licensing literature of the time. Ruger, *Plural Constitutionalism*, *supra*, at 354. I also find Tushnet’s framework more apt than Eskridge and Ferejohn’s for this particular topic, for although they criticize Tushnet for his apparent exclusion of courts from the interpretation of the “thin [“small c”] Constitution,” the courts did, in fact, remain on the sidelines of the antebellum medical licensing controversy.

objective was to restore the natural balance, which was accomplished by depleting or lowering the overexcited patient and by stimulating or elevating the patient enfeebled by disease.”<sup>29</sup> In the first decades of the nineteenth century, most regular doctors believed that most diseases were overstimulating, rather than enfeebling. The typical treatments used to restore the natural balance were thus depletive ones.<sup>30</sup> Mainstream doctors routinely enervated their patients through the use of therapies such as bleeding; the administration of massive doses of mineral-based purgatives, emetics, and diaphoretics;<sup>31</sup> and the application of blistering plasters to the skin. The two main symbols of this approach to medicine—among both its proponents and critics—were the lancet (an instrument used for bleeding) and calomel (a mercury-based purgative).

Later observers labeled this approach to healing “heroic” medicine because of the regular practitioners’ commitment to aggressive, interventionist treatment. As stated by a leading medical historian, “[D]uring the first two-thirds of the nineteenth century . . . the physician’s ‘redemptive role,’ his active therapeutic intervention in an effort to redeem patients from disease, was at the core of what it meant to be a physician in America.”<sup>32</sup> The most famous—or, in the eyes of critics, infamous—episode of heroic medicine’s reign occurred at the 1799 deathbed of George Washington, who was suffering from a severe throat infection. Physicians treating the stoic national hero dosed him with a purgative and emetic, applied blisters to his throat and legs, and drained about half of the blood from his body.<sup>33</sup>

Despite the frequent use of a single term, “heroic medicine,” to describe early American orthodox practice, disagreements sometimes arose among orthodox doctors with regard to both principles and remedies.<sup>34</sup> The United States’ most renowned and influential practitioner of depletive heroic medicine was Dr. Benjamin Rush, discussed in detail below.<sup>35</sup> In the 1790s, Rush was challenged by some other regular doctors who asserted that stimulative as well as

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29 JOHN HARLEY WARNER, *THE THERAPEUTIC PERSPECTIVE: MEDICAL PRACTICE, KNOWLEDGE, AND IDENTITY IN AMERICA, 1820-1885*, 85 (1986). Conventional medicine was later termed “allopathic” medicine by its homeopathic opponents, because it used drugs and remedies intended to produce effects opposite the symptoms being treated. JAMES C. WHORTON, *NATURE CURES: THE HISTORY OF ALTERNATIVE MEDICINE IN AMERICA* 18 (2004). In Greek, *allo* means opposite, and *pathos* means suffering.

30 WARNER, *supra* note 29, at 91.

31 These words are used to designate substances that induce bowel evacuation, vomiting, and sweating, respectively.

32 See WARNER, *supra* note 29, at 11.

33 RON CHERNOW, *WASHINGTON: A LIFE* 807–09 (2010); JARED SPARKS, *THE LIFE OF GEORGE WASHINGTON* 531–35 (1839). The purgative and emetic used were calomel and antimony potassium tartrate (“tartar emetic”), respectively.

34 BENJAMIN RUSH, *THE AUTOBIOGRAPHY OF BENJAMIN RUSH: HIS “TRAVELS THROUGH LIFE” TOGETHER WITH HIS COMMONPLACE BOOK FOR 1789-1813*, at 361–66 app. 1 (“Rush’s Medical Theories”) (G. W. Corner ed., 1970).

35 See *infra* Section II.C.

depletive remedies had a useful role in treatment.<sup>36</sup> His opponents' view reemerged in force in the middle of the nineteenth century, as orthodox practitioners increasingly prescribed stimulative therapies such as quinine (from cinchona bark), iron compounds, and alcohol.<sup>37</sup> Furthermore, around that time, growing numbers of regular doctors began to articulate an attitude of therapeutic skepticism, suggesting that physicians should merely provide palliative care while letting nature take its course.<sup>38</sup> Such trends, however, should not be overstated. Although bleeding largely disappeared, other depletive therapies were used—though often in smaller doses—throughout the century.<sup>39</sup> And even those orthodox practitioners who embraced the rhetoric of skepticism remained committed to pharmaceutical intervention in practice.<sup>40</sup>

Who were these “regular” doctors? The borders defining the orthodox medical profession were quite indistinct in early American history. Regular physicians were likely to be members of local and state medical societies, and they increasingly also tended to be graduates of foreign or domestic medical schools. Yet neither of these credentials was a precondition for practice before the Civil War.<sup>41</sup> As discussed in detail below,<sup>42</sup> orthodox medical practitioners sought to secure the boundaries of their profession by encouraging the passage of state medical licensing requirements. The details of these laws varied greatly, but even the strictest of them posed relatively low barriers to entry. As Paul Starr observes, “The preferred statuses—medical school graduate, society member, licensed practitioner—were continually invaded by the lower ranks of the profession as schools multiplied, societies became less exclusive, and licenses became easier to acquire.”<sup>43</sup>

The blurriness of the line dividing regular and irregular medicine does not, however, negate the fact that many practitioners were clearly outside the fraternity of regular physicians. The antebellum medical landscape was populated

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36 RUSH, *supra* note 34, at 361–66 app. 1 (“Rush’s Medical Theories”).

37 See WARNER, *supra* note 29, at 98.

38 *Id.* at 135, 240–41, 267–68.

39 Edmund D. Pellegrino, *The Sociocultural Impact of Twentieth-Century Therapeutics*, in THERAPEUTIC REVOLUTION: ESSAYS IN THE SOCIAL HISTORY OF AMERICAN MEDICINE 245, 247 (Morris J. Vogel & Charles E. Rosenberg eds., 1979).

40 Charles E. Rosenberg, *The Therapeutic Revolution: Medicine, Meaning, and Social Change in Nineteenth-Century America*, in THERAPEUTIC REVOLUTION: ESSAYS IN THE SOCIAL HISTORY OF AMERICAN MEDICINE 3, 19–21 (Morris J. Vogel & Charles E. Rosenberg eds., 1979); WARNER, *supra* note 29, at 29–31, 36.

41 ROTHSTEIN, *supra* note 6, at 63–72, 87–100.

42 See *infra* Section II.A.

43 PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE: THE RISE OF A SOVEREIGN PROFESSION AND THE MAKING OF A VAST INDUSTRY 46 (1984). The boundaries defining the orthodox armamentarium were somewhat permeable, as well. A few important remedies used by regular physicians, such as inoculation for smallpox and powdered cinchona bark (the source of quinine) for malaria, originated in folk medicine, and popular healers borrowed some remedies from orthodox medicine. *Id.* at 47.

by large numbers of indisputably lay practitioners, including botanical healers, midwives, bonesetters, unschooled inoculators, and abortionists.<sup>44</sup> In some instances, one's status as an "irregular" doctor was dictated by race or gender. Native Americans, African Americans, and women were virtually excluded from the orthodox medical profession, but they were extremely well represented among the ranks of lay and folk healers.<sup>45</sup> Indeed, women members of households were the nation's most important primary health care providers. Informed by oral tradition, by personal experience, and, increasingly, by published manuals on domestic medicine, many housewives were experts at the use of botanical and other household remedies.<sup>46</sup>

As the nineteenth century progressed, increasing numbers of alternative practitioners—including white men who might have been eligible to practice regular medicine—began to join organized groups that rejected orthodox medical practices and theories in favor of other healing systems. By the end of the nineteenth century, these irregular "schools" of medicine included eclectic medicine, homeopathy, Christian Science, and osteopathy, among many others. Because of this Article's focus on the antebellum years, the only alternative school that it will examine closely is Thomsonianism. This botanical medical sect was founded in the 1810s and thrived into the 1840s. It was the first significant organized alternative medicine group in the United States and was, by far, the most important of its time.<sup>47</sup> The Thomsonians were not merely adherents of a particular system of medicine; as the leaders of a nationwide fight against state medical licensing laws, they were also the core members of a popular constitutionalist movement for medical freedom. As the next section will show, however, the Thomsonians did not invent American health libertarianism. Examples of this attitude can be found in the nation's earliest years. It arose in response to the first attempts to establish medical licensing regimes, in the eighteenth century.

## II. AMERICAN HEALTH LIBERTARIANISM PRE-1820

### *A. The Rise of Medical Licensing*

Even prior to the Revolutionary War, orthodox physicians in America sporadically attempted to persuade colonial governments to pass laws mandating the examination and licensure of doctors. Their primary stated aim was to protect

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44 *Id.* at 48.

45 *Id.* at 47–51.

46 *Id.* at 32–37; ROTHSTEIN, *supra* note 6, at 32–34.

47 See CHARLES E. ROSENBERG, *THE CHOLERA YEARS 70* (1962) (explaining that the followers of Thomsonianism were the "most numerous and vocal" of the irregular medical groups); WHORTON, *supra* note 29, at 25 (asserting that Samuel Thomson was the "first into the field" of alternative medical movements).

the vulnerable and ignorant public from “quacks” and “mountebanks.”<sup>48</sup> They also bemoaned the disrepute that untrained and unorthodox practitioners brought down on the entire profession. “It is very injurious to regular-bred physicians,” one licensing advocate remarked, “that such impostors are suffered to deceive mankind and bring into contempt the honorable profession of physic.”<sup>49</sup>

These efforts to create licensing regimes were generally unsuccessful,<sup>50</sup> and those few licensing laws that passed were primarily honorific measures that did not penalize practice by unlicensed physicians.<sup>51</sup> Prior to the middle of the eighteenth century, efforts to institute medical licensing almost invariably encountered opposition or indifference among the majority of citizens, suggesting the deep-rootedness of the American preference for freedom of therapeutic choice. In the words of medical historian Richard Harrison Shryock, “Most men seem to have believed that a people who entrusted their souls to all sorts of preachers, could likewise entrust their bodies to all sorts of ‘doctors.’”<sup>52</sup>

The strongest colonial licensing laws, at least on paper, were those enacted by New York in 1760 and by New Jersey in 1772. These statutes required that doctors be examined and licensed by lay officials and imposed fines on violators. The fate of these two laws, however, illustrates how (consistent with the approach of popular constitutionalism) it is often necessary to look beyond formal legal sources to determine citizens’ attitudes towards medical liberty. The New York and New Jersey laws were extremely unpopular and thus barely enforced, if at all.<sup>53</sup> In discussing these statutes (as well as the colonial-era measures that failed to pass) one scholar has observed, “many people resisted licensure essentially because of the threat it posed to their traditional freedom to choose from among a broad range of healers.”<sup>54</sup>

On the eve of the Revolution, no effective constraint on practice by unorthodox and untrained doctors existed in the American colonies. One commentator facetiously remarked in 1774, “There is no law for *hanging* mountebanks, that I know of, in this land of liberty; and therefore they that are

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48 See, e.g., Anon., *The Correspondent*, No. XIV, CONN. J., Mar. 19, 1773, at 1.

49 Anon., *Untitled*, NEW-LONDON GAZETTE, Oct. 8, 1773, at 1.

50 For example, in 1767, the regular physicians of Litchfield County, Connecticut, organized themselves into a society that would examine and certify candidates, but the society’s effort to persuade the colonial legislature to formalize its status went nowhere. RICHARD HARRISON SHRYOCK, *MEDICAL LICENSING IN AMERICA, 1650-1965*, at 18 (1967); *Resolves of the Medical Corporation of Litchfield County*, CONN. COURANT, Feb. 23, 1767, at 1.

51 STARR, *supra* note 43, at 44. It was not, however, unheard of for courts to levy penalties. For example, in 1672, the Suffolk County Court fined a man for practicing medicine without its approval, as required at the time by Massachusetts law. SHRYOCK, *supra* note 50, at 14.

52 SHRYOCK, *supra* note 50, at 15.

53 *Id.* at 17; STARR, *supra* note 43, at 44.

54 JAMES H. CASSEY, *MEDICINE IN AMERICA: A SHORT HISTORY* 19 (1991). For discussions of the occasional gestures toward medical licensing in the American colonies, see *id.* at 18–19; ROTHSTEIN, *supra* note 6, at 37–38; SHRYOCK, *supra* note 50, at 13–19.

fond of them may . . . run after them as long as they please.”<sup>55</sup> The same year, a committee of Connecticut doctors complained:

[T]he power of the magistrate is very seldom or ever exerted, or any Notice taken in this country for the preservation of health, or distinguishing the eminent, the learned, from the illiterate and the ignorant. . . . The importance of a proper medical police is either not understood or very little attended to or regarded.<sup>56</sup>

After the signing of the Declaration of Independence, states gradually began to enact medical licensing laws in response to pressure from the growing body of regularly educated physicians.<sup>57</sup> By 1800, six states had medical practice acts of some kind on the books. The 1810s saw the multiplication and strengthening of state licensing regimes—a trend that peaked with a flurry of legislative activity in the late 1810s and early 1820s. The statutes of this period generally required examination and licensing by state medical societies—societies that were, in many instances, incorporated by the same laws.<sup>58</sup> By the end of 1825, eighteen of the twenty-four extant states, plus the District of Columbia, had adopted medical licensing.<sup>59</sup>

The nature and severity of the sanctions set forth in these licensing statutes varied significantly from state to state and also changed within states as the laws were amended. Some states’ medical practice laws established no penalty whatsoever for violators, and other states imposed fines too small to influence behavior.<sup>60</sup> In other jurisdictions, the sole sanction was a prohibition against unlicensed practitioners bringing suits for unpaid fees.<sup>61</sup> On the other side of the scale, about half of the states that enacted medical licensing laws during this era authorized the imposition of fines, and a few went so far as to allow the imprisonment of violators.<sup>62</sup> Despite the variation, overall, there was a trend toward stricter penalties until the mid-1820s.

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55 Anon., *Untitled Letter*, ESSEX GAZETTE, Mar. 15, 1774, at 129.

56 Anon., *Untitled*, NEW-LONDON GAZETTE, Apr. 15, 1774, at 4.

57 ROTHSTEIN, *supra* note 6, at 74.

58 *Id.*; SHRYOCK, *supra* note 50, at 23. In some states, candidates could qualify for a license by passing examinations in medical school rather than the examination administered by the state medical society. *Id.* at 25–27.

59 See ROTHSTEIN, *supra* note 6, at 332–39 app. II. The states still without medical licensing systems in 1825 were Kentucky, Missouri, North Carolina, Pennsylvania, Tennessee, and Virginia. Tennessee enacted medical licensing in 1830 and North Carolina did so in 1859. The other four states enacted no licensing legislation before the Civil War.

60 *Id.* at 76.

61 Unlicensed practitioners could circumvent such provisions by simply demanding payment before providing treatment. See STARR, *supra* note 43, at 44–45. In any event, even licensed practitioners had trouble collecting unpaid fees in the courts. ROTHSTEIN, *supra* note 6, at 76.

62 See ROTHSTEIN, *supra* note 6, at 332–39 app. II.

Nevertheless, this spread and toughening of medical licensing statutes does not necessarily evince widespread support among the population for such measures. One must assess a citizenry's embrace of a legal regime not only by the law in the books, but also by the extent to which that law is actually put into practice. Concededly, in New York—which, for a time, provided for imprisonment of unlicensed practitioners—the medical practice statute was “remarkably effective.”<sup>63</sup> But it appears that the licensing statutes in some other states were utterly ineffective in limiting the number of practitioners. For example, in 1811, the Maryland licensing examination committee grumbled that it was simply unable to bring violators of that state's medical practice act to justice.<sup>64</sup> In some jurisdictions, especially frontier states with sparse populations and small numbers of orthodox physicians, the antebellum licensing regimes failed due to half-hearted implementation and a lack of enforcement by government officials.<sup>65</sup> Moreover, juries routinely refused to convict unlicensed practitioners.<sup>66</sup> This jury conduct, in particular, suggests a widespread embrace of the notion of freedom of therapeutic choice—a notion that many jurors likely had never expressed, even to themselves, until they first encountered an actual instance of state intrusion into the medical sphere.

The steady proliferation and strengthening of state licensing statutes between the 1790s and early 1820s may have been due more to organizational than to ideological factors. During the early national period, regular physicians established many stable local and state medical societies,<sup>67</sup> while irregular doctors could point only to the network of small, local “Friendly Botanic Societies” that Thomson began to build around 1811.<sup>68</sup> This comparative lack of organizational structure—along with the relatively low literacy of many medical licensing opponents—may also help explain the dearth of a noteworthy body of American medical freedom literature prior to the emergence of significant Thomsonian societies and publications in the 1820s and 1830s. This scarcity of early anti-licensing literature makes it difficult to assess the precise basis—beyond economic self-interest—for the opposition to licensing by alternative practitioners and their supporters during the country's first few decades. There are, however, scattered clues.

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63 *Id.* at 75. According to one publication of the time, “many” botanical practitioners were imprisoned “for fifty or sixty days” in New York State. Anon., *Untitled*, 1 BOTANIC WATCHMAN 4, Jan. 1, 1834, at 5.

64 Rothstein, *supra* note 6, at 77.

65 *Id.* at 75–76.

66 *Id.* at 76.

67 *Id.* at 327–31 app. I.

68 HALLER, THE PEOPLE'S DOCTORS, *supra* note 3, at 35–36.

*B. Early Arguments Against Medical Licensing*

The meager record indicates that those who opposed medical licensing in the late eighteenth century did so for various reasons that would persist throughout the antebellum period examined in this Article. One theme that emerges from early anti-licensing statements is the threat to economic freedom posed by government-granted monopolies. For example, in 1769, an opponent of medical licensing in Connecticut raised the specter of a doctors' monopoly exacting excessive fees from the people. He contended, "[A] combination of Doctors perhaps gives them a greater advantage to impose on mankind, by extravagant demands, than if no such combination had been formed."<sup>69</sup> Importantly, foes of medical licensing seemed to fear that an orthodox doctors' monopoly would threaten their freedom as well as their pocketbooks. When the Connecticut legislature in 1787 considered, and rejected, a bill that would have established a state medical society with licensing power, one representative protested that he "did not like this plan: . . . it was a combination of the doctors: . . . they cost more than they do good: this society . . . was directly against liberty: they might shut out every body else: it was a very dangerous thing."<sup>70</sup>

Opposition to monopolies was widespread in Revolutionary America. Indeed, the American colonists' antagonism toward English grants of trade monopolies, such as the East India Company's monopoly over tea importation to the colonies, was a significant impetus for their bid for independence.<sup>71</sup> As reflected in the Connecticut legislator's remarks quoted above, many Americans of this period, drawing on a long tradition of anti-monopolism in English jurisprudence and political thought, viewed exclusive charters as not only detrimental to society's economic interests, but also as a violation of individuals' economic rights.<sup>72</sup> Indeed, Thomas Jefferson, as well as six state ratifying conventions, sought to include an anti-monopoly provision in the Bill of Rights of the United States Constitution.<sup>73</sup>

A related reason for the early opposition to medical licensing was suspicion of the motives of the exclusive medical societies that would administer these

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69 Anon., *Untitled*, CONN. COURANT, Jul. 31, 1769, at 5.

70 *State of Connecticut, In the House of Representatives, May 24*, CONN. J., June 6, 1787, at 3. On the defeat of this measure, see ROTHSTEIN, *supra* note 6, at 68.

71 Steven G. Calabresi & Larissa Price, *Monopolies and the Constitution: A History of Crony Capitalism* 27–28 (Northwestern Sch. of Law Pub. Law & Legal Theory Series, Working Paper No. 12-20, 2012), available at [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2130043](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2130043).

72 *Id.* at 7–22. *Dr. Bonham's Case*, 77 Eng. Rep. 646 (1610), an English case with an opinion by Sir Edward Coke, was frequently cited by American colonists to support their assertion that common law rights could abrogate Parliamentary Acts. Notably, the decision itself nullified a royal charter (confirmed and amended by statute) that gave the College of Physicians the authority (among other powers) to fine doctors for practicing without a license. See Theodore F.T. Plunkett, *Bonham's Case and Judicial Review*, 40 HARV. L. REV. 30 (1926).

73 Calabresi & Price, *supra* note 71, at 29–31, 33–34.



schemes. At the end of the eighteenth century, Americans exhibited widespread “concern with the deceit and dissembling of sophisticated elites.”<sup>74</sup> They saw “designs within designs, cabals within cabals.”<sup>75</sup> Any group or gathering perceived to have aristocratic pretensions was viewed not only as unrepugnant, but also a conspiratorial threat to liberty.<sup>76</sup> Thus another Connecticut legislator opposed to the creation of a state medical society with licensing power opined “[t]hat he was against all societies, whose constitutions & designs we did not know; such as [the Society of the Cincinnati], free-masons, and this medical society; that they were composed of cunning men, and we know not what mischief they may be upon.”<sup>77</sup>

Another premise in the sparse early record that would become an enduring theme in American medical freedom literature was the importance of freedom of inquiry. For example, in 1788 a Philadelphia newspaper observed that, although the state legislature could address the problem of incompetent and ignorant practitioners through legislation, “it has never yet interfered, not only from an unwillingness to multiply restraint in a free country, but perhaps from a doubt, whether some equivalent advantage might not arise from the liberty of attempting medical experiments.”<sup>78</sup> This statement suggests that foes of medical licensing thought that such laws not only constituted excessive state interference into citizens’ private affairs, but also threatened the progress of medical science by hindering free inquiry. The writer of this column further explained: “Unfortunate individuals suffer in the course of [the uneducated practitioner’s] inquiries, but the community at large is sometimes benefitted by an accession to experimental knowledge.”<sup>79</sup>

These two themes—first, the aversion to monopolies and elite fraternities that undermined economic freedom and republican values, and second, the need for free inquiry to advance medical knowledge—would dominate the medical freedom rhetoric of Dr. Benjamin Rush. Paradoxically, although Rush was perhaps the most prominent orthodox physician of the early national period, he was also that era’s most articulate opponent of licensing and proponent of therapeutic choice.

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74 GORDON S. WOOD, *THE IDEA OF AMERICA: REFLECTIONS ON THE BIRTH OF THE UNITED STATES* 104 (2011).

75 *Id.* at 88.

76 *See id.* at 81–126. On anti-aristocratic sentiments in the Revolutionary generation, see GORDON S. WOOD, *THE RADICALISM OF THE AMERICAN REVOLUTION* 240–43 (1992).

77 *State of Connecticut, In the House of Representatives, May 24, CONNECTICUT JOURNAL*, June 6, 1787, at 2–3. The Society of the Cincinnati was a hereditary fraternal order of army officers, of whom George Washington was the first president. The society was widely scorned as a secretive, elitist, aristocratic institution, and in 1787, George Washington tried, with mixed success, to force reforms on it, including abandonment of its hereditary character. *See* CHERNOW, *supra* note 33, at 497–500.

78 Anon., *Untitled*, *INDEPENDENT GAZETTEER*, Dec. 16, 1788, at 3.

79 *Id.*

*C. Benjamin Rush: Orthodox Advocate for Medical Liberty*

Philadelphia's Benjamin Rush (1746-1813), although less celebrated than some of his fellow Founding Fathers, was an influential figure during the birth of the nation and an extraordinary Renaissance man almost on the level of Franklin and Jefferson. He was not only an extremely prominent physician and a medical professor at the University of Pennsylvania, but also a member of the Continental Congress, a signer of the Declaration of Independence, a member of the Pennsylvania ratifying convention, an antislavery pamphleteer, a longtime Treasurer of the U.S. Mint, and the founder of Dickinson College.<sup>80</sup> Most crucially for the purposes of this inquiry, Rush was also the first well-known American opponent of medical licensing and advocate for medical freedom.

One might assume that Rush, as the nation's leading orthodox doctor, would have sided with the forces of exclusion and privilege. In fact, during the Revolutionary years, Rush was a staunch Federalist, apprehensive about extreme democracy and hostile to Pennsylvania's radicals. By 1789, however, he had undergone a dramatic conversion, and for the remainder of his life he was a confirmed Jeffersonian Republican who railed against aristocratic conspiracies.<sup>81</sup>

In light of Rush's background, his transformation was not as surprising as it might seem. As Rush himself was acutely aware, he was in many ways an outsider to the elite medical community of Philadelphia and its well-off clientele. He came from a family of modest means and no connections. He was also a Presbyterian in a city dominated by Quakers and Anglicans.<sup>82</sup> Moreover, his role as a leading patriot in the American Revolution alienated him from a large portion of the city's upper class with loyalist sympathies.<sup>83</sup>

The manner in which Rush conducted his medical career further alienated his orthodox colleagues. He enraged them by working with unlicensed and unorthodox practitioners. As he described the situation, "I frequently exposed myself to reproach from the regular bred [*sic*] of physicians by attending patients with quacks, and with practitioners of physic [medicine] of slender education."<sup>84</sup> At times, Rush rationalized such cooperation in terms seemingly designed to appeal to his orthodox colleagues' elitist sensibilities. He recalled, "I justified this conduct by saying that I rescued the sick from the hands of ignorant men, and gave them a better chance of being cured, and at the same time instructed

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80 See generally ALYN BRODSKY, *BENJAMIN RUSH: PATRIOT AND PHYSICIAN* (2004).

81 LANCE BANNING, *THE JEFFERSONIAN PERSUASION: EVOLUTION OF A PARTY IDEOLOGY* 120–21 (1978); STANLEY ELKINS & ERIC MCKITRICK, *THE AGE OF FEDERALISM: THE EARLY AMERICAN REPUBLIC, 1788-1800*, at 459 (1995); RUSH, *AUTOBIOGRAPHY*, *supra* note 34, at 58, 103; STARR, *supra* note 43, at 42.

82 ELKINS & MCKITRICK, *supra* note 81, at 459; RUSH, *AUTOBIOGRAPHY*, *supra* note 34, at 78–79.

83 RUSH, *AUTOBIOGRAPHY*, *supra* note 34, at 88–89.

84 *Id.* at 106.

[the irregular doctors] in a regular mode of practice.”<sup>85</sup> Elsewhere, however, Rush was more generous to unschooled and alternative practitioners, maintaining that regular doctors could learn valuable lessons from them.<sup>86</sup> He declared medicine to be “a science so simple”<sup>87</sup> that it required little study and was “obvious to the meanest capacities.”<sup>88</sup> He also condemned the standard practice of writing prescriptions and publishing medical dissertations in Latin, charging that the use of this language unnecessarily wrapped medicine in “mystery or imposture.”<sup>89</sup> Such views could not have failed to outrage Rush’s snobbish brethren in the orthodox medical community.

In addition, many elite regular physicians in Philadelphia disdained Rush’s particular medical ideas. First, he infuriated the city’s established doctors by embracing the theories of his Scottish mentor, William Cullen, while they stubbornly clung to the older views of the Dutch physician Herman Boerhaave.<sup>90</sup> Then, in the late 1780s, after most of his colleagues had finally embraced Cullen’s teachings, Rush invited their wrath again by developing his own theory of disease and treatment.<sup>91</sup> Although his new approach, based on extreme bleeding and purging, would ultimately serve as the foundation for standard American heroic medicine in the early nineteenth century, Philadelphia’s fraternity of regulars did not immediately embrace it.<sup>92</sup>

For this combination of reasons, Philadelphia’s medical elite refused to engage in consultations with Rush and urged medical students to avoid his lectures.<sup>93</sup> The acrimony between Rush and other regular physicians peaked in 1793, when a severe yellow fever epidemic ravaged the city. Rush vehemently disagreed with most others in the medical establishment concerning both the origin of and the correct response to this scourge.<sup>94</sup> The rancor of this dispute

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85 *Id.*

86 See BENJAMIN RUSH, OBSERVATIONS ON THE DUTIES OF A PHYSICIAN, AND THE METHODS OF IMPROVING MEDICINE ACCOMMODATED TO THE PRESENT STATE OF SOCIETY AND THE MANNERS IN THE UNITED STATES 10 (Philadelphia, Prichard & Hall 1789).

87 RUSH, AUTOBIOGRAPHY, *supra* note 34, at 88–89.

88 Benjamin Rush, “Lecture VI. Upon the Causes Which Have Retarded the Progress of Medicine and the Means of Promoting Its Certainty and Greater Usefulness” in BENJAMIN RUSH, SIX INTRODUCTORY LECTURES TO COURSES OF LECTURES UPON THE INSTITUTES AND PRACTICE OF MEDICINE 157 (Philadelphia, John Conrad & Co. 1801).

89 *Id.* at 156.

90 BRODSKY, *supra* note 80, at 91–92.

91 RUSH, AUTOBIOGRAPHY, *supra* note 34, at 82, 361–66 app. 1 (“Rush’s Medical Theories”); RICHARD HARRISON SHRYOCK, MEDICINE AND SOCIETY IN AMERICA: 1660–1860, at 67–72 (1960).

92 Rush recommended, in extreme cases, the removal of up to four-fifths of the blood from the body. *Id.* at 70.

93 RUSH, AUTOBIOGRAPHY, *supra* note 34, at 88, 96. Rush’s colleagues’ purported efforts to ruin him did not succeed; despite all the odium he was exposed to, he, by his own reckoning, “did more business, with more profit, between the years 1769 and 1800 than any contemporary physician in Philadelphia.” *Id.* at 108.

94 Rush attributed the epidemic to “domestic origins” (a “noxious miasma”), whereas “nearly the whole College of Physicians . . . derived it from a foreign country,” namely, the thousands of

was heightened by the curious fact that public attitudes towards the causes of yellow fever and its appropriate treatment corresponded to political divisions, with Republicans supporting Rush and Federalists backing his opponents.<sup>95</sup> Rush's colleagues were so vituperative toward him that following the epidemic, he resigned from the College of Physicians.<sup>96</sup>

Probably impelled, at least in part, by the intense antagonism of the medical establishment, Rush became an outspoken advocate for medical freedom. Despite having what his biographer calls a "somewhat immutable conviction in the correctness . . . of his ideas,"<sup>97</sup> Rush was a voice for tolerance of different medical views. He opposed most restrictions on medical choice, including at least some types of medical licensing. In a published 1801 lecture to the University of Pennsylvania Medical School, Rush enumerated many "causes which have retarded the progress" of medicine, including the following:

21c. The interference of governments in prohibiting the use of certain remedies, and enforcing the use of others by law. The effects of this mistaken policy has [*sic*] been as hurtful to medicine, as a similar practice with respect to opinions, has been to the Christian religion.

22d. Conferring exclusive privileges upon bodies of physicians, and forbidding men of equal talents and knowledge, under severe penalties, from practising medicine within certain districts of cities and countries. Such institutions, however sanctioned by ancient charters and names, are the bastiles [*sic*] of our science.

23d. The refusal in universities to tolerate any opinions, in the private or public exercises of candidates for degrees in medicine, which are not taught nor believed by their professors, thus restraining a spirit of inquiry in that period of life which is most distinguished for ardour and invention in our science.<sup>98</sup>

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Frenchmen who arrived in Philadelphia after fleeing the Haitian Revolution. RUSH, *AUTOBIOGRAPHY*, *supra* note 34, at 97; *see also* BRODSKY, *supra* note 80, at 326; ELKINS & MCKITRICK, *supra* note 81, at 823 n.182. Moreover, the medical establishment contemptuously rejected Rush's recommendation that doctors battle the scourge through the use of extreme purging and bloodletting. BRODSKY, *supra* note 80, at 329–32.

95 ELKINS & MCKITRICK, *supra* note 81, at 823 n.182.

96 RUSH, *AUTOBIOGRAPHY*, *supra* note 34, at 98.

97 BRODSKY, *supra* note 80, at 345.

98 Rush, *Lecture VI*, *supra* note 89, at 151–52. In the first quoted paragraph, Rush seems to have been alluding primarily to actions by governments in Europe, rather than the United States; at the time Rush composed the lecture, few if any American laws had ever actually prohibited or mandated the use of particular remedies. The second paragraph, by contrast, addressed what Rush may have perceived to be an extant and growing problem in his own country, for about six states had enacted such laws by the time Rush prepared this address. Rush's own state, Pennsylvania,

Rush's speech was not explicitly political or constitutional. He delivered it to medical students in the interest of "our science," and most of the obstacles to medical progress he identified concerned the attitudes and practices of physicians themselves. Nevertheless, the speech was deeply infused with Rush's republican worldview and his Jeffersonian devotion to limited government. Moreover, the three quoted paragraphs contain the seeds of three persistent medical liberty notions—freedom of conscience, economic freedom, and freedom of inquiry, respectively—that would eventually combine with the notion of bodily freedom to form the Thomsonians' explicitly constitutional argument for freedom of therapeutic choice.

In the first of the quoted paragraphs, Rush anticipated much subsequent medical freedom rhetoric by alluding to a parallel between medical freedom and religious freedom.<sup>99</sup> Like many Jeffersonians, he was a committed religious pluralist and outspoken advocate of religious liberty.<sup>100</sup> He equated the state imposition of orthodox medical doctrine with the despotism of an established church and the truth-stifling effect of religious intolerance.<sup>101</sup> Jefferson himself

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would not enact its first medical practice act until after the Civil War. ROTHSTEIN, *supra* note 6, at 339; Samuel Lee Baker, *Physician Licensure Laws in the United States, 1865-1915*, 39 J. OF THE HIST. OF MED. & ALLIED SCI. 173, 196 (1984). However, as Rush was likely aware, John Morgan, the founder of what later became the University of Pennsylvania Medical School, had petitioned the provincial legislature in 1769 for authority to found an elect College of Physicians with the power to examine and license practitioners. SHRYOCK, *supra* note 50, at 16–17. The Pennsylvania state legislature passed a medical practice statute in 1824, but the governor vetoed it. See John Andrew Shulze, *To the Assembly Vetoing "An Act to Regulate the Practice of Physics and Surgery Within this Commonwealth"* (Dec. 8, 1824), reprinted in PAPERS OF THE GOVERNORS 1817-1832, at 542 (George Edward Reed ed., 1990).

99 In 1789, Rush had similarly declared, "Medicine has its Pharisees, as well as religion. But the spirit of this sect is as unfriendly to the advancement of medicine, as it is to christian [*sic*] charity." RUSH, *DUTIES*, *supra* note 86, at 10.

100 BRODSKY, *supra* note 80, at 149, 290, 306, 346; RUSH, *AUTOBIOGRAPHY*, *supra* note 34, at 339–40. Jefferson himself was the author of the 1786 Virginia Act for Establishing Religious Freedom. In a widely circulated 1799 letter to Elbridge Gerry that became the platform for Jefferson's 1800 presidential campaign, Jefferson declared, "I am for freedom of religion, and against all maneuvers to bring about a legal ascendancy of one sect over another." THOMAS JEFFERSON & NOBLE E. CUNNINGHAM, *THE INAUGURAL ADDRESSES OF PRESIDENT THOMAS JEFFERSON, 1801 AND 1805*, at 3 (2001) (quoting Letter from Thomas Jefferson to Elbridge Gerry (January 26, 1799), in 9 *THE WORKS OF THOMAS JEFFERSON* 15, 18 (Paul L. Ford, ed. 1905)). On the Jeffersonian Republican commitment to the separation of church and state, see GORDON S. WOOD, *EMPIRE OF LIBERTY: A HISTORY OF THE EARLY REPUBLIC, 1789-1815*, at 587–89 (2009). In his *Notes on the State of Virginia*, Jefferson stated, "[d]ifference of opinion is advantageous in religion." THOMAS JEFFERSON, *WRITINGS*, *supra*, at 286 (1984).

101 The relationship between church and medicine was a longstanding one. As Rush may have been aware, when Parliament instituted a system of examination and licensure of physicians in 1510, it placed administration of the system in the hands of the Church of England. Ecclesiastical control over medical licensure, however, was relatively short lived. SHRYOCK, *supra* note 50, at 6–7.

reached the same analogy from the other direction in a discussion about religious liberty in his *Notes on the State of Virginia*. Bemoaning various symptoms of “religious slavery,” Jefferson remarked:

Reason and free enquiry are the only effectual agents against error. . . . Had not free enquiry been indulged, at the æra [*sic*] of reformation, the corruptions of Christianity could not have been purged away. If it be restrained now, the present corruptions will be protected, and new ones encouraged. Was the government to prescribe to us our medicine and diet, our bodies would be in such keeping as our souls are now. Thus in France the emetic was once forbidden as medicine, and the potatoe [*sic*] as an article of food. Government is just as infallible too when it fixes systems in physics. Galileo was sent to the inquisition for affirming that the earth was a sphere.<sup>102</sup>

Religious liberty (or freedom of conscience) and freedom of inquiry were thus intertwined for both Jefferson and Rush.

The second quoted paragraph, by condemning the artificial privilege and monopoly perpetuated by medical licensing, presaged the important role that the theme of economic freedom would play in Thomsonian medical freedom rhetoric. Just how wide Rush himself would have flung open the door to the medical profession is not clear; he complained in the address only about the exclusion of “men of equal talents and knowledge.” Nonetheless, Rush indisputably had a much less restrictive vision of the profession than many regulars. This opposition to special castes and exclusive privileges was a typically Republican position. Jeffersonians believed the granting of monopolies, particularly to favored elites, was “destructive of the principle of equal liberty” and inconsistent with a republican form of government.<sup>103</sup>

Rush’s reference to the relationship between freedom of inquiry and scientific progress illustrates yet another theme that would prove to be enduring. He contended that the prohibition of certain remedies was “hurtful to medicine,” that exclusive licensing regimes were “the bastiles of our science,” and that suppression of dissenting opinions in medical schools curbed “a spirit of inquiry in that period of life which is most distinguished for ardour and invention in our science.”

Importantly, Rush would have extended freedom of inquiry not only to medical school students and erudite physicians, but also to irregular practitioners. Earlier in the same address, he condemned the medical profession’s “neglect to inquire after, and record cures which have been performed . . . by medicines,

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<sup>102</sup> JEFFERSON, *supra* note 100, at 285.

<sup>103</sup> WOOD, *EMPIRE OF LIBERTY*, *supra* note 100, at 461 (citation omitted).

administered by quacks, or by the friends of sick people.”<sup>104</sup> Twelve years before, in a published speech to the University of Pennsylvania’s graduating medical students, Rush had declared:

Let me remind you, that improvement in medicine is not to be derived only from colleges and universities. . . . [T]hose facts which constitute real knowledge, are to be met with in every walk of life. Remember how many of our most useful remedies have been discovered by quacks. Do not be afraid, therefore, of conversing with them, and of profiting by their ignorance and temerity in the practice of physic. . . . But further.—In the pursuit of medical knowledge, let me advise you to converse with nurses and old women. . . . Even negroes and Indians have sometimes stumbled upon discoveries in medicine. Be not ashamed to inquire into them.<sup>105</sup>

Rush’s views regarding the value of experimentation by the common man were also typical of early nineteenth-century republicanism. Despite Jefferson’s own belief in a “natural aristocracy,” his followers increasingly asserted that popular knowledge was as accurate and beneficial as the knowledge of experts.<sup>106</sup>

As I will discuss in Part III,<sup>107</sup> similar themes to those contained in Rush’s medical freedom discourse would pervade the Thomsonians’ anti-licensing rhetoric of the 1830s. Like Rush, the Thomsonians emphasized the parallel between medical freedom and religious freedom. Their literature was similarly filled with attacks on monopoly and “aristocratic privilege.” They, too, asserted that scientific progress depended on freedom of inquiry and trumpeted the medical discoveries made by unschooled practitioners. However, as I will also explain in Part III, the Thomsonians added to their argument an important strain of medical freedom strikingly absent from Rush’s speech—namely, bodily freedom.

#### *D. Rush’s Legacy*

##### *1. Rush and the Thomsonians*

Before turning to the Thomsonian campaign against medical licensing, it is worth considering whether and how Rush influenced them. Interestingly, despite his heroic approach to medicine, Rush is generally portrayed with admiration in Thomsonian literature. This favorable attitude likely derived largely from Samuel

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<sup>104</sup> Rush, *Lecture VI*, *supra* note 88, at 151.

<sup>105</sup> RUSH, *DUTIES*, *supra* note 86, at 10.

<sup>106</sup> WOOD, *EMPIRE OF LIBERTY*, *supra* note 100, at 725–28.

<sup>107</sup> *Infra* Section III.E.

Thomson's depiction of his one encounter with Rush. In his widely circulated autobiographical narrative,<sup>108</sup> Thomson related how in 1813, he visited Rush and Benjamin Smith Barton, another University of Pennsylvania professor, to request their assistance in "introducing my system of practice to the world."<sup>109</sup> Although Rush "was so much engaged, that I was unable to have but little conversation," he "treated me with much politeness; and said that whatever Dr. Barton agreed to he would give his consent."<sup>110</sup> According to Thomson, Barton graciously agreed to accept some of Thomson's medicine and "make a trial of it."<sup>111</sup> Unfortunately, both professors died relatively soon afterward, thus depriving Thomson "of the influence of these two men, which I was confident would otherwise have been exerted in my favour."<sup>112</sup>

Thomson's followers, probably influenced by this account, regularly referred to Rush with adulatory phrases such as the "great Dr. Rush."<sup>113</sup> They highlighted the fact that the "much-distinguished" Rush, like their own mentor, believed in the "unity of disease and of cure."<sup>114</sup> They depicted Rush (somewhat accurately) as open-minded and (inaccurately) as ambivalent about his own variety of heroic treatments.<sup>115</sup> One Thomsonian lecturer, with some justification, characterized Rush as believing that "some lonely weed, trampled in the earth, might furnish a cure which had baffled all the wisdom of the schools."<sup>116</sup> But another speaker confused Rush's willingness to consider the benefits of herbal medicine with a wholesale rejection of orthodox principles. This lecturer asserted that Rush "opened the cry" in the United States against the orthodox "practice of poisoning the human system."<sup>117</sup> With no apparent basis, the Thomsonians repeatedly

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108 Because this narrative was published in the same volume as Thomson's *Guide to Health*, the handbook of Thomsonian medicine, enormous numbers of Thomsonians around the country possessed it. SAMUEL THOMSON, *NEW GUIDE TO HEALTH; OR, BOTANIC FAMILY PHYSICIAN. CONTAINING A COMPLETE SYSTEM OF PRACTICE ON A PLAN ENTIRELY NEW: WITH A DESCRIPTION OF THE VEGETABLES MADE USE OF, AND DIRECTIONS FOR PREPARING AND ADMINISTERING THEM, TO CURE DISEASE. TO WHICH IS PREFIXED A NARRATIVE OF THE LIFE AND MEDICAL DISCOVERIES OF THE AUTHOR* (2d ed. 1825) [hereinafter *NARRATIVE*].

109 *Id.* at 123. Whereas Thomson proudly highlighted this encounter in his autobiography, Rush did not mention it in his own.

110 *Id.*

111 *Id.*

112 *Id.* at 124.

113 See, e.g., Dr. T. Hersey, *A Lecture on the Comparative Merits of the Patent Steam Practice of Dr. Samuel K. Jennings and Dr. Samuel Thomson*, 2 THOMSONIAN RECORDER 193, 197 (1834) ("the great Dr. Rush").

114 R. H. Brumby, *Medical Botanist*, 2 THOMSONIAN RECORDER 367, 368 (1834).

115 See JAMES HARVEY YOUNG, *TOADSTOOL MILLIONAIRES: A SOCIAL HISTORY OF PATENT MEDICINES IN AMERICA BEFORE FEDERAL REGULATION* 37 (1972) (referring to the "self-confident way in which [Rush] advocated his theories").

116 Lecture by M. W. McCraw, in *Proceedings of the Mecklenburg Branch Society*, 2 THOMSONIAN RECORDER 401, 406 (1834).

117 SAMUEL ROBINSON, *A COURSE OF FIFTEEN LECTURES, ON MEDICAL BOTANY, DENOMINATED THOMSON'S NEW THEORY OF MEDICAL PRACTICE; IN WHICH THE VARIOUS THEORIES*



quoted Rush as saying that the art of healing was like “an *unroofed temple*:- Uncovered at the top, and cracked at the foundation.”<sup>118</sup>

Despite the Thomsonians’ high regard for Rush, and the seeming echoes of his 1801 address that sounded throughout their own writings, it is far from clear that they were actually familiar with the speech. They never quoted from the lecture. Nevertheless, as I will show below,<sup>119</sup> the Thomsonians appear to have absorbed Rush’s arguments through cultural osmosis, even if they did not borrow them directly. At the very least, the esteemed Philadelphia physician and the radical botanical healers drew from the same intellectual and political traditions.

## 2. *The Posthumous Transformation of Rush into Constitutional Advocate*

Rush’s speech eventually found its way into non-Thomsonian anti-licensing literature. In 1838 or 1839, an American journal dedicated to the growing school of homeopathy reproduced much of the 1801 address—including the above-quoted passages.<sup>120</sup> Thereafter, medical licensing opponents quoted Rush’s paragraph opposing “exclusive privileges” with increasing frequency for the remainder of the century. Then, in the first decade of the twentieth century, opponents of restrictive licensing creatively expanded Rush’s words into a *constitutional* argument for medical freedom. In 1907, the *Journal of the American Osteopathic Association* conjured up the following imaginary declaration by Rush:

The constitution of this republic should make specific provision for medical freedom as well as for religious freedom. To restrict the practice of the art of healing to one class of physicians and deny to others equal privileges constitutes the bastiles of our science. All such laws are un-American and despotic. They are vestiges of monarchy and have no place in a republic.<sup>121</sup>

Over the course of the twentieth century, this fictitious rendering of Rush’s

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THAT HAVE PRECEDED IT, ARE REVIEWED AND COMPARED 10 (Columbus, Horton Howard 1829).

118 The earliest attribution of this quotation to Rush (or anyone) that I can find is in an 1829 Thomsonian publication. *Id.* at 16.

119 *Infra* Section III.E.

120 MISCELLANIES ON HOMOEOPATHY 159 (Ass’n of Homeopathic Physicians ed., 1839) (including a reissue of the 1838-1839 *American Journal of Homeopathy*). Although the three paragraphs on medical freedom are identical to those in Rush’s 1801 University of Pennsylvania address, they are enumerated differently, and the speech overall is abridged. It is unclear whether the homeopathic publication shortened Rush’s speech on its own, acquired an abridged transcript of the speech, or acquired a transcript of a similar speech delivered by Rush at another event.

121 *Directory of Members (Attachment)*, 6 JOURNAL OF THE AMERICAN OSTEOPATHIC ASSOCIATION 29 (1907). Although this is the earliest instance I could find of a claim that Rush had called for a constitutional provision protecting medical freedom, the editor of this journal might, of course, have borrowed these words from some other unidentified source.

words took on a life of its own. A Google search today reveals thousands of web pages that ascribe this precise language, or some variant of it, to Rush. His imagined advocacy of a medical freedom amendment to the Constitution has become fact in cyberspace. The truth that he never actually called for such an amendment should not, however, obscure his actual emphatic opposition to state interference in medical affairs.

### III. AMERICAN HEALTH LIBERTARIANISM BETWEEN 1820 AND THE CIVIL WAR

Starting around 1820, two major shifts occurred in the story of medical licensing in America. First, Thomsonian practitioners, patients, and supporters transformed a previously widespread, but uncoordinated, anti-licensing sentiment into a passionate, multi-pronged popular constitutional movement. Second, and not coincidentally, state medical practice acts began to disappear from the statute books.

#### *A. The Decline and Fall of Antebellum Medical Licensing*

The 1820s were the fulcrum of an abrupt shift in state legislative activity with respect to medical licensing. In the first twenty-four states to enter the union and the District of Columbia, every pertinent legislative enactment passed prior to 1820 was designed to either create or strengthen a licensing regime. In stark contrast, between 1830 and 1860, every relevant legislative action in these states (with a couple of minor exceptions) either weakened or entirely revoked medical licensing.<sup>122</sup> Some states took initial steps of lowering the penalty for practicing without a license, exempting certain classes of irregular practitioners from the licensing requirement, or both.<sup>123</sup> Eventually, however, most states repealed their medical licensing regimes altogether.<sup>124</sup> Moreover, in about half of the states that still had licensing laws, these statutes did not subject violators to any penalty.<sup>125</sup> According to one author, “[F]or half a century after 1820 licensing requirements apparently deteriorated. By the 1850s, when German authorities were

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122 See ROTHSTEIN, *supra* note 6, at 332–39 app. II. One exception was an 1847 statute in Georgia, which reversed an 1839 evisceration of the licensing system, but created an independent Botanico-Medical licensing board to license botanical physicians. *Id.* at 334. The other exception was an 1859 statute in North Carolina, which established a licensing board for the first time in that state. *Id.* at 339.

123 See ROTHSTEIN, *supra* note 6, at 332–39 app. II. State statutes variously exempted Thomsonians, botanical practitioners, and homeopaths. *Id.*

124 It is difficult to gather precise statistics regarding the revocation of antebellum state medical licensing statutes, but the sources leave no doubt that repeal was extremely widespread. See CASSEDY, *supra* note 53, at 26 (between 1830 and 1845, eleven states repealed their laws); HALLER, THE PEOPLE’S DOCTORS, *supra* note 3, at 200 (“By mid century, fifteen state legislatures had repudiated medical licensure”); WHORTON, NATURE CURES, *supra* note 29, at 36 (“By 1850 all but two states’ licensing statutes had been swept from the books.”).

125 See ROTHSTEIN, *supra* note 6, at 332–39 app. II.

establishing uniform standards and when the British government was taking the first steps toward national control, the situation in the United States seemed to be approaching its nadir.”<sup>126</sup>

An examination of the statutes alone actually understates the disintegration of medical licensing in the antebellum period. As noted previously, even at the apex of medical licensing in the late 1810s and early 1820s, the laws’ effectiveness was uneven, at best.<sup>127</sup> But as the century advanced, the shrinking number of medical practice acts still on the books increasingly became wholly irrelevant. Executive authorities, apparently aware of the public’s growing distaste for restricting the practice of medicine, often simply failed to enforce the statutes.<sup>128</sup> Some of the remaining licensing boards settled into a state of permanent hibernation.<sup>129</sup>

By the 1840s, contemporary commentators agreed that medical licensing was, for all practical purposes, finished. In an 1844 article, a New York observer of the national scene remarked:

The conclusion which may be drawn is, that when restrictive laws are really efficient and enforced, they protect the community against inexperience and its consequences, but that popular sentiment is opposed to them; consequently the law is either so drawn as to be inefficient, or is, in nine out of ten cases, openly violated with impunity, whilst its existence is such as to get up a feeling of hostility to the regular profession.<sup>130</sup>

The president of the Ohio State Medical Society observed in 1849 that “all enactments upon the subject of medicine or prescriptions under fines, penalties, or the like, are extremely difficult of execution and have impracticability and soon become a dead letter.”<sup>131</sup> In his renowned 1850 report on public health in Massachusetts, Lemuel Shattuck wryly observed: “Any one, male or female, learned or ignorant, an honest man or a knave, can assume the name of a physician, and ‘practice’ upon any one, to cure or to kill, as either may happen, without accountability. ‘It’s a free country!’”<sup>132</sup> According to one scholar, “By

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126 SHRYOCK, *MEDICAL LICENSING*, *supra* note 50, at 27.

127 *See id.* (“the promise of early American laws proved illusory”); ROTHSTEIN, *supra* note 6, at 79 (“None of the licensing laws in this period was [*sic*] ever effective.”).

128 ROTHSTEIN, *supra* note 6, at 77–78.

129 *Id.* at 332–39 app. II.

130 Charles Coventry, *History of Medical Legislation in the State of New York*, 4 N.Y. J. OF MED. & COLLATERAL SCI. 151, 160 (Mar. 1845).

131 *See* ROTHSTEIN, *supra* note 6, at 78.

132 LEMUEL SHATTUCK, REPORT OF A GENERAL PLAN FOR THE PROMOTION OF PUBLIC AND PERSONAL HEALTH DEVISED, PREPARED AND RECOMMENDED BY THE COMMISSIONERS APPOINTED UNDER A RESOLVE OF THE LEGISLATURE OF MASSACHUSETTS, RELATING TO A SANITARY SURVEY OF THE STATE 58 (1850).

the time of the Civil War, no effective medical licensing existed in any of the states.”<sup>133</sup>

What happened? The antebellum medical licensing regimes succumbed to the country’s first broad popular movement promoting medical freedom, led by the Thomsonians. These medical freedom advocates drew copiously from all four of the contributing strands of medical liberty identified above—bodily freedom, economic freedom, freedom of inquiry, and freedom of religion and conscience. In petitions, journals, and speeches, the Thomsonians framed a successful, multidimensional libertarian argument against medical licensing. And although they advanced their case entirely outside of court, their contentions were unmistakably constitutional.

### *B. The Thomsonians*

Samuel Thomson (1769-1843) was raised on a remote New Hampshire farm in humble circumstances and lacked any formal education. As a boy, he became fascinated by herbal remedies under the tutelage of a local widow. He suffered a severe ankle wound at age nineteen and attributed his recovery to botanical cures. In his early twenties, Thomson renounced regular medicine altogether after watching in horror as the heroic treatments of orthodox doctors apparently hastened his mother’s death from consumption and then nearly finished off his young wife when she suffered complications following childbirth.<sup>134</sup>

Thomson began to develop his own healing system while treating his family and neighbors. Beginning in 1805, he roamed around northern New England, offering his services to townsfolk and establishing a few medical offices.<sup>135</sup> The commercially savvy Thomson soon conceived an innovative business plan; he sold franchises—the right to use his system and proprietary remedies—to families in advance of any illness.<sup>136</sup> Thomson obtained a patent for his medicines and their method of use in 1813, filed copyrights for his *New Guide to Health* and his autobiographical narrative in 1822, and fiercely guarded his intellectual property until the end of his life.<sup>137</sup> Eventually, Thomson built a nationwide business empire, undergirded by an army of agents, thirteen editions of his bestselling *New Guide to Health*, a network of Friendly Botanic Societies, and annual United States Thomsonian Botanic Conventions.<sup>138</sup> Thomsonianism became wildly popular in the 1830s, especially in the South and Midwest. In 1839, Thomson himself boasted that three million Americans—approximately

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133 JOHN S. HALLER, *AMERICAN MEDICINE IN TRANSITION, 1840-1910*, at 201 (1981).

134 HALLER, *THE PEOPLE’S DOCTORS*, *supra* note 3, at 10–13.

135 *Id.* at 14–19, 32.

136 *Id.* at 32–35.

137 *Id.* at 37–40, 49.

138 *Id.* at 35–36, 40–43, 143–47.

twenty percent of the population—were adherents of his method.<sup>139</sup> One modern scholar surmises that Thomson's estimate, while likely exaggerated, did not vastly exceed the true number.<sup>140</sup>

Although the Thomsonians stridently disparaged regular doctors' use of dangerous mineral remedies, their system shared certain central characteristics with orthodox medicine, including a reductionist understanding of disease as a fundamental bodily imbalance and a uniform therapeutic method based on the evacuation of bodily fluids.<sup>141</sup> Thomson posited that all illness derived from the body's loss of natural heat, and his treatment regime was designed to restore the patient's "vital warmth" by clearing bodily obstructions through perspiration, purging, and vomiting.<sup>142</sup> The emblematic components of the Thomsonian healing system were lobelia (an emetic herb), cayenne pepper, and steam baths.<sup>143</sup> Despite its resemblance to regular medicine, Thomson's course of treatment was probably less enervating than the use of calomel and bleeding.<sup>144</sup> Many were attracted to the Thomsonians' use of "natural" vegetable-based remedies instead of mineral compounds such as calomel.

Although Thomson derived his system largely *a priori* from unproven premises about the nature of the human body and disease, Thomsonians took pride in being more "empirical" than the regulars. They viewed themselves as ascribing more value to actual experience and less to abstruse theory than regular physicians.<sup>145</sup> Whereas orthodox doctors often used the term "empiric" as an insulting moniker for undereducated, "unscientific" alternative practitioners, the Thomsonians embraced the label.<sup>146</sup> They condemned orthodox medicine for its abstract speculation, as well as for its ineffective and dangerous treatments.

The 1830s (the period from which most of the quotations in this section derive) were a tumultuous decade for Thomsonians. Samuel Thomson himself became progressively more self-important, fanatical, and vengeful. He tolerated no variation from his therapeutic methods and denied that conventional scientific education had any value to medicine whatsoever.<sup>147</sup> But the patriarch's unquestioning disciples were increasingly outnumbered by flexible advocates of a more general botanic cause.<sup>148</sup> The most prominent of these open-minded Thomsonians was likely Alva Curtis, the editor of the *Thomsonian Recorder*, the

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139 WHORTON, *NATURE CURES*, *supra* note 124, at 39.

140 *Id.* at 39.

141 HALLER, *THE PEOPLE'S DOCTORS*, *supra* note 3, at 17–18, 29–30, 39–40.

142 *Id.* at 17–24.

143 *Id.* at 21–22, 24–29.

144 *Id.* at 30.

145 WHORTON, *NATURE CURES*, *supra* note 29, at 10–12.

146 HALLER, *THE PEOPLE'S DOCTORS*, *supra* note 3, at 51.

147 *Id.* at 147–59.

148 *Id.* at 67–73, 139, 154.

oldest and most popular botanic magazine in the nation.<sup>149</sup> In 1836, Curtis (whose words open this Article) defied Thomson on the educational issue by founding the initially unchartered Botanico-Medical College of Ohio, whose curriculum incorporated lectures and texts on basic science.<sup>150</sup> In 1838, Curtis led a secession of “Independent Thomsonians” away from the purists—a schism impelled by the Independents’ desire for freedom to explore improvements to Dr. Thomson’s system, including expansion of its *materia medica*.<sup>151</sup>

It is important to recognize the issues of social status that swirled around the Thomsonian movement. While by the 1830s Thomsonianism was attracting some middle class and wealthy followers,<sup>152</sup> it remained at its core “a rural and lower-class phenomenon.”<sup>153</sup> Thomsonians were, during this era, driven by populist passion—a rejection of elite practitioners, institutions, and knowledge. In this respect, they were representative of a broad, egalitarian political culture with affinity to President Andrew Jackson’s Democratic Party—a political culture that frequently exhibited a fierce libertarian opposition to government intrusion into private affairs.

### C. The Thomsonians and Jacksonian Liberty

To fully grasp the Thomsonians’ broad vision of medical freedom, and the appeal of their message, one must understand that they were overwhelmingly Jacksonian Democrats.<sup>154</sup> The Jacksonians generally were not laissez-faire absolutists.<sup>155</sup> Nonetheless, they, along with their Jeffersonian Republican

149 *Id.* at 215. Curtis renamed the publication the *Botanico-Medical Recorder* in 1838.

150 *Id.* at 94–98. The school was located in Columbus.

151 *Id.* at 170–73.

152 *Id.* at 143.

153 CHARLES E. ROSENBERG, *THE CHOLERA YEARS* 72 (1962). William G. Rothstein states that “[a]lthough most of the eastern supporters of Thomsonism [*sic*] were lower class . . . the system was popular with all social classes in the midwest and south.” ROTHSTEIN, *supra* note 6, at 141.

154 Scholars routinely identify Thomsonianism with Jacksonian Democracy. *See, e.g.*, STARR, *supra* note 43, at 56–57; HALLER, *THE PEOPLE’S DOCTORS*, *supra* note 3, at 63; WHORTON, *NATURE CURES*, *supra* note 29, at 33–35; SHRYOCK, *supra* note 50, at 31. One author recently contended that, at least in Connecticut, the Thomsonians who opposed licensing in the late 1830s and early 1840s were more “professionalized” and “conservative” than is usually assumed. He concluded that while the Connecticut Thomsonians drew more support from the state’s weak Democratic Party than from the Whigs, they were not interested in a broader populist Jacksonian agenda. *See* Toby A. Appel, *The Thomsonian Movement, the Regular Profession, and the State in Antebellum Connecticut: A Case Study of the Repeal of Early Medical Licensing Laws*, 65 J. OF THE HIST. OF MED. & ALLIED SCI. 153 (2010). Nevertheless, this scholar acknowledges, “Compared to other states, Connecticut’s Thomsonian story falls toward the conservative end of a spectrum.” *Id.* at 185.

155 Jacksonians mistrusted big business rather than economic regulation *per se* and thus embraced some regulation not deemed to advance the interests of self-aggrandizing moneyed aristocrats. DANIEL WALKER HOWE, *WHAT HATH GOD WROUGHT: THE TRANSFORMATION OF AMERICA, 1815-1848*, at 505 (2009); WILLIAM J. NOVAK, *THE PEOPLE’S WELFARE: LAW AND REGULATION IN NINETEENTH-CENTURY AMERICA* 43 (1996). Furthermore, the issue of slavery led southern Democrats in particular to support intrusive state interference with freedom of speech,

forebears, probably had the most comprehensive libertarian philosophy of any major political culture in American history.<sup>156</sup> As described by Marvin Meyers, Jacksonians believed that a “laissez-faire society . . . would re-establish continuity with that golden age in which liberty and progress were joined inseparably with simple yeoman virtues.”<sup>157</sup> Whereas the Jacksonians’ Whig opponents supported an active role for the government in funding and facilitating economic development, the Jacksonians tended to reject such measures as special legislation favoring privileged patricians. They had an almost paranoid view of the grasping “money power’s” ability to control the organs of government.<sup>158</sup> Jacksonian laissez-faireism was thus populist in spirit, reflecting a view that economic regulations were the instruments of corrupt, scheming elites striving to aggrandize their wealth and power at the expense of the common man. The Jacksonian journalist William Leggett believed (in Marvin Meyers’ words): “Freedom is . . . freedom *from* chartered exploitation, from ‘aristocratic innovation.’”<sup>159</sup>

The Whigs and Jacksonians also disagreed about government’s appropriate posture with respect to religion and the regulation of private behavior. The Whigs believed the state should enforce moral standards and promote cultural homogeneity; accordingly, they supported temperance laws, obligatory Sabbath observance, and a broad partnership between church and state to advance a “national religion.”<sup>160</sup> Jacksonians, on the other hand—with the support of the vast majority of the nation’s Catholics—opposed temperance laws, embraced the strict separation of church and state, and generally “made room for widely divergent private behavior.”<sup>161</sup>

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assembly, and petition. KENNETH IRA KERSCH, *FREEDOM OF SPEECH: RIGHTS AND LIBERTIES UNDER THE LAW* 76–80 (2003).

156 For a discussion of the “republican theory and practice” that bridged the Jeffersonian and Jacksonian political cultures, see HARRY L. WATSON, *LIBERTY AND POWER: THE POLITICS OF JACKSONIAN AMERICA* 42–72 (2006).

157 MARVIN MEYERS, *THE JACKSONIAN PERSUASION: POLITICS AND BELIEF* 12 (1960).

158 WATSON, *supra* note 156, at 167.

159 MEYERS, *supra* note 157, at 194–95. Samuel Thomson’s own view of the inordinate power of the regular physicians in combination with their governmental sponsors is illustrated by his complaint that “the doctors have so much influence in society . . . that the common people are kept back from a knowledge of what is of the utmost importance for them to know. If any man undertakes to pursue a practice different from what is sanctioned by the regular faculty . . . he is hunted down like a wild beast; and a hue and cry raised against him from one end of the country to the other.” THOMSON, *NARRATIVE*, *supra* note 108, at 8.

160 ARTHUR MEIER SCHLESINGER, *THE AGE OF JACKSON* 137–40, 352–54 (1945); HOWE, *supra* note 155, at 583; WATSON, *supra* note 156, at 245.

161 WATSON, *supra* note 156, at 242; SCHLESINGER, *supra* note 160, at 354–56. On Catholic support, see HOWE, *supra* note 155, at 581, 688. Interestingly, alcohol consumption presented a challenge to the Thomsonian philosophy, as demonstrated by the treatment of the topic in Curtis’ *Thomsonian Recorder*. Although alcohol was a common part of the regular physician’s dispensary, Curtis did not reject its use out of hand; for example, he acknowledged its efficacy as a cholera preventive. *Brandy, Cholera, and Cholera Syrup*, 2 THOMSONIAN RECORDER 117 (1834).

In short, in the words of historian Daniel Walker Howe, “Whigs had a positive conception of liberty; they treasured it as a means to the formation of individual character and a good society. Democrats, by contrast, held a negative conception of liberty; they saw it as freeing the common (white) man from the oppressive burdens of an aristocracy.”<sup>162</sup> The popular Jacksonian magazine *Democratic Review* maintained that the “principle of [America’s] organization” was a collection of four freedoms: “freedom of conscience, freedom of person, freedom of trade and business pursuits, [and] universality of freedom and equality.”<sup>163</sup> The Thomsonians would embrace all of these in their fight against medical licensing statutes.

#### *D. The Thomsonians’ Constitutional Struggle*

The Thomsonians’ battle for medical freedom was an explicitly constitutional one, even though they apparently did not attempt to challenge any state medical practice acts in court.<sup>164</sup> The Thomsonians and their supporters instead waged their successful struggle against the orthodox medical establishment by using the press, petitions, and party politics to influence legislators and governors. As mentioned above, citizens also used their power as jurors to undermine medical licensing statutes, and executive officials often responded to popular opposition to such laws by declining to enforce them.

Why did the Thomsonians and their supporters not use lawsuits as an additional or alternative tactic? Perhaps they believed that such actions would be futile. Jacksonians generally viewed the courts as bastions of antidemocratic aristocracy, especially in states that had not yet embraced judicial elections. The Thomsonians may thus have viewed judges as prejudiced in favor of the privileged class of regular physicians.<sup>165</sup> The concern about judicial bias in favor of licensing may have been exacerbated by Thomsonian knowledge of a parallel struggle occurring in the legal profession during this era. The elite portion of the bar, which many judges identified with, was fighting its own (losing) battle against a Jacksonian movement to eliminate the already-low requirements for

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Moreover, Curtis expressly advocated tolerance for the use of wine for sacramental purposes. *Temerance [sic] Society*, 2 THOMSONIAN RECORDER 279 (1834). At the same time, however, he saw the consumption of alcoholic beverages outside medical and religious uses as a “depraved appetite.” *Brandy, Cholera, and Cholera Syrup*, *supra*, at 118.

<sup>162</sup> HOWE, *supra* note 155, at 583.

<sup>163</sup> John L. O’Sullivan, *The Great Nation of Futurity*, 6 U.S. MAG & DEM. REV. 23, 430 (1839).

<sup>164</sup> I have been unable to identify a single antebellum case challenging the constitutionality of a state medical practice law.

<sup>165</sup> For discussions of attitudes toward courts and judges in Jacksonian America, see generally Caleb Nelson, *A Re-Evaluation of Scholarly Explanations for the Rise of the Elective Judiciary in Antebellum America*, 37 AM. J. OF LEGAL HIST. 191 (1993); Jed Handelsman Shugerman, *Economic Crisis and the Rise of Judicial Elections and Judicial Review*, 123 HARV. L. REV. 1061 (2010).



practicing law.<sup>166</sup> Arguably, the judiciary actually led this effort to maintain restrictions on access to the legal profession.<sup>167</sup>

Furthermore, opponents of medical licensing were likely aware that antebellum courts did not typically strike down legislation based on the application of broad constitutional principles.<sup>168</sup> As one scholar has noted, flexibly phrased constitutional provisions “could hardly form the bases for judicial review of legislation until jurists became used to adjudging the reasonableness of legislation in the late nineteenth century.”<sup>169</sup>

Finally—and importantly—Americans at this stage in history simply did not view courts as the exclusive, or even primary, arena for contesting constitutional principles. In the Jacksonian era, all of the nonjudicial methods used to shape constitutional meaning during the Revolutionary period—except perhaps mobbing<sup>170</sup>—were still considered valid vehicles for popular constitutionalism. The important difference was that party politics had become the chief means by which the people expressed their constitutional understandings.<sup>171</sup> In light of this development, one scholar describes the Jacksonian era as an age of “party-based popular constitutionalism.”<sup>172</sup> The legislative and executive departments were deemed to have at least as much of a role in constitutional interpretation as the courts, and the people sought, through a wide variety of party-based activities, to ensure that these elected branches acted in accordance with their constitutional vision. In Larry Kramer’s words, “Democratic-dominated governments at both the state and national levels successfully marginalized the judiciary . . . and

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166 RICHARD L. ABEL, *AMERICAN LAWYERS* 40–41 (1989); LAWRENCE M. FRIEDMAN, *A HISTORY OF AMERICAN LAW*, REVISED EDITION 315–18 (1985). In the antebellum years, admission to the bar required, at most, a period of apprenticeship and passage of an oral bar examination administered by a local judge. The proportion of states mandating a period of apprenticeship dropped from fourteen out of nineteen in 1800, to eleven out of thirty in 1840, to nine out of thirty-one in 1860. ABEL, *supra*, at 40. Lawrence Friedman points out, “In the 1840s, a few states eliminated *all* requirements for admission to the bar, except good moral character.” FRIEDMAN, *supra*, at 316–17.

167 See MAXWELL BLOOMFIELD, *AMERICAN LAWYERS IN A CHANGING SOCIETY, 1776-1876*, at 139 (1999) (“[I]t was the judiciary . . . that did most to establish the guidelines for legal practice.”).

168 Mark A. Graber, *Resolving Political Questions Into Judicial Questions: Tocqueville’s Thesis Revisited*, 21 CONST. COMMENT. 485, 529–30 (2004) (“Remarkably, hardly any constitutional question arose in the antebellum United States that was resolved into a judicial question.”).

169 Michael Les Benedict, *Laissez-Faire and Liberty: A Re-Evaluation of the Meaning and Origins of Laissez-Faire Constitutionalism*, 3 LAW & HIST. REV. 293, 322 (1985).

170 KRAMER, *supra* note 22, at 168.

171 *Id.* at 167–68.

172 Keith E. Whittington, *Give “the People” What They Want*, 81 CHI.-KENT L. REV. 911, 918 (2006). According to Whittington, mass political parties were especially effective instruments for vindicating constitutional principles during the Jacksonian era because they were organized around constitutional principles, exerted great centralized discipline over their members, and uncompromisingly controlled the government once in power. *Id.* at 914–15.

reasserted popular control over constitutional development.”<sup>173</sup> In short, the fact that the Thomsonians advanced their arguments in forums other than court should not obscure the fact they were *constitutional* arguments and that, for them, medical liberty was a *constitutional* imperative.

The earliest suggestion I have found of a widespread challenge to the constitutionality of medical licensing is contained in an 1824 message by Pennsylvania Governor Andrew Shulze accompanying his veto of a medical practice statute. In this document, Schulze questioned “the expediency of enacting a law, which a large and respectable [*sic*] portion of the community believe to be contrary to the best established principles of the [C]onstitution.”<sup>174</sup> It is unclear who exactly these members of the community were and how they communicated their views to the governor. Nonetheless, this veto message offers an intriguing hint that as early as 1824, citizens were, perhaps in an organized manner, voicing constitutional arguments for freedom of therapeutic choice to the political branches of the government.

Another of the earliest explicit assertions of the unconstitutionality of medical licensing came from the pen of a prominent member of the academic medical elite—Professor Benjamin Waterhouse of Harvard.<sup>175</sup> Waterhouse was a personal friend of Samuel Thomson and one of the few members of the regular medical profession who respected his work, although, in Waterhouse’s own words, he wished that Thomson’s “science had been commensurate to his experience and natural sagacity.”<sup>176</sup> Like Rush, Waterhouse was an ardent Jeffersonian and anti-Federalist, and he believed that Thomson was being vilified because of his Republican principles.<sup>177</sup>

In an 1825 letter to a New York correspondent, delivered by Thomson himself, Waterhouse asked, “How came your Legislature to pass so unconstitutional an act as that called the *anti-quack* law?”<sup>178</sup> This dispatch may have emboldened the Thomsonians to launch an explicitly constitutional fight

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173 KRAMER, *supra* note 22, at 205.

174 Shulze, *supra* note 98, at 542, 543, in 5 PA. ARCHIVES Fourth Ser. (George Edward Reed ed., 1900).

175 Waterhouse (1754-1846) served at Harvard from 1783 until 1812 as one of the school’s original professors of medicine but left because of personal conflicts with the rest of the faculty. He is best known as the pioneer of the use of cowpox vaccination for smallpox prevention in the United States.

176 JOHN W. COMFORT, THE PRACTICE OF MEDICINE ON THOMSONIAN PRINCIPLES, ADAPTED AS WELL TO THE USE OF FAMILIES, AS TO THAT OF THE PRACTITIONER. CONTAINING A BIOGRAPHICAL SKETCH OF DR. THOMSON xxxv–xxxvi (1850). Waterhouse came to approve of Thomson’s use of a combination of lobelia and vapor baths, although there is no evidence that he ever, like Thomson, embraced this as a primary or universal remedy. See *id.* at xxxvi.

177 HALLER, THE PEOPLE’S DOCTORS, *supra* note 3, at 54–56.

178 Samuel Waterhouse, *Copy of a Letter from Dr. Benjamin Waterhouse, Formerly Lecturer on the Theory and Practice of Physic, in Cambridge University, to the Late Samuel L. Mitchell, of New-York*, 1 THOMSONIAN RECORDER 104 (1832).

against medical licensing. The fact that the letter was, seven years later, reproduced early in the very first volume of the *Thomsonian Recorder* hints at the importance they ascribed to it.

Regardless of how the Thomsonians conceived the idea of launching an explicitly constitutional attack, in the early 1830s, they took the lead in elaborating on and publicizing the constitutional arguments. Consider, for example, a lengthy 1832 piece in the *Thomsonian Recorder* titled “An Essay in Relation to the Unconstitutionality, Injustice, and Injurious Effects, Resulting from Our Present Aristocratical Medical Law in the State of Ohio.”<sup>179</sup> Pseudonymously authored, in Revolutionary-era fashion, by “Honestus,” the article reads like a legal document—similar to a brief or bill of particulars. Honestus condemns the licensing statute as “contrary to the letter and spirit of the constitution and a direct and undeniable violation of the oath of legislators, whereby they are sworn to maintain that sacred charter of our liberties.”<sup>180</sup> He then goes on to explain why the law violates various provisions of the Ohio state constitution, including the guarantee of the “natural and unalienable rights” of “enjoying and defending life and liberty, acquiring, possessing and protecting property, pursuing and obtaining happiness and safety” and the prohibition against laws impairing the validity of contracts.<sup>181</sup>

Other examples of Thomsonian constitutional rhetoric abound. In 1834, the Friendly Botanic Society of New York City adopted resolutions against New York State’s medical practice law, including a preamble declaring, “[W]e . . . feel ourselves aggrieved by the passage of such an act, because we are restricted from and denied the privilege of exercising those dear rights guaranteed to us by our forefathers in the invaluable Constitution of our beloved nation.”<sup>182</sup> In an 1832 petition presented to the Ohio legislature, citizens declared their “unalienable and constitutional rights violated” by an 1824 Ohio medical act.<sup>183</sup>

When asserting the unconstitutionality of medical practice acts, the Thomsonians frequently appealed not only to the words of the state and federal constitutions, but also to fundamental rights embodied in the Declaration of Independence and vindicated on the battlefields of the Revolutionary War. Such statements were concrete examples of the “thin constitutionalism” celebrated by Mark Tushnet. Take, for instance, a lengthy 1837 editorial in the *Thomsonian Recorder* titled “The Declaration of Independence.” The author of this unsigned

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179 Honestus, *An Essay in Relation to the Unconstitutionality, Injustice, and Injurious Effects, Resulting from Our Present Aristocratical Medical Law in the State of Ohio*, 1 THOMSONIAN RECORDER 121 (1832).

180 *Id.* at 124.

181 *Id.* at 130–31.

182 *Preamble and Resolutions of the Friendly Botanic Society of the City and County of New York* (Apr. 7, 1834), reprinted in 2 THOMSONIAN RECORDER 242–43 (1834). These documents are discussed in more detail *infra* Subsection III.E.1.

183 *Petition to be presented to the next Legislature*, 1 THOMSONIAN RECORDER 24 (1832).

piece (possibly Alva Curtis) starts by roughly quoting the actual Declaration. “On July 4<sup>th</sup>, 1776, it was declared by the Representatives of these United States, in Congress assembled, to be ‘self-evident, that all men were created equal and endowed by their Creator, with certain inalienable rights, among which are life, liberty, and the pursuit of happiness.’”<sup>184</sup> He then asserts that the federal and state constitutions were formed “[i]n accordance with these principles” and that all of them “substantially declare[] that all enactments of men . . . which are opposed to these principles, are null, void and of no effect.”<sup>185</sup> The author continues his introduction as follows:

These propositions [from the Declaration of Independence], having been admitted for sixty-one years to be self evident, we shall spend a portion of this day in proving it susceptible of the clearest demonstration, that *all the laws* in the United States which make it a misdemeanor for any but a member of “the Regular Medical Faculty” to administer remedies to cure the sick, or for any person to employ and pay whom he pleases as his physician; or that prevent any man from recovering, by process of common law, a just reward for medical services that had been voluntarily solicited and faithfully performed, are unconstitutional, oppressive, and wicked.<sup>186</sup>

The editorial’s final call to action is addressed to the “[s]ons of the patriotic sires who nobly resisted laws made without their consent; who, half clothed and half starved, poured out for seven years their treasures and their blood, to secure to you, their posterity, equal enjoyment of your inalienable rights.”<sup>187</sup>

### *E. The Multiple Strands of Medical Freedom*

The Thomsonians’ specific arguments against medical licensing statutes demonstrate that they had a multidimensional vision of the constitutional right to freedom of therapeutic choice. In their view, medical freedom implicated various categories of inalienable liberties protected by the country’s founding documents and by higher law. As I will show below, the Thomsonians referred repeatedly to all four of the strands of freedom identified earlier—bodily freedom, economic freedom, freedom of religion and conscience, and freedom of inquiry.

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<sup>184</sup> *The Declaration of Independence*, 5 THOMSONIAN RECORDER 326, 326 (1837).

<sup>185</sup> *Id.*

<sup>186</sup> *Id.* The editorial concludes, “Thus we see that these laws . . . abolish inalienable, natural rights that are above all laws or constitutions: and not only this; they suspend the action of the very decree of Heaven, ‘Ye shall not defraud nor oppress your brother—and whoso sheddeth man’s blood, by man shall his blood be shed.’” *Id.* at 329.

<sup>187</sup> *Id.* at 329.

### 1. Bodily Freedom

To modern ears, the Thomsonian arguments that sound most familiar are those concerning the right of control over one's body. One version of this argument was the assertion that people have a right to decide what and what not to put into their bodies. In particular, the Thomsonians insisted that citizens should be free to avoid the dangerous remedies employed by regular physicians. Honestus asked, "If I be conscientiously opposed to bleeding, blistering, mercurialising [*sic*], or poisoning with emetic tartar, opium, arsenic, or prussic acid, shall I be compelled to employ a law-made doctor, who deals almost exclusively in these potent remedies?"<sup>188</sup> A legislative committee considering repeal of the New York medical practice law painted a particularly vivid picture, stating that the legislature should not "thrust calomel and mercury down a man's throat while he wills to take only cayenne or lobelia."<sup>189</sup>

A related Thomsonian argument with parallels in modern rhetoric was the contention that each individual has a right to choose what steps to take to protect his or her physical well-being. For instance, in resolutions adopted in 1834 by the Friendly Botanic Society of New York City against New York State's medical practice law, the Society maintained a "freedom to choose the means which we believe are best calculated to secure to us health and life."<sup>190</sup> This document further stated, "A large majority of us are private citizens [i.e., not practitioners], and are deprived of the privilege . . . of calling on such physicians as we prefer, that we may have health restored to us when suffering from the inroads of disease."<sup>191</sup> The author of the "Declaration of Independence," after condemning the "poisons" administered by regular physicians, maintained, "To give poisons, is to deprive men of sound health, if not the whole of vitality or life; and, therefore unconstitutional and wicked."<sup>192</sup> An 1831 or 1832 petition against the New Jersey medical practice act declared: "In matters which concern our LIVES, we conceive it to be *our* interest, and that it should be *our privilege*, to choose

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<sup>188</sup> Honestus, *supra* note 179, at 130.

<sup>189</sup> ROTHSTEIN, *supra* note 6, at 145 (quoting *Report of Minority of Select Committee*, in *TRANSACTIONS OF THE MEDICAL SOCIETY OF THE STATE OF NEW YORK* 241, 243–44 (1841)). The Thomsonians sometimes contended for a broader freedom of consumption, encompassing foods as well as medicines. For example, protesting a Columbus, Ohio ordinance prohibiting commerce in fruits and vegetables to control the spread of cholera, the *Thomsonian Recorder* asked: "Is it not an invasion of the rights and privileges of the people to refuse them the liberty of buying and using the usual articles of diet?" *For the Recorder (Editorial)*, 2 THOMSONIAN RECORDER 11, 11 (1833).

<sup>190</sup> *Preamble & Resolutions of the Friendly Botanic Society of the City and County of New York* (April 7, 1834), in 2 THOMSONIAN RECORDER 241, 243 (1834).

<sup>191</sup> *Id.* at 243. In his 1824 message accompanying his veto of a medical practice bill, the Pennsylvania governor similarly referred to "the right which every man claims of employing the person, who, in his opinion, may be best qualified to afford relief to his sufferings." Shulze, *supra* note 98, at 543.

<sup>192</sup> *Declaration of Independence*, *supra* note 184, at 329.

such Physicians for our relief, as we have most confidence in.”<sup>193</sup>

## 2. Economic Freedom

References to economic freedom were even more common in the Thomsonian literature than those to bodily freedom. Before I review these arguments, it is important to stress that the Jacksonians’ support of economic liberty was tied to their broader vision of political and human liberty. It was not based merely on a wish to maximize economic efficiency and growth. Moreover, it bears repeating that unlike many later proponents of the laissez-faire principle, the Jacksonians emphatically were not impelled by a desire to protect wealthy individuals and large businesses from the government. To the contrary, their opposition to economic regulation was directed primarily against “special legislation,” such as the bestowal of monopolies, which promoted the interests of the affluent and influential rather than the advancing the common good.<sup>194</sup>

Consequently, when the New York Thomsonians contemplated forming a third party to push for repeal of the New York medical licensing statute, they called it the “Anti-Monopoly Party.”<sup>195</sup> Their *bête noir* was not simply economic regulation in the medical field, but regulation used to prop up an aristocratic monopoly. Similarly, Honestus proclaimed, “The coalision [*sic*] of the medical faculty in this state [Ohio], and the protection of that coalision by legislative patronage, we confidently affirm to be contrary to the letter and spirit of the constitution.”<sup>196</sup>

Because they believed that medical licensing was a monopolistic plot by the medical establishment, the Thomsonians were certain that the medical practice acts’ stated goal of protecting health was mere camouflage for mercenary motives. This conviction was bolstered by the fact that many states, rather than prohibiting the unlicensed practice of medicine altogether, merely forbade the collection of fees by unlicensed doctors or banned suits by them for unpaid compensation. A New York statute’s exemption for freely provided botanical medical services led *The Thomsonian Recorder* to quip: “Quacks may kill whom they please . . . if they do not take any money for the commission of the act.”<sup>197</sup>

The battle over medical licensing was thus a quintessential Jacksonian era conflict, pitting, in Meyers’ words, “equality against privilege, liberty against domination; . . . natural dignity against factitious superiority; . . . progress against

193 Petition to the Hon. The Legislature of the State of New Jersey, *reprinted in Medical*, THE INDEPENDENCE, Feb. 15, 1832, at 1.

194 See Michael Les Benedict, *Laissez-Faire and Liberty: A Re-Evaluation of the Meaning and Origins of Laissez-Faire Constitutionalism*, 3 LAW & HIST. REV. 293, 314–26 (1985).

195 HALLER, THE PEOPLE’S DOCTORS, *supra* note 3, at 138.

196 Honestus, *supra* note 179, at 124.

197 *The Die is Cast*, 2 THOMSONIAN RECORDER 241, 241 (1834).

dead precedent.”<sup>198</sup> The Thomsonians saw themselves as commonsensical, empirical, and democratic, in contrast to the pretentious, doctrinaire, and cliquish regular physicians they struggled against. Whereas the regulars were attempting to fortify their economic and social position through the establishment of an artificial monopoly, the Thomsonians were fighting for an open medical services market in which the price and availability of different therapeutic approaches would reflect their actual value to patients. According to a Maine senator advocating the repeal of that state’s practice of medicine law, the public demanded:

[T]hat it will be the judge of its own wants—it will select its own servants. . . . —that there shall be no bar to competition between two classes of physicians; but that each individual shall stand or fall on his own merits—that he who pretends to superior attainments or endowments, shall support his claims, not by appealing to his lineage or associations, but by what he accomplishes.<sup>199</sup>

The Thomsonians viewed their fight for medical freedom as part of a larger war being fought by the country’s honest, productive citizens against aristocratic privilege and power. Calling for revocation of the New York practice law, the *Poughkeepsie Thomsonian* contended:

Nothing short of such a measure can wrest the reins of government from the polluted hands of aristocracy, and place its inhabitants on an equal footing. This step must eventually be taken, in order to break down that disgusting monopoly which has long been sapping the very foundations of American freedom. . . . Thomsonians are by no means the only class that suffer from corrupt legislation. Farmers, mechanics, and laborers in general experience . . . the demoralizing influence of unfair and unjust speculation, set on foot by the anti-republican nabobs that infest our country. These drones of community feast and fatten at the expense of the honest and industrious parts of society.<sup>200</sup>

This emphasis on aristocratic conspiracies and class conflict does not mean that the Thomsonians did not also view the medical licensing statutes as direct infringements of their *individual* economic rights. To the contrary, undergirding

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198 MEYERS, *supra* note 157, at 10.

199 *Speech of Mr. Smart*, 8 BOTANICO-MEDICAL RECORDER 270, 271 (1840).

200 *The Cause in New York*, 9 BOTANICO-MEDICAL RECORDER 248, 248-49 (1841) (excerpt from *Poughkeepsie Thomsonian*).

the Jacksonian attack against special legislation were fundamental constitutional norms of economic liberty—namely, a prohibition against the government taking the property of one citizen and giving it to another and a ban on laws impairing the obligation of contracts.<sup>201</sup> The Jacksonians drew from a constitutional tradition, most famously embodied in Supreme Court Justice Samuel Chase’s 1798 *Calder v. Bull* opinion, that these state actions were violative of “certain vital principles in our *free republican governments*” and “contrary to the *great first principles* of the *social compact*,” even when not directly forbidden by particular constitutional language.<sup>202</sup>

When antebellum judges grounded economic rights in specific constitutional provisions, they relied on state constitutional prohibitions against the deprivation of property without due process of law, state constitutional bans against the taking of property without just compensation, and state and federal constitutional language forbidding laws impairing the obligation of contracts.<sup>203</sup> The Thomsonians occasionally also referred to such provisions. For example, Honestus contended that the Ohio medical practice act’s prohibition against suits for fees by unlicensed practitioners violated the state constitutional bar against laws impairing the validity of contracts.<sup>204</sup> The statute did so, he maintained, by rendering “null and void” any contract “that has been, may or can be made between the unprivileged physician and his patient.”<sup>205</sup>

Overall, however, the Thomsonians tended to base the economic liberty strand of their medical freedom arguments not on the letter of the state and federal constitutions, but on basic principles of American justice—that is, on the “thin Constitution” described by Tushnet.<sup>206</sup> For example, the editorial titled “Declaration of Independence” invoked general free labor and free contract notions in remarking:

Our tradesmen and mechanics are permitted and encouraged to hire themselves for what they can earn, and to bring forward the

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201 See Benedict, *supra* note 194, at 321–23.

202 *Calder v. Bull*, 3 U.S. 386, 388 (1798) (Chase, J.). Among the legislative actions that Chase contended were prohibited were “a law that destroys, or impairs, the *lawful private* contracts of citizens” and “a law that takes *property* from A. and gives it to B.” *Id.*

203 See Benedict, *supra* note 194, at 324–26; Robert Brauneis, *The First Constitutional Tort: The Remedial Revolution Nineteenth-Century in State Just Compensation Law*, 52 VAND. L. REV. 57 (1999). The federal “Contracts Clause” is at U.S. CONST. art. I, § 10. The due process clause of the Fifth Amendment was originally not deemed to restrain the actions of state governments—a problem that was remedied by the ratification of the Fourteenth Amendment, which had its own due process clause, in 1868. U.S. CONST. amend. XIV, § 1. The takings clause of the Fifth Amendment was similarly deemed not to apply to actions of states until 1897, when the Supreme Court applied it to the states through incorporation into the due process clause of the Fourteenth Amendment. *Chicago, Burlington & Quincy R.R. Co. v. City of Chicago*, 166 U.S. 226 (1897).

204 OHIO CONST. of 1802, art. VIII, § 16.

205 Honestus, *supra* note 179, at 131.

206 See *supra* Section I.A.



fruits of their labor and sell them for what they are worth, without being questioned where, with whom, or how long they served as apprentices. . . . So should it be with the doctor.<sup>207</sup>

A proposed petition to the New York legislature, presented in the voice of patients, contended: "It is one of the privileges of an independent people to pay their money to whom they please, and for what they please, without the direct or indirect interference of any one."<sup>208</sup>

In this "thin constitutional" mode, the Thomsonians sometimes combined their arguments regarding economic freedom with appeals to bodily freedom. For instance, an editorial in a New York botanical newspaper, attacking the state's prohibition against compensation for unlicensed practitioners, explicitly linked the law's tyrannical economic coercion against unlicensed practitioners with an equally oppressive bodily coercion against patients.

Here we are gravely told by law that we shall not command our own property. If A. employs B. because he is a skilful [*sic*] practitioner, C. steps in and says if A. pays B. any thing [*sic*] for his services he will have B. fined and imprisoned for taking it. C. therefore commands the will and purse of A. and prevents B. from doing the service that A. must have done in order to save his life. But B. in consequence of being jeopardized both in his "*life, liberty and property*," and having a family to support, must go into other business, thereby throwing the sick man, or A. and his property into the power of a set of men in whom he has no confidence, or he must go without a doctor until he will come to the terms that are dictated to him, and be poisoned "*Secundum Artem*" [according to the accepted practice of the profession], and according to law.<sup>209</sup>

This paragraph illustrates how the different aspects of medical freedom in the Thomsonian literature were sometimes almost inextricably intertwined. The next strand of medical freedom that I will discuss—freedom of inquiry—similarly cannot be viewed in isolation from the other strands.

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207 *Declaration of Independence*, *supra* note 184, at 327.

208 *Memorial to the Honorable the Legislature of the State of New York*, 1 BOTANIC WATCHMAN 82 (1834). This was a draft petition offered by the editor of the *Botanic Watchman* for consideration by the Botanic Society of the State of New York. The petition ultimately promulgated by the Society is discussed in detail *infra* Section III.F.

209 *The Medical Pension Bill*, 1 BOTANIC WATCHMAN 57 (1834) (emphasis in original).

### 3. *Freedom of Inquiry*

The Thomsonians directed their anti-monopoly arguments not only at regular physicians' attempts to control the market for medical fees, but also at their efforts to control the marketplace of medical ideas. Like Benjamin Rush, the Thomsonians railed against the orthodox medical establishment's squelching of competing systems of medical knowledge and understanding.

Opponents of medical licensing invoked the general right of free inquiry as a necessary feature of a free and democratic society. For example, New York Senator Scott, in a report advocating repeal of that state's medical licensing statute, declared, "A people accustomed to govern themselves, and boasting of their intelligence, are impatient of restraint. They want no protection but freedom of inquiry and freedom of action."<sup>210</sup> The Thomsonian essayist Honestus maintained:

Learning and property are the elements of political power. These elements combined and put in operation, are the most efficient means for the elevation of the few and the subjugation of the many. . . . This monopolizing spirit constitutes . . . a literary aristocracy, a privileged order, whose ends and aims have been, are now, and ever will be hostile to the equal and unalienable rights and privileges of society at large.<sup>211</sup>

These statements demonstrate that the Thomsonians considered free inquiry to be essential for equality and political liberty. Importantly, they also deemed it necessary for intellectual progress. Honestus lamented the fact that, although "[w]e live in an enlightened era" marked by "the progress of science and the march of mind," the elite "renounce the demonstrations of reason, received from honest inquiry, devoutly idolize antiquated traditions, and in philosophy, medicine, and their kindred sciences adhere . . . pertinaciously . . . to the impress of superstition."<sup>212</sup> To buttress his contention that open inquiry advanced the attainment of truth, Honestus stressed a theme that would reverberate throughout the history of American medical liberty advocacy—the incompleteness and imperfection of present scientific knowledge. Honestus maintained that because of "the defective limitedness and imperfection of human intellect," many

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210 Quoted in Coventry, *supra* note 130, at 160. In this same spirit, the *Recorder* published a paean to "Liberty of the Press," which argued that truth would emerge from the clash of ideas. "Let then opinion meet opinion on all grounds of debate and controversy.—Let system combat system, and theory wrestle with theory. Let the Press work on with all its activity; throw not over it a single fetter. Who says that truth is powerless and cannot prevail? She must prevail." *The Liberty of the Press*, 1 THOMSONIAN RECORDER 477, 479 (1832).

211 Honestus, *supra* note 179, at 123.

212 *Id.* at 122.

supposedly established “facts and demonstrations . . . lie open for free enquiry [sic] and the most ample discussion.”<sup>213</sup> Freedom of inquiry was necessary, he explained, “not because there are no fixed immutable principles, relations and dependencies . . . existing inherently in the nature and fitness of things,” but because “these relations, connections and dependencies have never been perfectly understood, and therefore never fully developed by the boldest researches of science and time.”<sup>214</sup>

Consistent with their egalitarian Jacksonian world view, the Thomsonians frequently proclaimed that if people of all classes were liberated to exercise their natural genius, common folk would be at least as likely as book-trained physicians to advance medical knowledge.<sup>215</sup> Freedom of inquiry, if extended to ordinary citizens, would propel progress by emancipating medicine from the university-trained elite doctors’ stagnant, superstition-tainted orthodoxy. In a Georgia Senate debate on a bill that would revise the state medical practice act so as to permit botanical physicians to charge for their services, Senator Norborn B. Powell declared: “I feel unwilling to fetter the human mind, to bind men by law to any particular system of physic. Such a course must curtail the range of human intellect. Have not some of the most important discoveries in science been made by those in the humblest walks of life?”<sup>216</sup> In response to this rhetorical question, Powell pointed to the contributions that the “illiterate dairy-women of England,” the “unlettered Indians of Peru,” and the “cannibals of Brazil” had made to medicine by discovering the therapeutic qualities of cowpox matter, cinchona bark, and ipecac, respectively.<sup>217</sup>

In the Thomsonian literature, such celebrations of common people’s achievements usually presumed not that the unschooled masses possessed great intellectual sophistication, but rather that medicine was an uncomplicated discipline that did not demand much brainpower. A Maryland legislative committee observed, “Of all sciences, the knowledge of disease and the means of cure, must be supposed . . . as most simple and easy of attainment. It is, essentially, a science of experience.”<sup>218</sup> When medicine was viewed in this way, the “free inquiry” required for its progress was not complex scientific analysis, but simple practical experimentation, uncorrupted by abstract theory. Samuel Thomson himself, in an autobiography written in the third person, remarked:

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213 *Id.*

214 *Id.*

215 See WHORTON, *NATURE CURES*, *supra* note 29, at 40 (“The whole wide expanse of Thomsonian publications . . . fairly dripped with folksy egalitarianism.”).

216 *Legislature of Georgia. Equal Rights*, 5 THOMSONIAN RECORDER 136, 137 (1837).

217 *Id.* All three of these therapies were, by the late 1830s, part of the orthodox *materia medica*. “Cowpox matter” was used for smallpox vaccination, cinchona bark (from which quinine was derived) for malaria and fever, and ipecac as an emetic.

218 *Maryland Legislature*, 2 THOMSONIAN RECORDER 188, 188 (1834).

Dr. Thomson . . . had nothing to guide him but his own experience. He not having had an education, has received no advantages from reading books, which left his mind unshackled by the visionary theories and opinions of others; his whole studies have been in the great book of nature, and his conclusions have all been drawn from that unerring guide; by this he was enabled to form correct opinions of the fitness of things.<sup>219</sup>

As discussed previously,<sup>220</sup> Samuel Thomson was not himself actually a paragon of free inquiry, at least later in his life. Committed to protecting the purity of his system, he increasingly condemned explorations into improved or supplemental therapies as “mongrelism.”<sup>221</sup> But the increasingly dominant Curtis and his Independents were deeply devoted to free inquiry; indeed, their schism from the purists was based in large part on their commitment to this ideal.<sup>222</sup> The Independent Thomsonians opened the pages of their journals and the curricula of their classrooms to both conventional science and other alternative medical systems of the era, including Grahamism, Mesmerism, phrenology, and hydropathy.<sup>223</sup> In 1837, Curtis defended his Botanico-Medical College of Ohio from the purists’ attacks by boasting, “We have given the utmost freedom and latitude to inquiry, cheerfully confessed our ignorance where we felt it, and advised submission to nothing but demonstration by the best evidences that the nature of the cases would admit.”<sup>224</sup>

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219 THOMSON, *supra* note 108, at 8–10. Although the preface is written “By a Friend,” Haller ascribes it to Thomson himself. HALLER, THE PEOPLE’S DOCTORS, *supra* note 3, at 50.

220 *Supra* text accompanying notes 147–151.

221 HALLER, THE PEOPLE’S DOCTORS, *supra* note 3, at 180.

222 *Id.* at 163–67.

223 *Id.* at 201–02, 232–33. Later in his own life, Curtis also became somewhat doctrinaire and intolerant of dissension. He resisted merger with the Eclectics and circulated his own purity pledge. *Id.* at 248. He eventually even supported the licensing of educated botanical physicians. WHORTON, NATURE CURES, *supra* note 29, at 46.

224 *Medical Organizations*, 5 THOMSONIAN RECORDER 236, 236 (1837). As another sign of his commitment to free inquiry, Curtis proposed using surplus federal revenues to create something like today’s National Institutes of Health, although this entity would have rewarded completed discoveries instead of funding proposed research. Alva Curtis, *Quackery Again*, 5 THOMSONIAN RECORDER 91 (1836). Seeking a “constitutional use” for the federal surplus—“that is, an appropriation by which it should be made to benefit equally, all the citizens of the Republic,”—Curtis drafted a petition to Congress suggesting the creation of a permanent fund that would be used to grant “rewards or premiums to discoverers of useful truths in science, and the inventors of useful means and processes in the arts that are calculated to render the advantages of those scientific truths or principles, profitable to the community.” The distribution of prizes would have been determined by a five-member “committee on medical science.” *Id.* at 92.

#### 4. *Freedom of Conscience/Religion*

Finally, the Thomsonians' medical liberty arguments also invoked the principle of freedom of conscience. For example, in his essay, Honestus proclaimed himself "conscientiously opposed" to orthodox medicine and then rhetorically queried:

Might I not with equal propriety, and with equal justice, be compelled to attend at, or to erect and support certain places of worship, or maintain a patented clergy, either Papal or Protestant without my consent and against my conscience, as to be compelled to employ a physician of a certain class, contrary to my best judgment, and utterly against my will?<sup>225</sup>

It is difficult to determine exactly what the Thomsonians meant when they asserted that the American value of "freedom of conscience" demanded freedom of therapeutic choice. On the one hand, they may have believed that this term was synonymous with freedom of religion—and thus that a person's choice of health practitioner was in some way an exercise of religion. On the other hand, they may have believed that medical freedom and freedom of religion were distinct, though analogous, concepts under a broader umbrella of "freedom of conscience."<sup>226</sup> Both are possible. Dictionaries of the time did not limit the word *conscience* to religious belief. For example, Webster's *American Dictionary* of 1828 defined the word as, "Internal or self-knowledge, or judgment of right and wrong; or the faculty, power or principle within us, which decides on the lawfulness or unlawfulness of our own actions and affections, and instantly approves or condemns them."<sup>227</sup> But as Michael McConnell has observed, in the early years of the United States, "outside of dictionaries, the vast preponderance of references to 'liberty of conscience' . . . were either expressly or impliedly limited to religious conscience."<sup>228</sup>

At times, the Thomsonians emphasized freedom of opinion and belief in the more expansive sense. A letter to the *Thomsonian Recorder* proclaimed: "Legislatures may enact laws against Thomsonianism, but, thank heaven, they cannot bind the mind of man. . . . For freedom of thought and speech are the

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225 Honestus, *supra* note 179, at 130–31.

226 The best discussion of the relationship between the terms "free exercise of religion" and "freedom of conscience" is Michael W. McConnell, *The Origins and Historical Understanding of Free Exercise of Religion*, 103 HARV. L. REV. 1409, 1488–1500 (1990).

227 WEBSTER'S AMERICAN DICTIONARY OF THE ENGLISH LANGUAGE (1828), available at <http://1828.mshaffer.com/>. For discussion of other early dictionary definitions of *conscience*, see McConnell, *supra* note 226, at 1493.

228 McConnell, *supra* note 226, at 1493.

unalienable rights of man.”<sup>229</sup> Honestus implored, “In this land of freedom . . . shall we not as a free, magnanimous and independent people, dare to think and act for ourselves, to assume our proper rank and dignity in the scale of being . . . ?”<sup>230</sup>

But the Thomsonians—echoing Rush and Jefferson before them—usually linked their invocations of freedom of “conscience” or “thought” directly or indirectly to religious liberty.<sup>231</sup> For example, Honestus, immediately following the statement quoted above, urged the people to “shake off the reckless aspirations of a clerical, legal, and medical denomination, that invades our rights and holds them in contempt.”<sup>232</sup> Thomsonians frequently compared orthodox medicine to an established church and equated the right to choose a physician with the right to choose a minister. For instance, an unsigned editorial in the *Thomsonian Recorder* declared: “[W]e could never see what right any man, or any body of men, can have in the nature and fitness of things to control us in our choice of a lawyer, preacher or physician.”<sup>233</sup> Samuel Thomson himself opened the introduction to his magnum opus by equating the orthodox physicians of his own day to the priests of ages past, who “held the things of religion in their own hands, and brought the people to their terms.”<sup>234</sup>

As one scholar has observed, although “little in [Thomsonianism] could be called overtly or distinctively religious,” it nonetheless “had deep roots in the Second Great Awakening, which accentuated the role of humans in effecting the Kingdom of God on earth.”<sup>235</sup> The Thomsonians sometimes strengthened the association between medicine and religion by suggesting that the “natural” botanical remedies of their system were divinely sanctioned. The very first page of the first issue of the *Thomsonian Recorder* claimed a divine foundation for the Thomsonian system, bemoaning the persecution of any practitioner “who dares to remove disease with healing medicine, which the God of Nature has so profusely scattered for the benefit of all.”<sup>236</sup> The previously mentioned New Jersey petition similarly declared:

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229 B. W. S., *A Second Voice from New York*, 2 THOMSONIAN RECORDER 252 (1834).

230 Honestus, *supra* note 179, at 123.

231 One potential problem for the Thomsonians in relying on “freedom of conscience” is that, compared to “free exercise of religion” (the phrase chosen by the drafters of the First Amendment to the U.S. Constitution over James Madison’s proposed “rights of conscience”), “freedom of conscience” less clearly encompasses liberty of action as well as of belief. McConnell, *supra* note 226, at 1488–90. See also U.S. CONST. amend. I. Unsurprisingly, though, Thomsonians insisted on their right to act on their medical opinions, not merely to hold them.

232 Honestus, *supra* note 179, at 123.

233 *Untitled Editorial 1*, 2 THOMSONIAN RECORDER 246 (1834).

234 THOMSON, *NEW GUIDE TO HEALTH*, *supra* note 108, at 5.

235 ROBERT C. FULLER, *ALTERNATIVE MEDICINE AND AMERICAN RELIGIOUS LIFE* 34, 36 (1989).

236 *To our Patrons*, 1 THOMSONIAN RECORDER 1, 1 (1832).

As we believe, the God of Nature has bountifully caused to grow in our own country, and placed within our reach, medicines for the alleviation and cure of the various maladies with which we are from time to time afflicted; and we conceive it an infraction of our rights to debar us from the use of such remedies, or from employing such physicians as administer them.<sup>237</sup>

After the Civil War, when groups with more explicitly spiritual agendas assumed the role of leading advocates for medical freedom, the association between medical and religious liberty became stronger and stronger until, in the early twentieth century, Christian Scientists began regularly to cite constitutional religion clauses both inside and outside court.<sup>238</sup> By contrast, I have found no instance in which a Thomsonian-era commentator directly contended that a medical licensing statute violated a particular religion clause in a state constitution.<sup>239</sup> Nonetheless, the link between medical and religious choice was so close that when the Arkansas territorial governor vetoed a medical practice law in 1831, he asserted in his veto message that government should not control a citizen's "will and faith" on the subject of the choice of medical practitioners.<sup>240</sup>

#### F. *The Battle in New York*

The Thomsonians' popular constitutionalist articulation of medical freedom, with its four contributing strands, achieved its greatest triumph in 1844, with the revocation of the medical practice law of New York, the nation's most populous state.

New York had had a medical licensing statute on the books since colonial times, and the legislature had ratcheted up the penalties until, by 1827, unlicensed practitioners were subject to fines and imprisonment, at least in theory.<sup>241</sup> The Thomsonians' campaign for medical liberty in New York commenced in the late 1820s, when they conducted a statewide petition

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237 Petition, *supra* note 193, at 1. Thomson himself stated that his medical system and its cures derived from "the God of nature." THOMSON, *NEW GUIDE TO HEALTH*, *supra* note 108, at 16, 86.

238 See, e.g., RENNIE B. SCHOEPLIN, *CHRISTIAN SCIENCE ON TRIAL* 156 (2003); Margery Fox, *Conflict to Coexistence: Christian Science and Medicine*, 8 MED. ANTHROPOLOGY 292, 296 (1984). In an unpublished draft manuscript (available on request), I examine in detail the relationship between medical freedom and religious freedom and the late-nineteenth and early-twentieth century. Grossman, *You Can Choose Your Medicine*, *supra* note 7.

239 The free exercise clause of the First Amendment of the United States Constitution was not deemed to apply to the states by incorporation through the Due Process Clause of the Fourteenth Amendment until 1940. *Cantwell v. Connecticut*, 310 U.S. 296 (1940).

240 *The Governor's Veto*, ARKANSAS GAZETTE, Nov. 9, 1831, at 1.

241 LAWS OF THE STATE OF NEW YORK, PASSED AT THE SECOND MEETING OF THE 50TH SESSION OF THE LEGISLATURE Title VII, § 22 (1827); HALLER, *THE PEOPLE'S DOCTORS*, *supra* note 3, at 134–35; ROTHSTEIN, *supra* note 6, at 338 app. II.

campaign that persuaded the legislature, in 1830, to exempt from the licensing requirement any person “using or applying, for the benefit of any sick person, any roots, barks, or herbs, the growth or produce of the United States.”<sup>242</sup> Four years later, however, the regulars persuaded the legislature to repeal this exemption for botanical practitioners, although the 1834 amended statute allowed botanical doctors to perform their services “without fee or reward.”<sup>243</sup> Thus commenced a decade-long crusade, led by the Thomsonians, to revoke the state’s medical practice statute altogether.

In September 1834, the New York Botanic State Convention, comprising delegates from local botanic societies throughout the state, launched a campaign against the revised medical practice law. As described by the editor of the *Botanic Watchman*:

A spirit of unanimity pervaded the convention in all its deliberations, and as they felt the weight of their oppression, they were unanimously resolved to apply at the source of evil [the legislature] for a redress of their grievances, and a mitigation of the abuses, that have been unwarrantably heaped upon them, until the right of a free selection of their favorite physician, is left unfettered by legal restraint. If every state in the Union would pursue a similar course, we might ere long, throw off the shackles of despotism, which the lordly faculty are endeavoring [*sic*] to make fast, until the people are entirely lost to a sense of their freedom, and the right to exercise their constitutional privileges.<sup>244</sup>

The convention appointed two committees, one to draft a petition for repeal of the medical practice law and another to write resolutions expressing the views of the convention.<sup>245</sup> The resulting documents, discussed in detail below, are notable both for their explicit invocation of the Constitution and for their reference to all of the strands of medical freedom discussed above.<sup>246</sup>

The convention ordered the printing of one thousand copies of the resolutions and five hundred copies of the petition.<sup>247</sup> In February 1835, the *Thomsonian Recorder* reported that “[p]etitions are pouring in to the Capitol from every

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242 LAWS OF THE STATE OF NEW YORK, PASSED AT THE 53RD SESSION OF THE LEGISLATURE 126, § 2 (1830).

243 LAWS OF THE STATE OF NEW YORK, PASSED AT THE 57TH SESSION OF THE LEGISLATURE 68, § 2 (1834).

244 *The Botanic State Convention*, 1 BOTANIC WATCHMAN 145 (1834).

245 *Proceedings of the Botanic State Convention*, 3 THOMSONIAN RECORDER 17, 18 (1834). Both five-man committees included Samuel Thomson’s son, John. *Id.* at 18.

246 See *infra* Section III.E.

247 *Proceedings of the Botanic State Convention*, *supra* note 245, at 18, 20.



portion of the Empire State,”<sup>248</sup> and three months later the same publication claimed that the number of petitioners had “swelled to 40,000.”<sup>249</sup> A revocation bill passed the House, but lost in the Senate.<sup>250</sup> The Thomsonians nevertheless energetically continued their petition campaign; on one occasion Samuel Thomson’s son, John, paraded into Albany pushing a wheelbarrow containing a petition with so many signatures that it stretched to thirty-one yards.<sup>251</sup> The petitioners obtained the same disappointing result (passage in the House, defeat in the Senate) three additional times before they achieved total victory.<sup>252</sup> In 1844, the legislature finally repealed the New York medical practice statute and enacted a law explicitly stating: “No person shall be liable to any criminal prosecution or to indictment, for practising physic and surgery without license, excepting in cases of mal-practice, or gross ignorance, or immoral conduct in such practice.”<sup>253</sup>

An examination of the 1834 petition and resolutions demonstrates that the New York Thomsonians viewed themselves as vindicating fundamental constitutional principles. The petition declared, “[W]e believe said law is a direct infringement of our constitutional privileges.”<sup>254</sup> The resolutions presented the Botanic Convention’s mission as the prevention of the usurpation of New York citizens’ constitutional rights and privileges by an unholy alliance of orthodox physicians and legislators. The resolutions’ introduction characterized those legislators who supported medical licensing as “traitors to their constituents, and assassins to the principles of a liberal and just government.”<sup>255</sup> It continued, “Upon such men should not the mark of disapprobation be branded, so plainly as to warn all others from encroaching in like manner upon our constitutional rights?”<sup>256</sup>

In detailing which of their rights the despised statute invaded, the convention members used every libertarian argument in the Jacksonian arsenal. Because the 1834 New York law did not prohibit botanical practitioners from administering their remedies to patients, but only from receiving compensation, the petition and resolutions paid special attention to the idea of economic freedom. Indeed, the petition—a much shorter document than the resolutions, and focused especially on the ban on compensation—rested almost exclusively on principles of free contract and free labor. First, the petition declared from the perspective of

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248 *Untitled Editorial*, 3 THOMSONIAN RECORDER 159, 160 (1835).

249 *Untitled Editorial*, 3 THOMSONIAN RECORDER 253, 253 (1835).

250 HALLER, THE PEOPLE’S DOCTORS, *supra* note 3, at 137.

251 WHORTON, NATURE CURES, *supra* note 29, at 36; YOUNG, *supra* note 115, at 55.

252 HALLER, THE PEOPLE’S DOCTORS, *supra* note 3, at 137-38.

253 LAWS OF THE STATE OF NEW YORK, PASSED AT THE SIXTY-SEVENTH SESSION OF THE LEGISLATURE 406 § 3 (1844) (Ch. 275: An Act in relation to the practice of Physic and Surgery, passed May 6, 1844); *see also* HALLER, THE PEOPLE’S DOCTORS, *supra* note 3, at 138.

254 *Proceedings of the Botanic State Convention*, *supra* note 245, at 18.

255 *Id.* at 19.

256 *Id.*

patients:

We have a right, beyond doubt, to employ any person whom we may think proper, as our physician, without jeopardizing his life, liberty or property. If we employ a person to administer to us as our physician, common law and justice should give him a reasonable compensation for his services.<sup>257</sup>

Assuming the voice of practitioners, the petition then asserted: “In all matters of business, we have a right to manage our own affairs, and that right we wish to exercise unmolested by those who may make it their interest to thwart and perplex us in our just and legal avocations.”<sup>258</sup>

The resolutions echoed these themes, asserting, for example, that law should “leav[e] all professions to stand or fall by their own merits, regulated by a fair competition, and an accountability to their employers.”<sup>259</sup> But the committee on resolutions also set its advocacy for the economic strand of medical freedom within a broader, typically Jacksonian attack on corrupt special legislation favoring the economic aristocracy. Although the resolutions vigorously attacked the legislators who supported the medical practice law, the committee’s primary villains were the “medical men,” who had captured the legislative process to “invade in an unjust manner [our] rights and privileges.”<sup>260</sup> One resolution declared that the law “was obtained through the influence of a designing faculty, and expressly calculated to force a monopoly of practice into their own hands by the exclusion of all others.”<sup>261</sup> Another pledged, “[W]e will use all laudable endeavors to counteract the influence of all medical monopolies in the halls of Legislation, and to produce an equalized system of practice, resting on its respective merits.”<sup>262</sup>

The New York Thomsonians’ arguments were not solely economic, however. They also asserted a right to control one’s body and the treatment of it:

We are all sensitive beings, both in mind and body, and it is to protect these functions from insult and injury, that we object to the [law]. If we are distressed in body, what greater privilege can we enjoy than the free and independent right in the selection of our Physicians to relieve our maladies?<sup>263</sup>

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257 *Id.* at 18.

258 *Id.*

259 *Id.* at 19.

260 *Id.*

261 *Id.*

262 *Id.* at 20.

263 *Id.* at 19.

The resolutions proclaimed that the right to employ one's choice of physician was part of the "blood-bought freedom of our venerable sires, which was purchased by them on the field of battle for their posterity."<sup>264</sup> The committee on resolutions bolstered its argument for bodily freedom by reference to the dangers of heroic orthodox medicine. "[I]t were better to have no laws regulating the practice of medicine, than to place all power in the hands of a privileged few, and those using the most dangerous poisons for medicine."<sup>265</sup>

In the resolutions, the Thomsonians also invoked the parallel between medical freedom and religious freedom. "If our minds are diseased, who would have the audacity to dictate to us our spiritual Physician: would we not all of us consider ourselves fully competent to select the Physician for our souls as well as bodies?"<sup>266</sup> This argument proved to be persuasive to the legislative committee considering repeal measures, which, in supporting the petitioners, remarked, "Men cannot be legislated out of one religion and into another."<sup>267</sup>

Finally, although the resolutions did not greatly emphasize freedom of inquiry, they did allude to the merits of "unshackled" science.<sup>268</sup> The committee that drafted the resolutions, like Thomsonian commentators generally, embraced a populist empirical vision of medical science, in which therapeutic systems are "tested by experience" and any law restricting free access to different types of practitioners unfairly "charges the people with ignorance, and infringes on their rights."<sup>269</sup>

In short, the documents emerging from the 1834 New York Botanic Convention epitomize the Thomsonians' multidimensional view of medical rights as constitutional rights. Moreover, the tactics used by the Thomsonians in New York exemplify how medical freedom advocates, like others in Jacksonian America, did not treat courts as the only forum, or even the preferred forum, for asserting constitutional rights. Finally, the result of these struggles demonstrates that such extrajudicial constitutional campaigns could be astonishingly successful.

#### IV. CONCLUSION

The Independent Thomsonians continued to exist, under a series of different names, until the early years of the twentieth century.<sup>270</sup> After the revocation of

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<sup>264</sup> *Id.*

<sup>265</sup> *Id.* at 20.

<sup>266</sup> *Id.* at 19.

<sup>267</sup> ROTHSTEIN, *supra* note 6, at 145 (quoting "Report of Minority of Select Committee" and "Report of the Select Committee . . . Jan. 30, 1841," *Transactions of the Medical Society of the State of New York* 241, 243-44, 265, 268 (1841)).

<sup>268</sup> *Proceedings of the Botanic State Convention*, *supra* note 245, at 19.

<sup>269</sup> *Id.* at 20.

<sup>270</sup> The Independent Thomsonians changed their name first to Botanic-Medicals and then, after 1850, to Physio-Medicals.

most of the medical licensing statutes by the mid-1800s, however, there was a discernible change of character in the group. They lost their grass-roots, popular fervor (and much of their following) and assumed all the trappings of orthodox medicine, including state medical societies and a small network of diploma-granting medical schools.<sup>271</sup> Meanwhile, the purist Thomsonian faction shriveled away and disappeared following the dissolution of the United States Thomsonian Society in 1840 and the founder's death in 1843.<sup>272</sup> During the second half of the nineteenth century, botanical medicine proponents who traced their roots back to Samuel Thomson transformed from a "remarkable socio-medical movement" to "a small, ineffectual, and pseudo-scientific cult."<sup>273</sup>

Nevertheless, other botanical systems continued to prosper through the 1800s.<sup>274</sup> Moreover, botanical medicine was just the first in a long list of popular non-orthodox medical approaches that would emerge over the course of the century. In 1893, Henry Wood listed the various types of "irregulars" he was familiar with: "the homeopathists, eclectics, hydropathists, magnetic, electric, and 'biochemic' practitioners, Thomsonians, hygienists, metaphysicians, Christian scientists, mental healers, hypnotists, clairvoyants, mediumistic healers, faith curists, gospel healers, and members of the Christian Alliance."<sup>275</sup> In subsequent decades, these alternative systems would be joined by others, including osteopathy, chiropractic, and naturopathy. Indeed, alternative medicine movements continued to arise throughout the twentieth century, and they remain an important aspect of the American medical scene today.<sup>276</sup> While these different systems have produced a kaleidoscope of theories and philosophies, they have all tended to embrace the same cluster of attitudes: skepticism toward orthodox medical science, an embrace of more "natural" and lower-risk alternatives to regular drugs, and, in many instances, a populist suspicion of nefarious conspiracies involving the medical elite.

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271 See Berman, *supra* note 2, at 133, 139–42.

272 See HALLER, THE PEOPLE'S DOCTORS, *supra* note 3, at 180, 184–86. The remnants of the Thomsonian purists sought accommodation with the Independents after Thomson's passing. See *id.* at 187.

273 See Berman, *supra* note 2, at 135.

274 See William G. Rothstein, *The Botanical Movements and Orthodox Medicine*, in OTHER HEALERS: UNORTHODOX MEDICINE IN AMERICA 29, 47–50 (Norman Gevitz ed., 1988); James C. Whorton, *From Cultism to CAM: Alternative Medicine in the Twentieth Century*, in THE POLITICS OF HEALING: HISTORIES OF ALTERNATIVE MEDICINE IN TWENTIETH-CENTURY NORTH AMERICA 287, 288 (Robert D. Johnston ed., 2004). Before the Civil War, a botanical practitioner named Wooster Beach founded another branch of botanical medicine that came to be known as the "eclectics." Eventually, many Independent Thomsonian schools and practitioners converted to eclecticism, and the eclectics became (along with the regulars and the homeopaths) one of the three major organized medical sects during the latter part of the nineteenth century. *Id.*

275 Henry Wood, *Medical Slavery Through Legislation*, 8 ARENA 680, 687 (1893).

276 See generally OTHER HEALERS, *supra* note 274; THE POLITICS OF HEALING, *supra* note 274; WHORTON, NATURE CURES, *supra* note 29, at 287–307.

As I explore in a separate piece,<sup>277</sup> a second wave of medical licensing arose after the Civil War, as did a corresponding revival of medical freedom literature. By 1901, every state and the District of Columbia had a medical licensing system of some sort.<sup>278</sup> These new licensing regimes generally mandated more rigorous qualifications for medical practice and imposed more severe penalties on violators than did their antebellum counterparts.<sup>279</sup> The opponents of post-Civil War medical licensing were more likely than their early American forerunners to pursue constitutional challenges in court, but these challenges were almost invariably unsuccessful. Their litigation strategy suffered its severest blow in 1888, with the Supreme Court's upholding of a state licensing law in *Dent v. West Virginia*.<sup>280</sup>

Nevertheless, the almost universal adoption of medical licensing during the Gilded Age did not represent the demise of a widespread ethos in favor of freedom of therapeutic choice. During this later period, Americans increasingly recognized the benefits of professional expertise and thus embraced licensing systems designed to ensure that medical practitioners were sufficiently educated and trained.<sup>281</sup> But there was still broad consensus that government should not discriminate against or in favor of different systems of medicine. This continuing commitment to freedom of therapeutic choice is evidenced by the content of the state medical practice acts themselves,<sup>282</sup> by enforcement patterns and jury

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277 Grossman, *You Can Choose Your Medicine*, *supra* note 7.

278 STARR, *supra* note 43, at 104.

279 See *Medical Practice Laws*, 3 AM. MED. ASS'N BULL. 34, 103 (1907) (describing post-Civil War medical practice laws in each state).

280 129 U.S. 114 (1889). Dent was a West Virginia eclectic practitioner practicing without a license. The only version of "freedom" that he expressly fought for in this case was his own freedom to practice his trade and preserve his vested property interests in his profession under the due process clause of the Fourteenth Amendment. In the Supreme Court's opinion, Justice Stephen Field emphatically reaffirmed the existence of the "right of every citizen of the United States to follow any lawful calling, business, or profession he may choose." *Id.* at 121. He nonetheless upheld the constitutionality of medical licensing, observing: "Few professions require more careful preparation by one who seeks to enter it than that of medicine." *Id.* at 122. As I argue elsewhere, the fact that Field in this case upheld a licensing statute mandating a medical diploma from a reputable school does not mean that he would have upheld a discriminatory statute that accepted diplomas only from orthodox medical schools and not from their homeopathic and eclectic counterparts. See Grossman, *You Can Choose Your Medicine*, *supra* note 7.

281 See Samuel Lee Baker, *Medical Licensing in America: An Early Liberal Reform* S-6, 12 (1977) (unpublished Ph.D. dissertation, Harvard University) (on file with Yale Library); Grossman, *You Can Choose Your Medicine*, *supra* note 7.

282 Most of the second wave statutes explicitly preserved the rights of at least some alternative practitioners, if adequately educated, and they routinely included homeopaths and eclectic doctors in the administration of the licensing regimes. Moreover, some of these laws included explicit nondiscrimination clauses. See *Medical Practice Laws*, *supra* note 279 (offering a comprehensive review of the medical practice laws of every state as of 1907). Finally, these medical practice acts frequently exempted various types of drugless practitioners from their requirements altogether. See *id.* at 107.

behavior;<sup>283</sup> and by petition campaigns, mobbed legislative hearings, the formation of advocacy organizations, and the promulgation of medical freedom literature.<sup>284</sup>

As was the case before the Civil War, efforts to preserve medical freedom during the Gilded Age and Progressive Era were largely the product of organized movements by alternative practitioners and their supporters. These later opponents of discriminatory medical licensing—many of whom were intimately familiar with the Thomsonians' own struggle—inherited their predecessors' "thin constitutional" arguments as well as their articulation of the four strands of medical freedom identified in this Article. This is not to say that there were no differences in emphasis in the battle against the second wave of medical licensing. For example, arguments regarding the link between freedom of inquiry and medical progress assumed a more prominent—and sometimes dominant—role in the later rhetoric.<sup>285</sup> The rise of drugless therapies, such as Mind Cure and Christian Science, with spiritual and religious foundations, brought greater focus on the association between medical freedom and religious freedom. And because many of the dominant postbellum alternative medical movements were favored by the middle class and elites, much of the medical freedom literature lost the populist tone of the Thomsonian arguments. Nonetheless, the Thomsonians' lasting influence on the medical freedom rhetoric was unmistakable.<sup>286</sup>

The inexorable rise of effective scientific medicine and "wonder drugs" in the early twentieth century posed a serious challenge to alternative medicine. Nevertheless, interest in and use of alternative remedies have soared since the 1960s.<sup>287</sup> A notable feature of the story of American alternative medicine during

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283 Prosecutors and juries widely refused to prosecute or convict unorthodox practitioners during this era. ROTHSTEIN, *supra* note 6, at 310. James C. Whorton contends that these second wave medical licensing statutes were "applied more seriously" than the antebellum versions and that "hundreds, if not thousands, of irregular practitioners were fined and/or jailed for unlicensed practice." Whorton, *From Cultism to CAM*, *supra* note 274, at 293, 294. However, evidence suggests that these laws were rarely enforced by prosecutors and that defendants were rarely convicted by juries. See Samuel Lee Baker, Medical Licensing in America, *supra* note 281, at 183–84 (discussing the lack of enforcement of medical practice acts in the 1870s and 1880s); FREDERICK R. GREEN, STATE REGULATION OF THE PRACTICE OF MEDICINE 23 (1917) ("I venture to assert that there is not a single state in the Union today in which the medical practice act prevents any except the most flagrant quacks and charlatans from carrying on their business unmolested.").

284 Grossman, *You Can Choose Your Medicine*, *supra* note 7.

285 The most prominent and influential example of a Gilded Age argument for medical freedom based primarily on freedom of inquiry was William James' testimony in an 1898 legislative hearing against the application of the Massachusetts medical licensing law to mind curers. WILLIAM JAMES, THE WORKS OF WILLIAM JAMES: ESSAYS, COMMENTS, AND REVIEWS 56 (1987).

286 Notably, the Thomsonians' anti-monopoly theme would remain prevalent in the anti-medical licensing literature well into the twentieth century, when medical freedom advocates frequently leveled antitrust arguments against perceived machinations of the American Medical Association.

287 See Robert B. Saper, *Overview of Herbal Medicine and Dietary Supplements*, WOLTERS

the past half century has been the remarkable ability of its supporters—primarily outside of court—to thwart attempts by the government (frequently backed by organized medicine and the pharmaceutical industry) to restrict access to alternative practitioners and products.<sup>288</sup> Modern campaigns for medical freedom outside of orthodox medicine, though often led by financially-interested alternative medicine practitioners and manufacturers, are regularly bolstered by massive outpourings of popular support.<sup>289</sup> Moreover, the rhetoric supporting these campaigns bears many similarities to the antebellum struggle against medical licensing, including “thin constitutional” claims of individual rights, populist rages against unholy alliances between government and the medical establishment, and multidimensional freedom arguments invoking not only bodily liberty, but also economic freedom and freedom of conscience and religion.<sup>290</sup>

A related, but largely distinct, trend has been the emergence in the past four decades of movements for freedom *within* orthodox medicine. These movements have often taken the shape of campaigns by the terminally ill and their proponents for access to drugs that the FDA has either not yet approved or has rejected.<sup>291</sup> Because the pharmaceutical products sought by these drives are developed by profitable corporations using modern scientific techniques (often with the support of government grants), movements for access to these drugs have largely lacked the populist passion, religious overtones, and “natural rights”

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KLUWER HEALTH UPtODATE (Sept. 25, 2005), <http://www.uptodate.com/contents/overview-of-herbal-medicine-and-dietary-supplements#H4> (“In the US, use of herbal medicine declined in the early 1900s only to experience a resurgence beginning in the 1960’s that was part of a larger movement towards using natural nonconventional approaches to healthcare.”); David M. Eisenberg et al., *Trends in Alternative Medicine Use in the United States, 1990-1997*, 280 JAMA 1569 (1998) (reporting surge in use).

288 See generally Whorton, *From Cultism to CAM*, *supra* note 274. Indeed, alternative medicine has achieved a striking degree of positive government recognition, with the establishment in 1992 of the Office of Alternative Medicine (now called the National Center for Complementary and Alternative Medicine) at the National Institutes for Health.

289 For example, in the early 1990s, when the public perceived the FDA as threatening the availability of dietary supplements, Congress reportedly received more mail on this issue than on any other that session—including health care reform. See John Schwartz, *Next Week, FDA Will Take Vitamins; Lawmakers Get Avalanche of Letters About Agency’s Regulation of Dietary Supplements*, WASH. POST, Dec. 7, 1993, at A23; Editorial, *Vitamin Cease-Fire*, WASH. POST, Oct. 20, 1994, at A20.

290 For a variety of discussions of these trends, see WHORTON, *NATURE CURES*, *supra* note 29, at 141–307; and the excellent collection of essays in *THE POLITICS OF HEALING*, *supra* note 274.

291 However, these campaigns have not been limited to those suffering from fatal diseases like cancer and AIDS. For example, in response to impassioned protests by sufferers of irritable bowel syndrome, the FDA in 2002 permitted the return to the market of Lotronex, a drug earlier withdrawn because of occasional severe side effects. Denise Grady, *U.S. Lets Drug Tied to Deaths Back on Market*, N.Y. TIMES (June 8, 2002), <http://www.nytimes.com/2002/06/08/us/us-lets-drug-tied-to-deaths-back-on-market.html>. On its return, the drug was subjected to a restricted distribution regime. *Id.*

rhetoric of the alternative movements. But this may be changing, as disease groups increasingly express anti-statist outrage and invoke constitutional principles in favor of their cause. For example, a petition recently circulated by Freedom of Access to Medicine, an organization dedicated to preserving breast cancer patients' access to the drug Avastin, concludes:

We are a civilized society that values life. We also cherish individual freedom and the right of a patient to choose her medical options with her physician. By acting on this, you will confirm our belief that Life, Liberty and the Pursuit of Happiness is an inalienable right for all, including the seriously ill.<sup>292</sup>

Although such patient advocacy groups ordinarily emphasize bodily liberty, they are often backed by groups and publications that also advocate economic freedom and minimalist government more generally.<sup>293</sup> Most recently, the libertarian battle against state interference with freedom of therapeutic choice has paradoxically manifested itself in the context of government-reimbursed health care, with cries of "Death Panels!" directed at every hint or apparition of a limitation on Medicare coverage.<sup>294</sup>

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292 *Petition to Protect the Avastin Women*, FREEDOM OF ACCESS TO MEDICINES, <http://fameds.org/petition.php> (last visited Nov. 14, 2012).

293 See, e.g., Michael F. Cannon, *Why Should Politicians and Bureaucrats Decide Whether Breast-Cancer Patients Can Take Avastin?*, CATO@LIBERTY (Nov. 14, 2012), <http://www.cato-at-liberty.org/why-should-politicians-and-bureaucrats-decide-whether-breast-cancer-patients-can-take-avastin/>; Editorial, *The Avastin Mugging*, WALL ST. J. (Aug. 18, 2010), <http://online.wsj.com/article/SB10001424052748704271804575405203894857436.html>.

294 This attack line against health care reform exploded into the public discourse in August 2009, when Alaska governor (and former vice-presidential candidate) Sarah Palin posted comments on her Facebook page warning readers—with no apparent justification—that under the president's health care plans, they would have to "stand in front of Obama's 'death panel' so his bureaucrats [could] decide, based on a subjective judgment of their 'level of productivity in society,' whether they [were] worthy of health care." Ceci Connolly, *Seniors Remain Wary of Health-Care Reform*, WASH. POST (Aug. 9, 2009), <http://www.washingtonpost.com/wp-dyn/content/article/2009/08/08/AR2009080802367.html>. The "death panel" charge was leveled at the FDA recently, in November 2011, when the agency withdrew its provisional approval of the drug Avastin for the treatment of breast cancer. Conservative websites and editorial pages erupted with outrage at the notion that the government would remove a treatment option from victims of the disease. See, e.g., Editorial, *The Avastin Denial*, WALL ST. J. (Nov. 19, 2011), <http://online.wsj.com/article/SB10001424052970203611404577046133283707236.html>; Milton R. Wolf, *The FDA's One-Man Death Panel*, WASH. TIMES, June 21, 2011, <http://www.washingtontimes.com/news/2011/jun/21/the-fdas-one-man-death-panel/>. The author has on file comments posted on various media websites on November 18, 2011, the day the FDA announced its final decision. The FDA's withdrawal of Avastin's "accelerated approval" for breast cancer did not remove the drug from the market, because it is still approved for other cancers, and doctors remain free to prescribe it to breast cancer sufferers. The real fear of opponents of the FDA decision, therefore, is that government insurance (and, in response, private insurance plans) will stop reimbursing for this use. The "death panel" meme reappeared during the 2012 presidential campaign, when Republican



Importantly, however, as is the case with alternative remedies, few advocates for freedom of therapeutic choice within orthodox medicine have achieved victory in court. The most successful arguments have been advanced through vehicles such as testimony at legislative hearings and FDA advisory committee meetings, organized letter-writing drives, administrative filings, press campaigns, and public demonstrations. Although these campaigns have not been as explicitly constitutional as their nineteenth-century counterparts, recent trends indicate an increasing embrace of constitutional rhetoric.

It remains to be seen, however, whether current promoters of freedom of therapeutic choice within orthodox medicine will construct a persuasive multi-pronged argument similar to the Thomsonians' rhetoric. Not all people arguing for freer access to unapproved pharmaceutical products embrace economic libertarianism and broader hostility to government. To the contrary, some disease advocacy groups value the FDA's role as a gatekeeper ensuring drug safety and effectiveness, even as they exhort the agency to open the gate a bit wider, and virtually all groups lobby energetically for more government funding of medical research. In the 1980s, for example, the leaders of a demonstration at FDA headquarters by AIDS activists demanding earlier and greater access to experimental drugs warned participants to "be careful to keep their agenda . . . from being confused with the Bush/*Wall Street Journal*/Heritage Foundation agenda of sweeping drug industry deregulation."<sup>295</sup>

Furthermore, contemporary arguments for liberty within orthodox medicine rarely invoke the freedom of inquiry strand of medical freedom. Since the middle of the twentieth century, the gold standard for establishing medical effectiveness has been the meticulously structured, highly restricted, placebo-controlled clinical study. In this regime, the unregulated use of unproven remedies is perceived as undermining, rather than advancing, the pursuit of truth. Finally, while freedom of conscience continues to be an important theme for religious groups like Christian Scientists resisting the use of orthodox treatments, freedom of conscience arguments are largely absent from the rhetoric of activists urging freedom of patient choice within the field of regular medicine. This secular tone may dominate because modern scientific medicine, with its materialist and empirical underpinnings, has a tenuous connection to spiritual matters.

It is thus possible that the calls for freedom of therapeutic choice within orthodox medicine will never assume the features of a broad popular

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candidate Mitt Romney declared in a debate with President Barack Obama that he opposed "Obamacare" (the Affordable Care Act) in part because "it puts in place an unelected board that's going to tell people, ultimately, what kind of treatments they can have." Romney was referring to Independent Payment Advisory Board (IPAB), which in fact is forbidden by the statute from making any recommendation "to ration health care" or "otherwise restrict benefits or modify eligibility." See *Reality Check: Looking at Candidates' Claims*, CHIC. TRIB., Oct. 4, 2012, at C20.

295 Jim Eigo et. al., *FDA Action Handbook* (Sept. 12, 1988), <http://www.actupny.org/documents/FDAhandbook1.html>.

constitutionalist movement. But this result is not foreordained. Perhaps bodily freedom arguments alone can drive such a movement. Or maybe conditions will change so as to enhance the modern relevance of one or more of the other traditional strands of medical freedom. Or perhaps new strands will form. In any event, the stubborn American insistence on freedom of therapeutic choice is something policymakers inevitably will have to wrestle with as they struggle to devise solutions to the health care crisis of the twenty-first century.

# **Innovation Incentives or Corrupt Conflicts of Interest? Moving Beyond Jekyll and Hyde in Regulating Biomedical Academic-Industry Relationships**

**Patrick L. Taylor\***

## **ABSTRACT:**

The most contentious, unresolved issue in biomedicine in the last twenty-five years has been how to best address compensated partnerships between academic researchers and the pharmaceutical industry. Law and policy deliberately promote these partnerships through intellectual property law, research funding programs, and drug and device approval pathways while simultaneously condemning them through conflict-of-interest (COI) regulations. These regulations have not been subjected to the close scrutiny that is typically utilized in administrative law to evaluate and improve regulatory systems. This Article suggests that the solution to this standoff in biomedical law and policy lies in an informed, empirical approach. Such an approach must both recognize such partnerships' legal and practical variations, as well as classify them based on their benefit to innovation and their harm to research biases. Ultimately, this approach must facilitate administrative reforms that would convert what is now an inherently arbitrary, yet widespread, regulatory regime into an epistemically rich mechanism for distinguishing between harmful and beneficial partnerships.

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## INTRODUCTION

For several decades there has been a close and productive working alliance between universities, research institutes, Government agencies, and private industry in the area of biomedical research. These relationships were enhanced significantly during the 1980's through new laws and regulations that improved the collaborative environment for research and innovation among Government and industry laboratories and the nation's research institutions. This partnership was strengthened by powerful incentives designed to encourage development and commercialization of innovative technologies initially discovered during Government-sponsored research. . . . These goals have largely been achieved. America leads the world in biomedical research and innovation through the transfer of technology spawned by these policies.<sup>1</sup>

[T]here is no conceivable social benefit in researchers' having equity interest in companies whose products they are studying.<sup>2</sup>

The IOM committee is not familiar with any evaluations of the implementation or the consequences of different [conflict of interest] management strategies. This is a significant deficit.<sup>3</sup>

Medical innovation depends on academic discovery partnered with private sector corporate action, to translate novel science into practical applications. No longer may academic medical researchers simply labor in isolation for knowledge's own sake, producing glowing abstractions from the Ivory Tower's cocooned interior. Now, American society asks that researchers invent and that their inventions be available as cures. "Where are the cures?" is not just a headline,<sup>4</sup> but an expression of a common expectation. The law reflects this

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1 To Examine the Implementation of the Government Patent Policy Act, Which Allows Universities to Patent the Results of Research Funded By the Federal Government and License Their Inventions in the Marketplace: Hearing on P.L. 96-517 Before the Subcomm. on Patents, Copyrights and Trademarks of the S. Comm. on the Judiciary, 103d Cong. 2 (1994) (statement of the American Council on Education, the Association of American Universities, and the National Association of State Universities and Land-Grant Colleges).

2 Marcia Angell, *Is Academic Medicine for Sale?*, 342 NEW ENG. J. MED. 1516, 1517 (2000).

3 Inst. of Med. of the Nat'l Acad. of Sci., Conflict of Interest in Medical Research, Education and Practice 84 (Bernard Lo & Marilyn Field eds., 2009), available at <http://www.iom.edu/Reports/2009/Conflict-of-Interest-in-Medical-Research-Education-and-Practice.aspx> [hereinafter IOM report].

4 See, e.g., Sharon Begley, *Where Are the Cures?*, NEWSWEEK (Nov. 1, 2008), available at <http://www.newsweek.com/2008/10/31/where-are-the-cures.html>; Mary Carmichael & Sharon Begley, *Desperately Seeking Cures—How the Road from Promising Scientific Breakthrough to Real-World Remedy Has Become All but a Dead-End*, NEWSWEEK (May 15, 2010), available at

expectation by creating rewards for academic-industry collaboration and requiring compensation to be distributed accordingly. And this policy works; as incentivized collaboration streams inventions from academia to industry, this country's biotechnological development booms.

Yet in the midst of this biotechnological wealth, critics abound. Professional leadership within organized medicine condemns industry affiliations across the board, implying that professional virtue can never be reconciled with innovation economics. Headlines involving research gone awry imply that nefarious financial incentives cause research trials to be unsafe. Medical journals dutifully aggregate author disclosures of industry payments, giving no attention to their potential variety and treating the cumulative number of these payments as irrefutable evidence of corrupted judgment. Such approaches treat all academic-industry partnerships as corrupt, without identifying those forms that genuinely contribute to innovation with reasonable terms calculated to avoid unmanageable research bias.

In short, society promotes collaboration, yet also despises it. The federal government requires institutions to regulate conflicts of interest through general standards of unresolved ambiguity, through an isolated mandate that is disconnected from procedures to address research integrity, protection of human and animal research participants, and professional obligations to patients. Yet these regulations give no weight to the need for innovation or what drives it. At the same time, in the distinct arena of technology transfer and tax credit, the law incentivizes biomedical researchers to engage with industry, but neither provides clear ethical constraints nor requires practical accountability to identify and address the potential harms to patients or science that could be produced by these conflicts of interest (COIs). The law promotes researchers' active involvement in sharing knowledge with companies, but, in the name of transparency, or "sunshine,"<sup>5</sup> the law requires disclosure of nominal payments, without explanation of the purpose or context, as if this fact alone would conclusively establish an improper relationship. It is apparent that the values of the academic scientific community—such as sharing data and discoveries—are at war with proprietary standards. Yet private and academic institutions continue to fuel these conflicts.<sup>6</sup>

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<http://www.newsweek.com/2010/05/15/desperately-seeking-cures.html> (observing that "judging by the only criterion that matters to patients and taxpayers—not how many interesting discoveries about cells or genes or synapses have been made, but how many treatments for diseases the money has bought—the return on investment to the American taxpayer has been approximately as satisfying as the AIG bailout").

5 Physician Payment Sunshine Act, Pub. L. No. 111-148, tit. VI, § 6002, 124 Stat. 689 (2010).

6 See generally *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002) (construing narrowly the common law research exception for academic and other research within the scope of patent rights and discussing the growing industrial role of universities given the title transfer and other provisions of the Bayh-Dole Act, 35 U.S.C. § 202(c)(4) (2000)). For an account of academic medicine's reliance on Bayh-Dole to justify COIs, together with cogent arguments against its actual

This fierce, internal battle in innovation and research policy calls for careful reconciliation of the competing goals at issue along with precise management. Instead, COIs arising from industry-academic relationships are subject to decentralized institutional management under federal standards so incomplete and vague that they are impossible to apply consistently. The federal standards require risk assessments, which adjudicators on COI committees can make only by relying on often idiosyncratic, personal assumptions about human behavior and incentives, which vary among institutions and committee members, and have not been evaluated for their generalizability. The resulting range of COI “management plans” has never been systematically evaluated for either its efficacy or its necessity. No mechanism exists to reconcile precisely the values and laws constituting the “innovation ecology,”<sup>7</sup> whether in COI policymaking, in adjudicating and managing COIs, in licensing academic intellectual property to industry, or in creating academic-industry relationships. Currently, the regulatory system pays no heed to the benefit provided by innovation, fails to assess which compensated academic-industry relationships genuinely contribute to innovation, and lacks any factual basis to assess actual risk of bias. In this way, current regulations are unresponsive to the realities of both academia and the biotech industry. Current regulations also fail to establish basic requirements that would allow adjudications and policies to be consistently and soundly executed. Thousands of independent adjudicators, with no required qualifications, operate under an ambiguous standard. Their job is to identify collaborations that create bias risk; yet they have no empirical basis for doing so. Administrative law usually nests such tasks within a context of records, rights, and appeals, but this is not the case with these COI regulations. There is no mechanism for adjudicators to test their judgments with concrete evidence, correct themselves,

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applicability to clinical research in which intellectual property is already industry-owned, see Angell, *supra* note 2.

7 William A. Wulf, *Changes in Innovation Ecology*, 316 SCIENCE 1253 (2007). Law affects the innovation ecology through diverse and indirect means. Financially, it provides patent protection, at least for the inventive phase of discovery, as well as federal and state tax incentives to promote research. Recognizing that innovation involves both risk and investment, the legal regime shelters it within for-profit corporate forms that immunize shareholders and grants federal tax-exempt status to academic hospitals and universities, as well as research institutions by name. Fiduciary law holds directors to standards of reasonable care and loyalty, not perfection. Whether promoting innovation is its purpose, the resulting flexibility allows risk-taking in new areas and respects the search for plausible alternates to the status quo. U.S. federal regulations must now address the regulatory burdens they impose, although without special attention to innovation. Nonetheless, they do contemplate the burdens on small businesses, which are a rough proxy for one innovation trajectory, in which the progress of innovation is reflected in the transformation of small start-ups into large enterprises. Health care antitrust exempts clinically integrated arrangements, recognizing that their novelty coincides with an imperative to reduce health care organizational fragmentation. Legal conferences and symposia reflect a similar preoccupation with innovation. Innovation policy is intellectual property policy, deregulatory policy, tax policy, economic development policy, and corporate policy. But it is not yet COI policy.

or contribute epistemically to the body of case law. So operationally incomplete are these regulations that it will be useful to compare them and the conduct they set in motion to jurisprudential accounts of which enactments really qualify as “law”—including such basic concepts as whether regulations provide sufficient notice or can even be obeyed. Those accounts set standards, which current regulations fail, for what a legal regulatory system concerning COIs would minimally entail.<sup>8</sup>

Descriptively, this Article claims that current health policy fails to reconcile tensions that arise from its encouraging innovation through academic-industry collaborations, while simultaneously sanctioning these partnerships for their potential impact on research integrity. Policy mandates to work together do not distinguish those innovative collaborations, which could generate research bias, from beneficial ones. Furthermore, the administrative structure for COIs in this field demands guesswork about research harm and fails to distinguish between academic-industry partnerships on the basis of their innovation potential or the diverse nature of their contractual terms. These flaws render the regulatory structure inadequate, under general administrative law standards, and ineffective, in executing the specific task of distinguishing socially beneficial collaborations from destructive arrangements. Normatively, this Article claims that society may arrive at a better reconciliation of the competing imperatives of research integrity and biomedical innovations by precisely distinguishing among such collaborations—on the basis of their purpose, terms, and structure—and strengthening the form and factual basis for administrative regulation.

This reconciliation can occur by framing the choices facing these COIs in clear terms, rather than obscuring these challenges with an abstract demand for scientific independence that no longer comprehensively characterizes social expectations for research. With better data about which collaborations foster bias and which actually contribute unique scientific talent to the innovation process, regulation could be precise, predictable, factually founded, and reflect a conscious societal choice among potentially competing values. The key goals of this Article are thus: (1) to understand the basis for sound regulation and safe harbors, rather than grounding a system in ad hoc prohibitions relying on factual uncertainty; and (2) to establish default rules that lead us towards a greater understanding of what an optimal legal system would require to conservatively avoid human harms. The point is not to abandon virtue by permitting conflicts of interest. Rather, the goal is to reconcile our account of ethical research with social expectations by taking into consideration the likely effects of contractually

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<sup>8</sup> See, e.g., Robert Alexy, *The Argument from Injustice—A Reply to Legal Positivism* (Bonnie Litschewski Paulson & Stanley L. Paulson trans., 2010); John Austin, *LECTURES ON JURISPRUDENCE, OR THE PHILOSOPHY OF POSITIVE LAW* (Robert Campbell ed., 2002); Lon Fuller, *The Morality of Law* (rev. ed. 1969); H.L.A. Hart, *The Concept of Law* (2d ed. 1994); Cass Sunstein, *Legal Reasoning and Political Conflict* (1996).



distinct collaborations discerned from aggregate data.<sup>9</sup> This factual account, however, requires adopting an evaluative stance less governed by the currently venerable, but incomplete, account of scientific virtue.

This Article proceeds in three parts. Part I focuses on COIs, their source in legal mandates for collaboration, their consequences, and their variety. While collaboration is inevitable, COIs are not. The standard inference from COI cases—that all collaboration must be avoided to prevent COIs—is therefore mistaken. Even when an improper collaboration incentive is identified, it is of little help in deciding whether other forms of collaboration should be suspect. Many variables pertaining to the context, purpose, and structure of collaboration arrangements can materially affect intuitive judgments about COI risk.

Part II focuses on regulations. It starts with a basic query: Are United States regulations well-equipped to address the nuanced differences among diverse collaboration arrangements? Since collaboration mandates and programs do not address COI risk, the focus of this query is the two main regulatory approaches to COIs advanced by the Food and Drug Administration (FDA) and the U.S. Public Health Service (PHS), a component of which is the National Institutes of Health (NIH), as well as the self-regulatory structure offered by the Association of American Medical Colleges (AAMC). To a student of administrative law, these regulatory structures will be like visiting the land that time forgot: so conspicuous is the absence of even rudimentary forms of administrative accountability and control. To highlight the point, Part II assesses the effectiveness of these systems through the perspectives of the jurisprudential categories proposed by Cass Sunstein<sup>10</sup> and others. Ultimately, Part II shows that the regulatory proposals fail to attain their own goals, apart from the socially necessary goal of situating COIs in an innovation ecology that optimizes competing values.

Part III categorizes and discusses perspectives on COIs from the business and legal literature. Despite the merits of this literature, none of it recommends an empirical basis for COI management. Like the current regulations, the literature does not distinguish among collaborations on the basis of whether they make actual contributions to innovation or whether the arrangements find ways to minimize research bias while maximizing innovation value. The primary value of the existing literature is that it illustrates the limits of a nonempirical approach, with its energy spent on warring accounts of scientific virtue that yield no practical recommendation to reconcile collaborations' innovation and COI

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9 In, KWAME ANTHONY APPIAH, *EXPERIMENTS IN ETHICS* (2008), Appiah argues that, henceforth, no account of human virtue should be ungrounded in the lessons of behavioral economics and other empirically demonstrable patterns of human thinking. Only then can virtue ethics—as an account of the ideal human life leading to happiness—fulfill its practical promise to make people both virtuous and happy.

10 See generally SUNSTEIN, *supra* note 8 (contrasting perspectives on various forms of legal reasoning).

values.

Throughout the Article, I will build on the intuition that the very existence of a COI turns more on the terms, purpose, and context of academic-industry arrangements than on the simple fact of the industry-to-scientist payments to which most regulations attend.

### I. ARE CONFLICTS OF INTEREST NECESSARY?

Financial conflicts of interest are not inherent to the research enterprise. They are entirely optional, unlike intellectual or personal conflicts of interest to which they are often compared.<sup>11</sup>

Conflicts of interest are ubiquitous and inevitable in academic life, indeed, in all professional life. The challenge for academic medicine is not to eradicate them, which is fanciful and would be inimical to public policy goals, but to recognize and manage them sensibly and effectively.<sup>12</sup>

#### *A. Collaboration is Necessary and Unavoidable*

Both industry and government are indispensable players in biomedical research and development. Collaboration is a necessity, for reasons that are economic, historic, and legal, and it is important to understand why this is the case.

Biomedical research is divided into stages, from basic inquiry to research directly involving human beings or their identifiable data. Approximately \$30.9 billion was budgeted by the U.S. government for NIH funding for the fiscal year 2012.<sup>13</sup> Most of these dollars are allocated to basic scientific research (e.g., the stuff of petri dishes, signal transduction pathways, model organisms, novel chemical reactions, etc.); the remainder is for clinical (biobanking, biomarker diagnostics, novel surgical procedure development, etc.) and public health research (e.g., infectious disease preparedness, epidemiology of obesity, pervasiveness of self-destructive behaviors in the United States, etc.).<sup>14</sup> However,

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11 Marcia Angell, Remarks at HHS Conference on Human Subject Protection and Financial Conflicts of Interest (Aug. 16, 2000), *available at* <http://www.hhs.gov/ohrp/archive/coi/8-16.htm#Angell>.

12 David Korn, *Conflicts of Interest in Biomedical Research*, 284 JAMA 2234, 2234 (2000).

13 See NAT'L INST. OF HEALTH, NIH BUDGET FISCAL YEAR 2012, *available at* <http://officeofbudget.od.nih.gov/cy.html>.

14 NIH funds are awarded through a highly competitive application process spelled out in a continuously updated, publicly available constellation of policies called collectively "grants policy and guidance," together with refinements specific to a given program or funding opportunity publicized by the NIH. Applications can be found on the NIH website. NIH OFFICE OF EXTRAMURAL RESEARCH, <http://grants.nih.gov/grants/oer.htm> (last visited Dec. 2, 2012). For a

it takes much more to turn basic science into diagnostics and therapies. Translating discoveries into products that are safe and effective for human use, and making those products available, necessarily involves private industry.

Reflecting the growing demand for drugs, industry sponsorship of biomedical research (including payments to academic researchers) has increased exponentially in the past two decades. One widely cited authority estimates that, between 1980 and 2003, such expenditures by U.S. pharmaceutical companies increased from \$2 billion to \$33 billion.<sup>15</sup> Even if such figures are overstated,<sup>16</sup> there is no question that industry funding for research, development, and influence over physicians and scientists, collectively, matches or exceeds government funding for biomedical research. Its rate of increase far surpasses the rate for government spending (calculable from the sources cited) in which inflation offsets, in real terms, the modest numerical increases over time. This industry spending helps sustain a pharmaceutical market that exceeds \$200 billion per year in revenue in the United States alone.<sup>17</sup>

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formal, technically accurate, and binding set of official policies governing applications post-award management, see, *NIH Grants Policy Statement*, NAT'L INST. OF HEALTH (Oct. 1, 2012), available at [http://www.grants.nih.gov/grants/policy/nihgps\\_2012/index.htm](http://www.grants.nih.gov/grants/policy/nihgps_2012/index.htm). The application requires a detailed discussion of the importance of the general research background and focus, hypotheses, research aims, methods to be employed, qualifications and competencies, and resources available. Importantly, the grant application need not identify for reviewers conflicts of interest or contractual commitments to third parties, which could affect the selection of the research problem, the design of the research, its conduct, data analysis, and reporting. If awarded, the money will come with certain conditions. As far as the scientist is concerned, there will be data-sharing mandates of varying force and specificity. There must also be a promise that, if there is an invention from the research, the institution will promptly disclose it to the NIH, elect whether to hold the title and seek to develop the invention through, for example, patenting it and then licensing it to companies. In return, at least 15% of the net revenue goes to researchers. Notably, for NIH-funded research, a scientist maintains modest discretion to stray from the project proposal during the discovery process. It is understood, and, indeed expected, that initial discoveries will lead to novel hypotheses and therefore novel experiments, using methods that cannot be specified in the application in advance. This also means, of course, that the researcher has discretion to reallocate, within reasonable limits, proposed expenditures that were used to justify an initial budget request. Thus, a scientist has professional discretion to deviate from the description of a proposed project that merited an award, in a system that itself promotes COIs through the revenue-to-inventor process. Furthermore, peer reviewers are not aware of any past, present, or future COIs arising from a scientist's economic stake in licensed patents from previous or concurrent federally funded research. There is no COI review at the application review stage.

<sup>15</sup> See Gordon DuVal, *Institutional Conflicts Of Interest: Protecting Human Subjects, Scientific Integrity, and Institutional Accountability*, 32 J.L. MED. & ETHICS 613 (2004).

<sup>16</sup> MARCIA ANGELL, *THE TRUTH ABOUT THE DRUG COMPANIES* 3–20, 37–51 (2004) (discussing “How Much [t]he Pharmaceutical Industry Really Spend[s] on R&D”).

<sup>17</sup> *Id.* A company will wish to contractually commit a researcher to a definite course of research. The company then will claim for its own use the resulting intellectual property without necessarily sharing or developing it, and it will keep all data confidential, keep a researcher to a budget that is both justified and well defined, and focus on research aims that have a direct bearing on its business venture. If the sponsored research is clinical, then it is almost certain that the company is pursuing it in support of an application to the FDA to permit marketing of a diagnostic

Human testing is most often funded by industry, in connection with private companies exercising their rights and obligations under FDA regulations as “sponsors” of an application for approval to market a novel diagnostic or therapy.<sup>18</sup> FDA approval depends on data supporting safety and effectiveness through favorable outcomes in clinical research studies that are often large-scale, expensive, and uncertain. Sponsors’ functions, such as establishing manufacturing facilities, independent trial monitoring, and sales networks, are far removed from typical academic functions. Thus, while the law does not prohibit academic investigators from being sponsors, and while novel therapies may start this way, in practice industry involvement is essential and almost universal. Yet the reliability and disinterestedness of clinical research is important in evaluating results from clinical trials. For this reason, those who conduct clinical research, termed “investigators,” are often academic researchers paid by industry for their research.

This simple fact is at the core of the COI problem. Academic researchers are key players in research and development. Universities and academic hospitals are the main progenitors of biomedical discovery, and they are necessary at every stage of knowledge and product development, up to and including studies to test products’ safety and efficacy on human beings. Eliminating all industry payments to academic researchers is neither practical nor desirable. The result would be industry assessing the safety and efficacy of its own products—hardly an increase in disinterestedness!

Other government policies also reflect public expectations that academic scientists involve themselves directly with industry and industry projects. First, under the “NIH Roadmap” or “translational research initiative,”<sup>19</sup> an increasing amount of government funds will be spent on connecting the dots among basic research, the translational research that will lead to human applications, the clinical research on human participants to test safety and efficacy, and the resulting health care products. These products will, in turn, enable health care

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or therapeutic use. This will trigger the applicability of FDA regulations defining the role of a “sponsor,” or funder, and a “principal investigator” or basic inventor. See 21 C.F.R. §§ 312.50-.70(2012) (drugs); 21 C.F.R. §§ 812.40-.47 (2012) (devices).

18 With limited exceptions, these regulations prohibit the interstate marketing of drugs, devices, and biologicals for the diagnosis or treatment of a disease, unless the FDA has approved an application to market that establishes safety and efficacy. Regulations establish a process for seeking such approval, and it is this process that requires scientific data that must emerge, inevitably, from credible research. See generally 21 C.F.R. § 314 (2005) (drug approval process); 21 C.F.R. §812 (2005) (device approval process).

19 See, e.g., Declan Butler, *Translational Research: Crossing the Valley of Death*, 453 NATURE 840 (2008); Steven H. Woolf, *The Meaning of Translational Research and Why It Matters*, 299 JAMA 211 (2008). For an example of a specific application to a particular research area, in this case, drug abuse causes, diagnosis, and treatment, see *Cross-Disciplinary Translational Research at NIH*, NAT’L INST. OF HEALTH, <http://grants.nih.gov/grants/guide/pa-files/PA-07-109.html> (last visited Dec. 4, 2012).

reforms in a process interwoven with industry partnership.

Second, the need to accelerate the development and distribution of therapies for AIDS led to special regulatory provisions for rapid approval and treatment access outside traditional clinical research protocols.<sup>20</sup> However, decreased evidentiary review before human use means fewer opportunities to detect errors. Pressure to approve potential cures means, at the least, less incentive to question trial design or conduct, and perhaps even affirmative pressure to take a permissive approach (especially given the agency's funding through user fees).<sup>21</sup>

Third, a bundle of interrelated initiatives explicitly allows the FDA to approve drugs by relaxing standards that it might otherwise apply. For example, the FDA might permit a company to condense its clinical trial sequence into two phases (rather than the three or four phases normally required by regulation) or accept as sufficient data showing efficacy within shorter endpoints than it might otherwise demand.<sup>22</sup> This policy is, and ought to be, controversial, for the practical impact might be the approval of a drug whose short-term or long-term effectiveness and safety is uncertain or whose effectiveness in one clinically defined sense might be rebutted by a narrower or broader description of the objectives of the trial. If a COI affects trial design decisions and approvals proposals, the potential consequences are significant.<sup>23</sup>

Fourth, another incentive structure, designed to reward previous research and inventions, may also create COIs for future research. The 1980 Bayh-Dole Act, a cornerstone of innovation policy, revolutionized academic-to-industry knowledge transfers.<sup>24</sup> Academic institutions may retain title to inventions

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20 21 C.F.R. §§ 312.50–70 (2012); Sheila R. Shulman & Andrea Kuettel, *Drug Development and the Public Health Mission: Collaborative Challenges at the FDA, NIH, and Academic Medical Centers*, 53 BUFF. L. REV. 663 (2005).

21 See generally Shulman & Kuettel, *supra* note 20.

22 See 21 C.F.R. §§ 312.80–88, 314.500–.560 (1999).

23 Post-approval review does not resolve these COI-related concerns for three reasons. First, the FDA's post-marketing surveillance and review is historically deficient and is still weak, as reported in the General Accountability Office's most recent survey. See U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-68, DRUG SAFETY: FDA HAS BEGUN EFFORTS TO ENHANCE POST-MARKET SURVEILLANCE BUT ADDITIONAL ACTIONS ARE NEEDED (2009), *available at* <http://www.gao.gov/new.items/d1068.pdf>. Second, in post-approval review, as in pre-market approval, the FDA is still dependent, in whole or in part, on researchers. If these researchers are non-industry academics, they are the very individuals whose COIs we are examining. Third, these two regulatory pathways are intended to address the needs of people who are gravely ill, or the safety characteristics of drugs whose accelerated approval ought to be uncontested. Neither category would be well served by postponing evaluation of any effect of COIs until after patients and consumers have started consuming the drug to their detriment.

24 Bayh-Dole Act, 35 U.S.C. §§ 200–212 (2006); 37 C.F.R. § 401 (2012) (regulations associated with the Bayh-Dole Act). The Act (also called the Patent and Trademark Law Amendments Act) grants recipients of federally funded research grants and contracts, such as universities and research hospitals, the right to take title to intellectual property rights in any inventions that arise in the course of the federally funded research, provided that they are able to accomplish the following: (a) act diligently to protect the discovery, such as through patent filings

arising in the course of federally funded research, if, among other things, they actively seek to license the invention to the private sector for development, and if resulting net revenue is split between the academic inventors and the institution's educational and research purposes. Thus, the Bayh-Dole Act mandates that an inventive scientist share in a discovery's resultant revenue, if research and development confirm its potential value as a product. This would cause no COI if the inventing scientist then switched fields. But if, as is likely, the scientist continues to perform research in the same field, the potential profit stream from the discovery will readily create two forms of COIs. The first is in selecting research topics: a financial interest in confirming, perfecting and supplementing the licensed invention conflicts with exploring discoveries that would compete with it or break novel ground. The second reflects the scientist's financial interest in producing results consistent with the prior discovery's marketing.

Notably, none of these policy initiatives addresses the obvious potential they create for COIs. There are no requirements that collaborations be structured to avoid COIs, let alone parameters or safe harbors that might aid that purpose. In both regulation and academic discussion, two worlds emerge, instead of one. To create an integrated world, it is imperative to understand the source of potential conflict between legal imperatives for academic scientists to collaborate and other norms for academic scientists.

### *B. Collaborations Gone Bad: Individual Cases and Statistical Associations*

Three influences have grounded COI policy to date, and it is important to distinguish among them. The first influence is a set of professional values, originating in an era before innovation policy started to demand or incentivize academic-industry collaboration. It is primarily leaders of organized biomedical science that articulate these professional norms, including independent judgment, fiduciary duties to patients, and exclusivity for physicians in making health care judgments; these are often portrayed as values under siege.<sup>25</sup> These are the same values that led, in an earlier time, to legal doctrines rejecting the corporate practice of medicine, and, in modern times, to the medical profession's steadfast opposition to managed care, corporate forms of quality assurance, and integrated

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after having notified the agency funder of that intention; (b) actively seek to license its use by the private sector in a reasonable way that will promote public benefit; (c) return some of the net proceeds to the inventor(s); and (d) devote the balance of net proceeds to education or research. Previously, the agency funders took title, and few transfers of discoveries to industry for development occurred. Bayh-Dole was designed to incentivize academic inventors to invent, institutions to license to industry, and for both academia and industry to form enduring collaborative relationships through which academic discoveries could flow through industry to the public.

<sup>25</sup> See Robert K. Merton, *The Sociology of Science: Theoretical and Empirical Investigations* (1973); Patrick Taylor, *Research Sharing, Ethics and Public Benefit*, 25 *Nature Biotech.* 398 (2007).

delivery systems.<sup>26</sup> This value scheme teaches complete separation from industry, regards industry as quintessentially unable to make medically informed and disinterested research judgments, and prohibits all industry contact as inescapably threatening to the independence and integrity of physicians and scientists.<sup>27</sup>

The separation must be even stricter for academic scientists and physicians because of their role as creators and guardians of knowledge. Physicians and scientists who work for corporations legitimately focus on advancing corporate goals, and physicians in private practice may practice for a profit. But academic scientists have superseding ethical obligations to research participants, present and future members of the academic community, research funders, and the public at large. Their work must reflect values essential to the credible advancement of knowledge — integrity, competence, objectivity, transparency, and reliability in the discovery process, as well as respect for human and animal research participants—that trump competing concerns, including economic ones. These values are reflected in sources as diverse as the Internal Revenue Code,<sup>28</sup> policy manuals and regulations of the NIH,<sup>29</sup> associational guidelines, and institutional

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26 PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 198–232, 420–49 (1982) (discussing resistance to corporate control and employment and discussing the medical profession's opposition to managed care and corporate standards).

27 The medical literature by professional leaders is rich with debate in these terms. For leading examples of what I will call the “Virtue-Prohibitionist approach,” see JOHN ABRAMSON, *OVERDOSED AMERICA: THE BROKEN PROMISE OF AMERICAN MEDICINE* 120–21 (2004); ANGELL, *supra* note 16, at 115–34; JERRY AVORN, *POWERFUL MEDICINES: THE BENEFITS, RISKS, AND COSTS OF PRESCRIPTION DRUGS* 292–94 (2004); and Jerome P. Kassirer & Marcia Angell, *Financial Conflicts of Interest in Biomedical Research*, 329 *NEW ENG. J. MED.* 570 (1993) (analyzing the effects of financial conflicts of interest on biomedical research and critiquing the policies used to handle disclosure of such conflicts); see also Troyen A. Brennan et al., *Health Industry Practices that Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers*, 295 *JAMA* 429 (2006); Catherine D. DeAngelis, Editorial, *Conflict of Interest and the Public Trust*, 284 *JAMA* 2237 (2000) (introducing articles addressing the prevalence of conflicts of interest between physicians and companies that financially support teaching and research, along with the effects of this relationship on public trust of physicians). But for leading contrarians who argue that industry relationships should be cultivated as essential and beneficial, see William M. Sage, *Some Principles Require Principals: Why Banning “Conflicts Of Interest” Won’t Solve Incentive Problems in Bedical Research*, 85 *TEX. L. REV.* 1413 (2007); Thomas P. Stossel, *Regulating Academic-Industrial Research Relationships – Solving Problems or Stifling Progress?*, 353 *NEW ENG. J. MED.* 1060 (2005).

28 See IRS, *INTERNAL REVENUE MANUAL FOR SCIENTIFIC RESEARCH UNDER IRC 501(C)(3)* (1986), available at [www.irs.gov/pub/irs-tege/eotopico86.pdf](http://www.irs.gov/pub/irs-tege/eotopico86.pdf).

29 See, e.g., *Update on the Requirement for Instruction in the Responsible Conduct of Research*, NAT’L INST. OF HEALTH (Nov. 24, 2009), <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html> (discussing mandate for training in research integrity and the responsible conduct of research, with links to other government resources detailing the required topics); Taylor, *supra* note 25, at 398–401 (noting that researchers’ legal data-sharing obligations are related to fundamental ethical norms of science, reinforced by ethical force of promises of social benefit made to research participants and research review boards).

charters and policies. Academic scientists are expected to be in a position to collaborate with private interests, but they must do so without putting personal profit before the values espoused by their profession. This common sense approach stands in stark contrast to the more extreme demands of some medical leaders, which require complete disengagement from financial ties.

The problem is that public expectations and government policies no longer permit a full account of professional virtue to exclude industry engagement. To the contrary, according to both public expectation and policy changes, a virtuous scientist is one who will engage with industry to bring a discovery to useful fruition, yet retain her scientific independence and good judgment. This is law's ethical challenge to physicians and scientists.

If not overgeneralized, the other two forms of influence on COI policy provide some evidence that COIs can cause research lapses. First, there is a small set of publicly noted COI cases whose specific facts purportedly support broad conclusions about the negative effect of any industry relationship. Second, analyses and meta-analyses demonstrate correlations between scientist behaviors and industry relationships across populations, such as the statistical association between positive industry sponsorship of clinical trials and published positive trial results. Both forms of influence are contested, principally on the grounds that research mishaps in these publically noted cases are due to factors other than concurrent COIs and that population-based conclusions are best explained by other variables.<sup>30</sup> To evaluate these conflicting claims, it is essential to understand the nature of biomedical research and the opportunities for bias it presents.

### *C. The Nuts and Bolts of Biomedical Research*

Regulatory approval by the FDA is not based on a complete understanding of human biology or a universalized biochemistry. Instead, FDA approval depends on artfully designed experiments to demonstrate safety and effectiveness by showing that X is better than nothing for treating Y, with no other variables confounding the results, as measured at particular times and with specified measures.<sup>31</sup>

From the framing of hypotheses to the analysis and publication of results,

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30 For a comprehensive, if one-sided, treatment of these arguments, see Sigrid Fry-Revere & David Bjorn Malmstrom, *More Regulation of Industry-Supported Biomedical Research: Are We Asking the Right Questions?*, 37 J.L. MED. & ETHICS 420 (2009).

31 See, e.g., 21 C.F.R. § 314.50 (2008) (content and format of an application for FDA approval to market a new drug); 21 C.F.R. §§ 58.120-.130 (2012) (protocol for and conduct of a nonclinical laboratory study); FDA, CTR. FOR DRUG EVALUATION & RES. (CDER), CTR. FOR BIOLOGICS EVALUATION & RES. (CBER), GUIDANCE FOR INDUSTRY: E10 CHOICE OF CONTROL GROUP AND RELATED ISSUES IN CLINICAL TRIALS 14 (2001), available at <http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm125912.pdf>.



the research process is filled with strategic and tactical judgments about how a scientific question is best answered. Such discretionary choices can be plausibly defended, even when they might also appear as necessarily intended to misrepresent, or inadvertently biased. In the notorious Vioxx debacle, for example, Merck researchers had knowingly deleted three heart attacks that occurred after a designated date end point. If those data had been included, the Vioxx safety and efficacy analyses would have changed dramatically.<sup>32</sup> This deletion was discovered only because electronic editing traces remained. When revealed, the changes allegedly were justified by the general principle that one should not manipulate endpoints. Regardless of the legitimacy of Merck's rationale, this case illustrates the power of even one study parameter (out of many) to affect the manner in which results and their implications are portrayed.

Biomedical research is ideally a combination of inquiry focused on a well-defined question, using methods precise enough to control confounding variables, and complemented by thoughtful, thorough analysis and sound inferences. Biases often are associated with incorrect inferences, but biases go much farther. Biases in a scientific study may be errors of selection (e.g., in defining comparative groups), differences of measurement (e.g., perception differences or instrument use), or intervention (e.g., systematic differential treatment signals).<sup>33</sup> Some biases can be prevented easily, provided the study structure does not thereby become unethical.<sup>34</sup> Thus, selection bias otherwise affecting participant selection in a clinical trial, or participant-researcher signaling, can be overcome by randomization and double-blinding. However, these are not always ethical choices for ill participants for whom one research arm is less than the standard of care. Some biases, such as those that affect the selection and formulation of a scientific question, or biases that permeate every stage of a study, may be very difficult to detect.<sup>35</sup>

There are two kinds of evidence that COIs may create biases that affect outcomes. First, scholars have noted a number of notorious cases of research misconduct involving financially motivated investigators or institutions. David Blumenthal, for example, describes how a research fellow at the Massachusetts Eye and Ear Infirmary "benefited substantially from selling his holdings in a private company established to market a new drug he was testing in clinical

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32 See Gregory D. Curfman et al., *Expression of Concern: Bombardier et al., "Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis"*, 353 NEW ENG. J. MED. 2813 (2005).

33 See MASSIMO PIATELLI-PALMARINI, *INEVITABLE ILLUSIONS: HOW MISTAKES OF REASON RULE OUR MINDS* (1994); James M. Hartman et al., *Tutorials in Clinical Research: Part IV: Recognizing and Controlling Bias*, 112 LARYNGOSCOPE 23 (2002).

34 Consider a trial in which participants receive either a placebo or a test drug; it would be unethical to enroll seriously ill patients who would otherwise receive a moderately effective standard treatment.

35 See Hartman, *supra* note 33.

trials.” The fellow’s unpublished work, however, showed the drug to be ineffective and raised questions about participant harm.<sup>36</sup> More recently, in a contested and controversial case, the British Medical Journal asserted that the researcher who did most to link autism with certain measles vaccines and bowel disease committed scientific misconduct and hoped to profit from this academic fraud through product sales by his private company.<sup>37</sup> In these cases, proof of wrongdoing is perceived as proof of the influence of financial incentives.

A second kind of bias is subtler. Misconduct coexists with a financial interest, but the interest is not actually advanced through the misconduct, nor can one find unambiguous evidence that the financial interest was the sole, or even a “but for,” cause of harm. In a widely publicized case, a young volunteer, Jesse Gelsinger, with an effectively treated congenital liver ailment, died in a phase I gene therapy trial following a massive immune response to the viral vector used.<sup>38</sup> This clinical research trial was filled with mishaps, including a miscalculation of the risks, trial design errors, and flawed and untimely reporting of adverse events involving other participants. In addition, the decision to conduct the phase I trial using healthy volunteers became controversial, given the trial’s substantial risks. A more accurate assessment of the risks might have led to a decision to restrict the trial to those for whom existing therapies had failed—unlike Jesse, whose condition had been stable prior to the research study.

Yet while these risk assessments were noted, it was not these factors that captured the attention of Jesse Gelsinger’s father and the public. Rather, it was the fact that the investigator and the University of Pennsylvania had a substantial equity stake in the company owning the rights to the therapy being tested.<sup>39</sup> Reporters focused on this collaboration, even though it is not clear that financial interests were pertinent to the clinical wrong that occurred.<sup>40</sup> For example, there was no “smoking gun” evidence ever connecting dollars to improper shortcuts. Still, the financial relationship seemed to provide, in a single phrase, a simple explanation for how so much could have gone so wrong, through an imputation

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36 David Blumenthal, *Academic-Industry Relationships in the Life Sciences: Extent, Consequences, and Management*, 268 JAMA 3344–46 (1992).

37 Brian Deer, *How the Vaccine Crisis Was Meant To Make Money*, 342 BRIT. MED. J. 113 (2011).

38 See generally Sheryl Gay Stolberg, *The Biotech Death of Jesse Gelsinger*, N.Y. TIMES (Nov. 28, 1999), available at <http://www.nytimes.com/1999/11/28/magazine/the-biotech-death-of-jesse-gelsinger.html>.

39 See, e.g., Patricia C. Kuszler, *Biotechnology Entrepreneurship and Ethics: Principles, Paradigms, and Products*, 25 MED. & L. 491, 495 (2006) (“[L]apses in human subjects protection remains an ever-present hazard. This has been exemplified by a series of high profile research ethics scandals in the U.S.—the Jesse Gelsinger case in which a research subject in a gene-therapy experiment died and it was alleged that the researchers’ financial interest in the vector influenced them to prematurely engage in the clinical trial that resulted in Mr. Gelsinger’s death.”).

40 Robin Fretwell Wilson, *The Death of Jesse Gelsinger: New Evidence of the Influence of Money and Prestige in Human Research*, 36 AM. J.L. & MED. 295 (2010).

of bad character and overwhelming profit motives.<sup>41</sup> Unlike the first kind of misconduct case described above, the investigator and institution would have gained if the therapy had been effective, but instead gained nothing from the errors and flaws.<sup>42</sup>

Some industry proponents of academic partnerships argue that financial relationships are seldom a material cause of misconduct and that in almost all cases financial associations are absent or accidental.<sup>43</sup> On its face, this is an illogical argument, suggesting that from cases not involving financial interests one can learn something definitive about the causal role of financial interests in cases that do. Importantly, this contention also overlooks the first type of case mentioned, where the form and evidence of misconduct in fact demonstrates the salience of financial objectives. It is true that many cases of “bad science” or participant harm do not involve financial COIs. But this fact alone does not prove that the law and policy should not address financial COIs where they give rise to improper incentives. This argument suggests only that there are other sources of error beyond financial COIs.

Institutions need not accept this all-or-nothing characterization of the potential for financial COIs to negatively impact research integrity, any more than they need accept an all-or-nothing answer to the question of whether industry payments to scientists contribute to innovation. Both questions have

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41 See Frances H. Miller, *Trusting Doctors: Tricky Business When it Comes to Clinical Research*, 81 B.U. L. REV. 423 (2001); Paul Gelsinger, *Jesse's Intent: The Story of Jesse Gelsinger as Told by His Father*, available at <http://www.jesse-gelsinger.com/jesses-intent2.html> (last visited Dec. 8, 2012).

42 The second kind of case has attracted particular attention because of the special delegated authority to manage COIs entrusted to both academic institutions and industry trial sponsors, to which we shall return in discussing the regulatory structure. Can institutional committees perform this function responsibly and fairly when, through its financial or intellectual property arms, the institution has invested in the success of the tested technology or its corporate licensee or sponsor? No one really knows the answer to this question or, more precisely, the variables on which an affirmative or negative answer may depend. While there are many scandalous cases of institutions acting on such interests to defeat academic values, there are also many cases in which institutions have exercised bad judgment without financial investments in a sponsor. Thus, there are cases like that of the Hospital for Sick Children in Canada, which hounded Dr. Nancy Olivieri for her release of negative trial data, which a financially close sponsor had sought to suppress. See David Nathan & David Weatherall, *Academic Freedom in Clinical Research*, 347 N. ENG. J. MED. 1368 (2002). On the other hand, there are cases like Oklahoma's suppression of problems with a test melanoma vaccine, in which both the IRB chair and investigators, without such a financial interest, sought to avoid telling participants the truth about adverse effects and directly interfered in procedures. See Mark Barnes & Patrik S. Florencio, *Financial Conflicts of Interest in Human Subjects Research: The Problem of Institutional Conflicts*, 30 J.L. MED. & ETHICS 390 (2002). And surely, there are uncounted cases in which institutional investments are in effect walled off from review committees like IRBs, either through deliberate confidentiality or simply by the entropic force of administrative siloing within complex organizations, which is a daily feature of academic life.

43 For extensive, balanced discussion of cases of research misconduct disassociated from industry relationships, see Susan M. Kuzma, *Criminal Liability for Misconduct in Scientific Research*, 25 U. MICH. J.L. REFORM 357 (1992).

empirical dimensions that have not been explored. Isolated instances of harmful COIs are useful to raise public awareness, but they are neither numerous nor sufficiently diverse enough to ground all COI policy.

What makes the argument for some form of COI regulation compelling is not these isolated cases, but rather reported patterns of association between academic-industry collaboration and industry-favorable outcomes, such as above-average positive results for published industry-sponsored clinical trials compared to government- and non-profit-sponsored trials. In addition, the deeper insight that research is filled with discretionary judgments, which financial interests may conceivably influence, cannot reasonably be ignored. Finally, there is the interesting fact that, while the pharmaceutical industry has demonstrably succeeded in influencing researchers and physicians to some extent, the industry's tools for achieving influence are few and selective.<sup>44</sup> In short, the most interesting fundamental fact is that data indicate an incomplete association, suggesting that further analysis would reveal patterns worth exploring empirically for their differential assessment and remediation.

To address each of these points individually, first, research bias is often subtle. Compare this to discretionary prescribing of approved drugs for off-label uses, in which even small gifts can induce physicians to write these prescriptions, through the generation of good feeling and perhaps an unconscious desire on the part of the physician not to disappoint a pharmaceutical representative. This is not an outright quid pro quo exchange, as those affected are often completely unaware of this influence.<sup>45</sup> Notably, no comparable study exists to assess the impact of COIs on research across a population.

Second, industry has been selective in how it pays for influence. Some of the most egregious examples of bias arise from the arrangements that are most lacking in academic contribution to innovation: speakers' bureaus, in which a hired physician delivers an industry-prepared, pro-product talk for a significant stipend; ghostwritten manuscripts of industry-favorable clinical trial reports or articles in reputable journals to which physicians or scientists attach their name and reputation; studies that are so biased in design they would not pass independent scientific review; and reports of data that misrepresent clinical trial results to such an extent that the real conclusions oppose those that the company wishes to represent as truth.<sup>46</sup> These examples confirm the reality that some such arrangements are negative, while at the same time highlighting the need to distinguish positive from negative collaboration arrangements.

Third, there is extensive literature concerning bias in reporting and publishing data, which demonstrates that industry sponsorship is correlated,

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<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

<sup>46</sup> See, e.g., ANGELL, *supra* note 16; Angell, *supra* note 2; Catherine DeAngelis & Philip Fontanarosa, *Impugning the Integrity of Medical Science*, 299 JAMA 1833, 1834–35 (2008).

albeit incompletely, with positive reported findings and a systematically disproportionate number of proindustry publications. These biases are in part correlated with scientific journals' own financial interests in reprints and advertising.<sup>47</sup> Advocates for industry have argued that this is because industry wisely selects potential drugs and test compounds before commencing costly clinical trials. But studies demonstrate, in some cases, significant industry suppression of data relevant to safety-and-efficacy determinations.<sup>48</sup> Indeed, some sponsors' reports to mandated public trial result registries show, even across small samples, inconsistent data, and data deviations between published reports and registry information from the same sponsors.<sup>49</sup> Finally, apart from industry relationships, overwhelming evidence links scientists' personal stake in invention proceeds to delayed publication and reduced data sharing.<sup>50</sup> But "links" is a soft term, denoting an incomplete association; thus instead of demonstrating that all academic-industry collaborations are venal, this evidence, too, invites us to discover the circumstances in which the association is strong and the circumstances where the association is weak or nonexistent.

The conclusion one ought to draw is not that all academic-industry collaborations should be avoided because all involve a conscious lapse from academic independence. It is, rather, that there are grounds to distinguish among collaborations. Some, like speakers' bureaus and ghostwritten manuscripts, should be prohibited because of their obviously minimal contribution to innovation as weighed against their contribution to bias. Grounds for regulation of others exist to the extent that financial interests may, if improperly structured, operate on any medical researcher, consciously or unconsciously, to short-circuit ethical standards and technical quality, rather than reinforcing these values.

Addressing the moral hazards of these incentives is not an impossible task, but is merely one that is unfamiliar to biomedical researchers and doctors. Compare a familiar, time-tested and ubiquitous example: customers pay construction contractors a certain amount up front, but they make final payment contingent on satisfactory results. In medical research this is an incurable COI. In construction it is not; it is a desirable, routine incentive to drive high-quality results. Of course, research is not construction. But both share a reliance on

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47 See Andreas Lundh et al., *Conflicts of Interest at Medical Journals: The Influence of Industry-Supported Randomised Trials on Journal Impact Factors and Economy: A Cohort Study*, 7 PLOS MED. e1000354 (2010); Editorial, *Increased Responsibility and Transparency in an Era of Increased Visibility*, 7 PLOS MED. e1000364 (2010).

48 See, e.g., Fiona Godlee & Elizabeth Loder, *Missing Clinical Trial Data: Setting the Record Straight*, 341 BRIT. MED. J. c5641 (2010) (editorial introducing a British Medical Journal volume with a cross-section of pieces devoted to this subject); see also Benjamin Djulbegovic et al., *The Uncertainty Principle in Industry-Sponsored Research*, 356 LANCET 635 (2000).

49 Kerry Dwan et al., *Comparison of Protocols and Registry Entries to Published Reports for Randomised Controlled Trials*, 19 COCHRANE DATABASE SYST. REV. 1 (2011).

50 Eric G. Campbell et al., *Data Withholding in Academic Genetics: Data from a National Survey*, 287 JAMA 473 (2002); Taylor, *supra* note 25, at 398–401.

trusted expertise at every stage of an elaborate step-by-step process. They also share standards governing every stage whose primary focus is on how to make professional choices. It is primarily through the internalization of these standards by professionals in the field that they are given force. Violation of these standards can lead to misdeeds and abuse of trust in research, the death of research participants, and in construction, for example, a fire-resistant building that is consumed by flames in an instant. Institutions use externally codified standards and inspections to address the moral hazard of result-dependent payments, and they scrutinize payments that would induce corner cutting. The law provides homeowners with special rights in case a deal with a contractor goes wrong, and it strives to increase transparency in these relationships. This approach should inform our debate about industry-academic COIs in health care, as well.

As noted earlier, there are no data documenting management of COIs, an absence that ought to signal that academic and industry biomedical research has built a regulatory structure without a factual foundation. Yet, already datasets are available that, if correlated, could provide important insights into how the structure of incentives, compensation, and other terms affect whether a particular collaboration reinforces quality standards or undercuts them. COI evidence should lead us to explore the variety of ways in which collaborations may be structured and the richness of terms that may be material—both to actual value in promoting innovation and negative influence on research integrity. Perhaps surprisingly, current literature on COIs fails to describe this existing array. The next Section suggests ways in which this gap may be filled.

#### *D. Context, Terms and Structure: Collaboration Variables Material to COI Regulation*

The argument thus far traces two unreconciled imperatives: that academic scientists and physicians must collaborate with industry and that they must avoid conflicts of interest. Also, I have maintained that value-based arguments condemning all collaboration misread the ethical challenge to collaborate well; moreover, these arguments over-read the COI evidence to proscribe any relationship. So far, indirect evidence adduced for material variation is present when statistical associations for the whole category are less than 100%; direct evidence is manifest in the list of clearly malignant collaborations, like speakers' bureaus, ghostwriting arrangements, and payments for referrals and orders. But it is research agreements and consulting agreements that create the collaborations at the center of academic-industry relationships. This section is therefore devoted to demonstrating how the terms of these agreements affect the discretion that researchers retain and the existence and force of a COI. An overview of the categories of terms that might plausibly influence COIs leads to four hypothetical arrangements. These are designed to yield intuitive answers, but the fact-patterns

in these hypotheticals are composites of documented instances of COIs.

Industry relationships with academic researchers are common, but their details are little known. When the researcher is retained as an “investigator” under FDA regulations, the arrangement is called a “sponsored research agreement” and includes the researcher’s affiliated academic institution. But companies often seek advice from academic researchers through formal scientific advisory boards or in their capacity to serve as subject-matter experts. These arrangements are embodied in consulting agreements. While consulting agreements address many of the same issues as sponsored research agreements, they often do so differently. Sponsored research agreements must include precise descriptions of academic researchers’ responsibilities. However, consulting agreements may be more vague about what is expected of the researcher. Imprecision often raises questions about whether the payments are really for another purpose, such as influencing a physician researcher to prescribe the company’s product or encouraging a researcher involved in company research to report favorable outcomes. Some terms, such as intellectual property ownership and confidentiality, raise special problems where their scope seems to overlap with academic work. Applied literally, these terms may seize that academic work and assign it to industry or “gag” a researcher’s ability to publish results.<sup>51</sup>

It is important to understand at the outset the potential advantages and disadvantages of such arrangements. On the one hand, they are a vehicle both for disinterested expertise to influence corporate judgments and industry researchers to solicit a second opinion on matters with significant corporate financial implications. Indeed, through a payment structure independent of outcomes, consulting agreements may crucially insulate such research judgments from internal financial pressures faced by corporate scientists and executives. Industry and academia often have different perspectives on the significance of discoveries, and each may hold confidential data or rights to materials whose synergistic exchange would benefit knowledge and society. The translation from basic or medical science to industry clinical applications is often a complex one, where the scientific and clinical implications of alternative courses are unclear. The collaboration of researchers with industry is often useful to ensure that sufficient weight is given to noneconomic factors and to avoid costly mistakes, duplicated work, and misjudgments about who may benefit clinically from a discovery. Academic researchers may find that industry relationships help motivate their independent work in two ways: seeing a discovery benefit a patient may provide personal satisfaction, and consulting agreements may allow researchers, who

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51 See Nathan & Weatherall, *supra* note 42, at 1368 (noting that a company’s effort to suppress and punish doctor’s “ethical” publication of negative trial data in violation of a confidentiality provision led to successful pressure on the doctor’s eminent academic hospital employer, the Hospital for Sick Children in Toronto, to terminate her employment and medical staff privileges).

would otherwise seek more profitable careers, to remain in academia.

On the other hand, if consulting income is contingent on researcher actions that otherwise ought to be performed at the discretion of the researcher, or if these payments motivate the researcher to please industry through favorable research outcomes, the researcher's independence might be jeopardized. This could have consequences ranging from bias in how research is conducted or reported, to harms to human participants, through understated risks or trial designs where shortcuts unconsciously skew data in favor of success.<sup>52</sup>

The next question, therefore, is what contractual terms could present challenges to researcher independence through the behavior they incentivize. Consulting agreements reflect many of the same concerns as industry-sponsored research agreements.<sup>53</sup> In this case, however, the spine around which all limbs are arranged is not a research protocol and set of FDA regulations, but rather a contractual definition of "services" the researcher will provide to the company, which, once formally defined, will play out functionally in numerous contract sections. Usually, contracts note that "payment will be for services" and mutual indemnification by the researcher will be for claims "arising from services." These agreements mandate confidentiality related to all information received or created by the researcher that "relates to" or "arises out of" services, and the intellectual property assigned to the company will include any legally protectable materials relating to, or arising from, the researcher's services, as well as all intellectual property that makes use of confidential information.

"Relates to" is a dangerously broad phrase that recurs in these contracts. It implies a topical subject-matter comparison, rather than a causal relation, frequently encompassing the very academic work that has made the researcher of

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52 Under the model common to academic medicine, senior researchers are explicitly mentors for junior researchers. In addition, because of their roles as peer reviewers on NIH grant review committees and advisers on FDA advisory committees, their work and views influence many aspects of industry and academic research, including regulatory decisions by the FDA and EPA; the evaluation of biotech companies and their initiatives; the determination of who among their peers gets funded; and the public perception of science and medicine. If interaction with industry skews a researcher's judgment towards a particular company or approach, the ripple effects can magnify the impact of this influence.

53 Sponsored research agreements are complex, addressing many aspects of regulatory compliance, funding and oversight. *See, e.g.,* INST. OF MED., FORUM ON DRUG DISCOVERY, DEVELOPMENT AND TRANSLATION: TEMPLATE FOR CLINICAL TRIAL AGREEMENTS (2009), *available at* [http://www.iom.edu/~media/Files/Activity%20Files/Research/DrugForum/April27-28/Template\\_CTA%2042209.ashx](http://www.iom.edu/~media/Files/Activity%20Files/Research/DrugForum/April27-28/Template_CTA%2042209.ashx). The set of provisions that will affect academic independence is varied but discrete, including, for example, limits on publication, privately held intellectual property rights in academic discoveries, preservation of a researcher's medical discretion to remove a participant from a study, and payment structure. Suspect payment structures might include incentive payments to recruit fast, special payments for rapid publication, and side payments to staff to foster a sense of priority for that sponsor's studies. Because sponsored research agreements always involve the researcher's academic institution, to which all payments are directed, it is easier for institutions to prevent obvious forms of purchasing influence or priority.



interest to the company as a consultant. At the same time, the duties of assignment, confidentiality, and even indemnification are absolute, regardless of the degree of company contribution of information or ideas to the researcher's discoveries and inventions. Whether the contract involves a 1% contribution by the sponsoring company or a 99% contribution, by the company makes no difference. All discoveries belong to the company, and a little company information makes any discovery confidential and non-publishable, at the company's behest. This combines with the fact that industry services descriptions are nearly always vague and overbroad. If the principal investigator is interested in genetics, all of her NIH-funded research is in genetics, and the collaborating company is a start-up interested in genetics, then services will likely be described as "advising on genetics." A typical researcher is not likely to object to this description, assuming that it will allow him or her greater flexibility.

Consider the breadth of what is legally protectable—copyrights, patents, trade secrets, disclosures capable of being enjoined—and the result is the company proposal in almost all cases. The law prohibits the researcher from publishing academic manuscripts that overlap in topic. The researcher does not own the copyright, and the data may be confidential. The rights in discoveries have been exported from the academy, a world of communitarian scientific values<sup>54</sup> and competing Bayh-Dole incentives,<sup>55</sup> to a company with obligations primarily to its own profitability. This does not mean that companies abandon all discretion and enforce these rights regardless of their costs. To the company, continued academic work (funded by the NIH, not the company) and continued publications favorable to their cause will be useful. But when the stakes are high enough, companies use these rights, and in the short run they often "win." Unfortunately, a company's economic stakes are often directly proportional to the scientific and clinical importance of a discovery. For example, an iron-chelation compound used to mitigate thalassemia and a method for assessing the actual effectiveness of AIDS antiretroviral therapies each became embroiled in such company action.<sup>56</sup>

The exclusivity of an agreement for the researcher might also plausibly affect the existence and strength of a COI. The researcher's financial eggs will all be in one basket, and the negotiating leverage behind the company demands increases if the researcher is barred from comparable opportunities during and after the consulting arrangement. Exclusivity can be achieved indirectly through corporate ownership and control of a researcher's key inventions, or a founder's

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<sup>54</sup> See *supra* note 27 and accompanying text.

<sup>55</sup> See *supra* note 26 and accompanying text.

<sup>56</sup> See *supra* note 53 and accompanying text; see also *Bd. of Tr. of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 131 S. Ct. 2188, 2192 (2011) (holding that Roche's ownership through a private assignment of an academic method to assess AIDS antiretroviral therapies trumps both the Bayh-Dole structure and a university agreement stating that researcher "will assign" any invention made thereafter).

role in a start-up based on the researcher's invention with deferred and contingent vesting of optimally valuable stock options. A more direct method is through a "noncompete" clause. Noncompetes vary in duration, geography, and scope of the prohibition, but may go so far as to bar industry sponsorship of all of the researcher's academic work except by the company. Conversely, multiple consulting relationships will decrease economic concentration, although their overall COI impact will still depend on other factors. Note the counterintuitive result: other things being equal, researchers with more consulting relationships may be more resistant to the blandishments or pressure of any one company.

Finally, to illustrate the imprecision of payment registries, it deserves emphasis that payment terms, not just payment amounts, vary. Compensation can take the form of a one-time transfer, a per diem dispersal, or a more periodic payment schedule. If compensation is in securities, it is likely to be in unregistered founder's or common stock for companies that have not engaged in an initial public offering (IPO) or in options or warrants. The latter are most common if the researcher's role allows participation in a stock ownership plan, but they may be offered either by publicly traded or privately held corporations.

Similarly, the vesting of rights in securities may be directly or indirectly contingent on results of the research. A vesting that depends on enrollment of the first patient in a phase III trial does not explicitly require that data be favorable, but a drug will not get to phase III unless safety and efficacy data from phases I and II are favorable. Contract options create a layered COI, in which the company must have reached a certain form of acknowledged public success, whether through registration and an IPO or through an increase in the publicly traded price above the option purchase price.

This does not mean that securities are all alike and that all security arrangements create greater COIs than cash transfers. If the payment is twice the scientist's annual salary and is paid tomorrow, then the researcher might well prefer it to 30% of a 0.001 cent-per-share company that is ten years or more from an IPO. Or she might not. Even this comparison may be too coarse. If the cash deal comes with noncompetes, and the equity one does not, so that the researcher can consult for seven companies, diversify her risks, and multiply her benefits, which will she prefer? Or, to put the matter differently, which one creates the "greater" COI? To discuss the potential interplay of these terms in life-like transactions, the next section examines four COI cases in some contractual detail.

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#### CASE 1: Amount of Payment

Dr. Researcher is a department chair at a medical school and could easily command a \$100,000 per year fee were he retained as a consultant by a

pharmaceutical corporation. Instead, he has engaged in a consulting agreement to advise a private company on the development of an emergency antidote for adolescent suicidal drug overdoses. For his services, he will receive \$15,000, paid in advance, for two years of service. The agreement waives all equity and additional fees in return for a right of first refusal for his institution, which would allow a junior doctor who he is mentoring to act as principal investigator and conduct the first clinical trial. He sees the antidote as a breakthrough.

Case 1 undermines the concept that a payment registry accurately reflects problematic COIs. It shows that even a large compensation sum, like \$15,000, does not mean that there is a COI that will harm research behavior. Instead, this case is an example of an academic leader significantly discounting his high rate in order to test whether a novel therapy is effective. He is optimizing the benefit of the therapy for the target patients because they are a population to whom he has a long, clear record of commitment. In addition, he properly seeks to mentor a junior clinician scientist. The fact that the compensation is advance-paid means that he will be compensated whether his advice is favorable or challenging to the company. While the possibility of a clinical trial, with attendant revenue, might suggest the presence of an incentive to distort the results in the company's favor going forward, the incentive to engage in a clinical trial that would fail is small. Yet the incentive to engage in a sound clinical trial is probably substantial.

#### CASE 2: Scope of Discretion

Dr. Researcher is a Founder of Progressive Pharma, a pharmaceutical corporation. His \$15,000 per year consulting agreement as chair of Progressive Pharma's scientific advisory board (SAB) gives him a voice to object if Progressive seeks, based solely on business concerns, to terminate trials on several drugs he invented. Further, this money empowers the SAB to allocate 15% of company research funding among understudied diseases. Progressive Pharma, styling itself as "the ethical start-up," made these concessions partly in return for Dr. Researcher's waiver of start-up equity, partly because of the scientific and ethical profile he hopes Progressive Pharma will build, and partly because of the availability of FDA grants for understudied diseases.

Case 2 is an example of how consulting agreements in association with licenses of university-assigned inventions by the scientist might contain terms designed to protect the technology from business choices that, in the scientist's view, would unethically interfere with the process by which an important new technology reaches patients. Companies are loath to give scientists any influence on commercial decisions. Here, the approach succeeded because a traditional scientific function, sitting on a scientific advisory board, became a quality-control function. The scientist's commitment to this is evident in his sacrifice of his equity stake in a company developing a promising invention. Yet a payment

registry likely will not capture these nuances.

### CASE 3: Stock Options and Exclusivity

Dr. Researcher is a groundbreaking translational researcher, recruited at great expense by his academic institution, and fully funded by the government. Peer reviewers consider him among the most celebrated researchers in his field. He enters into a consulting agreement with a start-up pharmaceutical company, Mini-Progressive, for whom he agrees to consult exclusively. The agreement's noncompete bar him from accepting other industry sponsorships for institutional research or collaborating with other companies in his institutional role. His compensation is a series of low dollar-options, which will vest in slowly increasing proportions over a five-year period, with a "bubble" at the end of 50% of the options vesting. Their current value, based on liquidation value of the company after debt repayment, is zero. However, in ten years if Mini-Progressive can keep its research costs low and foster its most promising developments, the options might eventually be worth millions of dollars.

Case 3 could be a truly pernicious example of an academic-industry COI. This scientist has foreclosed not only his own future consulting options, but also his collaborative options with the industry in the course of his academic appointment, for personal gain. Indeed, through not diversifying his own consulting risks, he is now highly and solely invested in the company's success. The company wants to know which research projects to target, information he can likely share, given his expertise and the access the NIH will grant him as a reviewer of others' confidential applications. The company wishes to lower its research costs, which he can do by ensuring that his NIH-funded research is focused on topics that will benefit the company—and perhaps even suggesting that he collaborate with the company in just the sort of translational manner that some current programs might celebrate. The compelling story around that collaboration, and perhaps a management plan of occasional peer review of his pre-submission manuscripts, could allow it to be misunderstood as a public model for the resolution of competing concerns. Worse, the agreement might completely evade registry disclosure based on the cash value of the securities.

Yet peer review of his manuscripts, apart from its own limits, given that reviewers are dependent on manuscript assertions for facts, will never penetrate what could be going on: direction of his NIH-funded research and private transfer of its most novel and interesting results to one company, for its and his own benefit. Peer reviewers cannot expose the researcher's exclusive collaboration with one private partner, rather than more generally with industry for public benefit or the use of not-for-profit, tax-exempt resources for personal gain of a researcher and the for-profit enterprise in which he has investments. In this sense, peer reviewers do not act as a check on the supplanting of knowledge-seeking,

academic goals with profit-seeking applications. The latter are acceptable goals in the private sector, but they are mismatched for government-funded research operating under different rules and premises. Those scenarios are merely possibilities unless confirmed by investigation. Investigation is warranted not by some offensive pre-judgment of the researcher's unvirtue but by a pattern of circumstances: the alignment of terms already contrary to the primacy of academic obligations with personal profit and company leverage, the arrangement's exclusivity, the huge pay-off possible from violations the researcher can make almost impossible to detect, and the gap between modest academic salaries and industry's greater payscales, bonuses and stock packages, despite a common professorial belief that academic qualifications, expertise, and contributions are more significant.

#### CASE 4: Launching a Start-up Company

Dr. Researcher's suggestive papers that a newly identified "power molecule" could dramatically expedite wound healing have attracted the attention of several investors, who approach him about creating a start-up company around his discovery. His consulting agreement includes scientific supervision of the company's validation experiments, as well as being the "scientific voice" to other potential investors concerning the merits of his discovery. Those investors will contribute the cash necessary for the first two years of development, projected to require a high "burn rate." Discussions are amicable, and meetings with the investors go well. Soon, the company asks Dr. Researcher to leave academic work to become the company's Chief Scientific Officer, at a salary three times that of his academic salary and supplemented by stock and options that will, if the company succeeds as projected, be valued at over \$10 million. During these discussions, Dr. Researcher continues his research, which is partly funded by the NIH and partly by the company. From his expanded research funding, he is able to publish increasingly glowing accounts of the function of the "power molecule." He cites the intellectual property and confidentiality provisions of his consulting agreement to justify his refusal to make his reagents available to other scientists interested in replicating his work.

Case 4 has many of the indicators of a successful handoff of an important discovery to industry. In fact, it is what some in industry would feel is their "dream case," in which reagents, inventions, know-how, and personal credibility are all lent to the company. This arrangement is frequently the one that pharmaceutical companies strive to establish, yet it also has danger signals throughout. Marketing is no part of a scientist's special expertise, and the company ought to be seeking independent validation of his claims, rather than putting him in a position where he is expected to invalidate them if required but has every financial reason not to. In short, his actual contributions to innovation

from such consulting (distinguished from the company's interest in acquiring investors) are likely limited and undercut by competing concerns. The combination of interests and exclusivity bear investigation for their effect on research integrity.

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While new industry payment registries available to the public would treat all these cases in a categorical manner, by disclosing only the fact of a financial interest or relationship for whatever negative inference the public would draw, it is important to note that these are in fact very different cases. Equally important are the terms of the parties' agreements and whether the academic research institution employing the researcher is included. The incentive effects that corporate support might create are subject to variable mitigation through both means. If the institution is a direct payee as employer of the scientist, a transfer to the scientist of risk-sharing dollars dependent on research outcomes would be much more toxic than a guaranteed institutional salary arrangement that research revenue simply helps offset. Contrast this to direct payment arrangements, with no institutional intermediation of dollars. But even without a financial arrangement, the institution may still be an important player in addressing COI risks if the researcher has a medical staff or research staff appointment at an academic hospital, a non-employment relationship unique to health law. The appointment implies some oversight and watchfulness by the hospital of the researchers' qualifications and work, and it links the researcher to hospital-based systems for research approval. This could link research incidents and outcomes with a hospital's ongoing, highly detail-observant, legally mandated systems to assess and improve patient safety.<sup>57</sup>

Later, this Article will recommend collection of data on the multiplicity of arrangements and their COI effects. For now, coupling the sources and text from the COI section with the discussion of collaboration arrangements yields the following variables to examine in a multivariate analysis:

1. the precise scope of a researcher's industry services and their necessity in innovative progress;
2. the form, amount, and structure of compensation, including its independence from specific results;

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57 Patrick L. Taylor, *Overseeing Innovative Therapy Without Mistaking It for Research: A Function-Based Model Based on Old Truths, New Capacities, and Lessons from Stem Cells*, 38 J.L. MED. & ETHICS 286 (2010).

3. the degree to which the researcher may deviate from corporate interests (e.g., in publishing negative results or un-enrolling a participant for whom the burdens of participation are severe) without financial or other penalty;
4. the collaborative elements, or their absence, indicative of mutuality and public benefit, including mutual availability of reagents, data and rights;
5. the existence of other researcher motivations, such as the desire to shift employment from academia to industry, the desire to share in product profits, or a longstanding personal commitment to resolving specific diseases or aiding specified patients;
6. the areas of research judgment that the researcher has the discretion to influence, namely, their scope and impact;
7. corrective forces on the exercise of that discretion, such as guidance sufficiently clear to create standards, the role of collaborators without conflicts and their contributions, the strength, independence, and insight of oversight bodies, and the form of institutional involvement, if any;
8. the degree to which the academic scientist's services and inventions are nonexclusive and available to others; the degree to which the scientist herself, in her academic and non-company work, is affected by noncompetes and intellectual property provisions;
9. the degree to which the researcher's results will be confidential, affected by publication clauses, confidentiality provisions, exclusivity terms, and whether there are tacit agreements to funnel academic discoveries solely or first to the company, rather than to prompt publication;
10. the local social context and compliance environment in which the research will occur, and the clarity and force of its shared expectations.

Discerning the variety among collaborations is the key to identifying those that best reconcile genuine contributions to innovation with minimizing bias risk. The Article turns now to the COI regulatory structure, to assess its capacity to perform that task.

## II. THE ADMINISTRATIVE MIRAGE AND THE MYTH OF REGULATION

Industry collaboration is necessary. But due to the varieties of collaboration terms, the likelihood of a COI will vary. This Article now discusses an important question: What is the capacity of administrators under current regulations to distinguish among collaborations, based on their value to innovation and their

bias risk? The answer will sweep wider than the question, for the bases for incapacity will affect far more than the ability to distinguish: it will undercut the legitimacy of the regulations and the soundness of any of their principles.

The regulations do not reflect distinctions among industry arrangements, nor do they equip administrators to make sound judgments about bias risk and how to mitigate it. No comprehensive factual inquiry preceded these regulations, and, according to the Institute of Medicine (IOM),<sup>58</sup> no factual inquiry has been undertaken to assess their effectiveness. Nonetheless, grants and personal property rights can be removed without any due process, under a standard dependent entirely on unavailable facts, with no check on the qualifications or biases of institutional adjudicators to whom the government decision is broadly delegated. There is no required record; no right to counsel; no right to confront witnesses or review adverse evidence; no possibility for any person affected, such as a research subject, to intervene; no whistleblower protection; no requirement for a written decision, let alone a reasoned one; and no right to an appeal, by either an investigator or anyone affected by an actual COI, whether a colleague or a research subject in a trial so affected. The regulations thus omit traditional methods for epistemic soundness (such as qualified and unbiased adjudicators) and self-correction (such as transparent written decisions and possible appeals) that might otherwise have helped make up for the absence of empirical inquiry that ought to precede any legal regulation.

There is no comprehensive regulatory system for addressing COIs in research or even across all federal agencies. For COIs, there are regulations promulgated in 1995 by the NIH, and very similar ones by the National Science Foundation, governing academic recipients of their funds for research. FDA regulations require industry (and other) funders of research, who will be applying for approval to market a drug or device, to collect certain COI information. In addition, while there is no law or regulation that requires Institutional Review Boards (IRBs) to address COIs arising in clinical research, the Office of Human Research Protections has issued guidance on what IRBs might consider, if they choose to look at COIs.<sup>59</sup>

There are also five categories of self-regulation. First, the voluntary accrediting body for human research protection programs requires institutions to maintain COI management systems, with definitions that track the regulatory requirements. But this body does not assess the function or efficacy of such

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58 See IOM REPORT, *supra* note 3, at 4.

59 The latter is well summarized in I. Glenn Cohen, *Administrative Developments: New Human Subject Research Guidelines for IRBs*, 28 J.L. MED. & ETHICS 305 (2000). The primary significance of that guidance is in recommending that IRBs review COIs, including for a set of factors encompassing the range of FDA definitions and a subset of the AAMC ones I shall discuss below. It is an influential, important document. However, for purposes of evaluating its strengths and defects, I will rely on the below discussion of those aspects within their other sources.



systems.<sup>60</sup> Second, the PhRMA Code of 2009, a pharmaceutical industry association code, specifies that consulting should be for an appropriate purpose, compensated reasonably, and reflected in a written agreement that ensures it is for actual services.<sup>61</sup> Third, various professional medical societies have put out specialty-specific suggested guidelines. One example is the investment-prohibitory rules that the American Society for Gene Therapy published in the wake of the death of Jesse Gelsinger.<sup>62</sup> More commonly, rather than prohibiting whole categories of financial interest or relationship, guidelines recite both the importance of physician involvement with industry, and objectivity; exhort good judgment; and suggest that COIs always be disclosed to others such as colleagues, journals, and trainees, as if the issue were solely appearance, and later disclosure could address earlier unconscious bias effects. These guidelines parallel the requirements of journals mandating disclosure, but do not otherwise prohibit COIs or indicate that they have been disclosed to peer reviewers or that they have in any way affected the evaluation of a manuscript.<sup>63</sup> Fourth, a special committee of the Institute of Medicine published a lengthy report in 2009, whose principal objectives were to establish and document the pervasiveness of industry's interrelationship with medicine and medical education and make specific recommendations.<sup>64</sup> The report ultimately articulated important principles for evaluating COI policies, including treating people fairly under transparent policies. Yet distinguishing based on evidence among unlike cases was not an achievement of this report. Fifth, the AAMC, which had elevated local control over other values, sought to bring order to the evident institutional chaos through three major reports and recommendations with respect to clinical research and a data symposium directed to establishing, for once and for all, that COIs can cause bias. However, there are inherent limitations on addressing COI issues without data. The resulting elegant policies were procedural not substantive, did not improve the epistemic competence of COI adjudications by rooting them in a body of established knowledge about differential bias risks, and

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60 Human research protection programs are institutional or corporate systems for participant protection and ethical and scientific review, consisting, for example, of an IRB, investigator training, and scientific review committees. For more information about the accrediting body, the American Association of Human Research Protection Programs (AAHRPP), and its COI requirements, see AAHRPP, [www.aahrpp.org](http://www.aahrpp.org) (last visited Nov. 30, 2012).

61 For a concise and penetrating treatment of the PhRMA Code, in the context of those laws, see Howard L. Dorfman, *The 2009 Revision to the PhRMA Code on Interactions with Healthcare Professionals: Challenges and Opportunities for the Pharmaceutical Industry in the Age of Compliance*, 31 CAMPBELL L. REV. 361 (2009).

62 Am. Soc'y Gene & Cell Therapy, *Policy Statement on Financial Conflict of Interest in Clinical Research* (April 5, 2000), available at [http://www.asgct.org/position\\_statements/conflict\\_of\\_interest.php](http://www.asgct.org/position_statements/conflict_of_interest.php).

63 As a reviewer for several scientific journals, I can attest that I have never been made aware of the COIs of manuscript authors. Some scientific journals require submission of a COI disclosure with the initial manuscript submission, unlike law reviews, which require none.

64 IOM REPORT, *supra* note 3.

translated the complexity of potential arrangements into a single presumption against, rebuttable by compelling necessity. The beneficial cases, Cases 1 and 2, above, would likely be disallowed under that standard, while Case 4, a problematic case, would likely pass through untouched since the researcher's share of licensing revenue would not be considered conflicting, the uniqueness of his knowledge would justify his consulting relationship during the period he remained an academic and, for a simple reason applicable as well to problematic Case 3, the research involved is probably not clinical research.

*A. The NIH Standard*<sup>65</sup>

Since their adoption in 1995, the COI regulations applicable to NIH-funded research as a component of the Public Health Service have been amended only once, on August 25, 2011.<sup>66</sup> The amendments were focused and significant; where applicable, both former and new standards will be noted below. But the amendments did not address the most significant criticisms of the regulations that this Article will make.

The NIH standard for COIs always has been short and deceptively simple in appearance. Its purpose is to “promote[] objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS [Public Health Service] grants or cooperative agreements will be biased by any conflicting financial interest of an Investigator.”<sup>67</sup> It imposes no direct obligations on conflicted investigators, but institutions receiving such funds must have a system under which investigators are required to disclose to officials designated by the institution a listing of “the investigator’s significant financial interests (and those of the investigator’s spouse and dependent children).”<sup>68</sup> The institutional official(s) will review those disclosures and determine whether any of the reported financial interests “could directly and significantly affect the design, conduct, or reporting” of the research.<sup>69</sup> The recent amendments changed the definition of Significant Financial Interests from those that might reasonably appear affected by the research to those related to an investigator’s institutional roles—a much more objective standard, although one which goes far beyond research integrity matters.

If an official determines that a reported interest “could directly and

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<sup>65</sup> See *Objectivity in Research*, 24 NIH GUIDE (July 14, 1995); 42 C.F.R. §§ 50.601-.607 (2011).

<sup>66</sup> Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought and Responsible Prospective Contractors, 76 Fed Reg. 53256 (Aug. 25, 2011).

<sup>67</sup> 42 C.F.R. § 50.601 (2011).

<sup>68</sup> 42 C.F.R. § 50.604 (2011).

<sup>69</sup> *Id.*

significantly affect” the research, the official must report this to the NIH, within sixty days or before funds are expended, and ensure that the institution has taken unspecified measures to manage, reduce, or eliminate the COI.<sup>70</sup> Under the pre-amendment regulations the degree and manner of conflict reduction need not be disclosed, and potential management strategies noted in the regulation are neither mandatory nor exclusive. Through careful drafting, there is not even a conflict to report unless and until an institutional official determines there is one. Reporting is limited to cases of COIs as determined by the institution.<sup>71</sup> From reporting alone, the NIH will not know if an institution is biased towards under-determinations.

Before the October 2011 amendments, the government did not receive notice of the relationship of the interest to the research and the management strategy adopted. There was no requirement that the institution itself assess the adequacy and appropriateness of any of its determinations; now, however, the revised regulations require the institution to perform a retrospective review of cases of noncompliance. The regulations give COI officials and committees significant power over researchers. For example, the regulation states that institutions may limit the investigator’s participation in the research, monitor the investigator, and direct the investigator to divest personal assets (including assets belonging to the spouse or dependent children). The institutional official may direct the institution and investigator to terminate their industry contracts.

Society expects administrative agencies with such power to be restrained and protected by a familiar set of adjudicatory requirements. But this is not the case. Institutional determinations need not be made based on data. Indeed, the word “data” does not appear anywhere in the regulatory mandate itself. No qualifications are specified for the “official(s)” who are institutionally designated to make determinations. Furthermore, there is no protection of the COI official or committee from external or institutional pressure; no protection for third parties, such as concerned employees, from investigator retaliation; and no protected or privileged investigation requirement that the institutional official have access to other data sources within the institution, such as institutional COI reports directed to other purposes, like abuse of management authority or position for personal gain, or databases of noncompliance with IRB human subject protection processes. There is no requirement that the official be unbiased or that the institution identifies and avoids any adjudicatory conflicts of interest it has, such as its interest in grant revenue. The indefinite NIH standard of potential significance need not be translated into any more concrete specifications, whether prospective, as rules restraining unbridled discretion and providing notice to investigators, or retrospective, as “case law,” to explain determinations to investigators and the public.

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70 42 C.F.R. § 50.605 (2011); 42 C.F.R. § 50.604 (2011) (sixty-day mandate).

71 42 C.F.R. § 50.605 (2012).

Typically agencies also labor under requirements that ensure accountability, ranging from creation of a specified record, to an appellate review process. But not here. There is no requirement for a written decision; no requirement for any oral or written record of the proceedings; no investigator right to appeal (although the institution may appeal if the NIH sanctions it for not doing enough); no right to counsel; no required oversight or operational relationship to executive management, the board of trustees or directors or any operating component of the university or hospital; no required advisory board, let alone a board sufficiently inclusive to detect bias, promote legitimacy, give voice to ranging perspectives and approaches, audit the programs' fairness and effectiveness, or require and oversee any aspect of quality improvement.

For this purpose, a "significant financial interest" before the 2011 amendments meant "anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights)." Certain exempted categories include "salary, royalties and other remuneration from [an] institution"; outside payments to the investigator, spouse, and dependent children that are not "expected to" exceed \$10,000 in the subsequent twelve months; and equity interests, similarly aggregated for spouse and dependent children, that are worth less than \$10,000 by "reference to public prices or other fair market value."<sup>72</sup> Therefore, note the following: First, even where proposed research would definitely and dramatically affect the value of an investigator's royalty interests from university licensed technology, the COI is ignored. Second, all equity interests are pooled as if identical in the risks they pose, except that unregistered securities are *sui generis* in not benefitting from the \$10,000 threshold applicable to cash and publicly traded equity. And third, the purpose of the arrangement, and its contractual parameters, are irrelevant from beginning to end. The revised regulations made technical changes in some areas, such as reducing the threshold to \$5,000, but the first and third points remain apt.

Finally, there were actually two different versions of the "Significant Financial Interest" standard to promote objectivity. While the investigator was obligated to disclose personal financial interests that "would reasonably appear to be affected" by the research,<sup>73</sup> the official must tag those "interests that directly and significantly affect the . . . research."<sup>74</sup> One asks whether the interests could be affected; the other asks whether the research could be, and then the difference is spiced up with words like "reasonably," "appear," "significantly," and "directly." The difference between the two standards created worlds of complexity and uncertainty, singly and in their joint (or perhaps separate)

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72 42 C.F.R. § 50.603 (2011).

73 42 C.F.R. § 50.604(c)(1)(i) (2011).

74 42 C.F.R. § 605(a) (2011).

application. For example, it was unclear which standard required a judgment personal to the investigator and whether “significance” should be judged with reference to the investigator as subject, the official as subject, or from the viewpoint of the “reasonable man.” No guidance clarified whether a judgment was to be made abstractly or in light of circumstances, such as the share-price history of a particular company or the relative wealth and wealth-seeking propensities of the investigator.

The regulations left unclear what weight should be given to a mistake of fact that produces a subjective, but ill-founded, COI. For example, an investigator might mistakenly think her research will have no impact and thus feel no incentive to distort her findings—or mistakenly think her work is of pivotal value to the company and thus subjectively feel a temptation to distort the results of her research. It was also unclear how certain the required probability judgments should be. These questions remain under the recent revisions. While the investigator’s standard for disclosure has broadened to a simpler one about the relationship between an interest and institutional roles, the institution’s standard remains inherently probabilistic, with no guidance about whether judgments should be based on generalities or specifics, with what degree of probability, and with what evidence to justify the assessment.

### *B. FDA Regulations*

Since February 1998, the FDA has required anyone who submits a marketing application for a drug, biological, or other medical device to include a statement describing certain “disclosable financial arrangements” of any investigator involved in a clinical trial whose resulting data is submitted in support of a determination of efficacy. The agency has also required disclosure of any trial in which a single investigator makes a significant contribution to a determination of safety.<sup>75</sup> The applicant must have gathered that information before such a trial starts, and periodically thereafter until one year after a trial is complete. “Disclosable financial arrangements”<sup>76</sup> means “compensation made to the investigator in which the value of compensation could be affected by study outcome” or “a proprietary interest in the tested product” (whether the interest is direct or indirect, including, unlike the NIH standard, through a university license). It includes any equity interest in a publicly held company that exceeds \$50,000 in value or in the sponsor of a covered study regardless of value (with all forms of equity lumped together as the NIH regulation does).

While the FDA definitions are crisp and clear, this approach nonetheless has a number of defects. First, it not only fails to address COI issues for all of basic science research, it excludes many clinical trials, including, for example, phase I

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<sup>75</sup> See 21 C.F.R. § 54.2 (2011).

<sup>76</sup> 21 C.F.R. § 54.4(a)(3) (2012).

pharmacokinetic trials and any trial for which the sponsor chooses not to submit data. Indeed, it shares with the NIH approach a delegation of all responsibility to a highly interested judge (in this case, the industry sponsor). Unlike the NIH system, the sponsor must report in more detail both the nature of the COI and the measures taken to mitigate any negative effect on data. But like the NIH system, reported data will not reveal to the FDA whether the sponsor has failed to disclose completely these COIs, and the system conclusively presumes the sponsor, will act without bias. There are neither data nor guidance concerning what management strategies work or which of these situations is really problematic. The remedies of the FDA are also limited: monitoring, requesting further data analysis, soliciting additional studies, or declining to accept study data. The latter penalties certainly are financially consequential to a sponsor. The problem is that it is unknown whether they incent diligence or deceit. Indeed, this regulation, promulgated well before the COI incidents and evidence discussed above, was evidently insufficient to prevent them, and has continued unchanged to this day.

### *C. AAMC Self-Regulatory Efforts*

Finally, I turn to the sequence of AAMC reports discussing COIs. The first of these reports suggested institutional procedures to address investigator COIs in clinical research through newly described COI committees. Rather than implementing the old regulatory standards, it replaced them with a rebuttable presumption against certain interests. The second AAMC report addressed institutional COIs through separation of intellectual property functions from administrative functions, management of the COIs of senior executives, and newly minted institutional COI committees. Finally, in the wake of a report suggesting that institutions had taken little action to create and implement COI policies, the AAMC attempted to address institutions' evident uncertainty in how to apply the presumption with illustrative hypothetical examples. Throughout, the AAMC artfully attempted to couple preserving institutional local control under limited regulations, with an urgent message that institutions should voluntarily adopt uniform model policies. What made the policies "model policies" was less their empirical basis—the AAMC too was forced to act in the absence of data—than the blue ribbon membership and collective prestige of the commissions creating them, and the emphasis on maintaining public trust through stringent academic self-regulation. However, while procedures could point to competing values, they could not answer the very question they posed: Which arrangements are optimal?

### *D. Meaningful Law and Due Process Values*

The NIH regulation is a standard, rather than a rule under Kaplow's

understanding of these terms,<sup>77</sup> meaning a decisional principle for case-specific judgments that are not outcome determined by a specific, less contingent rule. It shifts, from the issuers to those who interpret it and those who are subject to it, the obligation to give a concrete practical answer to the central question whether a particular form of collaboration, interest, or relationship would likely bias research. For interpreters of this standard to apply it meaningfully and consistently, they need sufficient facts to reach rational conclusions in applying its terms.<sup>78</sup> They must understand the forms of collaboration and their effects, together with cultural factors affecting bias and contribution to innovation. Unfortunately, these interpreters do not have such pivotal facts at their disposal. The standard also fails to give them access to general or specific experience of others, and it does not include innovation-oriented values among factors to be weighed or reconciled. Interpreters are broadly empowered to dispose of assets and restrict personal freedom, but there is no appeal within or required by the regulations.<sup>79</sup> And information about the wisdom of the choices that interpreters have made is inaccessible even to the interpreters themselves. No prescribed processes yield facts certain to be material, let alone reasoned conclusions to be tested or incorporated in a body of experience.

Imagine the following hypothetical, illustrating the excessive flexibility of the regulations before the October 2011 amendments: Dr. Researcher owns 10,000 shares of Merck common stock and is also doing NIH-funded research on next-generation Merck orphan drugs. The chairperson of the COI committee, distinguishing small companies from global giants, believes, with some factual basis, that the share price of large companies is affected by so many factors that outcomes of one small-market drug trial will not materially affect it. On this basis, the chairperson determines that the research could not affect the company's value and thus that the value of Dr. Researcher's Merck stock could not be affected by her research. Basing his view on that perspective, the chairperson finds that Dr. Researcher's stock holdings do not create a COI requiring management. Dr. Researcher, however, believes that her ground-breaking work

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77 Louis Kaplow, *Rules Versus Standards: An Economic Analysis*, 42 DUKE L.J. 557 (1992).

78 See *supra* notes 25, 29 and accompanying text.

79 Of course, organizations have hierarchies and chief executive officers to whom one might or might not have recourse. Universities, academic hospitals, and research institutions may have academic or other procedures governing misconduct, and, perhaps informal processes that they may or may not choose to apply, without further guidance, to COI matters. Typically, these do not involve the array of due process rights—such as right to counsel, discovery, and cross-examination—required before permanent deprivation of property, because they are designed around withdrawal of what are generally academic privileges. Proceedings for research misconduct do require a record (though not counsel, discovery, or cross-examination), but they are limited to cases of fraud, plagiarism, and fabrication. The federal COI regulations, however, do not require such procedures. See 42 C.F.R. § 83 (2005). For ORI Policies and Regulations, see DEP'T OF HEALTH AND HUMAN SERVS., OFFICE OF RESEARCH INTEGRITY, <http://ori.hhs.gov> (last visited Dec. 8, 2012).

could affect stock price and has enough shares to find the potential profit interesting. Consciously or unconsciously, she distorts her results favorably to Merck. Yet, as far as the NIH COI regulations are concerned, both Dr. Researcher and the chairperson have complied with the regulations. Under the revised regulations, Dr. Researcher would have to disclose her interest as related to her institutional role. However, the same dichotomous results could occur: the chairperson determines that there is no COI, but the researcher, acting under different beliefs about how trial results affect share price, distorts her results.

With such an open standard, no uniform processes, and no data to appropriately shape discretion, there is no reason to believe that the many NIH-funded academic institutions will reach sound, consistent judgments. Instead, it is a reasonable hypothesis that they are reaching a diversely motivated set of judgments without any data concerning their actual necessity or effect.

That hypothesis has been tested, and it is true. A survey in 2000 of the ten top NIH-funded medical schools showed that “current conflict-of-interest policies at medical schools vary widely and have substantial shortcomings in the context of clinical trials.”<sup>80</sup> Only one medical school approached an ideal of comprehensiveness and avoided arbitrary exceptions. A contemporaneous survey of 304 major research institutions, including 127 medical schools, also found that “there was considerable variation among policies in all domains,” “important terms were not adequately defined,” and that “the only nearly universal feature was that management of conflicts and the penalties for nondisclosure were totally discretionary.”<sup>81</sup> Mandated disclosure to research participants, journals, funders, and colleagues was typically absent. On this basis the authors of this survey made several recommendations: that federal agencies should adopt a common and consistent rule; that institutions should report details of COIs and their management to funders; and that there ought to be complete disclosure to all journals, readers, and review committees such as IRBs. More than a decade has passed since the authors made these recommendations, but they have not yet been incorporated in laws or regulations, except as noted above.

In 2002, an NIH survey of grantee institutions found continuing variation with extraordinary lapses. The survey reported interesting statistics: 86% did not define “research,” 52% did not reference the appropriate regulation, 74% did not commit to making COI information available to the NIH, 45% did not require a conflict to be reported to the NIH, and 68% did not require corrective action to be reported in the event a conflicted investigator had biased the research.<sup>82</sup> A 2007

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80 Bernard Lo et al., *Conflict-of-Interest Policies for Investigators in Clinical Trials*, 343 NEW ENG. J. MED. 1616 (2000).

81 Stephen Van McCrary et al., *A National Survey of Policies on Disclosure of Conflicts of Interest in Biomedical Research*, 343 NEW ENG. J. MED. 1621 (2000).

82 See NAT’L INST. OF HEALTH, TARGETED SITE REVIEWS ON FINANCIAL CONFLICT OF INTEREST OBSERVATIONS (Feb. 15, 2007), available at <http://grants.nih.gov/archive/grants/policy/coi/index.htm>.



Targeted Site Review of funded biomedical research institutions found continuing compliance problems, including defining “investigators” too narrowly, untimely and inadequate reporting, having inconsistent reporting processes, submitting grants before collecting required COI information, expending funds before or without notifying the NIH of COI resolution, and failing to monitor sub-recipients. These are all critical problems.

In 2008, the AAMC published another guide for COI procedures, in the hope of accelerating progress.<sup>83</sup> That report did include model policies and some scenarios to guide consideration of cases. But it could not do what the federal government had not done: assemble or fund the assembly of the data necessary to determine whether a disclosed interest might actually affect research. This critical finding, required by the regulations, is impossible to make except through sheer guesswork or through generalizing one’s own biases in whatever context—whether anti-industry or pro-industry. There is no record except a disclosure, no factual basis for inferring its consequences as to the subject investigator, and both permissive exoneration and prohibitive disposition of the investigator’s assets or grant are equally arbitrary. With the key determinants of a judgment—the projections, experience, and intuitions of diverse members who require no qualifications—outside that limited record, what would or could an appeal even look like, and how could the process be subject to epistemic correction?

The FDA standards are more specific with respect to certain disclosures, but they too fall short. The regulations do not identify the standard by which the significance of disclosed arrangements shall be assessed. The FDA has made itself a black box, depriving investigators and industry of a means of ensuring that they have complied with applicable regulations.

As Professor Sunstein illuminates, there are good reasons that lawmakers sometimes prefer standards to rules, such as where facts sufficient to establish a specific rule are unavailable to issuers, but interpreters will have access to operative facts through the cases they adjudicate or otherwise.<sup>84</sup> Pertinent here, and in defense of the regulatory approach described above, it can sometimes be important that local culture influences both interpretive processes, and, to a degree, specific outcomes. Here, there is no question that a university or research institution’s culture of oversight, the views of its scientific community on potentially private arrangements, the intellectual and financial resources these institutions have to devote to such efforts, as well the prevalence and variety of

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83 AAMC-AAU Advisory Committee on Financial Conflicts of Interest in Human Subject Research, Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subject Research (2008), *available at* <https://services.aamc.org/Publications/index.cfm>.

84 See SUNSTEIN, *supra* note 8, at 149–51 (engaging in a pointed discussion of practical reasons to adopt a standard or case-based approach instead of a rule. The whole volume addresses the issue of rules, standards, and cases, as modes of lawmaking in a broader context, including their tolerance for political compromise as incompletely theorized agreements).

industry relationships, all might make a practical and cultural difference to how COIs are tolerated, ignored, or encouraged. Thus, a rule affecting diverse institutions might be under- or overinclusive and may be perceived as unfair, particularly if data are not used to formulate a sound rule. There might be multiple and diverse criteria affecting an outcome, and how to weigh such criteria might be uncertain a priori, as might the weight given to unpredictable nuances of specific cases. In addition, to the extent that fact-finding is more complete through the case-based observations and actions of many, rather than through the legislated policy generalizations of a few, it may be that the epistemic competence of the COI regulatory system as a whole would be maximized via committees acting rationally under a standard from a basic and evolving core of facts concerning collaboration variation, risks, and outcomes.<sup>85</sup> But even worse than an unsound rule, which has at least consistency to recommend it, is floating a vague standard in a factual vacuum of only partial policy-scope to adjudicators without known epistemic competence. Even worse is to place institutional committees in a system that wholly lacks any method to gather and compare foundational factual assertions, contest its factual conclusions, and learn from its mistakes.

Practically, such a system will produce contested, inconsistent results over a prolonged period amidst mounting questions about its credibility, regardless of the best efforts or good faith of the adjudicators. Conceptually, the flaws of such a system are so fundamental that it is questionable whether it is even law under generally accepted standards of jurisprudence. The flaws of this regulatory system go beyond being “bad law” or “unconstitutional law,” both of which might be given effect until struck down or legislatively altered. It means this

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85 Cf. ADRIAN VERMEULE, *LAW AND THE LIMITS OF REASON* (2009) (analyzing relative epistemic competence of judicial and legislative methods based on numerosity, diversity, timeliness, and potential for information aggregation, among other factors). Vermeule does not apply his analysis to a system where diverse adjudicatory committees, acting in effect like the arms of an administrative agency, operate under a standard. However, for purposes of his analysis, he groups the executive and the legislature together and distinguishes them from courts applying common law methods, leaving for the future how such an analysis might be applied to the regulatory agents of an executive agency. *Id.* This Article does not purport to lay out such an analysis. Among other things, that would make the practical question of how to address COIs in the innovation ecology depend on a branch-versus-branch debate among constitutional scholars, involving many distinct factors, that has no foreseeable definitive conclusion. However, the questions Vermeule asks of constitutional law ought to be asked of any law that purports to provide sound answers to important questions where facts are uncertain and proper policy is contested. Thus this article was conceived from asking about COIs within the innovation ecology these questions, to which existing law had no good answer: How will general and case-specific facts be ascertained and confirmed? How will general factual premises remain timely or evolve with system change? How will information aggregate and what are the epistemically relevant qualities of those who will gather and aggregate it? How will biases be avoided or corrected through the process leading to aggregation of information? Will the regulatory system address facts that support competing values?

regulation was never a successful act of lawmaking in the first place. A review of those jurisprudential standards, their defense, and the debate about their relative merits is outside the scope of this paper, but the standards are sufficiently well known that the discussion is warranted. To sidestep the debate about which is most “right,” I will investigate several that are leading candidates for defining “law.”<sup>86</sup>

The most basic initial test, originating with H.L.A. Hart, is whether there is a “rule of recognition” that distinguishes what is a valid legal obligation, concerning how to structure academic-industry arrangements, from what is not.<sup>87</sup> Ordinarily, promulgation through required administrative procedures would serve this purpose, but not here because each regulation involves an intermediary with incomplete legal authority. Thus, the NIH regulation provides a mandate for institutions to create a system affecting investigators. But from an investigator’s perspective it is unclear whether the institution will have done so in a valid manner. Compliance reports suggest that such institutions do not. In any event, since the regulations do not apply to investigators directly, whether the investigator has any legal obligations is an open question. Similarly, the FDA regulation imposes a rule on investigators to file certain disclosures with the sponsor and an obligation on sponsors to collect and file these disclosures, while imposing no obligation on institutions. The sponsor has no clear direction from the FDA about which arrangements to permit versus which to prohibit or manage. The sponsor has no authority to direct the investigator to do anything to alter arrangements, and neither does the FDA under its own regulations. For COI management and institutions more generally, there is no clear rule. To mandate that a researcher must disclose X—without knowing whether the state will or will not respond to this disclosure, and, if it were to take any action, would not reveal the criteria guiding that decision to act—is to create a rule that cannot be recognized as a law in the sense of “thou shall not X.”

Other less basic standards of jurisprudence would require more. They go beyond Hart’s “rule of recognition” test and demand realistic conformance to certain legal ideals to make a mandate “law.” Thus, they also look to whether there are either definitive rules, or less definitive standards coupled with the data and goal clarity sufficient to guide case law development; adequate, prospective notice of which conduct is permitted and which is proscribed; rational

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86 This analysis is not intended as a commentary on the constitutionality of the federal COI regulations or the constitutionality of any directives issued by universities or hospitals under their authority (such as a directive to investigators to divest personal assets even at a loss in order to participate in research necessary to provide them with required salary support). Apart from the interesting question of whether there is state action by those committees or officials not part of government institutions, an accurate answer would necessarily address the substantive and procedural effects, if any, of institutions’ supplementary academic procedures and policies’ unique wording.

87 HART, *supra* note 8, at 110–16.

promulgation of rules and standards, based on confirmable facts, case outcomes rationally explained by disinterested adjudicators applying a sufficiently clear standard to material facts adequately determined, and consistent predictable outcomes.<sup>88</sup>

The COI regulations do not satisfy even one of these criteria. Of course, some of these are alternative considerations. Law need not simply be rules, and it need not be just cases. But it must at least provide for the sound creation and interpretation of one or the combination, based on factual predicates that not only ground its rationality at inception, but also ground its interpretation. Indeed, if the goal is public trust and legitimacy, and compliance by the regulated, then presumably the presence of the elements above must be visible both to regulated parties and to unregulated public observers. Not so here. In creating both standards without procedures, and omitting data that could ground or inform sound discretion, our existing regulatory systems are not law that manages COI problems—even apart from due process questions, and even apart from the competing framework of the innovation ecology in which scientists practically reside.

Interestingly, this critique of the existing regulations, like the due process observations, is wholly new. Although the regulations have been criticized, it is not on these grounds, but on grounds wholly captured by the virtue and non-virtue polarity. Before I set about discussing how better systems may be built, I will rapidly survey the minimal literature on COIs, both to demonstrate its limits and to see if it that literature can nonetheless help.

### III. LITERATURE: VIRTUOUS ANSWERS TO HALF OF THE PROBLEM

If the real-world problem is to consider COIs and innovation together, the literature provides little direct assistance. Starting with the business literature, there are those who exhort corporations to be good citizens, obey the law, and avoid fraud, whether in general terms or through specified programs in corporate compliance with select mandates. There is also a separate literature on innovation. That innovators' individual integrity or subconscious biases might be affected by incentive structures, and require mitigation through means other than corporate value statements and employee discipline for wrongdoing, does not enter into the business literature's discussion of innovation.

But the business literature does speak, empirically, to a conception of innovation and its requirements that prove instructive for narrowing consulting agreements to where scientists' unique contributions might actually lie and in what context. The business literature is most focused on promoting innovation

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<sup>88</sup> See sources cited *supra* note 8 and accompanying text. Lon Fuller has suggested additional, more stringent threshold criteria and harsher judgment. See Fuller, *supra* note 8. Fuller's other criteria, however, remain disputed.

among corporate employees. Therefore, it naturally addresses how teams, organizational silos, and other commonplaces of the American corporate environment affect innovation. For example, it speaks to allowing innovators to be influential across organizational silos by focusing their contributions on their particular gifts, so that their credibility in different contexts is maintained, and what is particularly valuable in their approaches can be more widely disseminated. Reflecting a backdrop of American business bureaucracy, business literature discusses how one might systemize out-of-the-box thinking and foster teams with complementary expertise that will learn quickly, rather than demanding overbroad contributions from each individual. It recommends incentivizing scientists based on their discoveries rather than the degree to which nonscientific arms of corporations successfully exploit those discoveries. The literature further recommends using individual talent, within its bounds, for corporate goals without harming initiative by freezing it within a bureaucratic matrix more suitable for routine, high-volume tasks.<sup>89</sup>

In contrast, current academic consulting agreements with industry frequently define services broadly, with scientists ostensibly being invited to give advice and perhaps advocate, with potential investors or regulators, for very generally described topics superficially resembling scientists' specific expertise, but including matters outside their typical experience (e.g., such as marketing or patent strategies to avoid competition). Compensation is often contingent, linking payments or options to corporate revenue or new stock issuances supported by development or sales of a new drug or device. Such broad contingencies are outside a scientist's knowledge or control, but generally suggest that the fate of the scientist and the company are intertwined. Each person's financial interest becomes that financial milestone, each person's job, if it is to be compensated, becomes doing what he can to support the same key financial goal. The goal is not just paramount: it is essential.

In fact, the major activity within such relationships may be entirely outside the scope or methods of underlying scientific insights, innovation, or intuition. The latter might well be confined to likely compounds to test and their likely behavior, the needs and vulnerabilities of various research participants given specific diseases or conditions, potential research methods or tools, or other ways scientists contribute unique expertise in interpreting and overcoming scientific roadblocks from knowledge of their field. This dichotomy between the goal of compensating scientists for their actual expertise and the structure of consulting

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<sup>89</sup> See, e.g., Tim Brown, *Design Thinking*, HARV. BUS. REV., June 2008, at 85; Jeffrey Cohn, et al., *Finding and Grooming Breakthrough Innovators*, HARV. BUS. REV., Dec. 2008, at 64; Thomas H. Davenport et al., *Who's Bringing You Hot Ideas and How Are You Responding?*, HARV. BUS. REV., Feb. 2003, at 59; Peter F. Drucker, *The Discipline of Innovation*, HARV. BUS. REV., Aug. 2002, at 95; Amy Edmondson et al., *Speeding Up Team Learning*, HARV. BUS. REV., Oct. 2001, at 125; Jean-Pierre Garnier, *Rebuilding the R&D Engine in Big Pharma*, HARV. BUS. REV., May 2008, at 69.

arrangements should lead us to question whether broad-brush consulting arrangements are as critical to health care innovation as some opponents of COI regulation claim.<sup>90</sup> Nonetheless, scientists can make a core of innovative contributions through engagement with industry, and the fairness of compensating them for those contributions is undeniable. Narrowing consulting services and payment arrangements to that core would help alleviate some COIs.

Probably because of a lack of familiarity with the subject matter, legal academic scholarship has proposed no integrative solution either. Indeed, the legal academic literature on COIs, measured by volume, is surprisingly small.<sup>91</sup>

90 See, in particular, Stossel, *supra* note 29.

91 Although the following, nearly exhaustive, list may seem sizable, for a topic of this import, this is actually a small quantity of legal academic literature. See Mark Barnes & Patrik S. Florencio, *Financial Conflicts of Interest in Human Subjects Research: The Problem of Institutional Conflicts*, 30 J.L. MED. & ETHICS 390 (2002); Cohen, *supra* note 59; Janet L. Dolgin & Joel Weintraub, *Biomedical Research and the Law—Selected Issues: The Pharmaceutical Industry and Its Relationship with Government, Academic, Physicians and Consumers*, 35 HOFSTRA L. REV. 681 (2006); Janet L. Dolgin, *Debating Conflicts: Medicine, Commerce, and Contrasting Ethical Orders*, 35 HOFSTRA L. REV. 705 (2006); Gordon DuVal, *Institutional Conflicts of Interest: Protecting Human Subjects, Scientific Integrity, and Institutional Accountability*, 32 J.L. MED. & ETHICS 613 (2004); Robert Gatter, *Conflicts of Interest in International Human Drug Research and the Insufficiency of International Protections*, 32 AM. J.L. & MED. 351 (2006); Jesse A. Goldner, *Dealing with Conflicts of Interest in Biomedical Research: IRB Oversight as the Next Best Solution to the Abolitionist Approach*, 28 J.L. MED. & ETHICS 379 (2000); Jesse A. Goldner, *Regulating Conflicts of Interest in Research: The Paper Tiger Needs Real Teeth*, 53 ST. LOUIS U. L.J. 1211 (2009); Jennifer A. Henderson & John J. Smith, *Financial Conflict of Interest in Medical Research: Overview and Analysis of Institutional Controls*, 58 FOOD & DRUG L.J. 251 (2003); Marshall B. Kapp, *Drug Companies, Dollars, and the Shaping of American Medical Practice*, 29 S. ILL. U. L.J. 237 (2005); Sheldon Krimsky, *Combating the Funding Effect in Science: What's Beyond Transparency?*, 21 STAN. L. & POL'Y REV. 81 (2010) [hereinafter *Combating the Funding Effect in Science*]; Sheldon Krimsky, *The Funding Effect in Science and its Implications for the Judiciary*, 13 J.L. & POL'Y 43 (2005); Sheldon Krimsky, *The Profit of Scientific Discovery and its Normative Implications*, 75 CHI.-KENT L. REV. 15 (1999); Cinead R. Kubiak, *Conflicting Interests & Conflicting Laws: Re-aligning the Purpose and Practice of Research Ethics Committees*, 30 BROOK. J. INT'L L. 759 (2005); Patricia C. Kuszler, *Conflicts of Interest in Clinical Research: Legal and Ethical Issues: Curing Conflicts of Interest in Clinical Research: Impossible Dreams and Harsh Realities*, 8 WIDENER L. SYMP. J. 115 (2001); Susan M. Kuzma, *Criminal Liability for Misconduct in Scientific Research*, 25 U. MICH. J.L. REFORM 357 (1992); Karen A. Jordan, *Financial Conflicts of Interest in Human Subjects Research: Proposals for a More Effective Regulatory Scheme*, 60 WASH. & LEE L. REV. 15 (2003); Bryan A. Liang & Tim Mackey, *Confronting Conflict: Addressing Institutional Conflicts of Interest in Academic Medical Centers*, 36 AM. J.L. & MED. 136 (2010); Michael J. Malinowski, *Conflicts of Interest in Clinical Research: Legal and Ethical Issues: Institutional Conflicts and Responsibilities in an Age of Academic-Industry Alliances*, 8 WIDENER L. SYMP. J. 47 (2001); Michael J. Malinowski, *Foreword: Academic-Industry Collaborations in the Clinic*, 8 WIDENER L. SYMP. J. ii (2001); Frances H. Miller, *Trusting Doctors: Tricky When It Comes to Clinical Research*, 81 B.U. L. REV. 423 (2001); Pilar N. Ossorio, *Pills, Bills and Shills: Physician-Researcher's Conflicts of Interest*, 8 WIDENER L. SYMP. J. 75 (2001); Erica Rose, *Conflicts of Interest in Clinical Research: Legal and Ethical Issues: Financial Conflicts of Interest: How are We Managing?*, 8 WIDENER L. SYMP. J. 1 (2001); Robert M. Sade, *Dangerous Liaisons? Industry Relations with Health Professionals*, 37 J.L. MED. & ETHICS 398 (2009); William M. Sage, *Relational Duties, Regulatory Duties, and the Widening*

Nearly all of the existing literature expresses outrage at some of the COI cases discussed in Part I, or others. This outrage is not misplaced, but it is partial, leading almost all authors to focus on COIs as a character problem not requiring situational, factual analysis, and separated from the industry collaboration and robust innovation ecology that legal colleagues in other disciplines simultaneously urge. It is as if COIs belong to criminal law, where bad acts lead inevitably to a search for the bad actor.

Finally, if COIs are an ethical problem, then one ought to look for solutions within biomedical ethics. But classic bioethics has had almost nothing to say about COIs, despite its general confidence that medical and scientific ethical problems can be addressed by considering beneficence, respect for persons, justice, and respect for community values. If ethical principles are invoked here, they are different ones: stewardship, transparency, and disinterestedness.<sup>92</sup> A more balanced ethical approach would consider the virtues of industry collaboration, including both the altruistic and intellectual virtues associated with innovation. It would give due consideration to a practical orientation toward results, political collegiality, strategic thinking, credible candor, multidimensional thinking, conciliation, and devotion.<sup>93</sup> These are the same collaborative and activist virtues that bioethicists credit political activism as potentially involving when bioethicists act beyond the Ivory Tower: One could add many other virtues, including courage, ability to articulate and act in accordance with principles when other group members disagree, and public mindedness. Yet bioethics has offered no such full account of industry collaborations involved in COIs or of the range of human responses—good and bad—to industry collaboration and its incentives. The virtuous avoid COIs, the pragmatic manage them without data or adequate regulatory basis, and the conceptual space between COIs and innovation ecology is vacant, involving separate perspectives that never meet except in the dueling expectations visited on scientists themselves.

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*Gap Between Individual Health Law and Collective Health Policy*, 96 GEO. L.J. 497 (2008); William M. Sage, *Some Principles Require Principals: Why Banning "Conflicts of Interest" Won't Solve Incentive Problems In Biomedical Research*, 85 TEX. L. REV. 1413 (2007); Richard R. Sharp & Mark Yarborough, *Currents in Contemporary Ethics: Informed Trust and the Financing of Biomedical Research*, 34 J.L. MED. & ETHICS 460 (2006); Sheila R. Shulman & Andrea Kuettel, *Drug Development and the Public Health Mission: Collaborative Challenges at the FDA, NIH, and Academic Medical Centers*, 53 BUFF. L. REV. 663 (2005); Kevin W. Williams, *Managing Physician Financial Conflicts of Interest in Clinical Trials Conducted in the Private Setting*, 59 FOOD & DRUG L.J. 45 (2004); Lori A. Alvino, Note, *Who's Watching the Watchdogs? Responding to the Erosion of Research Ethics by Enforcing Promises*, 103 COLUM. L. REV. 893 (2003); Joseph B. Clamon, Note, *The Search for a Cure: Combating the Problem of Conflicts of Interest that Currently Plagues Biomedical Research*, 89 IOWA L. REV. 235 (2003).

<sup>92</sup> See, e.g., Krinsky, *Combating the Funding Effect in Science*, *supra* note 90, at 84–92.

<sup>93</sup> Martin Gunderson, *The Virtues of Scholarship and the Virtues of Political Action*, 19 KENNEDY INST. OF ETHICS J. 171 (2009).

Concerning the COI regulations themselves, there are principally three critiques of the regulations from the legal literature: the virtue-prohibitionist critique, the counter-fiduciary critique, and the circumstance-based, “probabilist” critique.

### *A. The Virtue-Prohibitionist Critique*

This critique, the primary response by leaders of organized medicine and most legal scholars who have written on biomedical COIs to COI cases, is that COIs are self-interested choices by scientists that reflect their weakening commitment to the traditional virtues of physicians and scientists, including independence, objectivity, and a single-minded fiduciary responsibility to patients.<sup>94</sup> The consequences of COIs are, in their view, unmanageable, because of the primary harm, which is the corruption of academic independence; objectivity is accomplished by the act of compensated collaboration. Moreover, secondary harms, like harm to participants, are certain to follow once those virtues are compromised. Their arguments are grounded in accounts of values and virtues and would prohibit all compensated collaboration. They claim that public trust requires a complete bar on academic-industry partnerships, because the public could not trust a scientist, physician, or research enterprise known to lack virtue.

There are three problems with this view. First, its account of virtue is historically false. Reimbursement, not just patient welfare, always has mattered with regard to defining such virtues,<sup>95</sup> as does engaging patients in research despite researchers’ conflicting interest in gaining knowledge.<sup>96</sup> Second, it ignores the potential variety of collaborations and the evolving role of scientists and physicians in applying knowledge. Third, it ignores the socially sanctioned competing values of innovation and the innovation ecology.

There are three principal variations on the virtue-prohibitionist approach.

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94 See, e.g., Kassirer & Angell, *supra* note 27 (analyzing the effects of financial conflicts of interest on biomedical research and critiquing the policies used to handle disclosure of such conflicts); see also Brennan, *supra* note 27; DeAngelis, *supra* note 27 (introducing articles addressing the prevalence of conflicts of interest between physicians and companies that financially support teaching and research, along with the effects of this relationship on public trust of physicians); Liang & Mackey, *supra* note 90; cf. Greg Koski, *Research, Regulations, and Responsibility: Confronting the Compliance Myth—A Reaction to Professor Gatter*, 52 EMORY L.J. 403, 408–09 (2003) (arguing that COI regulations are flawed for emphasizing administrative approaches and a culture of compliance rather than promoting a culture of conscience, because good values, not regulations, will provide an answer to COIs and research ethics).

95 See, e.g., STARR, *supra* note 26, at 25–26 (illustrating the connection among professional autonomy, professional ethics, and control of competition and pricing); *id.* at 385–86 (discussing features of physician practice and pricing designed to increase health care costs and increase profit, including reducing the scope of surgeons’ actual service to patients while maintaining full reimbursement).

96 Taylor, *supra* note 57, at 290–91.



The first variation is that responsibility for COI assessment and elimination should be transferred away from universities and hospitals, because their conflicting interests are unavoidable and surpassingly influential. Such assessment is factually outside the scope of the professional expertise and disinterested virtue required to justify the privilege of self-regulation.<sup>97</sup> Ensuring the credibility, knowledge, and disinterest of data-educated interpreters is essential, of course. It is the data-independent, binary good/bad approach and innovation-apart resolution that place this within the virtue-prohibitionist camp.

The second variation is treating human subject regulations and institutional assurances of compliance as creating legal rights and obligations to be enforced civilly by participants or through criminal penalties.<sup>98</sup> The apparent analogy is to antidiscrimination laws or the criminal law, except there are no defenses or affirmative defenses that might reflect some social weighing of competing concerns. (Consider the “No, I was innovating!” defense, for example.) This approach increases the size of the penalty and arguably has justice to commend it. However, it does nothing to address the fundamental question of what to hit, where, how hard, and whether perspicacious use of incentives would improve public policy.

The third version of the virtue approach starts from the same premises, but argues that if virtuous transparency is adopted through disclosure, COIs are adequately addressed.<sup>99</sup> Empirical surveys of research participants and studies of global cultural variation rebut this theoretical claim. Disclosure may produce confusion, and bargaining asymmetries or other factors may lead to embracing or acquiescing in problematic relationships.<sup>100</sup>

### *B. The Counter-Fiduciary Critique*

The Counter-Fiduciary critique, best articulated by William Sage, argues that a fiduciary conceptualization of COIs rests on mistake. Since fiduciaries are essentially agents, and researchers are not agents of participants, relational duties and language should be replaced by socially imposed duties reflecting a utilitarian calculus that accepts some participant harm as the cost of an appropriately balanced emphasis on promoting academic-industry collaboration.<sup>101</sup> In Sage’s view, COI discussion based on professional fidelity to

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97 See, e.g., Jordan, *supra* note 90.

98 See, e.g., Clamon, *supra* note 90.

99 See, e.g., Kuzma, *supra* note 43; Sharp & Yarborough, *supra* note 90.

100 See Timothy Caulfield, *Globalization, Conflicts of Interest and Clinical Research: An Overview of Trends and Issues*, 8 WIDENER L. SYMP. J. 31 (2001); Kuszler, *supra* note 39; see also Christine Grady et al., *The Limits of Disclosure: What Research Subjects Want to Know about Investigator Financial Interests*, 34 J.L. MED. & ETHICS 592 (2006); Mark G. Kuczewski, *Conflict of Interests in Biomedical Research: Beyond Disclosure*, 19 ANNALS HEALTH L. 103 (2010).

101 See Sage, *supra* note 27.

patients misses the reality of the researcher-participant relationship. Sage's position is the most powerful independent critique of the Virtue-Prohibitionist approach. Its difficulty is that, from the perspective of an opposing combatant, it is only as strong as the premise that fiduciary obligations are no more than agency obligations with a fancy name, which is contested both historically and jurisprudentially. In addition, absent data, it may well be premature to assume that supporting innovation will come only at the expense of increased and unmanaged bias in related research.

Far less sophisticated versions of the Counter-Fiduciary critique (typically advanced by researchers with consulting agreements) abound in the biomedical literature. However, they simply repeat in different forms the beneficence of collaboration in generalized terms, without grappling with competing views, articulating the basis for modified discussion, or formalizing an ethical defense.

### *C. The Circumstance-Based, "Probabilist" Critique*

The Circumstance-Based, "Probabilist" critique is a response to, and analysis of, demands that the regulations be interpreted to take into account individual researchers' propensities and scientific reputations in COI management. The leading example, the IOM 2009 report, defines a COI as "a set of circumstances that creates a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest . . . . A COI describes a situation, and is not per se a judgment about the character or actions of an individual."<sup>102</sup> A variation on this approach, deemphasizing a psychological focus on the researcher, looks to the probable effect on others. COIs are not wrong, only their bad effects are problematic where they occur.<sup>103</sup> The probabilist critique claims to avoid individual character determinations by turning to circumstances. It seems to promise objectivity, but it actually does not. The passive voice may conceal it, but one is still left with "risk for whom, me or you or some unknown reasonable man" and "as assessed by whom" and under what standards? Indeed, since the circumstantial categories may end up reflecting on character, the escape from personal character judgments is more apparent than real, unless the categories are gross enough that they only vaguely reflect differential risks. In addition, like virtue criticisms, it looks only at one side of the New Scientist equation, offering no assessment or model for integrating, adapting or optimizing the parameters for collaboration and innovation.

Since coherence with the innovation ecology is not a goal of the COI literature, and debating competing principles rather than investigating convergent facts is its main method, that literature provides neither data nor insight into how to foster both research integrity and innovative translation of discoveries through

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<sup>102</sup> See IOM REPORT, *supra* note 3, at 46.

<sup>103</sup> See, e.g., Kubiak, *supra* note 90; Ossorio, *supra* note 90.

precise adjustments in academic-industry relationships.

Understanding COIs requires richer knowledge of the context of collaborations and contract terms that guide those agreements. First, regardless of enforceability, these terms may represent understandings that have a psychological or behavioral impact. Second, they may be the basis of study, looking towards a fuller understanding of their influence in COI creation and mitigation and their utility or necessity in understanding optimal researcher participation with industry. In this light, the claim that consulting agreements of unspecified services are necessary for drug innovation is clearly overbroad. Conversely, implicit claims in “sunshine-oriented” databases – indicating only dollar amounts paid to researchers by private funders, not the payment purpose or terms of use – are insufficient, misleading and unjust to both researchers and industry. Consulting should neither be demonized nor canonized, but understood and represented in context. Third, if their links to behaviors and their social context are both understood, contract terms may be tools—other than divestment or limitations on research participation—for defining permissible and impermissible situations, particularly if they are considered within understanding the parties’ overall relationships. Indeed, if a scientist’s services are narrowed to providing advice on matters where their advice could support innovation development, with contractual terms eliminating distorting incentive structures and protecting academic values, then institutions will have a mechanism to connect COI analysis to the innovation ecology.

#### IV. RECOMMENDATIONS

The critiques of existing COI regulations are a fundamental starting point for reform. There is no reason to believe that a completely deregulated system will address these critiques, in part because of COIs’ potentially covert nature, and in part because of their extraordinary variability and the extraordinary variability in sophistication and insight among actors. Indeed, the federal government experimented with deregulation before 1995, when pressures to collaborate were fewer, and it did not work. Lack of regulation created the circumstances leading to the current regulations.

Thus, despite their fundamental invalidity as a matter of jurisprudence, and their wide-ranging departure from the established norms of administrative law, current regulations should be improved, not simply abolished. The process to do so should include (1) rectifying procedural defects, using lawyerly values and procedural devices for increasing accountability, case-specific accuracy and systematic epistemic competence; (2) empirical investigation, sufficient for regulation of COIs within the innovation ecology, and informed choices about forms of collaboration that create both significant benefit and significant risk; (3) interim use of default rules that create useful incentives until optimal ones can be created; and (4) creating “how-to” models for collaboration among institutions,

researchers, and industry, so that the efficiency, justice, consistency and rational basis of prospective, published, testable, factually-grounded regulatory guidance would replace unpredictable retrospective adjudications. I will take up each of these topics in turn below.

*A. Fix the COI Regulations Procedurally*

The procedural infirmities identified in Part III should be rectified, in order to respect due process values and to improve the epistemic competence of the system, through qualified interpreters ascertaining facts according to empirically defensible inferences concerning both behavioral responses to incentives and effective management strategies. There are three additional steps the NIH could take:

1. Ensure that regulatory interpreters, functioning as “judges” with extraordinary power, are qualified. Ensure also that COI committees themselves are sufficiently diverse, and organizationally situated, to be recognized as legitimate, knowledgeable, and independent. The regulations permit COI decisions to be made by individuals as diverse as a mid-level research administrator, the university provost personally, or a research hospital’s general counsel. It is obvious that each is likely to approach this open-ended inquiry with different dispositions, understanding, and authority. Specifically, committees should include the following personnel: senior scientists experienced in working with industry and with demonstrated ability to remain independent; legal counsel not involved in industry transactions being evaluated; community membership not limited to business representatives; the IRB chair; the chief academic officer or other officer in a position to regularly compare research endeavors and publications with collaborations; and, as staff to answer questions, but not participate in deliberation, advocacy, or decision making, a senior research administrator; and the head of the office responsible for technology transfer and industry relationships. In a training institution, the committee should include students and fellows.
2. Protect the COI process from institutional COIs. Regulations prohibit an IRB determination that research is unethical from being overturned by administrative decisions from above.<sup>104</sup> Should the same be true for a COI committee, to be committed to its independence? If some institutions are reluctant to accept this, it may be because, internally, arbitrary and unpredictable results may flow from the lack of any regulatory guidance on committee member qualifications, procedures, inferences, management

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104 45 C.F.R. § 46.112 (2011).

strategies, and data. The wise course would be to design a system sufficiently inclusive and rational in its thinking that it both deserves and receives that special, independent authority. The committee and its authority should be sanctioned by a directive of the Board of Directors, and the committee should report to that Board directly, in executive session. The board directive should clarify that the committee will consider requests for reconsideration, but that there is no appeal from its adverse decisions except based on error; and then the appeal is to a committee of the board.

3. Assuring the legitimacy of COI management may require changes in the obligations and goals of institutional technology transfer offices. Various recommendations exist that could be the basis of regulations, including a recently published, comprehensive National Academies Report that deserves careful attention,<sup>105</sup> and a recent Consensus Statement by The Hinxton Group on data and materials sharing in stem cell science.<sup>106</sup> The AAMC and others have urged the separation of intellectual property structures from integrity-related ones, in order to safeguard integrity. This is idealistic but imperfect, for it fails to address the institutional corollary of the innovative virtue of the new scientist. Moreover, the price in practice is technology transfer run amok, unless one thinks that the role of the university is to reduce access to medical care as long as doing so makes money, threaten academic stem cell researchers who might compete, and deceive donors of tissues and funds as long as the price is right.<sup>107</sup> Academic management of intellectual property and its licensing should not be divorced from the obligations of a university to the public, or of a research hospital to present and future patients. One of the great challenges of our time is to get this right, training the vine of idealism on the trellis of reality and practical fact. The issue for the institution is the issue of the profession spelled large: to reconcile competing concerns within a coherent framework.

### *B. Collect Data*

An empirical basis for regulation requires data and the systemic competence to use and revise it. The preceding Section provided a taste of how fine-grained data collection should be, collecting information about contractual variables from

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105 NAT'L RESEARCH COUNCIL OF THE NAT'L ACADS., *MANAGING UNIVERSITY INTELLECTUAL PROPERTY IN THE PUBLIC INTEREST* (2010), available at [http://www.nap.edu/catalog.php?record\\_id=13001](http://www.nap.edu/catalog.php?record_id=13001).

106 *Statement on Policies and Practices Governing Data and Materials Sharing and Intellectual Property in Stem Cell Science*, THE HINXTON GROUP (Feb. 8, 2011), available at [http://www.hinxtongroup.org/Consensus\\_HG10\\_FINAL.pdf](http://www.hinxtongroup.org/Consensus_HG10_FINAL.pdf).

107 See *Greenberg v. Miami Children's Hosp. Research Inst.*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003); Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3 (2003); Taylor, *supra* note 25.

result-dependent compensation structures to noncompetes. My goal in this Section is to move the discussion forward one more step, both by (1) describing the parameters of a system that would effectively generate inquiry and employ its answers and by (2) giving some examples of how data might help guide policy choices through verifying or falsifying their assumptions or premises. The following Sections will then (3) suggest interim default rules to use until data justify better ones and (4) outline steps towards the creation of constructive “how to” models to replace, at least in part, the retrospective and necessarily arbitrary structure that is in place now.

Before setting out what may appear as an ambitious agenda, it is useful to demonstrate that data are readily within reach. As the IOM observed, there are no data on effective management of COIs.<sup>108</sup> As this Article has reiterated, there are no public data supporting the judgments that COI committees are routinely asked to make, or analyzing the COI effects or innovation contributions of quite various collaboration arrangements. But what the government and academic institutions do have are datasets that, if correlated, could provide important answers to whether, as in other areas of law, the way incentives, compensation, and other terms are structured affects whether they reinforce quality standards or undercut them. What is missing is the effort and infrastructure to correlate these variables. Academic IRBs have isolated adverse event data from clinical trials, not presently evaluable against financial interest information. The federal government has data on research misconduct, arising from the Office of Research Integrity’s oversight of academic proceedings for scientific fraud and plagiarism, but these data are not publicly cross-linked or searchable for whether financial interests or financial relationships of various forms are differentially associated with misconduct. State and federal health departments, hospitals, and health-product consumers all have access to safety information, though this is also not cross-linked or searchable against research participation or financial interests. Yet all of these sources, and others outlined in the recommendations of this Article, provide a basis for optimism. Problems with financial interests and relationships could be linked in more interesting ways, if data sets are parsed. If not all relationships cause problems, but some do, and if only some really promote innovation, regulations could be promulgated accordingly. The data to determine this are already partly created. COI management could be reserved for those that are socially useful and regulations could prohibit those that are not as socially useful, or at least require institutions to internalize to scientists their management costs.

### *1. Creating a Networked System for Collection and Use of Data*

Situating COIs in the innovation ecology will require a networked system of

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<sup>108</sup> See IOM REPORT, *supra* note 3.

data collection. This data collection should occur longitudinally through time, yet should be comparable and searchable across cases for correlations among key variables relating to incentives, behaviors, misconduct, and management. If decisions are to be made locally, then data must be collected locally, shared, aggregated, and analyzed nationally. It also must be made available, with analytic results, both locally and nationally, publicly and academically.

Data must be maintained in a manner that permits new premises and hypotheses to be tested, trends to be noted, and conclusions to be shared and examined. Data should encompass and link outcomes such as harms to participants, misconduct allegations and determinations, protocol deviations, results that cannot be replicated, and withdrawn publications. Those and other harms should be assessed for their degree of correlation with key variables, such as incentives and their structures; industries, since industries seem to vary in their COI and misconduct susceptibility; and the others used in current population studies referred to above. Studies that would examine the linkages described above are currently impossible, not because informatics tools are lacking, but rather because there is no recorded data. Or if these data exist, they are not linked or shared. Yet this sort of study, involving other variables, is now very possible in most other areas of medicine and biotechnology. The informatics tools exist and are in widespread use.

In collecting data, creating standards, formulating rules, and evaluating impact, it would be beneficial to examine contract terms in determining whether an academic-industry relationship is positive or negative and whether its consequences are probable or improbable. So-called sunshine public databases that purport to justify an inference of wrongdoing based only on dollar values should become more sophisticated, rather than more unjust. A \$3.00 “payment” of unregistered securities can be far worse than a \$20,000 payment for consulting. Registries should be improved through additional data fields, so that the public and regulators alike can distinguish toxic and dangerous relationships from praiseworthy and innovation-producing ones.

In this regard, relevant and correct data categories must be assessed and separated from those policy-driving factual categories that are not demonstrably consequential. Above, for example, I rejected the principle that COIs from securities are always worse than COIs from cash because contracts and context make a pivotal difference. Yet that overbroad principle is widespread, and the NIH’s zero-dollar threshold for unregistered securities reflects precisely this. Presumably it is based on the view that securities can inflate in value (while cash cannot) and an identifiable cognitive transposition error: since lawyers call options, warrants, privately held stocks, and publicly traded stocks all “securities,” this term should be defined in precisely the same way in COI policy. But in this context, the definition should optimally depend on clusters of like behavioral effects.

It is necessary to examine the effect of the network of obligations that surround a scientist. The current regulations, which do not do this, presume that the significance and effect of interests can be assessed in isolation. To the contrary, the network of obligations both shapes the actual impact of agreements and provides a tool to mitigate their effect. A sponsored research agreement that prohibits sidebar agreements or requires that consulting revenues be assigned to a general departmental research fund immediately mitigates or prevents COIs. A sponsor's per-participant research payments can create a COI if paid to a principal investigator, but not if pooled with other studies' payments, and distributions are made, regardless of the incentives, for charitable purposes. NIH, IOM, and AAMC recommendations miss these important tools.

Continuing our network concept, COI management should be linked to the network of other existing systems that could support the identification and management of COIs, to improve participant protection and to correct our current reliance on self-reporting of adverse events by financially interested researchers—the very matter criticized in the Gelsinger case,<sup>109</sup> which still, ten years later, remains uncorrected by mandated system improvements. Legally mandated systems devoted to patient safety, which can be as fine grained as reporting on the EKG and CO2 levels of a patient every few seconds, should be enlisted to support the safety of research participants. This would be more beneficial than, for example, insulating from the clinical team all knowledge of their patient's participation in a research study that would allow them to distinguish clinical trial expected side effects from unexpected and troubling morbidities requiring naive exploration at the expense of patients' time, energy, and suffering.

## 2. *Using These Data*

Science and data cannot dictate directly which conflicts of interest to tolerate and what balance of innovation and bias to tolerate. This involves inescapably normative decisions that ought to be publicly transparent and publicly influenced. As Robin Feldman has argued, legal importation of scientific standards, under the false assumption that data themselves will establish decisional norms, inevitably oversimplifies complex factual questions and conceals complex normative ones.<sup>110</sup> It is as mistaken as using virtue narratives, without empirical roots, to make COI policy.

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109 See *supra* note 41 and accompanying text.

110 ROBIN FELDMAN, *THE ROLE OF SCIENCE IN LAW* 49–78 (2009) (providing examples where the transfer of scientific results or principles to justify reasoning or create rules misstated the scientific evidence or founded normative rules on fragile empirical foundations); *id.* at 200 (“[R]elying on science creates the illusion of reasonable resolution [and] masks our failure to resolve the issues at hand or to take responsibility for the decisions we have made. We gain authority through obscurity rather than the careful unfolding of legal analysis.”).



Data can and should be used to confirm or falsify the assumptions used in policy-making. As examples, I shall start with the easy (and unlikely) outliers. If every form of consulting arrangement and every Bayh-Dole payment always produces substantial uncontrollable bias or corruption, Bayh-Dole should be altered, and consulting, barred. It will have been demonstrated that they uncontrollably harm research, and it will be equally evident—since development depends on accurate research results—that biased results do a disservice to innovation development. In that event, the aims and preconditions for research integrity and robust innovation would be one and the same, so current conflicting imperatives would be replaced by a more consistent one: protect the innovation ecology, research objectivity, and human research participants by eliminating all forms of compensated academic-industry advising. The link would also be established by the contrary, equally unlikely finding that no consulting arrangements or Bayh-Dole licenses harmed research objectivity or participants and that in all cases, regardless of the nature and scope of services, they benefitted innovation development.

More realistically, in order to demonstrate how powerful and worthwhile data collection could be, let us consider the following example in which hypothetical data concerning the differential positive effects of contractual noncompetes and unregistered equity might support a currently counterintuitive policy outcome:

A scientist's area of expertise is in a certain biological factor, found in human blood, believed to play multiple roles in red blood cell metabolism. Through continuing NIH-funded research, he discovers that a particular enzyme enhances the metabolic effect of the factor and hypothesizes that the enzyme could be used to alleviate certain anemias. The university files a method patent claiming use of this enzyme as a therapy for this purpose and licenses it to a start-up. Consulting by the scientist is limited to addressing side effects given the factor's other multiple roles, and, non-exclusively, other enzymes that might also increase the factor activity. Noncompetes are barred, but company confidential information will be strictly protected. The company has no claims to his future inventions, except the nonexclusive one noted. In this case, his research is intimately related to the company's application — in fact there is no possible separation. But his independent academic research goal, finding other enzymes that enhance this one, is consistent with both societal therapeutic goals and company goals. The danger that he will siphon off novel information to the company, which may suppress competition, is plausible, but given the bar on noncompetes, and the potential to engage with another company

around other factors, so is the opposite. He is allowed to hold unregistered equity in the company, with no further options or deferred vesting, provided processes can ensure that his novel information is really nonexclusively provided and is generally published through the scientific media. So put, with the burden of doing so on him, he has an incentive to help design and maintain a sufficiently transparent system. Failing that, his privilege to hold equity will be revoked. Data show that holding unregistered equity without further result-dependent options or vesting is actually harmless, because its ultimate sale will occur only after a long process of multiple independent valuations of the technology. Scientists know this and the remoteness and hypothetical nature of the benefit produce negligible bias incentives compared to their academic and personal incentives to do innovative, replicable, sound science.

To Virtue-Prohibitionists, and even to COI-moderates, the example above is provocative, given their belief that equity is always evil.<sup>111</sup> This example challenges a reflex to deny equity and involvement by the scientist in a project squarely within his academic research, as well as an opposing reflex in industry to turn him into a jack-of-all-trades scientific salesman with potential investors. The scientist's role is really quite precise: do your academic work, continue to publish it nonexclusively, and, if in the development of this there are insights that would protect patients from side-effects, or boost the therapeutic value, tell the company. The scientist takes a part, as Bayh-Dole demands, of the value of the original invention, and remains aligned to see that it works in practice. At the same time, no commitment is made to this company that it will be the only one, and if he generates more discoveries, other companies will be interested in competing for his attentions. He is in a position of having to maintain confidentiality among companies, something that lawyers have become accustomed to without difficulty, as have doctors with patients.

For our second example, let us suppose that data show that institutionally managed service arrangements can effectively mitigate bias influences that would otherwise arise under certain consulting arrangements:

A scientist, who is an expert in genomic informatics analysis, is approached by a large company that wants her to adapt her already powerful analytic software tools to a "new generation" of DNA sequencers that look beyond single nucleotide polymorphisms (SNPs) and exomes. The key challenge in DNA

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<sup>111</sup> See, e.g., Angell, *supra* note 2.

sequencing is determining which elements and associations are meaningful, how meaningful they are, and which are recurring, but accidental. Hybridizing the company's premier sequencing capabilities with the next stage in her informatics platform is exciting to her, and, if it works, worthwhile, given the new window into understanding genes in operation. The company wants to engage her exclusively to consult and to own her output, which would be funded in part by NIH grants already awarded for the same work. They would offer her \$150,000 per year.

Given what data show and the normative appreciation for the social importance of the work, the agreement is converted into a service agreement between the university and the company. Improvements to the platform that are not unique to the company's technology will be owned by the university and made available open source. Unique improvements that co-depend on company technology and would therefore reveal trade secrets are co-owned, but the university's uses are limited to internal research. And the collaboration is mutual, not unilateral, in that the company agrees to make its advanced sequencing services available at discount for a well-publicized effort to address certain pediatric orphan diseases. Publication is joint with respect to materials that are not trade secrets. She receives \$150,000 per year: half personally as salary support with an increment, and half, by her choice, paid directly to a research fund for her at the university. She intends to use these funds in the event that her NIH funding dries up.

This example is also deliberately provocative. Yet, I submit it is possible that it may be eminently sensible in promoting industry innovation at the same time it co-funds NIH-funded scientific advances for the public good that are made available in an open-source format. Based on a combination of real examples negotiated by the author, it takes seriously the idea that even where originally misaligned, company and academic goals can become realigned in a way faithful to academic values and the purposes of federal funding. This case is better than the first one, because the company is playing an active reciprocal role. The scientist's contribution to innovation is real and direct. The company's contribution to co-funding, with the federal government, improvements to technology that will become publicly available also is tangible and direct. The generation of applications for the private sector, sought by Bayh-Dole, is direct. The benefit to the public from open source improvements is direct. And yet, if

one had posed the question of whether the doctor can take \$150,000 per year from a company to do consulting work in the area of her funded research, the conventional COI answer would have been “absolutely not.”

### *C. Default Rules*

A comprehensive regulatory framework cannot be adopted until more data collection occurs. In the interim, however, some basic default rules can guide policy implementation and practice:

1. Prohibit deferred vesting, noncompetes, result-dependent transfers of unrestricted publicly traded equity, publication restrictions except for trade secrets, terminations without cause, company sole ownership of academically overlapping IP, and service definitions not tied to the original innovation or that aspect of development within contributory expertise.
2. Require collaborative improvement licenses or co-ownership by academic institutions for internal research, and ensure, at the least, nonexclusive availability of academic improvements subject to company trade secrets and distinct company patent rights.
3. Convert direct payments into institutionally managed payments provided that no institutional COIs are created in the process. This would require taking action to assure the independence of institutional review processes.

Our default rules should incentivize issuers, interpreters, and subjects of contractual agreements to act appropriately. Interpreters, for example, might be incentivized to develop pertinent databases and quality improvement program-based approaches by inflicting the severer sort of prohibition. In effect, this takes the AAMC presumption and kicks it up one notch, from the individual to the organization interpreter, and up two notches in the case of the funder or regulator as issuer. Harsher rules are likely to incentivize the faculty to participate in such efforts in data collection to support some other, perhaps local, rule, although, given what is at stake, the biases inherent in their impulse would also have to be controlled for. A funder’s default rule could be prohibitory, or it could possibly be disclosure oriented, to require scientists to self-identify to peer reviewers their form and degree of industry involvement (including purpose, role, and contract commitments). The goal would be for NIH to develop and fund research programs and databases devoted to resolving the fundamental issues.

Our default rules should also internalize to researchers and companies the costs of assessing and managing self-serving and socially ambiguous COIs by imposing a financial assessment on researchers engaged in such COI-generating activities. In its ideal state, this would distinguish between researchers based on a

behaviorally validated function, differentially cost-shifting arrangements that deviate from a socially ideal mixture of functions that optimize ethical and efficient development of safe and effective diagnostics while minimizing bias. It seems unlikely that there is a single point at which all values are maximized, while biases are minimized. Yet the thought that utility maximization, with or without de-consequentialist parameters, may be more complex than X, Y, and an asymptote, or a straight inclined line within a region of zero risk, has not defeated utilitarianism yet. Indeed, competing functions may disparately weigh many variables. But whether the justification is as theoretical as internalizing costs, as pragmatic as disincentivizing COI complexities, or as practical as funding the management process so it can actually occur, there seems little to be said in favor of allowing the present COI management system to continue – allowing scientists to free-ride on other systems to pursue private benefit, if it is socially undesirable and solely self-serving.

#### *D. Move from Retrospective COI Determinations to “How To” Models*

COI management currently involves retrospective, nontransparent administration under a vague standard. Voluntary compliance is difficult. The value of data-informed transactional safe harbors, or “here is how to do it right” models, is obvious. Describing such models means rethinking the boundaries of researchers’ and doctors’ professional virtues. This is an exercise long overdue. Some fear that doing so will require abandoning professional virtue. Let us address this important concern through an example from health care professionalism itself.

Fifteen years ago, in the heights of managed care, the great conflict-of-interest issue was the antagonism perceived between cost containment and a fiduciary obligation to individual patients to provide optimum care. It was in such terms that the issue came to the Supreme Court. A patient’s appendix ruptured, due to a belated referral to an in-network provider incentivized by a physician payment structure in a physician-owned HMO.<sup>112</sup> The Court was asked whether, in the ERISA context in which the case arose, the physician had a fiduciary duty to the patient. The Supreme Court answered in the negative, issuing a binary decision in a complex area. This was a pyrrhic victory for managed care, because it spelled the beginning of a series of legislative reversals in almost every state around the country that ultimately destroyed managed care.

Drawing the connection between the death of managed care and professional self-definition, Einer Elhauge predicted that, for care cost to be addressed, physicians would have to redefine their fiduciary focus from the individual to the group—an idea that no doubt seemed wholly demonic from the perspective of

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<sup>112</sup> Pegram v. Herdrich, 530 U.S. 211 (2000).

physician leaders.<sup>113</sup> Yet, I would submit that this is exactly what has occurred, and in a manner that has enhanced, not undermined, the virtue of the profession.

The route was through the concurrent development of evidence-based medicine and safety systems, linked with concerns about undertreatment, overtreatment, and mistreatment. It is only a small step to move from those concerns to defining overtreatment as treatment with diminishing marginal benefits and increasing individual patient harms across a population. It is another small step to create treatment protocols, based on the population, that will typify proper treatment in similar terms. It is only one more small step to broaden the concept of marginal benefit and marginal cost to take into account the allocation and optimal investment, from a care perspective, of limited physician, nursing, and other professional resources in a context of diminishing benefit. Given that labor costs drive the bulk of hospital and physician bills, such a concept implies a virtuous “group” model. The virtue of physicians is no longer measured just by an intention towards an individual patient. It is measured by the physician’s devotion, judgment, and skill in relationship to a clinical treatment ideal, the ability to weigh competing concerns, and the ability to make exceptions when clinically appropriate in relationship to outcomes: in short, the ability to act justly – to treat like cases as like and different cases differently, where there is a special justification. Justice and treatment based on knowledge sound like virtues. Fulfilling Elhauge’s prediction did not require abandoning virtue. It required an interlinked maturation of how the profession conceived itself and the systems that would allow it to act consistently with that definition. With that maturation it became possible to design incentives and care structures that promoted appropriate utilization as an aspect of patient care.

Here, data are needed to establish when collaborations are useful, and what collaboration structures should be avoided or followed. There are plausible candidates already. Institutional collection, pooling, and redistribution of consulting revenue in connection with technical advisory services, all mediate incentives and focus contributions. The default rules, if vindicated empirically, suggest others.

## V. CONCLUSION

Industry and academic biomedical research draw continuously closer, as inevitable partners in creating the practical fruits of scientific discovery. If industry relies on academia for new insights, academia relies on industry to

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113 See Einer R. Elhauge, *Can Health Law Become a Coherent Field of Law?*, 41 WAKE FOREST L. REV. 365, 387 (2006). Professor Elhauge’s prediction was made in the context of two important observations: that the law supports systems of payment and care that not only compete but mutually detract; and that professional and public morality have had an extraordinary influence on the chosen paradigms. *Id.* at 379–84. His views on the causes of mutual incoherence, as well as the professional challenges they create, are applicable in this context as well.

demonstrate the practical value of basic science to a public that requires more than knowledge for knowledge's sake. Fear of research bias, or its appearance from industry contact, has been a preoccupation of academic medicine, its funding agencies, and its political arms. Reputable journals decry highly paid relationships with industry as "typical," implying that all public advice and academic research have become untrustworthy.<sup>114</sup> Yet such conflict has been addressed without collecting data as to whether, how, and when it occurs or assessing the actual benefit of different forms of industry collaboration, or offering precise guidance reflecting those facts.

The regulatory structures created in consequence are loose and weak. Agencies are divided among several government entities and hundreds of research universities and research hospitals—all operating under unarticulated or inconsistent standards, created with limited or no data concerning their necessity or effect, and many without processes to control the institutional conflicts of interests that could demonstrably affect their reliability and bias. So piecemeal and inconsistent is the legal structure, so diversely rationalized, and so premature compared to datasets, that a student of law might well ask whether the structure is law and what makes it so. It is law in only the barest of senses. There is a basic mandate to do X. And if X is not done, the issuer will do something predictably bad. Except that not even that has happened; the NIH did not enforce these regulations, even when the system repeatedly failed over the course of many years.

This aerial sense of law rightly has been replaced by a more sophisticated

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114 See, e.g., Charles Seife, *How Drug Company Money is Undermining Science*, SCI. AM. (Nov. 21, 2012), available at <http://www.scientificamerican.com/article.cfm?id=how-drug-company-money-undermining-science>. Although he observed that "such relationships are not all bad," Seife does not identify or establish that any are actually beneficial. Instead he describes as "typical" (1) known cases in which senior government advisors on drug or device approval have simultaneously maintained highly compensated advisory relationships with industry; (2) extreme practices, such as companies "ghost writing" publications describing research results that are signed by academic researchers who had little involvement, but accepted both fees and attribution; and (3) critics' claims that the NIH is doing little to police such situations. Seife asserts that only a change in research culture can restore trustworthiness to science. This Article, however, disputes the assertion that such arrangements are typical of all scientists and collaboration arrangements, and the conclusion that cultural segregation is the only (or even a complete) solution. As I have shown, collaboration arrangements are far more varied, and the arrangements to which Seife refers are neither representative nor ubiquitous. The small number of senior advisers to both pharma and government, who have met the substantive and political selection criteria each imposes, are hardly representative of the thousands of relatively unknown academic scientists whose primary work is in laboratories in research universities. The disgraceful practice of ghost writing is limited to some companies and faculty. Institutional and professional culture are important, but Seife fails to mention the ways in which they have been fostered by the NIH and the HHS Office of Research Integrity (ORI), nor does he reconcile it with our innovative ecology. See, e.g., Brian C. Martinson et al., *Scientists behaving badly*, 435 NATURE 737 (2005); Brian C. Martinson et al., *Scientists' Perceptions of Organizational Justice and Self-Reported Misbehaviors*, 1 J. EMPIR. RES. ON HUM. RES. ETHICS 51 (2006); 42 C.F.R. § 93.300(c); and 45 C.F.R. §§ 689.1-10 (2002).

one that seeks (1) an interplay of law and facts – a connection between the issuer's objectives and the interpreter's methods based on facts reasonably known to be material, both to predictable resolution of foreseen problems and to wise resolution of unforeseen ones; and (2) an assessment of the rationality against multiple perspectives, including the perspectives not just of issuer and interpreter, but those subject to regulation, and those observing, and sees how a law is understood and thus made real, not once, but over time, again and again and again, as it travels through society. The COI problem therefore teaches a general lesson about the dangers in the law-making domain of even the highest virtue when it is separated from the interrelationship of law and fact. Those who ride under the banners of virtue and public trust and seek to make law their mount must bend to the demands that lawmaking places on all of us, including the truthfulness of their empirical premises, the rationality and empirical testability of their solutions, the values that law translates into paradigm and practice, and the transparency and acceptability—and therefore authority—of a proposed resolution.

The solution proposed by this Article is simple yet radical: to recognize our mistake and to correct it with an epistemically competent system operating from ascertained and pertinent facts. This will require critical novel features: a set of common and clear norms rationally derived from data and evidence, representative of both innovation and research integrity; competent and qualified agencies that will consistently teach and enforce them; and mechanisms for sharing and aggregating information, self-assessment, accountability, and evolution.

The point is not that morals should be abandoned. Rather, it is that the temptations of a facile hypocrisy incentivizing collaboration with one hand, while punishing with another, should be relinquished. What is at stake is more than whether researchers are forced into the discomforts of eternal cognitive dissonance. It is whether the social compact that underlies the sanctioned pursuit of knowledge will hold. The Virtue-Prohibitionists have this right: to the extent that scientists are perceived as trading integrity for personal wealth, the lay society will respond accordingly. Our current scheme for biomedical research is a powerful recipe for destroying public trust, since internal conflicts make failure inevitable. Neither knowledge nor democratic influence over scientific direction will benefit from one-sided, incomplete renditions of COIs in the innovation ecology.

A fuller discussion of the variety of collaboration arrangements—both the net of contracting parties in a research-related relationship and the diversity of contractual terms—is beyond the scope of this article. But such detail is not necessary to understand the basic frame of the argument or recommendations. Resolving these tensions ethically, practically, and effectively is one of the major challenges of our time. It will take a practical, fair, data-grounded, but still



principled, approach. This will not arise through disintegrated policy that dispenses with precision about the drivers and checks on human fallibility, and the true contributions of academic knowledge.

# Are Independent Pharmacies in Need of Special Care? An Argument Against an Antitrust Exemption for Collective Negotiations of Pharmacists

Danielle Beth Rosenthal\*

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## INTRODUCTION

The last half-century has witnessed a dramatic rise in both health care spending and associated efforts to rein in costs.<sup>1</sup> As these factors and others coalesced, the “managed care revolution” was born.<sup>2</sup> In the last several decades, health maintenance organizations (HMOs) — along with other managed care organizations (MCOs), such as preferred provider organizations (PPOs), point of service (POS) plans, and managed indemnity plans — have attempted to balance patients’ quality of care against steadily rising health care costs.<sup>3</sup> Although insurers greatly have improved access to care, they have faced sharp criticism from health care providers. Physicians and pharmacists, in particular, have accused insurers of using their unbridled market power to threaten providers’ decision-making autonomy, endanger their livelihoods, and reduce the quality of patient care.<sup>4</sup> As a result, a growing number of providers have begun to search for ways to bolster their bargaining power in order to negotiate more advantageous terms with MCOs.<sup>5</sup>

As one solution for equalizing bargaining power, health care providers have proposed the relaxation of antitrust restrictions, thereby allowing these providers to join together with their competitors and collectively bargain with MCOs. Despite considerable support among the medical community for this approach, current antitrust and labor laws prevent providers from engaging in these activities. As a general matter, “[o]rganizations of independent [medical providers] who collectively mandate health-care prices fall directly within the scope of illegal price fixing. Likewise, a collective refusal by such groups to comply with the terms of managed care plans or a collective boycotting of managed care plans may constitute illegal trade restraints.”<sup>6</sup> Although the labor exemptions under the antitrust laws and the National Labor Relations Act

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1 See generally Gail B. Agrawal & Howard R. Veit, *Back to the Future: The Managed Care Revolution*, 65 L. & CONTEMP. PROBS. 11 (2002) (discussing the factors that converged to produce the “managed care revolution”).

2 See *id.* at 34 (“Health care costs continued to escalate. During the decades that followed the passage of the [Health Maintenance Organization (HMO)] Act, increasing numbers of employees had the opportunity to enroll in HMOs. The managed care revolution was underway.”).

3 Robert P. Navarro & Judith A. Cahill, *The U.S. Health Care System and the Development of Managed Care*, in MANAGED CARE PHARMACY PRACTICE 3, 5 (Robert P. Navarro ed., 1999).

4 See, e.g., Elizabeth M. Devine, *Physician Unionization: A Prescription for Modern Managed Care*, 4 QUINNIPIAC HEALTH L.J. 39, 40 (2000) (discussing physician frustrations with managed care organizations (MCOs)); Dionne Koller Fine, *Exploitation of the Elite: A Case for Physician Unionization*, 45 ST. LOUIS U. L.J. 207, 211–14 (2001) (arguing for physician unionization); Navarro & Cahill, *supra* note 3, at 4, 24 (discussing pharmacists’ frustration with MCOs); Kevin J. Smith, *Power and Control of Managing Medicine: Recent Developments*, 33 UWLA L. REV. 191, 195–99 (2001) (discussing physician unionization).

5 John G. Deis, Comment, *The Unionization of Independent Contracting Physicians: A Comedy of Errors*, 36 Hous. L. REV. 951, 951 (1999).

6 *Id.*

(NLRA) allow “employees” engaged in collective-bargaining activities to escape antitrust scrutiny,<sup>7</sup> many health care providers are not likely to fall within this exemption.<sup>8</sup>

As a result, these providers have turned to Congress to obtain their own antitrust exemption. Most recently, in May of 2011, New York Representative Anthony Weiner introduced the Community Pharmacy Fairness Act of 2011. If passed, this Act would grant independent pharmacies negotiating with a health plan over the provision of health care items or services the same preferable treatment as is afforded to employees engaged in collective bargaining with their employer under the NLRA.<sup>9</sup> Weiner’s bill followed on the heels of a similar proposal, introduced only one month earlier, to exempt, under certain conditions, *all* health care professionals engaged in contract negotiations with insurers from antitrust restrictions.<sup>10</sup>

While numerous scholars have written about physicians’ efforts to obtain an exemption to federal antitrust laws,<sup>11</sup> the academic community has paid little attention to the unique circumstances of pharmacists. Pharmacists and physicians cannot be treated in the same fashion, as the two groups have distinct practices, insurance arrangements, and concerns. Independent pharmacists (“independents”),<sup>12</sup> in particular, have fought hard for an antitrust exemption.

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7 National Labor Relations Act (NLRA), 29 U.S.C. § 157 (2006) (giving private-sector employees the “right to self-organization, to form, join, or assist labor organizations, to bargain collectively through representatives of their own choosing, and to engage in other concerted activities for the purpose of collective bargaining or other mutual aid or protection”).

8 For a discussion of why this is the case, see *infra* Subsection II.A.2.

9 Community Pharmacy Fairness Act of 2011, H.R. 1839, 112th Cong. (2011).

10 Quality Health Care Coalition Act of 2011, H.R. 1409, 112th Cong. (2011).

11 See, e.g., Carl F. Ameringer, *Federal Antitrust Policy and Physician Discontent: Defining Moments in the Struggle for Congressional Relief*, 27 J. HEALTH POL. POL’Y & L. 543 (2002); Roger D. Blair & Jill Boylston Herndon, *Physician Cooperative Bargaining Ventures: An Economic Analysis*, 71 ANTITRUST L.J. 989 (2003); Roger D. Blair & Kristine L. Coffin, *Physician Collective Bargaining: State Legislation and the State Action Doctrine*, 26 CARDOZO L. REV. 1731 (2005); Thomas L. Greaney, *Thirty Years of Solitude: Antitrust Law and Physician Cartels*, 7 Hous. J. HEALTH L. & POL’Y 189 (2007); Warren S. Grimes, *The Sherman Act’s Unintended Bias Against Lilliputians: Small Players’ Collective Action as a Counter to Relational Market Power*, 69 ANTITRUST L.J. 195 (2001); Richard M. Scheffler, *Physician Collective Bargaining: A Turning Point in U.S. Medicine*, 24 J. HEALTH POL. POL’Y & L. 1071 (1999); John A. Powers, Note, *The Stifling of Competition by the Antitrust Laws: The Irony of the Health Care Industry*, 15 J.L. & HEALTH 223 (2000-2001).

12 The definition of an “independent” pharmacist has differed somewhat depending on who has defined the term, when, and in what context. Essentially an independent is a pharmacy with a low market share and/or single (or small number) of store locations. See, e.g., Preserving Our Hometown Independent Pharmacies Act of 2011, H.R. 1946, 112th Cong. § 2(i)(3)–(4) (2011) (defining the term “independent pharmacy” to “mean[] a pharmacy that has a market share of—(A) less than 10 percent in any PDP region [as defined in section 1680D-11(a)(2) of the Social Security Act (42 U.S.C. § 1395w-111(a)(2))]; and (B) less than 1 percent in the United States”); KAITLIN BOYLE, FRED ULLRICH & KEITH MULLER, RUPRI CTR. FOR RURAL HEALTH POLICY ANALYSIS, UNIV. OF IOWA COLLEGE OF PUB. HEALTH, BRIEF NO. 2011-5, INDEPENDENTLY OWNED PHARMACY

They argue that their weak bargaining power in relation to that of insurers has prevented them from effectively competing in the marketplace against chain and mail-order pharmacies to the detriment of their patients. In support of their position, independents have asserted that they are essentially powerless to oppose MCOs. Specifically, independents claim that MCOs have interfered with the patient-provider relationship, established draconian restrictions on pharmaceutical delivery, and reduced independents' reimbursements to unsustainable levels.<sup>13</sup>

This Note argues that the proposed antitrust exemption for independent pharmacies cannot be justified under the economic principles underlying antitrust law, on which independents have based their arguments. This Note begins by providing a novel analysis of the struggle of independent and community pharmacists in their efforts to obtain an antitrust exemption separate from that of physicians and other health care providers, including pharmacists working at supermarkets and chain pharmacies. In order to illustrate why independents feel such an exemption is needed, Part I lays out the landscape of the pharmaceutical supply chain. Next, Part II describes the current antitrust and labor laws to explain why independents currently are prohibited from collectively bargaining with MCOs. It then proceeds to outline the recent legislative initiatives to allow independents to bargain collectively with insurers.

Finally, Part III provides an analysis of the economic rationales put forth to justify the exemption initiatives identified in Part II. It explains — and ultimately rejects—independents' arguments that an antitrust exemption would improve patients' quality of care, while stabilizing or lowering health care costs. Specifically, it challenges independents' claim that there is sufficient evidence that MCOs reduce consumer welfare and undermine the efficiency of the health care market. This Note further argues that the proposed exemption would not be the appropriate method for remedying such a market failure, even if it could be said definitively to exist. In doing so, this Part concludes that in their quest for an antitrust exemption, independents have not compellingly demonstrated that an exception would achieve any societal goal that would trump the efficiencies created by free-market competition.

## I. THE CONTOURS OF THE PHARMACEUTICAL SUPPLY CHAIN

To evaluate the proposed antitrust exemption, one must begin with an

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CLOSURES IN RURAL AMERICA, 2003-2010, at 4 n.1 (2011) (noting that the National Council for Prescription Drug Programs defines “an independent pharmacy as one to three pharmacies under common ownership”); *What Happened to the Independent Pharmacy Antitrust Exemption Bill?*, 6 H. D. SMITH PHARMACY FORUM 2 (2011) (noting that the Community Pharmacy Fairness Practice Act of 2007 was amended to “narrow the bill’s definition of independent pharmacy to those [that] have less than 10 percent of the market share of a Medicare Part D prescription drug region”).

<sup>13</sup> Navarro & Cahill, *supra* note 3, at 24.

understanding of independents' current position within the pharmaceutical industry. Numerous parties, intertwined through complex and often inconspicuous financial relationships, form the pharmaceutical supply chain.<sup>14</sup> It is within this complicated framework that independents — located at the bottom of the pharmaceutical supply chain — claim that they are being squeezed in their negotiations with pharmacy benefit managers (PBMs).

The chain begins with the pharmaceutical manufacturers, who sell pharmaceuticals in bulk to wholesalers. These wholesalers, in turn, sell manufacturers' drugs to pharmacies and hospitals, which finally distribute them to patients.<sup>15</sup> When a consumer fills a prescription at a pharmacy, the pharmacy either accepts a cash payment directly from the patient or, alternatively, seeks reimbursement from the patient's MCO or employer. Rather than directly reimbursing pharmacists who serve insurers' customers, the vast majority of insurers have outsourced the administration of their prescription drug programs to PBMs, who typically are either stand-alone entities or subsidiaries of the MCOs.<sup>16</sup> As PBMs "specialize[] in managing drug benefits," the advent of PBMs has allowed insurers to manage drug costs more effectively.<sup>17</sup> Acting as a middleman, the PBM reimburses the pharmacy for its expenditure and service, while simultaneously charging the patient's MCO more for the expense.<sup>18</sup>

One of the ways that the PBM earns profits is by maximizing the "spread": the difference between the price that the PBM charges an MCO for a given drug and that which it reimburses the pharmacy.<sup>19</sup> Thus, a PBM optimizes profits by seeking to charge an MCO the highest amount possible for a drug, while reimbursing a pharmacy as little as possible.<sup>20</sup> PBMs' primary mechanism for

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14 For an excellent, detailed discussion of the pharmaceutical supply and the role of pharmacy benefit managers in the delivery of pharmaceuticals, see FED. TRADE COMM'N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES (2005).

15 HEALTH STRATEGIES CONSULTANCY, LLC, FOLLOW THE PILL: UNDERSTANDING THE U.S. COMMERCIAL PHARMACEUTICAL SUPPLY CHAIN, OREGON WORKERS' COMPENSATION DIVISION 1 (2006), available at [http://www.cbs.state.or.us/wcd/rdrs/mqi/follow\\_pill.pdf](http://www.cbs.state.or.us/wcd/rdrs/mqi/follow_pill.pdf).

16 *J.E. Pierce Apothecary, Inc. v. Harvard Pilgrim Health Care, Inc.*, 365 F. Supp. 2d 119, 126–27 (D. Mass. 2005); Robert P. Navarro, *Pharmacy Benefit Management Principles and Practices*, in *MANAGED CARE PHARMACY PRACTICE*, *supra* note 3, at 29, 33–32 and accompanying text.

17 PETER R. KONGSTVEDT, *MANAGED CARE: WHAT IT IS AND HOW IT WORKS* 90 (3d ed. 2009). By contracting on behalf of multiple MCOs, pharmacy benefit managers (PBMs) have more bargaining power than an individual MCO or sponsor would have on its own. See HOWARD BRODY, *HOOKED: ETHICS, THE MEDICAL PROFESSION, AND THE PHARMACEUTICAL INDUSTRY* 63 (2007). This may be the case both with respect not only to negotiations with pharmacies, but also (and perhaps most importantly) with respect to negotiations with manufacturers. See *infra* notes 27–31.

18 MARIE A. CHISHOLM-BURNS ET AL., *PHARMACY MANAGEMENT, LEADERSHIP, MARKETING, AND FINANCE* 181 (2001).

19 *Id.*

20 PBMs compensate pharmacists for their services through a formula based on the drug's average wholesale price (also known as the "AWP") minus a percentage plus a dispensing fee. *J.E. Pierce*, 365 F. Supp. 2d at 127.

gaining bargaining leverage vis-à-vis the pharmacists with whom they contract is to create “pharmacy networks.”<sup>21</sup> These consist of the retail pharmacies from which a given MCO’s customer can fill a prescription.<sup>22</sup> A pharmacy can only join a network if it agrees to a low, yet guaranteed, reimbursement formula.<sup>23</sup>

A given pharmacy will want to join as many networks as economically feasible in order to gain access to the PBMs’ client bases as well as to ensure stable and reliable sources of income.<sup>24</sup> It can be devastating for a pharmacy to be excluded from a network because MCOs either force their patients to only purchase their drugs from network pharmacies or entice them to do so by offering significant financial incentives.<sup>25</sup> Constraining their customers in this way allows MCOs to gain the bargaining leverage necessary to negotiate the low rates at which they reimburse pharmacies for supplying drugs and services to MCOs’ customers. At least according to independents, because the independent needs the PBM more than the PBM needs the independent, PBMs are able to force “take-it-or-leave-it” contracts—termed contracts of adhesion—on the independents with whom they contract.

A PBM is able to leverage bargaining power not only by controlling which pharmacies the MCO’s plan subscribers can frequent, but also by determining the pharmaceuticals that subscribers’ plans will cover.<sup>26</sup> By engaging in these strategic negotiations, a PBM receives payments from manufacturers called “rebates,” which the PBM then passes on to the MCOs through below-market prices.<sup>27</sup> While the PBM passes a portion of this rebate on to the MCO, it retains a fraction of the rebate for itself.<sup>28</sup> It is through these additional transactions that independents, as discussed later, allege, in part, that the PBM is able to inflate its profits, reimbursing pharmacists at rates that do not reveal these additional

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21 FED. TRADE COMM’N, *supra* note 14, at 4–5.

22 *Id.* at 4.

23 Robert P. Navarro, *Prescription Drug Benefits in Managed Care*, in *ESSENTIALS OF MANAGED CARE* 293, 311 (Peter R. Kongstvedt ed., 4th ed. 2003).

24 HEALTH STRATEGIES CONSULTANCY, LLC, *supra* note 15, at 1–2.

25 FED. TRADE COMM’N & DEP’T OF JUSTICE, *IMPROVING HEALTH CARE: A DOSE OF COMPETITION: A REPORT BY THE FEDERAL TRADE COMMISSION AND THE DEPARTMENT OF JUSTICE* 11–12 (2004); SHANE P. DESSELLE & DAVID P. ZGARRICK, *PHARMACY MANAGEMENT: ESSENTIALS FOR ALL PRACTICE SETTINGS* 267 (2005).

26 See WILLIAM N. KELLY, *PHARMACY: WHAT IT IS AND HOW IT WORKS* 266–67 (2d ed. 2007); Michael J. Dillon, *Drug Formulary Management*, in *MANAGED PHARMACY CARE PRACTICE* 145, 145–63 (Robert P. Navarro ed., 2d ed. 2009).

27 S. Glied & K. Janus, *Managed Care*, in *HEALTH SYSTEMS POLICY, FINANCE AND ORGANIZATION* 332 (Guy Carrin et al. eds., 2009).

28 *Id.*; Regina Sharlow Johnson, *PBMs: Ripe for Regulation*, 57 *FOOD & DRUG L.J.* 323, 328 (2002). The PBM must carefully balance its interest in charging MCOs the high prices necessary to earn profits, while still offering more competitive rates than its competitors; if a PBM sets its prices too high, an MCO will choose another PBM with more aggressive pricing to administer its plan. FED. TRADE COMM’N, *supra* note 14, at 8. See generally Terry Latanich, *Pharmacy Benefit Manager “Spread”: A Reasonable, Rational, Realistic Business Practice*, 44 *J. AM. PHARMACISTS ASS’N* 10 (2004) (discussing the business considerations surrounding the spread).

payments received from manufacturers.

A PBM obtains a rebate from a pharmaceutical manufacturer by developing a preferred list of medications called a “formulary.”<sup>29</sup> Just as a pharmacy wants to be included in a PBM’s network, a manufacturer seeks to have its drug included on the PBM’s formulary. Having a formulary-listed drug drastically increases a manufacturer’s sales because an MCO either only reimburses patients for formulary-listed drugs or gives patients great financial incentive to purchase these drugs over others, such as by offering lower copayments.<sup>30</sup> Thus, a manufacturer will offer a PBM a rebate if the PBM lists the manufacturer’s drug on the formulary over others<sup>31</sup> and/or if the PBM is able independently to increase the manufacturer’s market share or sales volume.<sup>32</sup>

PBMs supplement the revenue received from both the spread and rebates by offering a variety of other services. Many of these services increase both efficiency within the pharmaceutical market and the provision of high-quality and safe health care services. First, PBMs charge MCOs directly for assisting pharmacies in checking whether a pharmaceutical poses a threat of drug interaction; whether a cheaper, generic drug substitute is available; and whether a consumer is currently eligible for a medication refill.<sup>33</sup> Second, PBMs collect, package, and sell non-identifiable aggregations of data to manufacturers on their beneficiaries’ medication use.<sup>34</sup> Finally, PBMs also administer their own mail-order pharmacies,<sup>35</sup> allowing them to sell pharmaceuticals directly to consumers and cut out the middlemen retail pharmacies.<sup>36</sup> Independents view this final practice as suspect, given the potential for conflicts of interest and what independents see as a serious challenge to health care quality — not to mention the vitality of the independent pharmacy industry.

In sum, one of the primary ways that a PBM maximizes the spread is by

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29 Sandra J. Branda, *Pharmaceutical Pricing Policies and Their Quality Implications*, in *ACHIEVING QUALITY IN MANAGED CARE: THE ROLE OF LAW* 155, 157–59 (John D. Blum ed., 1997) (providing a general overview of the use of formularies); Sharlow Johnson, *supra* note 28, at 328–30. A committee, which is composed of physicians, pharmacists, the plan’s medical director, and external consultants, usually develops a formulary for a PBM based upon factors, including, but not limited to: cost, efficacy, safety, and patient-compliance rates. *Id.*

30 BRODY, *supra* note 17, at 63; David A. Balto, *A Whole New World?: Pharmaceutical Responses to the Managed Care Revolution*, 52 *FOOD & DRUG L.J.* 83, 85 (1997); Andrew S. Krulwich, *The Response to Health Care Reform by the Pharmaceutical Industry*, 50 *FOOD & DRUG L.J.* 1, 2–3 (1995); Sharlow Johnson, *supra* note 28, at 328.

31 Balto, *supra* note 30, at 85; Krulwich, *supra* note 30, at 2–3; Navarro, *supra* note 16, at 41; Sharlow Johnson, *supra* note 28, at 330.

32 Navarro, *supra* note 16, at 41.

33 *FED. TRADE COMM’N*, *supra* note 14, at 2.

34 *Id.* at 7.

35 See *infra* notes 218–220, 232–236.

36 Michael Johnsrud et al., *Comparison of Mail-Order with Community Pharmacy in Plan Sponsor Cost and Member Cost in Two Large Pharmacy Benefit Plans*, 13 *J. MANAGED CARE PHARMACY* 122, 123 (2007).



setting low reimbursement rates for pharmacies in exchange for admitting the pharmacy into the PBM's network. In independents' campaign for an antitrust exemption, the crux of their complaint is that they are being left out of this negotiation over reimbursement formulas. While the independent cannot bear to lose the insurer's tens of thousands of plan subscribers as customers, the PBM conversely has little incentive to negotiate with the independent. As a result, PBMs allegedly force independents into contracts of adhesion, leaving them unable, or just barely able, to cover their costs.

Independents posit that they would be able to "level the playing field" vis-à-vis the PBMs if they were permitted to band together to negotiate collectively their reimbursement formulas. In other words, independents could obtain more favorable reimbursement rates, perhaps equal to or greater than those obtained by chain pharmacies, if they could together leverage their power to convince the PBM to raise prices to competitive levels. As the next Part will explain, however, current antitrust and labor laws prohibit independents from engaging in such collusion, thus leading them to turn to Congress to circumvent the confines of antitrust law.

## II. THE CURRENT LEGAL AND LEGISLATIVE FRAMEWORK

This Part describes the current legal landscape, which prohibits independents from banding together to negotiate collectively with PBMs over reimbursement rates. First, Subsection II.A.1 outlines the antitrust legal framework, highlighting the goals from which this jurisprudence — at least in its current form — has sprung. This discussion forms the foundation necessary to understand the later discussion, in Part III, about both why it makes economical sense for such collective action to be prohibited and why a legislative exemption would be antithetical to the values that antitrust law is crafted to protect.

Next, Subsection II.A.2 briefly examines the relevant labor law. It proceeds to illustrate why independents currently do not fall under the NLRA antitrust exemption for "employees," the applicability of which would obviate independents' need for further immunity. Moreover, it explains why an antitrust exemption does not fit comfortably within the philosophy underlying and the structure of existing labor jurisprudence.

Having demonstrated that both antitrust and labor laws prohibit collective action by pharmacists, Section II.B finally presents independents' current legislative proposals for reform. Specifically, it outlines the history and nature of the legislative initiatives that independents have championed to permit them to bypass the constraints that labor and antitrust law currently impose.

### A. The Current Legal Landscape

#### 1. Antitrust Law

Antitrust law is the primary mechanism through which the U.S. legal system safeguards competition. Cooperation among competing sellers is governed by section 1 of the Sherman Act, which declares illegal “[e]very contract, combination . . . or conspiracy, in restraint of trade or commerce.”<sup>37</sup> Implementing this landmark statutory provision, courts have differentiated between those trade restraints they view as inherently anticompetitive—and thus illegal per se—and those that they must evaluate under a fact-specific, rule-of-reason standard.<sup>38</sup> Arrangements treated as per se illegal are those, such as horizontal price-fixing conspiracies, “whose nature and necessary effect are so plainly anticompetitive that no elaborate study of the industry is needed to establish their illegality.”<sup>39</sup> Not per se illegal, however, are agreements “[w]here the competitive effect of [the] alleged restraint is not readily apparent.”<sup>40</sup> This latter category of agreements “can only be evaluated by analyzing the facts peculiar to the business, the history of the restraint, and the reasons why it was imposed.”<sup>41</sup> A court will allow such an arrangement where the procompetitive effects outweigh the anticompetitive effects of the restraint at issue.<sup>42</sup>

Since the seminal case *United States v. Socony-Vacuum*, cartels, or “group[s] of competitors who have agreed to limit or eliminate their competition in some economically relevant dimension,”<sup>43</sup> have fallen into the former category of per se illegality.<sup>44</sup> Such agreements are considered “so inherently pernicious that proof of the actual practice alone carries with it proof of the unreasonableness and illegality of the restraint.”<sup>45</sup> Under this standard, a group of pharmacists who band together to negotiate collectively with PBMs are effectively limiting or

37 15 U.S.C. § 1 (2006).

38 U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE 71 (1996).

39 *Nat’l Soc’y of Prof’l Eng’rs v. United States*, 435 U.S. 679, 692 (1978); see also *N. Jackson Pharmacy, Inc. v. Caremark Rx, Inc.*, 385 F. Supp. 2d 740, 745 (N.D. Ill. 2005) (“Per se treatment is appropriate for a restraint ‘that falls into the category of agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable and therefore illegal without elaborate inquiry as to the precise harm cause or the business excuse for their use.’” (citations omitted) (quoting *Nw. Wholesale Stationers, Inc. v. Pac. Stationery & Printing Co.*, 472 U.S. 284, 289 (1985) (internal quotation marks omitted))).

40 *N. Jackson Pharmacy, Inc.*, 385 F. Supp. 2d at 745.

41 *Nat’l Soc’y of Prof’l Eng’rs*, 435 U.S. at 692.

42 U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N, *supra* note 38, at 71.

43 Peter C. Carstensen, *Buyer Cartels Versus Buying Groups: Legal Distinctions, Competitive Realities, and Antitrust Policy*, 1 WM. & MARY BUS. L. REV. 1, 9 (2010).

44 *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 218 (1940).

45 Murray S. Monroe, *Trade and Professional Associations: An Overview of Horizontal Restraints*, 9 U. DAYTON L. REV. 479, 483 (1984).

eliminating competition by fixing prices. This behavior is designated as per se illegal irrespective of any showing of the actual economic effect of the group's activities.

While prohibiting pharmacists from forming cartels, current antitrust laws do allow certain types of collaboration. Under the *1996 Statements of Antitrust Enforcement Policy in Healthcare*, pharmacies can in many instances form pharmacy-owned PBM joint ventures, joint buying arrangements for purchasing pharmaceuticals from wholesalers and manufacturers, and PPOs.<sup>46</sup> Many of these arrangements are deemed procompetitive<sup>47</sup> (and thus legal under antitrust laws), as they improve efficiencies and health care quality by utilizing electronic health records and shared support mechanisms.<sup>48</sup> Except for per se illegal agreements, such as those involving price fixing or boycotts, the Department of Justice (DOJ) and Federal Trade Commission (FTC) evaluate joint collaboration on a case-by-case basis under the rule-of-reason standard.<sup>49</sup> The rule-of-reason

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46 Janet D. Steiger, Comm'r, Fed. Trade Comm'n, Prepared Remarks Before the National Association of Retail Druggists (Apr. 22, 1996); see also *Competition in the Healthcare Marketplace: Hearing Before Subcomm. on Consumer Protection, Product Safety, & Ins. of the S. Comm. on Commerce, Sci., & Transp.*, 111th Cong. 6–7 (2009) [hereinafter *Healthcare Competition Hearing*] (statement of Richard A. Feinstein, Dir., Bureau of Competition, Federal Trade Commission) (“The FTC recognizes that certain forms of collaboration . . . have the potential to foster proconsumer innovations in healthcare organization. . . . Properly applied, antitrust standards distinguish between price-fixing by healthcare providers, which is likely to increase costs, and effective clinical integration among providers that has the potential to achieve cost savings and improve outcomes.”).

47 For example, as then-Commissioner, Christine A. Varney, explained as to pharmacy-PBM joint ventures:

[T]here may be significant procompetitive benefits from the emergence of pharmacy-owned PBM joint ventures. . . . Absent these ventures, community pharmacies might be unable to participate in PBMs, and PBM consumers might have less choice in their selection of a pharmacist.

These ventures may also improve the efficiency and competitiveness of their members by aggregating buying power. . . . A joint buying group alone could not achieve these savings, because only a PBM has the power to solicit discounts based on share shifting (e.g., preferential listing on the formulary). The savings from the joint buying arrangement should enable community pharmacies to compete more effectively.

Christine A. Varney, Comm'r, Fed. Trade Comm'n, Prepared Remarks Before the Citizens Fund Conference: The Dangers of Health Industry Consolidation and Corporatization and the Effect on Quality, Cost and Accessibility (May 10, 1995).

48 See *Healthcare Competition Hearing*, *supra* note 46, at 7 (statement of Richard A. Feinstein, Dir., Bureau of Competition, Federal Trade Commission).

49 *Id.* Furthermore, while typically courts deem most market-allocation, price-fixing, and bid-rigging agreements to be per se illegal, in the health care context, courts have been very generous in applying the rule-of-reason standard rather than a per se rule. This is because generally courts disfavor per se treatment “in the context of business relationships where the economic impact of certain practices is not immediately obvious,” Fed. Trade Comm’n v. Ind. Fed’n of Dentists, 476

standard considers a variety of factors in determining legality, including: (1) whether the pharmacies together have market power;<sup>50</sup> (2) whether the activities produce efficiencies; and (3) whether the collaboration produces anticompetitive effects that outweigh any associated efficiencies.<sup>51</sup>

Dissatisfied with options for collaboration under the current antitrust laws, professionals have argued that the activities of “learned professions” do not constitute “trade or commerce” within section 1 of the Sherman Act.<sup>52</sup> Despite historical support for such an approach,<sup>53</sup> in *Goldfarb v. Virginia State Bar*, the Supreme Court switched course, ruling that there is no “support for the proposition that Congress intended any such sweeping exclusion” and that “[t]he nature of an occupation, standing alone, does not provide sanctuary from the Sherman Act.”<sup>54</sup> Unable to escape antitrust law’s confines through the doctrine of

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U.S. 447, 458–59 (1986). This same ambiguity often exists in the health care context. See DEBORAH HAAS-WILSON, *MANAGED CARE AND MONOPOLY POWER: THE ANTITRUST CHALLENGE* 77 (2003). Courts particularly rely on this principle in cases implicating medical judgment or health care quality. ABA SECTION OF ANTITRUST LAW, *ANTITRUST HEALTH CARE HANDBOOK* 51 (4th ed. 2010). But see U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N, *supra* note 38, at 3 (“The Agencies emphasize that it is not their intent to treat such [health] networks either more strictly or more leniently than joint ventures in other industries, or to favor any particular procompetitive organization or structure of health care delivery over other forms that consumers may desire.”).

50 In his testimony before the Senate Subcommittee on Consumer Protection, Product Safety, and Insurance, Richard Feinstein, FTC Director of the Bureau of Competition, stated that as long as a group of health care providers “cannot exercise market power,” collaboration “is unlikely to raise significant antitrust concerns, because it has the potential to benefit consumers rather than harm them.” *Healthcare Competition Hearing*, *supra* note 46, at 7 (statement of Richard A. Feinstein, Dir., Bureau of Competition, Federal Trade Commission). Courts have held that under the rule-of-reason standard, market power, or the power “to force a purchaser to do something that he would not do in a competitive market,” such as raise prices and reduce output, is a key consideration in determining legality. See, e.g., *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 36 (2006); *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 464 (1992).

51 *Healthcare Competition Hearing*, *supra* note 46, at 7 (statement of Richard A. Feinstein, Dir., Bureau of Competition, Federal Trade Commission).

52 See *Goldfarb v. Va. State Bar*, 421 U.S. 773, 786 (1975).

53 William M. Sage & Peter J. Hammer, *A Copernican View of Health Care Antitrust*, 65 L. & CONTEMP. PROBS. 241, 249 (2002) (“[M]edical practitioners . . . follow a profession and not a trade.” (quoting *Fed. Trade Comm’n v. Raladam Co.*, 283 U.S. 643, 653 (1931))); see also *United States v. Or. State Med. Soc’y*, 343 U.S. 326, 336 (1952) (noting that “there are ethical considerations where the historic direct relationship between patient and physician is involved which are quite different than the usual considerations prevailing in ordinary commercial matters”).

54 421 U.S. at 787. The *Goldfarb* Court ambivalently warned that it might later retreat back to its historically deferential posture towards professional activity. *Id.* at 788 n.17 (“The fact that a restraint operates upon a profession as distinguished from a business is, of course, relevant in determining whether that particular restraint violates the Sherman Act. It would be unrealistic to view the practice of professions as interchangeable with other business activities, and automatically to apply to the professions antitrust concepts that originated in other areas. The public service aspect, and other features of the professions, may require that a particular practice, which could properly be viewed as a violation of the Sherman Act in another context, be treated differently. We intimate no view on any other situation than the one with which we are confronted today.”).

professional immunity, some health care professionals, who fit squarely within the NLRA's independent-contractor exclusion, have argued instead that they fall within the labor exemption, which gives private-sector employees the right to organize.

## 2. The Labor Exemption

The NLRA gives private-sector employees the "right to self-organization, to form, join, or assist labor organizations, to bargain collectively through representatives of their own choosing, and to engage in other concerted activities for the purpose of collective bargaining or other mutual aid or protection."<sup>55</sup> To reconcile the conflicting policies of labor and antitrust, Congress and the courts have created statutory<sup>56</sup> and non-statutory<sup>57</sup> exemptions to protect labor organizations and employees engaged in collective-bargaining activities from the reach of antitrust laws.

Only "employees," defined as those who "work[] for [an employer] for hire,"<sup>58</sup> are protected under the NLRA and thus receive antitrust immunity. Independent contractors who, in contrast to employees, are "entrusted to

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However, "none of the subsequent cases gave any indication that judicial lip service to professionalism had substantive meaning." Sage & Hammer, *supra* note 53, at 250.

55 National Labor Relations Act (NLRA), 29 U.S.C. § 157 (2006).

56 Sections 6 and 20 of the Clayton Act and sections 1, 4, 5, and 13 of the Norris-LaGuardia Act collectively exempt conduct in which "a bona fide labor organization act[s] in its own self-interest to further a labor objective, where the union has not combined with a non-labor group." ABA SECTION OF ANTITRUST LAW, *supra* note 49, at 109 (footnote omitted).

57 The complementary nonstatutory exemption, created by the courts, "protects from . . . antitrust challenge a labor union's collective bargaining with an employer over wages, hours, and other terms and conditions of employment, as well as the resulting agreements between labor and management covering these matters." *Id.* In addition,

[c]ourts have extended the nonstatutory exemption to other concerted activities and agreements between labor groups and other parties that arise in a collective bargaining setting, are intimately related to a mandatory subject of bargaining, and lack the potential to restrain competition in business markets in ways not flowing naturally from eliminating competition over wages and working conditions. The nonstatutory exemption also protects multiemployer agreements in the context of collective bargaining between employers and their employees.

*Id.* at 109–10 (footnotes omitted).

58 H.R. REP. NO. 80-245, at 18 (1947). The National Labor Relations Act (NLRA) is similar to other federal labor and employment statutes in its circular definition of the term "employee": "[t]he term 'employee' shall include any employee." 29 U.S.C. § 152(3). As a result of this unhelpful definition, the National Labor Relations Board (NLRB) and the federal courts have been charged with developing a legal definition of the working class and of the employment relationship conferring membership in it. Marc Linder, *Towards Universal Worker Coverage Under the National Labor Relations Act: Making Room for Uncontrolled Employees, Dependent Contractors, and Employee-Like Persons*, 66 U. DET. L. REV. 555, 558 (1989).

undertake a specific project but who [are] left free to do the assigned work and to choose the method for accomplishing it,”<sup>59</sup> are explicitly excluded from coverage.<sup>60</sup> While there is much controversy over the bounds of the independent-contractor exception and employers’ attempts to squeeze certain groups of workers within it, independents fit squarely outside the bounds of immunity under current labor jurisprudence.

The National Labor Relations Board (NLRB) applies the traditional common law right-to-control test—the same test used to determine vicarious liability in tort suits<sup>61</sup> — to distinguish employees from independent contractors.<sup>62</sup> There is some variation in application, but courts typically balance ten factors laid out in the *Restatement (Second) of Agency*,<sup>63</sup> with a particular focus on “the employer’s right to control the physical conduct of the individual.”<sup>64</sup> Where an employer has control over both the manner and means of the worker’s labor, a court is likely to find the worker to be an employee.<sup>65</sup> Oppositely, where a worker is able to

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59 BLACK’S LAW DICTIONARY 839 (9th ed. 2009).

60 Harvey M. Adelstein & Harry T. Edwards, *The Resurrection of NLRB v. Hearst: Independent Contractors Under the National Labor Relations Act*, 17 U. KAN. L. REV. 191, 192 (1969).

61 Myra H. Barron, *Who’s an Independent Contractor? Who’s an Employee?*, 14 LAB. LAW. 457, 459 (1999).

62 Adelstein & Edwards, *supra* note 60, at 192–93. The RESTATEMENT (SECOND) OF AGENCY § 220 (1958) states that “[a] servant [i.e. an employee] is a person employed to perform services in the affairs of another and who with respect to the physical conduct in the performance of services is subject to the other’s control or right to control.”

63 These factors are:

- a. the extent of control which, by the agreement, the master may exercise over the details of the work;
- b. whether or not the one employed is engaged in a distinct occupation or business;
- c. the kind of occupation, with reference to whether, in the locality, the work is usually done under the direction of the employer or by a specialist without supervision;
- d. the skill required in a particular occupation;
- e. whether the employer or the [worker] supplies the instrumentalities, tools, and the place of work for the person doing the work;
- f. the length of time for which the person is employed;
- g. the method of payment, whether by the time or by the job;
- h. whether or not the work is part of the regular business of the employer;
- i. whether or not the parties believe they are creating the relation of master and servant; and
- j. whether the principal is or is not in business.

RESTATEMENT (SECOND) OF AGENCY, *supra* note 62, § 220.

64 Nancy E. Dowd, *The Test of Employee Status: Economic Relations and Title VII*, 26 WM. & MARY L. REV. 75, 80 (1984).

65 See John Bruntz, *The Employee/Independent Contractor Dichotomy: A Rose Is Not Always a Rose*, 8 HOFSTRA LAB. & EMP. L.J. 337, 350 (1991) (“[T]he test which has been consistently

dictate the circumstances surrounding his employment, a court is likely to find the worker to be an independent contractor without statutory protection.<sup>66</sup> Under the factors considered by the NLRA's right-to-control test, pharmacists clearly constitute independent contractors rather than employees of MCOs or PBMs, and thus it would be anomalous for a court to bestow upon them the benefit of the labor exemption under existing labor jurisprudence. Whether one analyzes all ten factors<sup>67</sup> or simply considers control over the manner and means of work, independent pharmacists<sup>68</sup> are not employees of insurers, but rather are uncovered independent contractors. MCOs and PBMs restrict neither how pharmacists design and operate their businesses nor the services pharmacists provide. Furthermore, pharmacists are free to sell additional products, such as food and beauty supplies, as well as medication to cash-paying customers, without insurers' approval. Likewise, insurers play no part in the provision of ancillary services, such as home delivery, which pharmacists offer without insurer compensation. While the NLRB has yet to consider formally whether pharmacists are "employees" of insurers, the NLRB has considered and rejected a similar argument in the physician-HMO context.<sup>69</sup> Given that PBMs exert even less control over independents than HMOs do over physicians, the chances of the NLRB or courts construing the definition of "employee" sufficiently broadly to encompass independents are slim.

Moreover, not only does the labor exemption currently exclude independents from coverage, but independents' stated goals are in tension with the motivations and values behind the labor-law framework within which this exemption is

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applied has been the common law right to control test. Control has been construed to mean control of both the result and the 'manner and means' by which the purported employee brings about the result." (quoting *Lorenz Schneider Co. v. Nat'l Labor Relations Bd.*, 517 F.2d 445, 451 (6th Cir. 1975)); Marc Linder, *Dependent and Independent Contractors in Recent U.S. Labor Law: An Ambiguous Dichotomy Rooted in Simulated Statutory Purposelessness*, 21 COMP. LAB. L. & POL'Y J. 187, 194 (1999).

66 Dowd, *supra* note 64, at 80–81.

67 See *supra* note 63.

68 Pharmacists are subject to the same test for employee status as all other workers under the NLRA. Thus, of course, the NLRB may indeed consider pharmacists working at others' pharmacies, such as chain stores and supermarkets, to be employees of the stores at which they work. They, however, still would not be employees of PBMs or insurers.

69 In *AmeriHealth Inc./AmeriHealth HMO*, 329 N.L.R.B. 870 (1999), the NLRB considered whether a group of primary-care and specialty physicians were employees rather than independent contractors within the meaning of section 2(3) of the NLRA. Rejecting the argument that the HMO substantially controlled the physicians' manner and means of work, the NLRB analogized the relationship to that between an advertising agency and a freelance advertisement photographer, as contrasted to a master and servant. *Id.* at 885. That said, the NLRB acknowledged that it was "not necessarily precluding a finding that physicians under contract to HMOs may, in other circumstances, be found to be statutory employees." *Id.* at 870 n.1. For a more comprehensive analysis of how physicians have argued that they should be considered to be employees under the NLRA, see Micah Berman, Note, *The "Quality Health Care Coalition Act": Can Antitrust Law Improve Patient Care?*, 53 STAN. L. REV. 695, 707–11 (2000).

situated. Passed during the New Deal — when policymakers’ feared a recurrence of the Great Depression — the NLRA is geared at bettering employees’ wages, hours, and working conditions; protecting the free flow of commerce by channeling the disruptive nature of industrial disputes into the collective-bargaining process; and preventing the recurrence of depressions.<sup>70</sup>

Although it may be true that an antitrust exemption for independents would fulfill some of the NLRA’s goals, such arguments do not comport with those independents currently advance in arguing for an exemption—and thus would need to be assessed on their own terms. Rather, as explained below,<sup>71</sup> independents seeking an antitrust exemption purport to be motivated, at least primarily, by the desire to restore the market to competitive equilibrium and to bolster patient welfare and health care quality<sup>72</sup> — not to remedy disruptive disputes or to improve their own wages, even if at the expense of consumers. The drafters of the NLRA never intended the Act to address issues concerning product or service quality, let alone that of the crucial service of health care. As David Wales of the FTC testified before Congress:

The labor exemption . . . was not created to solve issues regarding the ultimate safety and quality of patient care. . . . [but] to raise incomes and improve working conditions of union

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70 Section 1 of the NLRA states in pertinent part:

The inequality of bargaining power between employees who do not possess full freedom of association or actual liberty of contract, and employers . . . substantially burdens and affects the flow of commerce, and tends to aggravate recurrent business depressions. . . . Experience has proved that protection by law of the right of employees to organize and bargain collectively safeguards commerce from injury, impairment, or interruption, and promotes the flow of commerce by removing certain recognized sources of industrial strife and unrest, by encouraging practices fundamental to the friendly adjustment of industrial disputes arising out of differences as to wages, hours, or other working conditions, and by restoring equality of bargaining power between employers and employees.

National Labor Relations Act (NLRA), 29 U.S.C. § 151 (2006); *see also* *United States v. Silk*, 331 U.S. 704, 713 (1947) (“The aim of the Act was to remedy the inequality of bargaining power in controversies over wages, hours and working conditions.”).

71 *See infra* Part III.

72 Community Pharmacy Fairness Act of 2011, H.R. 1839, 112th Cong. (2011); Quality Health Care Coalition Act of 2011, H.R. 1409, 112th Cong. (2011). In fact, not only is collective bargaining an inappropriate way to achieve such goals, but relying on collective bargaining to do so creates a perverse conflict of interests for those engaged in bargaining. If, in their negotiations with PBMs, pharmacists secured the types of benefits that would assist patients, such as broader formulary lists and reduced preapproval requirements, they presumably would have to compensate for these concessions through reductions (or smaller gains) in their own fee schedules and reimbursement rates. Awkwardly, this position forces pharmacists to choose between their own interests and those of their customers.



members. The law protects, for example, the United Auto Workers' [UAW] right to bargain for higher wages and better working conditions, but we do not rely on the UAW to bargain for safer, more reliable, or more fuel-efficient cars. Congress has addressed those types of concerns in other ways, as well as relying on competition in the market among automobile manufactures to encourage product improvements.<sup>73</sup>

With little hope of exemption under the NLRA, health care providers, including independents, have turned to Congress, looking for a legislative basis for an antitrust exemption.

### *B. Congressional Proposals for Reform*

Supported by a strong pharmacy lobby, several congressmen have introduced bills proposing antitrust exemptions for independent pharmacies.<sup>74</sup> The year 2005 saw the introduction of the bipartisan Community Pharmacy Fairness Act of 2005.<sup>75</sup> This bill, premised on an effort "[t]o ensure and foster continued patient safety and quality of care," would have "ma[de] the antitrust laws apply to negotiations between groups of independent pharmacies and health plans and health insurance issuers in the same manner as such laws apply to protected activities under the National Labor Relations Act."<sup>76</sup> Limited in that it exempted federal programs from coverage,<sup>77</sup> the bill was politically popular, with 113 cosponsors, but neither the House nor Senate passed the bill.<sup>78</sup> Undeterred, advocates introduced the very similar Community Pharmacy Act of

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73 *Impact of Our Antitrust Laws on Community Pharmacies and Their Patients: Hearing Before the Task Force on Antitrust & Competition Policy of the H. Comm. on the Judiciary*, 110th Cong. 64 (2007) [hereinafter *Community Pharmacies Hearing*] (statement of David Wales, Deputy Dir., Bureau of Competition, Federal Trade Commission) (testifying in opposition to the Community Pharmacy Fairness Act of 2007).

74 See, e.g., Laura Dean, *Independent Pharmacists Battle Big Pharma on Health Care*, HUFFINGTON POST (Sept. 5, 2009), [http://www.huffingtonpost.com/2009/08/05/independent-pharmacists-b\\_n\\_251787.html](http://www.huffingtonpost.com/2009/08/05/independent-pharmacists-b_n_251787.html); Jim Frederick, *With New Push, Pharmacy Groups Seek Inclusion in Health Reform's ACOs*, DRUG STORE NEWS, Dec. 7, 2010, <http://drugstorenews.com/article/new-push-pharmacy-groups-seek-inclusion-health-reform-s-acos>; Press Release, Pharm. Care Mgmt. Ass'n, Drugstore Lobby Wants New Collective Bargaining Powers, <http://pcmanet.org/2012-press-releases/drugstore-lobby-wants-new-collective-bargaining-powers> (last visited Dec. 11, 2012).

75 Community Pharmacy Fairness Act of 2005, H.R. 1671, 109th Cong. (2005).

76 *Id.* The bill defined an independent pharmacy as one that is "not owned (or operated) by a publicly traded company." *Id.* § 2(h)(3).

77 *Id.* § 2(g) (exempting, for example, "[t]he Medicaid Program under title XIX of the Social Security Act (42 U.S.C. [§] 1396 et seq.)" and "[t]he SCHIP program under title XXI of the Social Security Act (42 U.S.C. [§] 1397aa et seq.)").

78 See H.R. 1671 (109th): *Community Pharmacy Fairness Act of 2005*, GOVTRACK, <http://www.govtrack.us/congress/bill.xpd?bill=h109-1671> (last visited Nov. 13, 2012).

2007<sup>79</sup> and the Community Pharmacy Fairness Act of 2009<sup>80</sup> during the following two Congresses. Again, the bills were fairly popular with 180<sup>81</sup> and 99<sup>82</sup> cosponsors respectively. While the 2009 iteration never emerged from committee,<sup>83</sup> the House Committee on the Judiciary favorably received the 2007 version and recommended its passage.<sup>84</sup> Despite these strong showings of support, neither bill became law.<sup>85</sup> More recent iterations of the bill, including the Community Pharmacy Fairness Act of 2011<sup>86</sup> and the Preserving Our Hometown Independent Pharmacies Act of 2011,<sup>87</sup> have had less support.

In addition to lobbying for their own exemption, independent pharmacies also have campaigned with other groups, such as physicians, to press for an industry-wide exemption for *all* health care providers.<sup>88</sup> Again, several iterations of essentially equivalent bills have been introduced in Congress over the years, with varying degrees of support,<sup>89</sup> only eventually to die. The precise reason for

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79 Community Pharmacy Fairness Act of 2007, H.R. 971, 110th Cong. (2007). Note that Senator John Isakson also unsuccessfully introduced two versions of the Community Pharmacy Fairness Act of 2007 in the Senate. See *Community Pharmacy Fairness Act of 2007*, S. 885, 110th Cong. (2007); *Community Pharmacy Fairness Act of 2007*, S. 2161, 110th Cong. (2007).

80 Community Pharmacy Fairness Act of 2009, H.R. 1204, 111th Cong. (2009).

81 Steve Berberich, *Druggists Unite to Speed Payments*, GAZETTE (Md.) (July 20, 2007), [http://www.gazette.net/stories/072007/businew211348\\_32356.shtml](http://www.gazette.net/stories/072007/businew211348_32356.shtml).

82 See *H.R. 1204 (111th): Community Pharmacy Fairness Act of 2009*, GOVTRACK, <http://www.govtrack.us/congress/bill.xpd?bill=h111-1204> (last visited Nov. 13, 2012).

83 *Id.*

84 For the House Committee on the Judiciary's report, see H.R. REP. NO. 110-898 (2008).

85 See *H.R. 1204 (111th): Community Pharmacy Fairness Act of 2009*, *supra* note 82; *H.R. 971 (110th): Community Pharmacy Fairness Act of 2007*, GOVTRACK, <http://www.govtrack.us/congress/bill.xpd?bill=h110-971> (last visited Nov. 13, 2012).

86 Community Pharmacy Fairness Act of 2011, H.R. 1839, 112th Cong. (2011). Similarly to the previous iterations, the bill exempts from antitrust coverage (with some express exclusions) "[a]ny independent pharmacies who are engaged in negotiations with a health plan regarding the terms of any contract under which the pharmacies provide health care items or services for which benefits are provided under such plan." *Id.* § 2(a).

87 Preserving Our Hometown Independent Pharmacies Act of 2011, H.R. 1946, 112th Cong. (2011).

88 Health care providers are defined under the Quality Health Care Coalition Act of 2011 as those who "provide[] health care items or services, treatment, assistance with activities of daily living, or medications to patients and who, to the extent required by State or Federal law, possesses specialized training that confers expertise in the provision of such items or services, treatment, assistance, or medications." Quality Health Care Coalition Act of 2011 § 3(5), H.R. 1409, 112th Cong. (2011).

89 While some iterations have been relatively successful — one bipartisan bill passed the House only to fail in the Senate — others have faced a greater struggle to gain traction. For example, in 2003, Representative Ron Paul (R-Tex.) introduced a revised Quality Health Care Coalition Act of 2003 in the House. See *Quality Health Care Coalition Act of 2003*, H.R. 1247, 108th Cong. (2003). This iteration of the bill, similarly to the Community Pharmacy Fairness Acts, explicitly renounced any impact on the NLRA, stating that "[n]othing in this [bill] shall be construed as changing or amending any provision of the National Labor Relations Act, or as affecting the status of any group of persons under that Act." *Id.* § 3(b)(2). As a result, the bill's provisions were broader than its predecessor in that the exemption was not limited to the activities

the bills' respective failures is unclear<sup>90</sup> — and, in the case of the 2009 iteration, may have had much to do with a lack of support from party leadership given its failure to be reported out of committee.<sup>91</sup> Still, it is not implausible that the failures to pass were motivated by the economic arguments put forth by opponents of the bills, most notably the FTC, which strongly opposed the bills on the ground that they would not achieve the procompetitive and health care quality-enhancing benefits claimed by their supporters.<sup>92</sup>

The statutory language of the most recent version of the bill, the Quality Health Care Coalition Act of 2011 suggests that, if enacted, it would include in its ambit both pharmacists working at chain pharmacies and independents.<sup>93</sup> That said, only independents and their affiliated associations, such as the National Community Pharmacists Association, have testified on behalf of previous

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enjoyed by bargaining units under the NLRA. Instead, it stated: “Any health care professionals who are engaged in negotiations with a health plan regarding the terms of any [health care] contract . . . shall, in connection with such negotiations, be exempt from the Federal antitrust laws.” *Id.* § 3(a). Again, the bill exempted many federal programs from its reach, *id.* § 3(c), but it gained much less traction than its 1999 predecessor and had only one cosponsor. *See* 150 CONG. REC. H6997 (daily ed. Sept. 9, 2004). Undeterred, in 2005, 2007, and 2009, representatives introduced similar bills. *See* Quality Health Care Coalition Act of 2009, H.R. 1493, 111th Cong. (2009) (introduced by Representatives Paul and Price); Quality Health Care Coalition Act of 2007, H.R. 3341, 110th Cong. (2007); Quality Health Care Coalition Act of 2005, H.R. 3074, 109th Cong. (2005). All three died in committee without hearings. *See* H.R. 3074 (109th): *Quality Health Care Coalition Act of 2005*, GOVTRACK, <http://www.govtrack.us/congress/bill.xpd?bill=h109-3074> (last visited Nov. 13, 2012); H.R. 3341 (110th): *Quality Health Care Coalition Act of 2007*, GOVTRACK, <http://www.govtrack.us/congress/bill.xpd?bill=h110-3341> (last visited Nov. 13, 2012); H.R. 1493 (111th): *Quality Health Care Coalition Act of 2009*, GOVTRACK, <http://www.govtrack.us/congress/bill.xpd?bill=h111-1493> (last visited Nov. 13, 2012). On April 7, 2011, Representatives Ron Paul (R-Tex.), John Conyers (D-Mich.), and Jeff Miller (R-Fla.) introduced yet another iteration of the bill — this time the Quality Health Care Coalition Act of 2011. *See* H.R. 1409. Again, the bill purports “[t]o ensure and foster continued patient safety and quality of care by clarifying the application of the antitrust laws to negotiations between groups of health care professionals and health plans and health care insurance issuers.” *Id.* Like those bills previously introduced by Representative Paul, it does not intertwine the health care exemption with the NLRA’s labor exemption, keeping the two entirely separate and stating that the bill “shall [not] be construed as changing or amending any provision of the National Labor Relations Act, or as affecting the status of any group of persons under that Act.” *Id.* § 2(b)(2). The bill also exempts several federal programs from its reach. *Id.* § 2(c).

90 *See generally* William N. Eskridge, Jr., *Interpreting Legislative Inaction*, 87 MICH. L. REV. 67, 99 (1988) (arguing that because there are a “variety of reasons, unrelated to the merits or legislative support, for the failure of an idea or a measure in Congress,” little can be concluded from legislative inaction).

91 *See generally id.* (“The legislative agenda is severely limited; to gain a place on that agenda, a measure must not only have substantial support, but be considered urgent by key people (such as the President and/or the party leadership in Congress). . . . A bill can effectively be killed by a hostile committee or subcommittee chair in either chamber.”).

92 *See, e.g., supra* note 73 and accompanying text; *infra* note 141 and accompanying text.

93 H.R. 1409. The text of the bill simply refers to all “health care professionals,” *id.* pmbl., § 2, and does not contain a provision exempting providers in excess of a given size. *But see, e.g.,* Community Pharmacy Fairness Act of 2011, H.R. 1839, 112th Cong. § 2(i)(3) (2011).

versions of the bill, and the impact on larger pharmacies has been under-scrutinized. This is not surprising, as an antitrust exemption for Wal-Mart and Rite Aid to join together and collectively bargain with MCOs presumably would be politically unpopular.

Although no bill has yet become law and more recent iterations have enjoyed less success than those before them, the almost uninterrupted introduction of these bills, the tenacious lobby advocating their passage, and their bipartisan support and periods of near-success demonstrate that an antitrust exemption is a live, important issue deserving of serious scholarly attention. The next Part explores the substantive arguments for and against a legislative antitrust exemption to evaluate whether such protective legislation is warranted. After considering the economic realities of the pharmaceutical supply chain, conventional economic theory, and the principles underlying antitrust regulation, this Note concludes that these congressional proposals have, at least for now, met their proper fate.

### III. ECONOMIC ANALYSIS OF THE PROPOSED ANTITRUST EXEMPTION

Certain antitrust exemptions, such as the labor exemption, are premised, at least in part, on the idea that the market at issue should be removed from the bounds of competition to achieve some ancillary societal goal at the expense of economic efficiency.<sup>94</sup> In contrast, independents have met antitrust doctrine on its own terms. In other words, independents have not argued that the health care market should eschew economic efficiency as its overarching goal; rather, independents have argued that market imperfections prohibit unrestrained competition from best achieving this goal of efficiency. Specifically, the crux of independents' argument is that an exemption would counteract failures and imperfections in the pharmaceutical market and that this improvement, in turn, would increase health care quality at equal or lower cost to consumers. This Part argues, however, that conventional economic theory and empirical data predict otherwise. Section III.A responds to independents' claim that an exemption definitively would not increase health care costs. Section III.B addresses independents' argument that an exemption would increase consumers' quality of health care irrespective of any cost increases. After concluding that both of the arguments advanced by independent pharmacies are flawed, this Note reasons that an antitrust exemption is not wisely grounded in economic policy.

#### *A. Market Price and Health Care Costs*

Independents' first argument for an exemption is premised on the notion that

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<sup>94</sup> For example, the labor exemption is largely premised not on economic arguments but rather on the principle that human labor is not a commodity. See Harry Shulman, *Labor and the Anti-Trust Laws*, 34 ILL. L. REV. 769, 774 (1940).

the pharmaceutical market suffers from heavily entrenched PBM monopsony, “[a] market situation in which one buyer controls the market.”<sup>95</sup> They allege that allowing independents to counteract this anticompetitive market power would bring the market back into equilibrium, keeping independents in business without passing additional costs on to consumers. Subsection III.A.1 applies conventional economic theory to show how an antitrust exemption for independents effectively would legitimize the formation of a sellers’ cartel and likely increase health care costs. Following a description of the argument of countervailing market power in Subsection III.A.2, Subsection III.A.3 concludes that an antitrust exemption cannot be justified on the ground that the creation of a bilateral monopoly would reduce the harmful effects of PBMs’ aggregation of market power. Finally, Subsection III.A.4 reinforces this economic analysis by showing that existing empirical data supports the conclusion that an exemption indeed would raise costs as conventional economic models predict.

### *I. Antitrust Doctrine and Sellers’ Cartels*

Today, the foremost policy of U.S. antitrust law has become the protection of “competition, not competitors.”<sup>96</sup> As such, it prohibits cartelization activities, such as collective-bargaining agreements, which seek to immunize certain competitors from market forces at the expense of consumer welfare. Because the collective bargaining of independent pharmacies falls directly within the scope of this prohibition, the cartelization of independents would contravene the current policy underlying antitrust laws, such as that driving the enforcement of the

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95 BLACK’S LAW DICTIONARY, *supra* note 59, at 1098. By way of elaboration, *Black’s Law Dictionary* quotes LAWRENCE A. SULLIVAN & WARREN S. GRIMES, *THE LAW OF ANTITRUST: AN INTEGRATED HANDBOOK* 137–38 (2000):

Monopsony is often thought of as the flip side of monopoly. A monopolist is a seller with no rivals; a monopsonist is a buyer with no rivals. A monopolist has power over price exercised by limiting output. A monopsonist also has power over price, but this power is exercised by limiting aggregate purchases. Monopsony injures efficient allocation by reducing the quantity of the input product or service below the efficient level.

BLACK’S LAW DICTIONARY, *supra* note 59, at 1098.

96 It is ironic that this phrase, “competition, not competitors” has come to stand for modern antitrust policy of protecting consumer welfare and economic efficiency, given that the Supreme Court first used this phrase in *Brown Shoe Co. v. United States*, 370 U.S. 294, 344 (1962), a case that is criticized today as doing exactly the opposite: protecting small, locally owned businesses at the expense of economic efficiency. As the meaning behind the phrase has evolved over time, however, the Court has quoted this *Brown Shoe* language in numerous widely cited antitrust opinions of the modern era, including *Leegin Creative Leather Products, Inc. v. PSKS, Inc.*, 551 U.S. 877, 906 (2007); *Copperweld Corp. v. Independent Tube Corp.*, 467 U.S. 752, 767 n.14 (1997); *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 224 (1993); *Atlantic Ritchfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 338 (1990); and *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977).

## Sherman Act.

During the Warren Court era of the 1960s, antitrust law often focused on the protection of small business to the detriment of economic efficiency.<sup>97</sup> The 1970s and 1980s, however, witnessed a shift in policy to the “Chicago School” line of thinking,<sup>98</sup> which views consumer welfare as the sole legitimate objective of antitrust.<sup>99</sup> In his canonical book, *The Antitrust Paradox*, Robert Bork put forth a multifaceted argument supporting the principle that the antitrust laws’ statutory language, legislative history, and structural features all point towards consumer welfare being the only tenable criterion on which antitrust should rest.<sup>100</sup> Moreover, Bork maintained that the goal of consumer welfare as a legislative policy best “renders the law internally consistent,” “makes for ease of judicial administration,”<sup>101</sup> and “permits courts to behave responsibly and to achieve the virtues appropriate to law.”<sup>102</sup>

Under traditional economic theory, consumer welfare<sup>103</sup> is highest when the

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97 This populist ideology is embodied by Judge Hand’s *Alcoa* opinion:

[G]reat industrial consolidations are inherently undesirable, regardless of their economic results. In the debates in Congress Senator Sherman himself in the passage quoted in the margin showed that among the purposes of Congress in 1890 was a desire to put an end to great aggregations of capital because of the helplessness of the individual before them. . . . Throughout the history of these statutes it has been constantly assumed that one of their purposes was to perpetuate and preserve, for its own sake and in spite of possible cost, an organization of industry in small units which can effectively compete with each other.

United States v. Aluminum Co. of Am., 148 F.2d 416, 428–29 (2d Cir. 1945); see also ROBERT H. BORK, *THE ANTITRUST PARADOX: A POLICY AT WAR WITH ITSELF* 51–52 (10th prtg. 1993) (quoting from the above *Alcoa* passage in discussing court opinions championing “[v]alues in conflict with consumer welfare”).

98 Timothy J. Muris, Chairman, Fed. Trade Comm’n, Remarks: Looking Forward: The Federal Trade Commission and the Future Development of U.S. Competition Policy 10–11 (Dec. 10, 2002).

99 See BORK, *supra* note 97, at 51; see also Robert A. Skitol, *The Shifting Sands of Antitrust Policy: Where It Has Been, Where It Is Now, Where It Will Be in Its Third Century*, 9 CORNELL J.L. & PUB. POL’Y 239 (1999).

100 BORK, *supra* note 97, at 56–69.

101 *Id.* at 69.

102 *Id.* at 89. Another scholar who has vigorously championed consumer welfare as antitrust’s only guiding policy concern is Judge Richard A. Posner of the Seventh Circuit. Posner rejects populist concerns surrounding antitrust law, questioning smallness as a virtue and the merit of noneconomic arguments. See RICHARD A. POSNER, *ANTITRUST LAW* 2 (2d ed. 2001) (arguing that there is no “justification for using the antitrust laws to attain goals unrelated or antithetical to efficiency, such as promoting a society of small tradespeople, a goal that whatever its intrinsic (and very dubious) merit cannot be attained within the framework of antitrust principles and procedures”).

103 It is important to note that the term “consumer welfare” is a bit of a misnomer. The key inquiry is the total effect of consumer *and* producer surplus—not just that of consumers. See J. Thomas Rosch, *Monopsony and the Meaning of “Consumer Welfare”: A Closer Look at*

market operates under perfectly competitive, and thus non-regulated, conditions.<sup>104</sup> Under perfect competition, the intersection of the market demand and the market supply curves determines the competitive market price and output. Each individual seller is a “price taker” in that it takes the market price as given and cannot unilaterally change the price of its goods by withholding or increasing output.<sup>105</sup> Applying this model to the pharmaceutical industry, an individual pharmacist in a competitive market cannot unilaterally influence reimbursement rates or the quantity of sold pharmaceuticals. From an allocative efficiency standpoint, this outcome is socially optimal, maximizing the sum of consumer and producer surplus.<sup>106</sup>

In contrast to the price-taking seller in a competitive regime, a cartel acts like a multiplant monopoly,<sup>107</sup> with an ability to determine market price through restricting quantity. Because a monopolist is the only seller in the market, it faces the market’s downward-sloping demand curve. Therefore, while the competitive seller’s output is determined only by the price that he can demand for each unit,

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Weyerhaeuser, 2007 COLUM. BUS. L. REV. 353, 355 (“Judge Bork, like other Chicago School adherents, believed that consumer welfare could only be maximized when total (societal) surplus was maximized. In his view, antitrust policy and rules should guard against all practices and transactions creating allocative inefficiencies; thus, the antitrust laws could and would facilitate the maximization for consumer wealth in the aggregate without regard to distribution.”). Although this Note proceeds using this definition of consumer welfare — that of allocative efficiency — it is important to recognize that this view is not shared by all. See *id.* at 354 (“To some, consumer welfare focuses on the effects of the anticompetitive conduct on consumers in the relevant market. According to this view, antitrust liability ultimately turns on whether the seller will have market power over consumers purchasing the output in the relevant market.”). Still, many have noted that the precise definition of this term “is largely an academic debate with no real world impact because there is very little difference between the two standards.” *Id.* at 355; see also Thomas O. Barnett, *Substantial Lessening of Competition—The Section 7 Standard*, 2005 COLUM. BUS. L. REV. 293, 297 (“[T]he consumer welfare and total welfare standards can diverge, although I think it is a rare case in practice.”). Although many of the same arguments would apply, a full explanation as to how the theoretical economic analysis would diverge when one definition is substituted for the other is beyond the scope of this Note.

104 See MARC ALLEN EISNER, *ANTITRUST AND THE TRIUMPH OF ECONOMICS: INSTITUTIONS, EXPERTISE & POLICY CHANGE* 116 (1991) (“The ascendance of the Chicago school also shaped the prevailing understanding of policy by virtue of its faith in the self-sufficiency of markets and its distinct antistatism. As noted earlier, the fundamental assumption underlying this position is that the most efficient level of activity is the market. Managers tend to act rationally, seeking out new and greater efficiencies as a means of maximizing profits.”).

105 See Phillip Areeda, *Introduction to Antitrust Economics*, 52 ANTITRUST L.J. 523, 524 (1984).

106 *Id.* at 525 (“Monopoly means that society will have the wrong mix of products in the sense that a different mix would make consumers happier.”).

107 A multiplant monopoly is where a monopolist has more than one plant, among which it allocates its production. See RICHARD LIPSEY & ALEC CHRYSTAL, *ECONOMICS* 159 (12th ed. 2007). When one “assum[es] that 100 percent of the sales of a good are incorporated into the cartel,” the cartel can be treated “as a multiplant monopoly, where the member firms are analogous to the plants operated by a monopolist.” STEPHEN MATHIS & JANET KOSCIANSKI, *MICROECONOMIC THEORY: AN INTEGRATED APPROACH* 447 (2002).

“[f]or the monopolist, the decision to sell an additional unit of output is determined not merely by the price he can demand for that unit alone, but also the fact that each additional unit sold drives down the price he receives for *all* the other units he sells.”<sup>108</sup> Because to increase sales, the monopolist must lower the price for all units sold, the monopolist’s revenue curve is downward sloping and lies underneath the demand curve. Accordingly, when maximizing profits by producing at the point at which marginal revenue equals marginal cost,<sup>109</sup> the monopolist will sell a lower quantity of output at a higher price than that which it would under competitive conditions.<sup>110</sup>

When competitors join together and centralize decision-making to engage in collective bargaining, they can act essentially as a single firm and thus achieve the anticompetitive results just described of a single-seller monopoly.<sup>111</sup> Because consumer welfare is impaired by such an aggregation of seller power, U.S. antitrust laws declare cartelization *per se* illegal.<sup>112</sup> As explained earlier, when an agreement is considered illegal *per se*, the *actual* effects on price and output of the good or service at hand are irrelevant to the court’s analysis because these agreements are considered to be “so ‘plainly anticompetitive,’ and so often ‘lack[ing] . . . any redeeming virtue,’ that they are conclusively presumed illegal.”<sup>113</sup>

Current U.S. antitrust policy — in attempting to “maximize consumer welfare by promoting the efficient use of scarce resources”<sup>114</sup> — is at odds with laws that “protect individual competitors from the consequences of normal market forces, from aggressive competition by others, [or] from more efficient competitors.”<sup>115</sup> Since focusing on consumer welfare as the guiding principle of

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108 Laura Alexander, Note, *Monopsony and the Consumer Harm Standard*, 95 GEO. L.J. 1611, 1616 (2007).

109 Analogously to a monopolist, a cartel, which is made up of multiple sellers, will restrict the output of every member firm in the cartel so that the marginal cost of production for every member firm is equal to marginal revenue.

110 Areeda, *supra* note 105, at 525.

111 *Id.* at 527.

112 See BORK, *supra* note 97, at 66–67.

113 *Broad. Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1, 8 (1979) (alteration in original) (citations omitted) (quoting *Nat’l Soc’y of Prof’l Eng’rs. v. United States*, 435 U.S. 679, 692 (1978); *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 5 (1958)).

114 The efficient use of resources in a competitive market results in “high output, low prices, high quality, varied services, access, innovation, and efficiency in production and distribution.” ABA SECTION OF ANTITRUST LAW, *supra* note 49, at 8.

115 *Id.* at 8. As Judge Posner has explained,

Antitrust enforcement is not only an ineffectual, but a perverse, instrument for trying to promote the interests of small business as a whole. Antitrust objectives and the objectives of small business people are incompatible at a very fundamental level. The best overall antitrust policy from a small-business standpoint is no antitrust policy. By driving a wedge between the prices and costs of the larger firms in the market . . . monopoly enables the smaller firms



antitrust, the Supreme Court explicitly has rejected the theory that courts should protect or subsidize inefficient small firms at the expense of a more efficient allocation of resources that flows from free-market conditions.<sup>116</sup> Instead, antitrust law seeks to stimulate, rather than retard, competition in order to “lower prices, encourage[] greater innovation, and generate[] faster responses by business to changing consumer needs and desires.”<sup>117</sup>

Applying this model to the health care industry, an exemption that would allow pharmacy owners who were formerly in competition with each other to cartelize by collectively negotiating pharmaceutical reimbursement rates would sacrifice consumer welfare for that of small business. Such an approach would fly directly in the face of our current antitrust policy, which is rooted in a concern for consumer welfare. First, pharmacists would prosper at the expense of PBMs and consumers. In effect, PBMs would have to pay higher reimbursement rates to pharmacists, which PBMs then would demand from MCOs. MCOs would, in turn, pass these added costs on to plan subscribers (the consumers) through higher insurance premiums. Second, because pharmacists would not only increase prices, but also would sell a lower than allocatively efficient level of output, resources would not be “automatically funneled into the production of goods consumers find most valuable.”<sup>118</sup> In economic terms, while pharmacists would be made better off as a result of cartelization, they would not be made sufficiently better off to compensate for the accompanied loss in welfare of consumers.

Because it is important both to society as a whole and to individual patients in particular that pharmaceuticals are not sold in suboptimal quantities or at above-optimal prices, increased costs and decreased output are particularly troubling. Conventional microeconomic theory dictates that when faced with cost increases, patients almost certainly will fill fewer prescriptions. A large body of research in both the United States and Canada has correlated increased copayments and associated prescription costs with prescription noncompliance and reduced drug use.<sup>119</sup> At least one study has found that the primary reason for

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to survive even if their costs are higher than those of the large firms. The only kind of antitrust policy that would benefit small business would be one that sought to prevent large firms from underpricing less efficient small firms by sharing their lower costs with consumers in the form of lower prices. Apart from raising in acute form the question whether society should promote small business at the expense of the consumer, such a policy would be unworkable.

POSNER, *supra* note 102, at 26.

116 BORK, *supra* note 97, at 56.

117 Muris, *supra* note 98.

118 E. THOMAS SULLIVAN & JEFFREY L. HARRISON, UNDERSTANDING ANTITRUST AND ITS ECONOMIC IMPLICATIONS 24 (4th ed. 2003).

119 Rachel A. Elliot et al., *Understanding Medication Compliance and Persistence from an Economics Perspective*, 11 VALUE IN HEALTH 600, 602 (2008).

unfulfilled prescriptions among Medicare beneficiaries is medication cost.<sup>120</sup> Unfortunately, cost increases are most likely to impact populations with the least income and job security, such as the poor and elderly, who are also the populations most prone to disease.<sup>121</sup> The failure to follow through with needed medication only serves to further strain our health care system; researchers consistently have found that prescription nonadherence is associated with increased total health care costs,<sup>122</sup> poorer health care outcomes, and greater use of urgent care and inpatient health facilities.<sup>123</sup>

In sum, under the conventional economic models on which antitrust doctrine is predicated, by allowing pharmacists to boycott collectively any PBM or insurer that fails to meet fee demands, the proposed exemption would increase pharmaceutical prices by raising fees paid to smaller, more inefficient pharmacies at the expense of consumers' pocketbooks. Independents counter, however, that while conventional antitrust doctrine assumes a perfectly competitive market, the pharmaceutical supply chain is rife with market imperfections, particularly PBMs' exertion of market power. The next Subsection will evaluate independents' argument that traditional economic analysis is inapplicable because the idealized economic model does not accurately reflect the nature of the competition in the pharmaceutical market.

## 2. *The Argument of Countervailing Market Power in Response to Monopsony*

Theoretically, negotiations of the reimbursement schedule between pharmacists and PBMs should occur within a competitive market, with no individual PBM — and also no individual pharmacist — unilaterally being able

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120 See Jae Kennedy et al., *Unfilled Prescriptions of Medicare Beneficiaries: Prevalence, Reasons, and Types of Medicines Prescribed*, 14 J. MANAGED CARE PHARMACY 553 (2008) (finding that of a sample of 1.6 million Medicare beneficiaries who did not fill their prescriptions, 55.5% stated their failure to do so was due to the fact that they “thought it would cost too much” (internal quotation marks omitted)).

121 See, e.g., Ira B. Wilson et al., *Cost-Related Skipping of Medications and Other Treatments Among Medicare Beneficiaries Between 1998 and 2000: Results of a National Study*, 20 J. GEN. INTERNAL MED. 715, 720 (2005) (“[C]ost-related skipping of medications and other treatments is associated with several different factors, including poverty and poor health. If a prescription drug plan requires significant cost sharing, certain vulnerable subgroups will almost certainly continue to experience relatively high cost-related medication skipping rates, particularly low-income seniors whose income or assets may not qualify for any low-income subsidies because their income or assets make them ineligible.”).

122 Researchers have found that medication adherence results in overall health care savings even when accounting for the increased costs associated with patients purchasing needed medications. M. Christopher Roebuck et al., *Medication Adherence Leads to Lower Health Care Use and Costs Despite Increased Drug Spending*, 30 HEALTH AFFAIRS 91, 91 (2011).

123 *Id.*; see also Elliot et al., *supra* note 119, at 602 (stating that reduced drug use associated with increased costs is linked with increased morbidity, hospitalization, and costs).

to affect the market price of a given quantity of medication.<sup>124</sup> As demonstrated by various complaints filed by pharmacists in federal district court against MCOs, however, independents allege that this illustration of a perfectly competitive pharmaceutical market does not reflect the actual market in which negotiations between an independent pharmacy and a PBM occur. According to independents, a handful of PBMs, who would individually be price-takers in a competitive regime, control the market and are able to force below-market prices on independents in their negotiations for reimbursement rates.<sup>125</sup> This allows them to circumvent true negotiation, which should result in competitive prices.<sup>126</sup> Instead, a PBM can force a reimbursement rate on an independent that is not only “far below” that which “would apply in a true competitive market,” but also “generally below any measure of [an] Independent Pharmacist’s actual costs including their variable, marginal, and/or actual costs.”<sup>127</sup> As a result, “fewer goods are transacted, wealth is transferred from the party without market power [(i.e., the seller)] to the party with market power [(i.e., the buyer)], and there is a loss of social welfare.”<sup>128</sup>

Independents argue that they can effectively counteract PBMs’ monopsony power—and thus restore the market to competitive equilibrium—by exerting countervailing market power through a *bilateral monopoly*—a market characterized by the possession of market power by both sellers and buyers.<sup>129</sup> Theoretically, facilitating a bilateral monopoly does counteract to some extent the effects of a monopsony power. Because “the buyer and seller” are unable “simultaneously . . . [to] exploit their respective market power,”<sup>130</sup> meaning that

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124 For an economic analysis of buyer behavior in a competitive market, see James Murphy Dowd, *Oligopsony Power: Antitrust Injury and Collusive Buyer Practices in Input Markets*, 76 B.U. L. REV. 1075, 1081–84 (1996).

125 See *Healthcare Competition Hearing*, *supra* note 46, at 28–36 (statement of David Balto, Senior Fellow, Center for American Progress Action Fund).

126 In addition to extracting below-competitive market prices, PBMs allegedly also use their market power to compel pharmacists to bear additional costs, such as forcing them to buy software from the PBM and charging them for processing fees. See, e.g., Plaintiffs’ Reply to Defendants Caremark RX, Inc. and Caremark Inc.’s Motion To Dismiss Plaintiffs’ Second Amended Class Action Complaint at 5, *N. Jackson Pharmacy, Inc. v. Caremark Rx, Inc.*, 385 F. Supp. 2d 740 (N.D. Ill. Nov. 1, 2004) (1:04-CV-05674), 2004 WL 5549836.

127 Plaintiffs’ Memorandum in Support of Class Certification at 15, *N. Jackson Pharmacy, Inc.*, 385 F. Supp. 2d 740 (CV 03-HS-2696-NE, CV 03-HS-2697-NE), 2005 WL 2016439 (making such allegations). This can be contrasted to “conditions of perfect competition,” under which “a firm always maximizes profits (or minimizes losses) by producing that output at which its marginal cost equals the market price. This occurs because the perfectly competitive firm accepts the market price as given since it is, by definition, too small to affect market price by any variations in output.” Philip Areeda & Donald F. Turner, *Predatory Pricing and Related Practices Under Section 2 of the Sherman Act*, 88 HARV. L. REV. 697, 702 (1975).

128 Alexander, *supra* note 108, at 1614.

129 See JAMES W. HENDERSON, *HEALTH ECONOMICS & POLICY* 75–76 (4th ed. 2009) (explaining the economics of a bilateral monopoly).

130 Blair & Boylston Herndon, *supra* note 11, at 1006.

neither the monopolist nor the monopsonist outcome is tenable, some accommodation is necessary. Accordingly, profit incentives force the seller and buyer to cooperate, either in the form of vertical integration or through the bargaining process.<sup>131</sup> If done through the latter, by making a credible threat of refusal to sell unless the buyer raises prices, the now legalized sellers' cartel will be able to move price and output to competitive or near competitive levels.<sup>132</sup> As a result of this negotiation, consumers are better off than had the monopsony conditions alone prevailed.

In making this argument, independents do not dispute that the same result could be achieved through vigorous enforcement of antitrust laws against PBMs' alleged monopsony power. Independents claim, however, that federal law enforcement essentially has "dropped the ball" in bringing action against monopsonist PBMs. As a result, monopsonist PBMs continue to use market power to engage in anticompetitive activity,<sup>133</sup> offering independents unfavorable terms through contracts of adhesion.<sup>134</sup> Independents argue that by exerting countervailing market power through an antitrust exemption, they will act procompetitively by bringing reimbursements in line with competitive levels.<sup>135</sup> In response to the objection that these additional costs would be passed through higher insurance rates on to consumers, independents argue that PBMs already are extracting supracompetitive profits through their exercise of market power. Because "PBMs have great flexibility in determining how much they shift over to patients and taxpayers,"<sup>136</sup> any decision to increase rates as a result would be "strictly a decision of the PBM."<sup>137</sup> As discussed in the Subsections that follow, however, the argument advanced by independents rests on faulty assumptions that are belied by empirical evidence.

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131 ROGER D. BLAIR & JEFFREY L. HARRISON, *MONOPSONY IN LAW AND ECONOMICS* 128 (2010).

132 Cf. Carstensen, *supra* note 43, at 25–26 ("[I]f a group of small, powerless buyers face a monopoly or oligopoly supplier, then individually they are powerless to bargain for better prices and larger outputs. The small buyers are compelled to pay the monopoly or oligopoly price demanded by the sellers. However, if these individual buyers can group together and make a credible threat that they would withhold their purchases unless lower prices and greater quantity were offered, they might succeed in bargaining down prices and increasing output. . . . such that the market moves toward the price and output that would exist if the industry was competitive.").

133 *Healthcare Competition Hearing*, *supra* note 46, at 28, 30–31 (statement of David Balto, Senior Fellow, Center for American Progress Action Fund).

134 *Id.*

135 *Community Pharmacies Hearing*, *supra* note 73, at 15 (statement of Mike James, Vice President, Association of Community Pharmacies Congressional Network & Pharmacist/Owner, Person St. Pharmacy, Raleigh, N.C.); Leo Mallard, *Give Local Pharmacies a Level Playing Field*, *BALTIMORE SUN*, July, 8, 2007, at 19A.

136 *Community Pharmacies Hearing*, *supra* note 73, at 15.

137 *Id.* at 10 (testimony of Rep. Ric Keller, Ranking Member, Task Force on Antitrust and Competition).

### 3. Questioning Independents' Assumptions: PBM Monopsony

The argument of countervailing market power rests on three fundamental assumptions. First, PBMs exercise unequal bargaining power vis-à-vis pharmacists. Second, this power translates into a decrease in consumer welfare as defined by antitrust law. And third, the most effective way for independents to counteract the anticompetitive effects of PBM monopsony and restore the market to competitive equilibrium is to cartelize. Examining each of these assumptions in turn, this Subsection challenges the claim that there is sufficient evidence that PBMs exercise monopsony power, which necessarily translates into a decrease in consumer welfare. Moreover, this Subsection asserts that even accepting independents' claim of inefficient monopsony, Congress would be remiss to remedy this market failure by sanctioning collective bargaining for the purpose of creating a bilateral monopoly.

#### a. Extent of Monopsony Power Among PBMs

The first dubious assumption on which independents' argument rests is that there is sufficient evidence that PBMs have monopsonistic power<sup>138</sup> in the pharmaceutical market to support such drastic legislative action.<sup>139</sup> Although the pharmacy lobby claims that the PBM market is "tremendously concentrated,"<sup>140</sup> a strong body of evidence points in the opposite direction. Supporters of an exemption emphasize that there are only a couple of PBMs controlling the market, but this claim fails to account for the fact that FTC-promulgated statistics reflect that "[t]here are approximately 40 to 50 PBMs operating in the United States," not just a few.<sup>141</sup> Without the critical assumption of overly concentrated PBM market, the countervailing market-power argument is a nonstarter.

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138 By alleging that a handful of PBMs control the market — rather than a single monopsonistic firm — pharmacists are in actuality referring to an oligopsony rather than a monopsony. That said, for simplicity (and because independents often still use the word "monopsony," albeit incorrectly, to refer to PBMs' behavior), "monopsony" is used throughout the Note.

139 While, historically, antitrust law chiefly has focused on anticompetitive agreements among sellers, "buying power, is economically objectionable for the same policy reasons that underlie antitrust's opposition to monopoly." Clark C. Havighurst, *Antitrust Issues in the Joint Purchasing of Health Care*, 1995 UTAH L. REV. 409, 411. Instead of focusing on the *output* side of the market, however, as a monopolist would do, a monopsonist, or buyers' cartel, focuses on the *input* side of the market. Accordingly, the fundamental objective is the mirror image of a monopolist's: "to eliminate competition in some aspect of their input purchasers in order to reduce the prices associated with such purchases or otherwise control supplier conduct." Carstensen, *supra* note 43, at 9–10. In short, a monopsonist, exerting its market power, extracts goods from a seller at lower than competitive price.

140 *Healthcare Competition Hearing*, *supra* note 46, at 28 (statement of David Balto, Senior Fellow, Center for American Progress Action Fund).

141 *Id.* at 13 (statement of Richard A. Feinstein, Dir., Bureau of Competition, Federal Trade Commission).

Additionally, existing economic models, empirical data, and anecdotal evidence support the view that independents' bargaining leverage may not be as low as independents suggest. One economic study found that during the time period studied, "independents themselves appear[ed] to have greater bargaining power individually than chain pharmacies."<sup>142</sup> One explanation for this might be that certain laws not only prohibit health plans from offering mail order as an only option,<sup>143</sup> but also provide that consumers must be able to frequent a certain number of pharmacies in a given geographical area.<sup>144</sup> In rural areas, where there are limited numbers of pharmacies, many of which are independent, a PBM theoretically may be forced to accept whatever terms the *independent* demands.<sup>145</sup> Additionally, there have been reports suggesting that the contract-of-adhesion model does not reflect reality; independent pharmacies have in fact rejected proposed insurer contracts due to low reimbursement rates rather than blindly accepted the rates offered, regardless of how meager.<sup>146</sup>

Moreover, that PBMs are forcing pharmacists to agree to reimbursement rates below costs defies economic logic. As Caremark Rx, Inc. and Caremark Inc. remarked in response to antitrust litigation brought by two plaintiff pharmacies:

If, in fact, reimbursement rates were below their 'marginal, variable and/or actual costs' as Plaintiffs allege, no rational business person would seek to 'receive a greater volume of business' at such rates. The fact that Plaintiffs have continued to enter into those contracts belies the contention that reimbursement rates are below their costs.<sup>147</sup>

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142 John M. Brooks et al., *Factors Affecting Bargaining Outcomes Between Pharmacies and Insurers*, 34 HEALTH SERVS. RESEARCH 439, 448 (1999).

143 See *infra* note 272 and accompanying text.

144 *Preserving Our Hometown Independent Pharmacies Act of 2011: Hearing Before the H. Subcomm. on Intellectual Property, Competition, & the Internet of the Comm. on the Judiciary*, 112th Cong. 53 (2012) (statement of Richard Feinstein, Dir., Bureau of Competition, Federal Trade Commission) ("I just want to make the point that there are places in those networks where they have to deal with independent pharmacies, because there are rural locations, for example, where the independent pharmacies may be the only one [sic] in a town."); *id.* at 141 n.31 (statement of Peter J. Rankin et al., Charles River Associates International).

145 See *supra* note 144.

146 Brooks et al., *supra* note 142, at 440; Andrea Radford et al., *The Experience of Sole Community Rural Independent Pharmacies with Medicare Part D: Reports from the Field* 2, 9 (N.C. Rural Health Research & Policy Analysis Ctr. & RPRI Ctr. for Rural Health Policy Analysis, Working Paper No. 87, Policy Paper P2006-3, 2006), available at <http://www.shepscenter.unc.edu/rural/pubs/report/WP87.pdf>.

147 Motion of Caremark Rx, Inc. & Caremark Inc. To Dismiss the Second Amended Complaint, at 11, *N. Jackson Pharmacy, Inc. v. Caremark Rx, Inc.*, 385 F. Supp. 2d 740 (ND. Ill. Oct. 1, 2004) (1:04-CV-05674), 2004 WL 5549835 (citations omitted). Ultimately, the case was not resolved by the district court, but went to arbitration. See *In re Pharmacy Benefit Managers*

It is dubious that independents would agree to reimbursement rates below their costs, forcing them to operate at a loss<sup>148</sup> (unless for instance, the independents believed such losses would only be short term). Moreover, such a strategy may be contrary to PBMs' own interests given its potential to force all of their suppliers out of business. Finally, evidence shows that at least a group of independents remain profitable. In the congressional hearings on the Community Pharmacy Fairness Act of 2007, Charles River Associates (CRA) International, a leading global consulting firm, presented evidence that in 2005, independent pharmacies enjoyed, on average, a gross profit margin rate of 19.3% on sales to commercial insurers, including Medicare managed care plans.<sup>149</sup> Not only did this figure increase 1.5% from the previous year, but this growth also coincided with an increase in independents' overall gross profit margin on prescriptions from 21.2% in 2004 to 22.7% in 2005.<sup>150</sup> Moreover, in 2003, the number of independent pharmacies increased by over 400, which CRA International testified "would have been unlikely to occur had the market for their services not been profitable."<sup>151</sup> Again in 2008, independently owned community pharmacies' total sales increased on average by 7.6%, amounting to \$3.9 million.<sup>152</sup>

Finally, to the extent that concentrations of market power do exist, the FTC and DOJ vigilantly have worked to break up and monitor aggregations of market power in the insurance industry. One way in which the FTC has done so is by

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Antitrust Litig., 582 F.3d 432 (3d Cir. 2009) (reinstating a district-court order compelling arbitration).

148 Motion To Dismiss, *supra* note 147, at 11.

149 *Community Pharmacies Hearing*, *supra* note 73, at 30 (statement of Peter J. Rankin, Principal, Charles River Associates International).

150 *Id.*

151 *Id.* at 31. Moreover, at least some of the pharmacies that are closing have not folded from bankruptcy but rather have sold their businesses for a profit. See *Chain Drug Stocks on Upswing*, CHAIN DRUG REV., June 30, 2008, at 23 (quoting research analyst as saying "[p]harmacy operations are expected to be a key focus, reflecting what we see as CVS's ability to succeed in the rapidly growing managed care arena and its ongoing purchase of prescription files from independent pharmacies" (internal quotation marks omitted)); Andrea Chang, *Big Chains a Headache for Small Drugstores*, L.A. TIMES (Oct. 8, 2008), <http://articles.latimes.com/2008/oct/08/business/fi-drugstore8> (quoting a pharmacy owner as saying, "We get offers, I would say probably not every week, but at least once or twice a month. . . . Usually it's just a little feeler-type letter: 'Why don't you sell to us now while you still can make some money?'" (internal quotation marks omitted)); Ralph de la Cruz, *Independent Drugstores: Going, Gone?*, LONG BEACH PRESS—TELEGRAM, Oct. 23, 1997, available at 1997 WLNR 1402045 ("Chain stores are coming into the independent market and making very attractive offers," Tilley said. Tilley, who owns Zweber Apothecary pharmacies, said he's been approached five times by chains."). These confounders cast doubt on the independent pharmacists' arguments that the magnitude of closures reveals an inability of independents to compete with chains or mail-order pharmacies.

152 Jim Frederick, *Facing Economy, Indy Pharmacists Stand Firm*, DRUG STORE NEWS, Nov. 16, 2009, at 17, available at <http://www.drugstorenews.com/article/facing-economy-indy-pharmacists-stand-firm>.

proactively reviewing proposed mergers and acquisitions that potentially could threaten competition in the health care industry. For example, in 2004, the FTC investigated Caremark Rx's proposed acquisition of Advance PCS.<sup>153</sup> In approving the transaction, and thus closing its investigation, the FTC found that post-merger Caremark Rx would continue to face robust competition from Medco and Express Scripts (two other national PBMs) as well as several other health plans and retail pharmacy chains offering PBM services.<sup>154</sup> Moreover, the FTC concluded that "there [was] no reason to expect a monopsony or oligopsony outcome . . . even if the acquisition enable[d] the merged PBM (or PBMs as a group) to reduce the dispensing fees they pay to retail pharmacies."<sup>155</sup> The FTC based this finding on the fact that (1) each PBM negotiated contracts individually with each retail pharmacy company and that (2) "the post-acquisition share of the merged firm for all purchases of prescription dispensing services would be below the level at which an exercise of monopsony power [was] likely to be profitable."<sup>156</sup> Other PBMs have not fared as well as Caremark Rx and Advance PCS when faced with FTC scrutiny; several FTC investigations of PBM activity have resulted in consent orders restricting the transactions.<sup>157</sup>

When one recognizes the flaws inherent in independents' claims, it becomes clear that larger chains are driving some smaller, independent pharmacies out of business not because of some inherent market unfairness, but rather because larger pharmacies, including those owned by chain stores and supermarkets, benefit from economies of scale, which allow them to offer the same pharmaceuticals at lower prices.<sup>158</sup> Independents themselves have attributed their

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153 Caremark Rx, Inc./AdvancePCS, F.T.C. File No. 031-0239, (Feb. 11, 2004 (statement of the FTC closing its investigation of the Caremark-AdvancePCS merger).

154 *Id.*

155 *Id.*

156 *Id.*

157 For example, in *Merck & Co., Inc.*, 127 F.T.C. 156, 159 (1999), the FTC found that when Merck (a leading pharmaceutical manufacturer) acquired Medco (a PBM), it substantially lessened competition in violation of section 7 of the Clayton Act, as amended 15 U.S.C. § 18 (2006), and section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. As a result, the FTC issued a consent order directing Merck and Medco to maintain and disclose an open formulary with information regarding the relative costs of listed drugs and prohibiting them from communicating proprietary and other nonpublic information. *Merck*, 127 F.T.C. at 162, 164.

158 Chang, *supra* note 151, at 1. Consolidation in the drugstore industry is driven in part by the cost savings that can be found when different functions, such as distribution, purchasing and management, are combined."); see also *Community Pharmacies Hearing*, *supra* note 73, at 2 (statement of Rep. John Conyers) ("We are told and we will hear today, how they are being driven out of business because they can't compete with large retail pharmacies and cannot survive with the low reimbursement rates that are given to them now. . . . [S]mall pharmacies have suffered because of higher administrative costs, approximately some \$15 billion a year."). According to one 2008 study, "independent drugstores in the state of Florida charged an average of 15 percent more for four widely used prescription drugs than the statewide average." *New Study: Independent Drugstores Charge 15% More for Prescription Drugs; New 'Collective Bargaining' Rights Would Empower Them To Raise Costs Even More*, BUS. WIRE, Nov. 3, 2008.



market struggles to the fact that they cannot compete with chains' competitive prices. Although much of this may very well be attributed to greater average bargaining power (at least in certain markets), there may be other explanations as well. For example, one reporter quoted an independent pharmacy owner as candidly admitting that "[a] chain store can afford to sell prescription drugs at lower prices, because once they get a customer in the store, they can make money selling them thousands of other products. Most independent pharmacists do not have that luxury."<sup>159</sup> Chain stores benefit from more efficient computer systems,<sup>160</sup> high-tech dispensing technology,<sup>161</sup> and the ability conveniently to offer consumers the opportunity to buy a wide variety of "front end" items, such as beauty supplies and toiletries.<sup>162</sup> By saving labor costs and procuring revenue from additional products, chains offer consumers lower prescription prices irrespective of any bargaining-power differential. Again, this is not to say that such a differential does not exist, just that it is unclear to *what extent* lower prices are a result of greater bargaining leverage stemming from greater market share. Thus, at a minimum, a legislative exemption would be a blunt tool to address this perceived problem. The evidence that PBMs benefit from monopsony and that they use this aggregation of market power to drive independents out of business is too speculative to support legislative reform.

#### *b. Impact on Consumer Welfare*

The second major assumption on which independents' arguments rest is that PBMs' and chain pharmacies' monopsony power translates into higher prices and lower output, or, in economic terms, a reduction in allocative efficiency. Even if

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<sup>159</sup> Mark Mandernach, *A Dose of Reality: Independent Pharmacy Chains Fight for Survival*, CHI. TRIBUNE (Apr. 3, 2004), [http://articles.chicagotribune.com/1994-04-03/features/9404030199\\_1\\_independent-pharmacies-suburbs-fill](http://articles.chicagotribune.com/1994-04-03/features/9404030199_1_independent-pharmacies-suburbs-fill).

<sup>160</sup> Eric Fisher, *Pharmacy Veteran Helps Small Stores Fight Chains*, WASH. TIMES, Apr. 7, 1997, at D20 ("A major hurdle in competing with national chains remains technology. Each of the nationals has an integrated computer system to transmit customer information. Care Drug stores [a smaller, local chain] use nine different software configurations.").

<sup>161</sup> See Chris Birk, *Service, Technology Are Keeping Mom-and-Pop Stores Alive*, ST. LOUIS POST-DISPATCH, July 9, 2008, at C1.

<sup>162</sup> According to a reporter, one pharmacist complained: "I don't sell televisions, tires, motor oil or fruits and vegetables. . . . There's nowhere I can send my customers to buy something else while they wait for their prescription to be filled." Chris Starrs, *Independent Pharmacies Use Different Techniques To Compete*, ATHENS ONLINE ATHENS BANNER-HERALD (Ga.) (Sept. 21, 2008), [http://onlineathens.com/stories/092108/bus\\_335045938.shtml](http://onlineathens.com/stories/092108/bus_335045938.shtml) (internal quotation marks omitted); see also *Everybody Wants a Piece of the 'Drug Store' Market*, CHAIN DRUG REV., OCT. 27, 2008, at 40 ("Independent drug stores . . . typically are much smaller than a chain outlet and have far fewer front-end products to draw traffic."); Michael Schroeder, *The War on Drugs: Pharmacies on Front Lines as Supermarkets Fight To Draw Customers*, J. GAZETTE (Fort Wayne, Ind.), Aug. 24, 2008, at 1H ("Superstore and supermarket officials say being a one-stop destination for everything from medications to banking (offered through in-store tenants) is appealing to consumers who want to spend less on gas. By the way, gas is also sold by many of these stores.").

PBMs and/or chain pharmacies do exercise monopsony market power, it is not evident that this market power reduces the level of output and/or translates into higher prices in the market downstream. There are several reasons why this might be the case. First, although there may be numerous sellers and one buyer in a given market, if the supply curve of pharmacists is elastic (i.e., flat) the quantity demanded will no longer dictate reimbursement rates.<sup>163</sup> The same quantity of pharmaceuticals is demanded regardless of the reimbursement rate. Since controlling quantity will no longer influence the reimbursement rate when the supply curve is elastic, the single buyer cannot exercise monopsony power.

Second, the supply curve in the pharmaceutical industry may not mimic the conventional economic model. Typically, the “supply curve identifies the amount of services [or goods] that will be supplied at every price when suppliers can make marginal adjustments in the quantity supplied in response to price changes.”<sup>164</sup> In some industries, however, this is not the case and suppliers face a decision that is all or nothing, in which they must choose between supplying a given quantity of goods or no goods at all.<sup>165</sup> If the seller is forced onto the all-or-nothing supply curve, the monopsonist will be able to achieve even greater returns than in the typical monopsony scenario because it can now reduce average reimbursement rates without simultaneously reducing output.<sup>166</sup> Because short-run<sup>167</sup> output remains the same as it would under competitive conditions, the resulting short-term effects will be distributional, with the buyer capturing the entire producer surplus.<sup>168</sup> Several scholars have posited that this scenario may indeed hold true in the health provider context, where the quantity of services provided may not be left entirely to the health care provider’s discretion.<sup>169</sup>

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163 See Blair & Boylston Herndon, *supra* note 11, at 1001–02 for a discussion of this phenomenon in the context of physician cartels.

164 *Id.*

165 *Id.* at 1002–03.

166 *Id.* at 1003. The all-or-nothing supply curve “traces out the average cost curve since the supply decision ultimately becomes a choice between operating at the indicated quantity or shutting down.” *Id.* at 1002 n.42. This is because “a supplier will choose to operate as long as it is able to cover its average costs.” *Id.*

167 While output is not reduced in the short run, this may not be the case in the long run, as sellers may leave the industry for another in which price is not below average cost. See Roger D. Blair & Jeffrey L. Harrison, *Antitrust Policy and Monopsony*, 76 CORNELL L. REV. 297, 319 (1991). This would not be the case if the seller could “peg[] a price that [would] permit[] just the right number of sellers to comfortably stay in business.” *Id.* However, “[t]his argument rests on unrealistic assumptions about the availability of information and the rationality of business conduct.” *Id.*

168 Blair & Boylston Herndon, *supra* note 11, at 1003.

169 *Cf. id.* at 1002–03 (“There may be instances in which a health plan is able to push physicians onto their all-or-none supply curve. Physicians may face an all-or-none decision when the purchaser of their services is a dominant health plan that is concerned about coverage as well as price and, therefore, desires to maintain the *same* quantity of physician services while imposing a lower reimbursement rate. Because the health plan negotiates services for a collection of patients, a physician’s refusal to provide the stipulated services to one of the health plan’s subscribers may

Ironically, in seeking an antitrust exemption, independents have in fact argued that they face all-or-nothing decisions in the face of monopsonist PBMs.<sup>170</sup>

Finally, often despite being able to extract below-competitive prices in the “upstream” market, a monopsonist (or a member of a buyers’ cartel that has monopsony power) is not always the only seller in the resale market downstream.<sup>171</sup> In this world, a monopsonist does not impact directly the prices that individual members of the cartel will charge consumers for the outputs.<sup>172</sup> This is because “[d]ownstream prices are a function of the market or markets in which such sales are made.”<sup>173</sup> If the downstream market is competitive, a monopsonist still will be forced to sell to consumers at a competitive level of

result in deselection by the health plan, thereby losing access to all of its subscribers. Physicians will continue to participate in the health plan, even if they object to these terms, when they are financially dependent on the dominant insurer. When confronted with lower reimbursement rates, the terms of the contract with the health plan, in addition to ethical and reputational considerations, constrain the physician’s ability to restrict the services provided to a particular patient. For example, the physician’s contract with a health plan often specifies certain minimum service requirements that the physician must meet.”); see also Blair & Harrison, *supra* note 167, at 319.

170 *In re Pharmacy Benefit Manager (PBM) Antitrust Litig.*, No. 1:04-cv-05674, 2006 WL 5502869 (N.D. Ill. Apr. 7, 2006) (“Defendant PBMs present Plaintiffs with take-it-or-leave it contracts that set the prices for reimbursement and impose other anticompetitive terms.”); see also Allison Dabbs Garrett & Robert Garis, *Leveling the Playing Field in the Pharmacy Benefit Management Industry*, 42 VAL. U. L. REV. 33, 46 (2007) (“The retail pharmacies are generally offered a ‘take it or leave it’ deal to be included in the network, with only the largest pharmacy chains having any ability to negotiate with the PBMs.”). Physicians have made the same argument in their dealing with insurers as well. See, for example, *Kartell v. Blue Shield*, 749 F.2d 922 (1st Cir. 1984), in which physicians argued that Blue Shield offered insurance contracts on a take-it-or-leave-it basis.

171 As one scholar notes, this arrangement still will be economically attractive to a monopsonist: “When buyers can make an ‘all or nothing’ offer to a producer that has increasing marginal cost, the buyer can offer to buy a large volume at a price equal to the average cost of production. It will be rational for the producer to accept this offer and deliver the same quantity that it would have delivered at a market price equal to the marginal cost of its last unit. This means the buyer can induce a level of production comparable to the competitive level, but at the same time transfer all [of] the infra-marginal gain (Riccardian Rents) to themselves.” Carstensen, *supra* note 43, at 21.

172 Where the monopsonist (or a member of a buyers’ cartel) *does not* sell in a competitive downstream market, but rather is the only seller in the resale market, consumers are likely to face supercompetitive prices. This is because

[t]he monopsony buyer, unlike the competitive buyer, can reduce the purchase price by scaling back its purchases. Because the monopsonist ordinarily reduces its buying power by purchasing less, it sells less downstream. This reduction in its own output will, if it has market power on the selling side, mean higher prices for customers. Thus, lower buying prices upstream may translate into higher seller prices downstream.

PHILLIP AREEDA ET AL., *ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION* § 574 (1978).

173 Carstensen, *supra* note 43, at 10.

output at a competitive price.<sup>174</sup> Therefore, unless PBMs act *both* as monopsonists in the upstream market and monopolists in the downstream market, economists have posited that the consumer-harm argument loses steam.<sup>175</sup> While the monopsonist still will have extracted a surplus from the seller who sold its inputs at a below-competitive price, in the short run, “there is no efficiency harm because there is the same production and price is not increased.”<sup>176</sup> There is at least some reason to believe that this scenario might accurately reflect reality in the case of PBMs. Even assuming that PBMs exert monopsony power vis-à-vis pharmacists, PBMs still may not exert sufficient monopoly power in the downstream market to “resell” the pharmaceuticals to plan sponsors and consumers at above-market rates.<sup>177</sup>

Given the failure of independents to account for such contingencies in their analysis, it cannot be taken as a foregone conclusion that PBMs’ bargaining power necessarily translates into the type of harm to consumers that the antitrust laws were designed to prevent *or* the magnitude of harm that independents assert. This analysis is not to say that such aggregations of buying power are innocuous or that they should be permitted to exist absent intervention. It also is not to assert the necessary existence of such conditions that may mitigate the harmful effects on consumer welfare. It is to say, however, that independents’ economic analysis is underdeveloped and under-theorized. Sophisticated economic models are needed to predict an intermediate buyer’s ability to effect a change in the welfare of primary-market consumers downstream.<sup>178</sup> Still, even if one rejects entirely the above analysis put forth by economists, independents’ lobbying efforts rest on an additional premise. Assuming, arguendo, the existence of an inefficient PBM monopsony, the next Subsection examines and ultimately rejects independents’ presumption that the legalization of independent pharmacy cartels would be the appropriate mechanism to return the market to equilibrium.

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174 This scenario will hold true where either: (1) “buyers can compel the producers to deliver approximately the same output at the lower price” or (2) “buyers compete in a resale market with many other producers such that the resale is set competitively and the cartel has no incentive or capacity to raise the prices of its output.” *Id.* at 21.

175 This outcome will be different if after purchasing discrete units of goods from sellers, buyers resell those goods in a market in which they are the only sellers. *See id.* at 20. In this world, when buyers reduce the price that they pay for their inputs, output of that commodity in the resale market (i.e., sales to individual consumers) declines. *Id.* Here, a buyers’ cartel harms consumers by reducing production and increasing prices charged to consumers. *Id.* at 20–21.

176 *Id.* at 21. “[T]he contemporary economic welfare model is not concerned” with “transfer[s] of surplus from seller to buyer” without any accompanying impact on consumers. *See id.* at 21 & n.83.

177 *See Healthcare Competition Hearing*, *supra* note 46, at 14 (statement of Richard A. Feinstein, Dir., Bureau of Competition, Federal Trade Commission) (noting that “[t]he FTC found in its most recent antitrust investigation of the PBM industry, that competition among PBMs for contracts with plan sponsors is ‘vigorous’”).

178 Frances H. Miller, *Health Insurance Purchasing Alliances: Monopsony Threat or Procompetitive Rx for Health Sector Ills?*, 79 CORNELL L. REV. 1546, 1551 (1994).

*c. The Promise of Bilateral Monopoly in Returning the Market to Equilibrium*

Finally, even when one accepts that the PBM market is anticompetitive, in that PBMs constitute a monopsony and this power translates into a reduction in consumer welfare, independents' argument still rests on the critical assumption that the cartelization of pharmacists — and thus the creation of a bilateral monopoly — is the only (or, alternatively, best) way to counteract these anticompetitive forces. Although superficially attractive, the argument that Congress should legalize cartels of pharmacists in order to facilitate the formation of a bilateral monopoly is subject to several fallacies.

First, while the economic effects can be predicted to some extent in the case of a perfect bilateral monopoly, where there is one seller and buyer, the analysis becomes significantly less clear when the model accounts for multiple buyers and sellers with market power, which would be the case in the pharmaceutical supply chain. As noted by two scholars:

In the extreme case of bilateral monopoly, we know what the welfare consequences are. In cases involving substantial concentration (i.e. oligopoly or oligopsony), it is not clear that the formation of countervailing power is desirable. This ambiguity follows from the lack of a unified theory of oligopoly. Since we cannot be sure a priori what the welfare effects of oligopoly are, it is not possible to say what the consequences of the countervailing oligopsony power will be.<sup>179</sup>

Therefore, as long as the given industry's "very specific behavioral characteristics" remain unidentifiable or unstable, economists are unable to predict accurately the precise effects of a sanctioned oligopsony.<sup>180</sup> Such uncertainty makes this policy choice risky.

Second, others have expressed concern that sanctioning the formation of countervailing market power in an intermediate market creates great risk that this power will spill over into the downstream output market, ultimately hurting consumers.<sup>181</sup> This conclusion is intuitive: allowing pharmacists to collude on the reimbursement rates received from PBMs for their sale of pharmaceuticals will translate into collusion with respect to other consumer goods sold in pharmacies. As noted by one scholar: "[T]here may be something approaching economies of scale in collusive activities. Thus, the costs of gathering together and deciding on a common plan could be spread over plans associated with both

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<sup>179</sup> BLAIR & HARRISON, *supra* note 131, at 140–41.

<sup>180</sup> *Id.* at 141.

<sup>181</sup> *Id.* at 138–39. Blair and Harrison discuss this risk in general terms rather than apply their insights to one particular market. *See id.*

buying and selling.”<sup>182</sup> In other words, once independents already have expended resources to collude with respect to the reimbursement rates obtained from a given PBM, the costs of colluding with respect to other areas of their businesses declines. Furthermore, once pharmacists begin collaborating in one market, it will be more difficult to detect where they have overstepped their bounds and reached a tacit agreement elsewhere.<sup>183</sup> As the risk of detection and cost per agreement declines, the likelihood of such an agreement increases.<sup>184</sup>

Furthermore, there is concern that even in the case of a perfect bilateral monopoly, where there is a single buyer and seller, the monopolist and monopsonist will not have exactly equivalent market power. In order “for bilateral monopoly to benefit society, bargaining strengths of buyers and sellers must be approximately equal. If either side has a disproportionate share of the bargaining power, it will be able to tilt the balance in its favor to the detriment of society.”<sup>185</sup> Accordingly, although “the bilateral monopoly is, at least theoretically, closer to the competitive equilibrium than the pure monopoly equilibrium,” “[e]ven in the perfect bilateral monopoly situation, where there is only one buyer and one seller, the equilibrium price will likely be above the perfectly competitive price.”<sup>186</sup>

Finally, given that agreements between insurers and health care providers are not immune from antitrust scrutiny, pharmacies are able to fight any suspected anticompetitive activity through litigation. This reduces the need to fight collusion through collective bargaining, which, as explained above, theoretically may bring the market closer to equilibrium, but is unlikely to produce the competitive prices characteristic of a market plagued neither by monopoly nor monopsony.<sup>187</sup> Since *Group Life*, pharmacists certainly have taken advantage of their right to bring private claims under the Sherman and Clayton Acts.<sup>188</sup> Independent and community pharmacies might charge that, unlike chain pharmacies, they do not have sufficient financial resources to engage in expensive litigation, but past experience proves otherwise.<sup>189</sup> For example, in

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182 *Id.* at 139.

183 *Id.*

184 *Id.*

185 JAMES W. HENDERSON, *HEALTH CARE ECONOMICS AND POLICY* 62 (5th ed. 2010).

186 Alexander, *supra* note 108, at 1620.

187 ABA SECTION OF ANTITRUST LAW, *supra* note 49, at 19 (“[A]ny person (including federal and state governments) who is injured or threatened by a violation of federal antitrust law may bring a civil suit in federal court to enjoin conduct violating the antitrust laws, and any such person who is injured in his or her business or property by such a violation may commence a federal civil action to recover three times the party’s actual damages.”).

188 See, e.g., *Stop & Shop Supermarket Co. v. Blue Cross & Blue Shield*, 239 F. Supp. 2d 180, 182, 183–84 (D.R.I. 2003).

189 Another version of this argument is that exercising countervailing market power is “a less restrictive method” of bringing the market back into competitive balance than “the more problematic alternatives of bringing a costly and unpromising antitrust suit.” Havighurst, *supra* note 139, at 445.

*North Jackson Pharmacy, Inc. v. Express Scripts, Inc.*, independent pharmacists brought a class action against a pharmaceutical manufacturer and three PBMs alleging that the defendants agreed both amongst themselves and with other PBMs to fix prices in the sale of pharmaceuticals to the class of independents.<sup>190</sup> Similarly, in *Bellevue Drug Co. v. Advance PCS*, several independent pharmacies and two not-for-profit organizations, each composed of thousands of independent community-pharmacy owners, brought suit against a PBM, alleging that it had engaged with competitors in a horizontal agreement with the effect of restraining trade in the drug dispensing industry.<sup>191</sup>

It is for these reasons that economists have advised against combating a perceived monopsony through creation of a countervailing market power. As Peter Rankin, Principal at CRA International, an economics and management consulting firm, testified before Congress, “The regulatory agencies and most economists have regularly dismissed the concept of combating perceived competitive imbalances in market power by creating ‘countervailing’ market power. The appropriate response, instead, is to determine if there is a legitimate competitive imbalance and address the economic factors creating that imbalance.”<sup>192</sup> Thus, because it is not clear that the PBM market is anticompetitive, and, even if it were, litigation directly challenging PBM monopsony would serve as a more appropriate mechanism for independents and law enforcers to combat anticompetitive activity and fully remedy market failures, an antitrust exemption for independent pharmacies is neither warranted nor advised.

#### 4. Empirical Evidence

Empirical data also supports the conclusion that an antitrust exemption will not result in lower health care costs. According to research, if it had been passed, the Quality Health Care Coalition Act of 2000 would have “rais[ed] annual medical costs by as much as \$29-\$141 billion over a five-year period as a result of higher physician fees, changes in practice patterns, and the ripple effect on

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<sup>190</sup> 345 F. Supp. 2d 1279, 1283 (N.D. Ala. 2004). Acknowledging that under *Socony-Vacuum*, a horizontal conspiracy to fix prices at below market-rate levels is a per se violation of the Sherman Act, the district judge denied the defendants’ motion to dismiss and ruled that the plaintiffs’ amended complaint “afford[ed] no sound basis for ruling out the possibility that the Plaintiffs w[ould] be able to establish facts which establish a right of recovery for violation of the Sherman Act.” *Id.* at 1296.

<sup>191</sup> No. Civ. A. 03-4731, 2004 WL 724490, at \*1 (E.D. Pa. Mar. 2, 2004). Again, the district court denied the defendants’ motion to dismiss. *Id.* at \*6.

<sup>192</sup> *Community Pharmacy Fairness Act of 2007: Hearing on H.R. 971 Before the H. Comm. on the Judiciary*, 110th Cong. 4–5 (2007) (statement of Peter J. Rankin, Principal, Charles River Associates International).

government program costs.”<sup>193</sup> More specifically, the Congressional Budget Office (CBO) estimated that if passed, the Quality Health Care Coalition Act of 1999 would have (1) elevated private health insurance premiums;<sup>194</sup> (2) decreased federal tax revenues by \$145 million in 2001 and \$3.6 billion between 2001 and 2010 as a result of reductions in taxable income and fringe benefits;<sup>195</sup> (3) increased federal direct spending by several billion dollars across a number of federal programs by 2011;<sup>196</sup> and (4) increased various federal agencies’ discretionary spending by \$150 million over ten years.<sup>197</sup> Under the CBO’s assumption that one-third of pharmacists would have taken advantage of their newfound immunity, pharmacists’ collective activity alone would have raised private health insurance expenditures by 0.1%, with the average pharmacist increasing his or her net margin by fifteen percent.<sup>198</sup>

The CBO also ran cost estimates for the Community Pharmacy Fairness Act of 2007, which would have exempted only independent pharmacies (rather than all health professionals) from antitrust laws for five years.<sup>199</sup> First, the CBO estimated that the bill, if enacted, would have increased payments for prescription drugs dispensed by independent pharmacies by one percent commencing in 2010—the year that most affected contracts would have been

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193 Thomas J. Greaney, *Whither Antitrust? The Uncertain Future of Competition Law in Health Care*, 21 HEALTH AFFAIRS 191 & n.27 (2002) (citing various studies with “different assumptions about effects on utilization management, percentage of physicians that would take advantage of the legislation, and spillover effects”).

194 CONG. BUDGET OFFICE, H.R. 1304: QUALITY HEALTH-CARE COALITION ACT OF 2000, at 2–3 (2000). As a corollary to the elevated private-insurance premiums, the Congressional Budget Office (CBO) predicted that employers sponsoring health plans would have passed these higher costs on to employees in the form of decreased wages and fringe benefits. *Id.* at 3. These reductions would have in turn affected the federal tax revenues. *Id.* at 7.

195 *Id.* at 1, 7. Because the bill, as passed by the House, contained a three-year sunset provision, the CBO estimated that “the full effects that the antitrust exemption could have on the health insurance market [were] likely not to be realized.” *Id.* at 2. Despite this, the CBO concluded:

[T]he effects of the legislation would likely persist beyond the third year for several reasons: contracts negotiated during the first three years might extend beyond the period; health plans might go through an adjustment period while re-establishing utilization controls in the post-sunset period; and, since fee levels for health professionals would have been established at higher levels than would occur under current law, the market would take some time to re-adjust once the original antitrust treatment were restored.

*Id.*

196 *Id.* at 1, 7.

197 *Id.* at 1.

198 *Id.* at 5.

199 CONG. BUDGET OFFICE, H.R. 971: COMMUNITY PHARMACY FAIRNESS ACT OF 2007 (2008).



renegotiated.<sup>200</sup> The CBO predicted that as a result of these cost increases, group health insurance premiums would have risen, and employers would have passed these increases on to workers in the form of reductions in the scope or generosity of health insurance benefits, such as higher copayments and deductibles as well as reductions in taxable income and fringe benefits.<sup>201</sup> Because of these reductions in taxable income, the bill, if enacted, would have depressed federal tax revenues by \$5 million in 2009 and by \$120 million from 2008 to 2018.<sup>202</sup> Federal direct spending for health benefits also would have increased by \$488 million from 2008 to 2013 and by \$520 million from 2008 to 2018.<sup>203</sup> The combined effect of reduced tax revenues and increased direct spending would have served to reduce government surpluses or to increase government deficits by \$640 million between 2008 and 2018.<sup>204</sup> Therefore, neither economic theory nor empirical evidence can support an antitrust exemption on the basis that it would reduce or preserve health care costs.

### *B. Quality of Care*

Still, supporters of the exemption claim in the alternative that while an exemption may increase pharmaceutical prices, a simultaneous boost in the quality of patient care would offset this escalation and thus be procompetitive. Indeed, the pharmacy lobby has packaged the exemption proposals as attempts “[t]o ensure and foster continued patient safety and quality of care.”<sup>205</sup> While not always expressed in economic terms, this argument too is predicated on claims of market failure and imperfection. Independents claim that while they provide superior service as compared to chain and mail-order pharmacies — service that drastically increases quality of health care — market imperfections prevent this enhanced quality from being reflected in the allocation of goods and services in the marketplace as it would in a perfectly competitive market.

This Section argues, however, not only that these claims of quality deficiency are overblown, but also that collective bargaining by independents is an improper mechanism through which to improve health care quality. Subsection III.B.1 explains the relationship between competition and quality, demonstrating that restraining market competition will lead to inefficient

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200 *Id.* at 3. In formulating this approximation, the CBO accounted for the fact that health providers would want to both establish an attractive list of in-network pharmacies and to meet their adequacy-of-network requirements. *Id.* at 3–4.

201 *Id.* at 4.

202 *Id.*

203 *Id.* at 1.

204 *Id.*

205 Community Pharmacy Fairness Act of 2011, H.R. 1839, 112th Cong. (2011); Quality Health Care Coalition Act of 2011, H.R. 1409, 112th Cong. (2011).

outcomes.<sup>206</sup> Subsection III.B.2 then considers and rejects independents' contention that collective bargaining must be permitted to correct these market failures and improve quality of care.

### *I. Market Efficiency and Quality of Care*

In order to “play[] to consumers’ fears, as well as those of policy makers and politicians,”<sup>207</sup> the medical lobby has packaged its exemption platform on the notion that the closing of small pharmacies hurts not only their owners, but also patient welfare. In part, these claims are built on those of monopsony rejected above. According to independents, because their pharmacists build strong relationships with their patients, they provide care superior to that of chain and mail-order pharmacies.<sup>208</sup> As a result, when PBMs force independents out of business, patient health care declines. Moreover, independents claim that even if they are not forced out of business, PBMs have cut independents’ reimbursement levels so drastically that independents are forced to “increase volume, reduce the level of service, increase waiting times, and reduce staff,” all of which reduce patient satisfaction, compromise the pharmacist-patient relationship, and damage the level of care.<sup>209</sup> While chain and supermarket pharmacies too have reported frustration with PBMs, independents allege that larger entities often have circumvented these pressures through exercising superior bargaining power or by

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206 HAAS-WILSON, *supra* note 49, at 38; Peter J. Hammer & William M. Sage, *Antitrust, Health Care Quality, and the Courts*, 102 COLUM. L. REV. 545, 611 (2002). In finding restraints on trade anticompetitive (absent procompetitive justifications in rule-of-reason cases), the courts largely stick to this economic model. Therefore, courts presume that “[c]ompetition in the health care markets [will] . . . lower health care prices, reduce health care costs, and improve health care quality.” *Id.* at 612; *see also id.* at 612, 636 (concluding, after conducting “a comprehensive empirical review of judicial review of judicial opinions in medical antitrust litigation between 1985 and 1999, with specific attention to courts’ handling of quality and other nonprice concerns,” that “[o]f the opinions that expressed general beliefs about the role of competition, the vast majority adhered to traditional economic assumptions”); *see also* Fed. Trade Comm’n v. Ind. Fed’n of Dentists, 476 U.S. 447, 459–62 (1986) (taking as given traditional economic assumptions when conducting its rule-of-reason analysis); *Ambroze v. Aetna Health Plans*, No. 95 CIV. 6631 (DLC), 1996 U.S. Dist. LEXIS 7274, at \*21–\*22 (S.D.N.Y. May 28, 1996) (expressing faith in the market’s ability to strike appropriate market-price tradeoffs); *Koefoot v. Am. Coll. of Surgeons*, 652 F. Supp. 882, 904 (N.D. Ill. 1986) (“[T]he ‘best’ product or service will be selected by consumers where when their choice is made in an open market free of restraints.”).

207 CARLE F. AMERINGER, *THE HEALTH CARE REVOLUTION: FROM MONOPOLY TO MARKET COMPETITION* 177 (2008) (discussing, in particular, the American Medical Association’s strategy of introducing bills, such as the Quality Health-Care Coalition Act, with a “quality” focus).

208 Independents believe that this pharmacist-patient relationship is responsible for the fact that independents’ patients are “more likely to take their medicines on-time, more likely to take them properly, more likely to refill meds before they run out and more likely to avoid harmful drug interactions [than those of mail-order or chain pharmacies].” *Community Pharmacies Hearing*, *supra* note 73, at 80 (statement of David Balto, Senior Fellow, Center for American Progress Action Fund).

209 *Id.* at 88.

operating their own PBMs.<sup>210</sup>

Given the dismissal of claims that PBMs constitute a monopsony in Section III.A, these contentions that the market power of PBMs diminishes quality should be dismissed easily as well. This is because microeconomic theory dictates that “absent identifiable market failures,” competition will yield consumers’ desired “range of price-quality combinations.”<sup>211</sup> In other words, it is not within the province of an economist’s role to determine whether a high-priced but high-quality good is preferable to one that is low priced and of low quality. Rather, the goal is more limited: to preserve competitive conditions in which consumers can “effectively vote with their wallets and their feet, deciding which products to buy and from which sellers.”<sup>212</sup> When everything functions as it should, society’s resources should be “naturally directed into the production of those products that consumers value most highly.”<sup>213</sup>

Applying this concept to the pharmaceutical company, the market if competitive should reflect the proper quality/cost tradeoffs through consumers’ purchase of insurance. Therefore, even assuming that independents provide a greater level of service, consumers indicate their willingness to forgo the superior service for the associated cost savings by frequenting mail-order and chain pharmacies and purchasing insurance plans that emphasize cost savings over a broad range of pharmacy choices. All else being equal, every consumer presumably would prefer the customized service provided by independents and the superior health outcomes that independents assert they produce. But, at some point in the tradeoff, the conflicting desire for low-cost health care and greater output of health care goods and services prevails.<sup>214</sup>

Although quality-of-care claims premised on the monopsony power of

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210 See *PBMs Emerge as a Dominant Force in Retail Pharmacy*, CHAIN DRUG REV., Aug. 26, 1996, at RX13; David Pinto, *Chains Need to Step Up Involvement in PBM Business*, CHAIN DRUG REV., Apr. 27, 1998, at 1; Harry Wessel, *Tiny Pharmacies Feeling Squeeze*, ORLANDO SENTINEL, July 11, 2007, at C1; Joanne Wojcik, *Drug Chains Trying Another Dose of PBM Business To Compete*, BUS. INS., May 2, 2005, at 1.

211 Hammer & Sage, *supra* note 206, at 611. In economic terms, allocative efficiency is “achieved when each good is produced up to the point where the value consumers place on the last unit produced is equal to the cost of producing the last unit.” HAAS-WILSON, *supra* note 49, at 38.

212 HAAS-WILSON, *supra* note 49, at 39.

213 *Id.*

214 As Professor George Priest has noted:

In many respects, no two consumers are alike and each consumer would prefer products and services most closely designed to meet his or her preferences. Over some range, however, the cost reductions from taking advantage of scale economies prevail over the magnitude of differences in consumer values and preferences for individually designed products. Large business emerges where the cost savings from scale economies prevail.

George L. Priest, *Small Business, Economic Growth, and the Huffman Conjecture*, 7 J. SMALL & EMERGING BUS. L. 1, 7 (2003).

PBMs rest on shaky ground, independents also point to a variety of other PBM practices that they perceive to diminish invidiously health care quality, and which they hope to correct through collective bargaining. In doing so, independents contest an “assumption of conventional antitrust economics: that markets with active competition over price and output will also compete effectively over quality.”<sup>215</sup> First, independents point to a heavily entrenched practice of PBM self-dealing and vertical consolidation.<sup>216</sup> These claims are heavily targeted towards PBMs’ operation of their own mail-order facilities, which “give[s] them an additional opportunity to profit from transactions by health plan participants.”<sup>217</sup> One of independents’ most frequent contentions is that PBMs disturbingly have forced or heavily incentivized a large number of vulnerable patients (particularly the elderly in rural areas) to fill their prescriptions through PBM-owned mail-order programs.<sup>218</sup> Accusing mail orders of being “shady operators that threaten neighborhood pharmacists,” pharmacists charge that mail-order restrictions not only prevent patients from being able to fill prescriptions immediately, but also inhibit the personal pharmacist-patient relationship that many patients want and that is necessary to effective care.<sup>219</sup> Mike James, the

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215 Sage & Hammer, *supra* note 53, at 257.

216 Garrett & Garis, *supra* note 170, at 61, 66–68.

217 *Id.* at 66.

218 *Community Pharmacies Hearing*, *supra* note 73, at 17 (testimony of Mike James, Vice President, Association of Community Pharmacies Congressional Network & Pharmacist/Owner, Person St. Pharmacy, Raleigh, N.C.); Starrs, *supra* note 162 (quoting a pharmacy owner as saying “I think our biggest competition is mail-order and online prescriptions, and some PBMs have their own pharmacies . . . . And a lot of managed-care plans will require that clients buy from PBMs or make it so difficult for them that they don’t have many other choices”). Though independents claim their main issue with mail-order pharmacies is the disturbing health consequences for their patients, their rhetoric in the debate make clear that their economic interests are front and center. For example, independents claim that when PBMs do not officially require patients to use their mail-order facilities, they put retail pharmacies at a distinct disadvantage by charging below-competitive prices for mail-order prescriptions and offering gimmicks such as allowing patients the opportunity to obtain a three-month supply of medication at a time through mail order, while only allowing retail pharmacies to dispense a one month supply. *Community Pharmacies Hearing*, *supra* note 73, at 15 (testimony of Mike James, Vice President, Association of Community Pharmacies Congressional Network & Pharmacist/Owner, Person St. Pharmacy, Raleigh, N.C.). Independents believe that these practices are unethical, as PBMs’ mail-order divisions directly compete against the independent pharmacies with whom they contract. *Id.* at 15, 17. Absent sufficient evidence of market failure, however, questions are raised as to whether this attitude is paternalistic and detrimental to consumers’ ability to choose the quality/price mix they find most appealing. See, e.g., M. Joseph Sirgy & Dong-Jin Lee, *Ethical Foundations of Well-Being Marketing*, in CONTEMPORARY ISSUES IN BUSINESS ETHICS 49, 55 (Mary W. Vilcox & Thomas O. Mohan eds. 2007); cf. Michael D. Bromberg, *Flexibility in Antitrust Enforcement*, 12 HEALTH AFFAIRS 150, 150 (1993) (discussing the need for “consumers [to] vote with their pocketbooks based on their own values and perceptions of quality, access, and cost options” with regard to available health care plans).

219 Lisa Wangsness, *A Big Push on Mail-Order Drugs Savings, Efficiency Hailed, Disputed*, BOSTON GLOBE, Feb. 2, 2009, at A1; see also *Community Pharmacies Hearing*, *supra* note 73, at 17 (statement of Mike James, Vice President, Association of Community Pharmacies

Vice President of the Association of Community Pharmacies Congressional Network and an independent himself, testified before Congress that this relationship is critically important when “[t]he pharmacist is the only health care professional who knows all of the patient’s medications, their interactions, and whether there are low cost generics available to address the patient’s needs.”<sup>220</sup>

Finally, independents point to the lack of transparency and asymmetric information in PBM practices, which exacerbates or creates agency problems. According to independents, without proper and full information, consumers, employers, and pharmacists are unable to make the decisions necessary for the market to run properly. It is true that even absent monopsony,<sup>221</sup> competition only works if:

- (1) consumers know about or can learn about the prices and qualities of products offered by various sellers; (2) consumers have the incentive to search for the sellers offering the best deals; (3) sellers know about or can learn about their consumers; [and] (4) sellers can enter profitable markets and exit unprofitable ones.<sup>222</sup>

Independents correctly may argue that the market is not accurately pricing the higher level of quality they offer if any one of these four conditions does not hold true.

In part, these allegations are those of intentional deceit,<sup>223</sup> which

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Congressional Network & Pharmacist/Owner, Person St. Pharmacy, Raleigh, N.C.) (“The take-over by PBMs is also resulting in movement . . . to mail-order prescription programs. This has provided a perverse outcome for patients, who have no say in how their pharmacy benefits will be delivered, and are afraid to complain in fear of losing their benefit. These patients are denied their traditional right to seek personal and confidential professional assistance from local, hometown pharmacy professionals.”).

220 *Community Pharmacies Hearing*, *supra* note 73, at 17 (testimony of Mike James, Vice President, Association of Community Pharmacies Congressional Network & Pharmacist/Owner, Person St. Pharmacy, Raleigh, N.C.).

221 Not only does information failure inhibit the running of an efficient market, but it also can entrench monopsony itself. Garrett & Garis, *supra* note 170, at 63 (“Arguably, the market power that PBMs wield stems both from market share and also from the paucity of information available to those who deal with the PBMs.”).

222 HAAS-WILSON, *supra* note 49, at 39; *see also* Sage & Hammer, *Competing on Quality of Care: The Need To Develop a Competition Policy for Health Care Markets*, 32 U. MICH. J.L. REFORM 1069, 1089 (1999) (“[A]ntitrust laws assume that competitive mixes are allocatively efficient. This assumption implies that markets will determine the appropriate prices for medical services, the appropriate tradeoffs between price and quality, and the appropriate tradeoffs among different quality attributes. However, failures endemic in health care markets make it necessary to seriously question this assumption.”).

223 Independents complement their claims of intentional deceit with that of inherent and inevitable market failure in health care markets. For example, David Balto, a staunch advocate of an exemption, explained in his testimony before the Ohio Senate Insurance, Commerce, and Labor

independents posit is widespread and systematic. According to independents, employers and MCOs are being tricked by informational asymmetries in their dealings with PBMs. The primary contention is that “PBMs, which are ostensibly hired by health plans as the agents for those plans to negotiate with manufacturers and retail pharmacies, hide from their own clients what they pay for prescriptions and often fail to disclose appropriate information regarding rebates.”<sup>224</sup> Similarly, another advocate has argued that “the self insured employer never sees on their monthly itemized statement how much was actually paid to the provider but only what they were charged for the product or service by the PBM.”<sup>225</sup> Furthermore, “[p]articipating network pharmacies are contractually prohibited from directly contacting the clients (the employers) of the PBM’s [sic] and disclosing the compensation that they receive directly from the PBM[,] thereby eliminating a vital component of the free market system necessary to maintain competitive forces in the marketplace.”<sup>226</sup> Other allegations include PBMs “[u]sing aggressive marketing tactics to steer patients

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Committee:

[T]here is a tremendous need for reform in the PBM market. The fundamental elements for a competitive market are transparency, choice, and a lack of conflicts of interest. This is especially true when dealing with health care intermediaries such as PBMs and health insurers where information may be difficult to access, there are agency relationships, and securing adequate information may be difficult to access . . . . Transparency is necessary for consumers to evaluate products carefully, to make informed choices, and to secure the full range of services they desire.

*Hearing on S.B. 154 Before the S. Comm. on Ins., Labor, & Commerce*, 2010 Leg., 128th Gen. Assemb. (Ohio 2010) [hereinafter *Ohio Hearing*] (statement of David Balto, Senior Fellow, Center for American Progress Action Fund), available at [http://www.americanprogressaction.org/issues/2010/02/pdf/balto\\_testimony\\_pbms.pdf](http://www.americanprogressaction.org/issues/2010/02/pdf/balto_testimony_pbms.pdf).

224 Garrett & Garis, *supra* note 170, at 61.

225 Dan Benamoz, *Pharmacists Must Lead the Way to Fixing America’s Health Care Crisis 4* (Jan. 2008) (unpublished white paper), available at <http://www.pharmacyowners.com/Portals/37772/docs/White-Paper-Demise-of-Mail-Order.pdf>.

226 *Id.*; see also David Balto, *Bending the Cost Curve: Regulating Healthcare Middlemen*, HILL (Sept. 4, 2009 1:29 PM), <http://thehill.com/blogs/congress-blog/healthcare/57371-bending-the-cost-curve-regulatinghealthcare-middlemen> (“A lack of transparency is one of the key problems in the pharmacy benefit management industry. For example, PBMs often charge the health plans they serve significantly more for the drugs than they pay the pharmacies that distribute the drugs to patients. PBMs also may switch patients to a drug other than the one their doctor prescribed[,] sometimes a drug more expensive for the health plan and patient[,] to take advantage of rebates the PBM receives from drug manufacturers, which are often hidden from the PBM’s customers.” (internal quotation marks omitted)); Robert I. Garis et al., *Examining the Value of Pharmacy Benefit Management Companies*, 61 AM. J. HEALTH-SYS. PHARMACISTS 81, 85 (2004) (“What seems clear from this navigation of the PBM maze is that prescription benefit plan sponsors (either private employers or government entities) should insist on full disclosure of cash flows to and through the PBM that is administering their drug benefit. Without this level of scrutiny, the plan sponsor cannot be sure if its PBM is providing a good service for a fair price or is acting primarily in its own interest.”).

to [their own] pharmacies”; “[t]aking advantage of access to independent pharmacies’ claims data in order to target their customers and steer them to [their own] pharmacies”;<sup>227</sup> participating in crooked pricing and deceptive advertising schemes; and forcing “gag clauses” on pharmacists, prohibiting them from informing patients about non-formulary-listed medications.<sup>228</sup> These claims boil down to the fact that “restrictions on pricing transparency ‘increase the difficulty of discovering the lowest cost seller,’” who also offers the highest degree of quality.<sup>229</sup>

Independents also allege that the consumers themselves are being deceived. As one advocate writes, “America is . . . being told that money grubbing community pharmacies are overcharging them. Little does the typical American know that this argument is a classical ruse, a method to distract them so they don’t feel the boney fingers of shadowy figures inside their pockets seizing their wallets.”<sup>230</sup> According to independents’ allegations, PBMs’ deceitful practices compound already-existing agency problems, as consumers already “find it difficult to evaluate the cost and quality of health services” given “the technical nature of medical information and the complexity of diagnoses and treatment alternatives.”<sup>231</sup> The message of independents is clear: if consumers, MCOs, and employers cannot adequately evaluate quality and cost, the market falls victim to inefficient resource allocation. Although intuitively plausible, one should not take independents’ arguments pertaining to these market failures for granted, but rather, should examine critically the set of assumptions about the market on which these arguments are based.

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227 *Ohio Hearing*, *supra* note 223. Indeed, commentators have noted that “[i]n health care, a variety of circumstances undermine the neoclassical assumption that buyers and sellers possess adequate information to assess the quality and costs of the services provided.” Thomas L. Greaney, *The Affordable Care Act and Competition Policy: Antidote or Placebo*, 89 OR. L. REV. 811, 818 (2011).

228 Mila Ann Aroskar, *Ethical Aspects of Pharmacy Practice in Managed Care*, in *MANAGED CARE PHARMACY PRACTICE*, *supra* note 3, at 507, 509; *see also Community Pharmacies Hearing*, *supra* note 73, at 87 (statement of David Balto, Senior Fellow, Center for American Progress Action Fund) (discussing provisions that “prevent[] pharmacies from informing consumers of less expensive and more appropriate prescriptions”); *Healthcare Competition Hearing*, *supra* note 46, at 56–57 (statement of Mark Riley, Nat’l Treasurer, National Community Pharmacists Association) (explaining that “[m]ail-order is steeped in deceptive pricing schemes that are intended to dupe employers into believing that they are saving money”).

229 Garrett & Garis, *supra* note 170, at 63 n.161 (quoting *Bates v. State Bar of Ariz.*, 433 U.S. 350, 377–78 (1977)).

230 Benamoz, *supra* note 225, at 1.

231 Thomas L. Greaney, *Quality of Care and Market Failure Defenses in Antitrust Health Care Litigation*, 21 CONN. L. REV. 605, 633–34 (1989) (“[T]he considerable uncertainty that attends medical treatment makes judgment on causation (and hence costs and benefits of treatment) difficult. In addition, information is asymmetrically distributed among providers, patients, and payers. This characteristic may permit physicians to induce demand for their services; at a minimum it makes information costly for buyers to acquire.”).

## 2. *Questioning Independents' Assumptions: Quality of Care*

Independents' argument relating to quality enhancement relies primarily on two assumptions: (1) independents provide superior health care quality as compared to chain and mail-order pharmacies, but are unable to compete with them under current market conditions; and (2) collective bargaining would be able to compensate for these distortions by delivering an optimal level of care to consumers, as under perfect competition. This Subsection examines each of these assumptions in turn.

### *a. Superior Health Care Quality*

The first assumption is that while independents provide superior health care services, they are unable to compete with mail-order and chain pharmacies due to the PBMs' lack of transparency and deceptive trade practices. There is little evidence, however, supporting the assertion that independent and community pharmacies provide superior health care as compared to chain or even mail-order pharmacies. While a retail pharmacist can provide in-person medication counseling, which a mail-order pharmacist cannot, it is not obvious why a pharmacist at an independent pharmacy would provide superior counseling to one at a chain or supermarket pharmacy. Simply because an independent pharmacist may know more patients' names or faces does not result necessarily in a superior level of treatment quality.

Moreover, from a safety standpoint, mail-order services offer vastly lower error rates. Because mail-order pharmacies benefit from economies of scale, they can afford immensely superior processing and dispensing equipment, with built-in infrared scanners that check and re-check each prescription bottle for accuracy.<sup>232</sup> Highly automated prescription dispensing systems can achieve accuracy rates twenty-three times higher than those reported in a benchmark study of retail community pharmacies.<sup>233</sup> Furthermore, because mail-order pharmacies are so large — some physically as big as six football fields — they can hire pharmacists who only handle medications for a given disease, such as cancer or diabetes.<sup>234</sup> These pharmacists review each patient's file, highlight any potential drug interactions, and verify that no cheaper alternative exists.<sup>235</sup> Finally, mail-order pharmacists are available to answer patients' questions twenty-four hours per day.<sup>236</sup> Given the fact that independents have not been able to offset the objective data indicating that chain or mail-order pharmacies

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232 Wangsness, *supra* note 219, at A1.

233 J. Russell Teagarden et al., *Dispensing Error Rate in a Highly Automated Mail-Service Pharmacy Practice*, 25 J. PHARMACOLOGY & DRUG THERAPY 1629, 1633 (2005).

234 Wangsness, *supra* note 219, at A1.

235 *Id.*

236 *Id.*



actually may provide *higher* quality care with any empirical support to the contrary, it would be imprudent to conclude that the provision of preferential treatment to independents in their negotiations with PBMs would improve health care quality.

Finally, to the extent that independents actually do provide a higher quality of care, it is unclear that collective bargaining is the answer. First, higher reimbursement rates effected through collective bargaining may have unintended consequences when one takes at face value independents' assertion that health care quality is the ultimate goal. First, as the price increases to use independents to fulfill the needs of MCOs' customers, the law of demand dictates that PBMs will seek to substitute the services of independents where possible.<sup>237</sup> No doubt PBMs will be constrained to some extent in their endeavors given requirements that insurance plans include a certain number of pharmacies per any given area. That said, to the extent that PBMs currently are exceeding such requirements, they logically will seek to reduce the number of PBMs in their networks in favor of chain pharmacies who may now have relatively less economic clout. To the extent that such substitution is impossible, PBMs may seek to increase the incentives for patients to use alternative mechanisms of fulfilling their prescriptions, such as mail-order pharmacies, which independents say so perniciously impact health care quality.<sup>238</sup>

Moreover, not only does economic theory dictate that competition keeps prices in check, it also predicts that competition stimulates innovation, leading to higher quality — an argument that independents have not countered successfully in their lobbying efforts.<sup>239</sup> As the Ninth Circuit stated in *Freeman v. San Diego Association of Realtors*, the failure of some competitors is inherent in the nature of competition: "Inefficiency is precisely what the market aims to weed out. The Sherman Act, to put it bluntly, contemplates some roadkill on the turnpike to Efficiencyville."<sup>240</sup> Or in the words of Judge Posner, "[b]usiness failures are an

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237 Cf. RONALD G. EHRENBERG & ROBERT S. SMITH, *MODERN LABOR ECONOMICS: THEORY AND PUBLIC POLICY* 492–94 (7th ed. 2000) (explaining how unions incentivize firms to substitute capital for labor, train nonunion workers, or subcontract services currently provided by union employees).

238 It still may be worth it financially for independents to enter into such arrangements (i.e., the increased reimbursement may compensate sufficiently for any decrease in business).

239 This is not to say that there are not arguments that independents *can* make, though they almost certainly would be controversial and thus in need of further analysis. For example, in the labor context, one theory in favor of the beneficial societal impact of unions is "that employers are not as knowledgeable about how to maximize profits as standard economic theory assumes. Because management finds it costly to search for better (or less costly) ways to produce, so the argument goes, we cannot be sure that it will always use labor in the most productive way possible. . . . When unions organize and raise the wages of their members, firms may be 'shocked' into the search for better ways to produce." EHRENBERG & SMITH, *supra* note 237, at 516.

240 322 F.3d 1133, 1154 (9th Cir. 2003); *see also* *Novell, Inc. v. Microsoft Corp.*, 505 F.3d 302, 315 (4th Cir. 2007) ("[T]he Sherman Act does not protect competitors from being destroyed

indispensable means of imparting incentives for efficient business behavior, by placing the costs of mistakes on the firms that make them.”<sup>241</sup>

Evidence shows that on this road to “Efficiencyville,” competition *has* forced pharmacists to be more efficient. Those pharmacies that have done the best, thriving in recent years, have carved out niches for themselves by appealing to customers drawn to independents who provide more personalized service;<sup>242</sup> who invest in new technologies that have improved patient care while reducing operating costs;<sup>243</sup> and who specialize in unique products and services, such as home delivery,<sup>244</sup> curb service,<sup>245</sup> hard-to-find medical items (e.g., shoes for diabetics),<sup>246</sup> the compounding of medications from scratch,<sup>247</sup> nutrition services,<sup>248</sup> and patient charge accounts.<sup>249</sup> These pharmacies are fulfilling one of the primary roles of small businesses in the U.S. economy: not just to stimulate economic growth but rather “to meet the demand of limited sets of

through competition; on the contrary, such destruction can signal healthy functioning of the enterprise system.”).

241 POSNER, *supra* note 102, at 28.

242 See Tamara Best, *Independent Pharmacies Adapt to New Competitors, Economic Challenges*, CHATTANOOGA TIMES FREE PRESS (Tenn.), Feb. 28, 2010, at C1; Frederick, *supra* note 152, at 17; Dana M. Nichols, *Service First for Mom-and-Pop Shop Owners: Calaveras Pharmacy Gives Personal Attention*, RECORDNET.COM (Stockton, C.A.) (July 5, 2009), [http://www.recordnet.com/apps/pbcs.dll/article?AID=/20090705/A\\_BIZ/307059998/-1/A\\_NEWS13](http://www.recordnet.com/apps/pbcs.dll/article?AID=/20090705/A_BIZ/307059998/-1/A_NEWS13); Hilary Potkewitz, *Drugstores Surviving Onslaught of Chains by Banding Together*, 27 L.A. BUS. J. 2 (2005); *Resilient Community Pharmacies Rely on Patient Services To Weather Economic Downturn*, BUS. WIRE, Oct. 19 2009 [hereinafter *Resilient*]; Maria Sonnenberg, *Independent Stores Thrive with Services*, FLA. TODAY (Brevard Cty., Fl.), Sept. 5, 2009, at 10C; Starrs, *supra* note 162.

243 See Birk, *supra* note 161 (“His independent pharmacy in Beverly Hills will be among the first in the region to employ Parata Max, the latest generation of robotic pill dispensers from a pharmacy-automation manufacturer based in North Carolina. Scheduled to be unveiled this week at a trade show in Las Vegas, the machine can fill about 200 prescriptions an hour with a miscount of 1 in 10,000”); *Resilient*, *supra* note 242 (“The ability of community pharmacies to modify their business operations through greater efficiencies has been critical. Technological advancement has played a prominent role. For example, 67% use point-of-sale systems, 42% use integrated voice response systems, and 31% use automated dispensing counters”); Sonnenberg, *supra* note 242, at 10C (“Already focused on individualized care, the independents are striving to take the lead in medication adherence. The association has already developed a technology software company called Mirixa that helps facilitate pharmacies’ review of medications to determine whether certain drugs are redundant or should be modified.”).

244 Birk, *supra* note 161, at C1; R. Leonard Felson, *Small Pharmacies Struggle To Survive*, N.Y. TIMES, Aug. 15, 1993, at 13CN; Nichols, *supra* note 242; *Resilient*, *supra* note 242; Sonnenberg, *supra* note 242, at 10C.

245 Starrs, *supra* note 162.

246 Best, *supra* note 242, at C1.

247 Allison Miles, *Independent Pharmacies Face Issues and Obstacles, but Industry Remains Strong*, VICTORIA ADVOCATE (Tex.) (Dec. 16, 2009), [http://www.victoriaadvocate.com/news/2009/dec/16/ym\\_am\\_pharmacies\\_122009\\_77207/?business](http://www.victoriaadvocate.com/news/2009/dec/16/ym_am_pharmacies_122009_77207/?business); Nichols, *supra* note 242; *Resilient*, *supra* note 242; Sonnenberg, *supra* note 242, at 10C.

248 *Resilient*, *supra* note 242.

249 *Id.*; Starrs, *supra* note 162.

consumers for particularized products or services” where the cost of coordination prevents larger business from satisfying that demand.<sup>250</sup>

Accordingly, existing evidence calls into question both the assumption that independents provide superior quality and that their continued existence is threatened by PBMs.

*b. The Promise of Collective Bargaining in Increasing Quality of Care*

Even if independents could demonstrate a clear quality advantage, they still would need to prove that an antitrust exemption would be the best — or at least a good — way to improve patients’ quality of care. There is no guarantee, however, that if Congress exempted pharmacists from antitrust laws, these pharmacists would focus their efforts on attempts to secure real gains for consumers, such as lower medication prices and preapproval requirements or expanded PBM formularies.

The only available evidence points exactly in the opposite direction. Where pharmacists in the past flagrantly have disregarded antitrust laws, they have colluded not to secure gains for consumers but rather only to raise reimbursement levels to increase their own profit margins. For example, in the mid- to late-1990s, the Asociacion de Farmacias Region de Arecibo (AFRA), a Northern Puerto Rican association composed of 125 pharmacies, colluded to set the price schedule associated with a government-sponsored insurance program for the indigent.<sup>251</sup> In threatening to boycott the plan administrator if it did not accede to the association’s fee demands, AFRA obtained an immense twenty-two percent increase over the price levels that members would have obtained under the prior fee schedule.<sup>252</sup> Similarly, in the 1980s, the Chain Pharmacy Association of New York State attempted along with several individual pharmacies to participate in a group boycott of the New York State Employees Prescription Program.<sup>253</sup> After agreeing amongst themselves to refuse to participate in the plan at the proposed reimbursement levels, the pharmacies coerced the State of New York into paying additional sums in excess of seven million dollars for prescription drugs.<sup>254</sup> In case after case, where pharmacists have disregarded antitrust laws, it has been to benefit their own fee schedules and reimbursement rates rather than to obtain direct quality enhancements for consumers.<sup>255</sup>

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250 Priest, *supra* note 214, at 7.

251 Asociacion de Farmacias Region de Arecibo, 127 F.T.C. 266, 268–69 (1999), *available at* 1999 WL 33912988 (F.T.C.) (consent order).

252 *Id.* at 270.

253 Peterson Drug Co., 115 F.T.C. 492 (1992), *available at* 199 WL 12011049 (F.T.C.) (consent order).

254 *Id.* at 496–97.

255 *See, e.g.*, Institutional Pharmacy Network, 126 F.T.C. 138 (1998), *available at* 1998 WL 34300603 (F.T.C.) (consent order); RxCare of Tenn., Inc., 121 F.T.C. 762 (1996), *available at* 1996 WL 33412062 (F.T.C.) (consent order); Baltimore Metro. Pharm. Ass’n, 117 F.T.C. 95

Even if one accepts the dubious possibility that pharmacists could secure transparent gains for consumers through collective bargaining,<sup>256</sup> bargaining is an ill-fitted mechanism to employ in trying to accomplish that goal. The drafters of the NLRA never intended the Act to address issues concerning product or service quality, let alone that of the crucial service of health care.<sup>257</sup> Instead, “[c]ollective bargaining rights are designed to raise the incomes and improve the working conditions of union members.”<sup>258</sup>

Collective bargaining is not set up as a natural mechanism for achieving higher levels of quality because bargaining over wages is inherently self-interested. If pharmacists, in their negotiations with PBMs, secured the types of benefits that would assist patients — such as broader formulary lists and reduced preapproval requirements — they would have to compensate for these concessions through reductions (or smaller gains) in their own fee schedules and reimbursement rates. Inevitably, this would place pharmacists in the conflicted position of having to choose between interests of their customers and of themselves.

Finally, independents gloss over the fact that current antitrust regulations already permit other forms of quality-enhancing, procompetitive collaboration. Under the *1996 Statements of Antitrust Enforcement Policy in Healthcare*, pharmacies, in many instances, can form pharmacy-owned PBM joint ventures, joint buying arrangements in the purchase of pharmaceuticals from wholesalers and manufactures, and PPOs.<sup>259</sup> Because many of these arrangements improve efficiencies and health care quality by utilizing electronic health records and shared support mechanisms, they are legal under antitrust laws.<sup>260</sup>

Specifically with regards to joint purchasing arrangements, the DOJ and FTC have recognized that such collaboration frequently creates economies of scale (and thus benefits rather than harms consumers).<sup>261</sup> To eliminate

(1994), available at 1994 WL 16010975 (F.T.C.) (consent order); *Se. Colo. Pharmacal Ass’n*, 116 F.T.C. 51 (1993), available at 1993 WL 13009600 (F.T.C.) (consent order); *Pharm. Soc’y of Orange Cty., Inc.*, 113 F.T.C. 645 (1990), available at 1990 WL 10012620 (F.T.C.) (consent order); *Pharm. Soc’y of the State of N.Y., Inc.*, 113 F.T.C. 661 (1990), available at 1990 WL 10012621 (F.T.C.) (consent order).

256 See *supra* Section III.B.

257 See *supra* note 73 and accompanying text.

258 Letter from Maureen K. Ohlhausen, Dir., Office of Policy Planning, Fed. Trade Comm’n, to Sen. William J. Seitz 9–10 (Feb. 14, 2008), available at <http://www.ftc.gov/os/2008/02/V080001homecare.pdf>.

259 See *supra* note 46–49 and accompanying text.

260 *Healthcare Competition Hearing*, *supra* note 46, at 7 (statement of Richard A. Feinstein, Dir., Bureau of Competition, Federal Trade Commission).

261 U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N, *supra* note 38 at 53 (“Such collaborative activities typically allow the participants to achieve efficiencies that will benefit consumers. Joint purchasing arrangements usually involve the purchase of a product or service used in providing the ultimate package of health care services or products sold by participants. . . . Through such joint purchasing arrangements, the participants frequently can obtain volume discounts, reduce

uncertainty among providers who fear antitrust exposure from forming such a cooperative, the DOJ and FTC, through guidelines, have “set[] forth an antitrust safety zone that describes joint purchasing arrangements . . . that will not be challenged, absent extraordinary circumstances, by the [two] Agencies under the antitrust laws.”<sup>262</sup> The agencies have pledged that “absent extraordinary circumstances,” they will not challenge “any joint purchasing agreement among health care providers,” provided the following two conditions are met:

- (1) the purchases account for less than 35 percent of the total sales of the purchased product or service in the relevant market; and
- (2) the cost of the products and services purchased jointly accounts for less than 20 percent of the total revenues from all products or services sold by each competing participant in the joint purchasing arrangement.<sup>263</sup>

Moreover, the FTC and DOJ further have identified a set of conditions under which “[j]oint purchasing arrangements . . . that fall outside the antitrust safety zone” remain unlikely to “raise antitrust concerns.”<sup>264</sup> While pharmacists are typically acting as sellers rather than buyers in their negotiations with PBMs,

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transaction costs, and have access to consulting advice that may not be available to each participants on its own.”).

<sup>262</sup> *Id.* at 54. In addition to relying on the published Guidelines, pharmacists have the option of directly requesting advisory opinions from the FTC that are customized to their own specific fact situations. FED. TRADE COMM’N, GUIDANCE FROM STAFF OF THE BUREAU OF COMPETITION’S HEALTH CARE DIVISION ON REQUESTING AND OBTAINING AN ADVISORY OPINION (2011), *available at* <http://www.ftc.gov/bc/healthcare/industryguide/advop-general.pdf>; *see, e.g.*, Letter from Michael D. McNeely, Assistant Dir., Federal Trade Comm’n, to Allen Nichol (Aug. 12, 1997), *available at* <http://www.ftc.gov/os/1997/08/newjerad.htm> (stating that the FTC would not recommend a challenge to a proposal to implement two “pharmacist service networks,” which would offer health education and monitoring services to patients with diabetes and asthma); Letter from Richard A. Feinstein, Assistant Dir., Health Care Services and Products, Bureau of Competition, Fed. Trade Comm’n, to Paul E. Levenson (July 27, 2000), *available at* <http://ftc.gov/bc/adops/neletfi5.shtm> (advising that the FTC would not challenge a proposal to establish a network of independent pharmacists that would provide medical management of patients with chronic or long-term illnesses in order to increase medication compliance and reduce patient error).

<sup>263</sup> U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N, *supra* note 38, at 54–55. While the first of these conditions ensures that the joint purchasing arrangement will not “be able to drive down the price of the product or service being purchased below competitive levels,” “[t]he second condition addresses any possibility that a joint purchasing arrangement might result in standardized costs, thus facilitating price fixing or otherwise having anticompetitive effects.” *Id.* at 55.

<sup>264</sup> *Id.* at 57 (identifying three “safeguards [that] will reduce substantially, if not completely eliminate, use of the purchasing arrangement as a vehicle for discussing and coordinating the prices of health care services offered by the participants” and stating that “[t]he adoption of these safeguards also will help demonstrate that the joint purchasing arrangement is intended to achieve economic efficiencies rather than to serve an anticompetitive purpose”).

these guidelines still apply in their dealings with wholesalers and manufacturers in purchasing pharmaceuticals. Accordingly, these guidelines may be used by independents in reducing the cost of their inputs, thus raising profits margins. With such procompetitive mechanisms to increase simultaneously market efficiency and health care quality, there is no reason to allow pharmacists to resort to the formation of cartels, whose quality-enhancing effects are highly questionable and rest on unsound economic policy.

### CONCLUSION

The pharmaceutical industry has changed dramatically in response to the explosion in managed care and MCO efforts to cut costs. Pharmacists have reacted by charging that such measures for cost cutting not only shut small community pharmacists out of the market, but also negatively impact the quality of care that they can provide. In response to these concerns, legislative representatives have put forth numerous bills over the past two decades hoping to secure an exemption under the antitrust laws for pharmacists so that they can bargain collectively with PBMs and MCOs. While these attempts have failed to date, some of the bills have enjoyed bipartisan political support, and providers have demonstrated their tenacity in continuing to fight for an exemption.

Notwithstanding the effectiveness of the pharmacy lobby in pushing its agenda in Congress, such an exemption would be unwise from an economic and public-policy perspective. In their quest for an exemption, independents have not identified any sufficiently compelling societal goal to trump the gains created by free-market competition. Permitting independent pharmacy cartels would be antithetical to the policies underlying our nation's antitrust laws, which have recognized explicitly that in order to safeguard competition and further consumer welfare, those businesses that are less than maximally efficient are destined to struggle or fail. This conclusion is supported by empirical data suggesting that an exemption for pharmacists significantly would increase health care costs without a necessary boost in health care quality. Furthermore, it is not clear from the relative bargaining power wielded by health care providers or the industry success of independent pharmacies that an exemption is needed. Many report that the insurance market is indeed competitive and that pharmacists may not be in as precarious positions as some suggest. In addition, under current laws that pertain to health care providers, pharmacists already have a variety of tools at their disposal to collaborate where such collaboration would be procompetitive.

Because collusive behavior directly harms consumers in favor of a select group of producers, academics and practitioners alike have criticized harshly exemptions similar to that proposed by the various iterations of the Quality

Health Care Coalition Act.<sup>265</sup> Commentators argue that while “exemptions proposed to Congress are normally justified on the basis of one or more of a handful of economic arguments[,] . . . these claims often lack substantial documented empirical support.”<sup>266</sup> Instead, exemptions tend to be special-interest-group legislation designed to benefit a few at the expense of many.<sup>267</sup> Consistent with public-choice theory,<sup>268</sup> small groups, like the pharmacy lobby, who are more willing to organize and spend money on lobbying efforts tend to monopolize the legislative process at the expense of diffuse, unorganized groups such as health care consumers.<sup>269</sup> Because Congress has designed many of these exemptions to benefit select groups of producers, rather than consumers, exemptions end up serving as “a form of indirect subsidy for favored actors . . . [who] will be made wealthier without serving the sought-for public interest goals.”<sup>270</sup>

It is important to note that this is not to say that the preservation of small business in the United States, even at the expense of other values, such as economic efficiency and lower prices, is not a laudable goal—or one that is undeserving of legislation. This question is not at the heart of this Note and must be evaluated on its own terms. It *is* to say, however, that it is disingenuous to advance these goals under the catch phrases of “economic efficiency,” “lower prices,” and “greater health care quality” when these claims remain unsupported by the evidence. To do so is to cloak a subsidy in an antitrust exemption imbibed with consumer-welfare arguments. Once the true issues and values at stake are brought to the forefront, we as a society can engage in a more honest and open

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265 For example, the American Bar Association has criticized the Soft Drink Interbrand Competition Act, the Sports Broadcasting Act, and the Newspaper Preservation Act as all having “transferred wealth, but hav[ing] not produced the public interest benefits on which they were initially justified.” SECTION OF ANTITRUST LAW, AM. BAR ASS’N, FEDERAL STATUTORY EXEMPTIONS FROM ANTITRUST LAW 293 (2007) [hereinafter ABA EXEMPTIONS MONOGRAPH].

266 *Id.* at 4.

267 See *Small Business Competition Policy: Are Markets Open for Entrepreneurs?: Hearing Before the H. Comm. on Small Bus.*, 110th Cong. 58–59 (2008) (statement of William E. Kovacic, Chairman, Federal Trade Commission).

268 For an excellent analysis applying public choice theory to antitrust exemptions, see Am. Bar Ass’n, Comments, in ABA EXEMPTIONS MONOGRAPH, *supra* note 265, app. B, at 331–32.

269 See ABA EXEMPTIONS MONOGRAPH, *supra* note 265, at 295 (“Exemptions and modifications have normally been sought by the relevant industry itself or by some other interest with a pecuniary stake in the affected market. . . . [I]n different contexts separate constituencies have varying levels of influence and varying incentives to exercise it. . . . [G]roups that would not favor the exemption are diffuse and lack incentives to organize and challenge the merits of the proposed exemptions effectively.”); ANTITRUST MODERNIZATION COMM’N, REPORT AND RECOMMENDATIONS 335 (2007), available at [http://govinfo.library.unt.edu/amc/report\\_recommendation/amc\\_final\\_report.pdf](http://govinfo.library.unt.edu/amc/report_recommendation/amc_final_report.pdf) (explaining that antitrust exemptions typically “create economic benefits that flow to small, concentrated interest groups, while the costs of the exemption are widely dispersed, usually passed on to a large population of consumers through higher prices, reduced output, lower quality, and reduced innovation”).

270 ABA EXEMPTIONS MONOGRAPH, *supra* note 265, at 25.

debate as to what we wish to achieve and best mechanisms to obtain those goals. For example, if we value small business and want to keep independents alive, is collective bargaining the best route or would a more honest approach be to grant a direct subsidy to the desired group through the structuring of our tax system?<sup>271</sup> Moreover, if we want to preserve small business, do we want to help those in all sectors of society equally or is there something about independent pharmacists that make them particularly worthy of attention?

Finally, even though collective bargaining may not be a logical method of addressing pharmacists' concerns, pharmacists may very well have legitimate concerns about the conduct of PBMs and MCOs in the pharmaceutical arena. The place to address these grievances, however, is not through legislation that would offer a broad antitrust exemption. Lawmakers should regulate PBMs' anticompetitive practices directly and continue to fight anticompetitive activity through litigation rather than leave the fate of vulnerable patients up to the unsupervised market power of the PBMs. For example, state legislators have passed laws including, but certainly not limited to regulating or banning requirements that beneficiaries obtain drugs solely by mail order,<sup>272</sup> setting PBM disclosure and transparency requirements,<sup>273</sup> mandating that networks include a certain number of pharmacies in a set geographical area or preventing discrimination against pharmacies that agree to meet a plan's terms and conditions,<sup>274</sup> and recognizing that PBMs have certain fiduciary duties with respect to covered entities.<sup>275</sup> Such direct targeting is preferable to sanctioning the cartelization of independent pharmacies. Through these efforts to restrain the anticompetitive practices of PBMs, the interests of pharmacists and lawmakers may align to resolve pharmacists' concerns about their bargaining power while truly improving patients' quality of care.

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271 *See id.* at 298–99.

272 *See, e.g.*, ARIZ. REV. STAT. ANN. § 20-1410 (2010); ARK. CODE ANN. § 11-5-114 (2012); CONN. GEN. STAT. ANN. § 38a-510 (West 2012); GA. CODE ANN. § 33-30-4.3 (2005); LA. REV. STAT. ANN. § 22:1011 (2009); MISS. CODE ANN. § 83-9-6 (2011); NEB. REV. STAT. § 44-513.02 (2010); N.J. STAT. ANN. § 26:2J-4.7 (West 2007); TENN. CODE ANN. § 56-7-117 (2008).

273 *See, e.g.*, CAL. HEALTH & SAFETY CODE § 1367.20 (2008); GA. CODE ANN. § 33-30-4.3 (2005); ME. REV. STAT. ANN. tit. 22 § 2699 (2004 & Supp. 2010); MINN. STAT. ANN. § 151.214 (West 2011); N.M. STAT. ANN. § 27-2E-1 (LexisNexis 2004); S.D. CODIFIED LAWS § 58-29E-4 (2004); TENN. CODE ANN. § 56-7-3203 (Supp. 2012); VT. STAT. ANN. tit. 18 § 9472 (Supp. 2012).

274 *See, e.g.*, KAN. STAT. ANN. § 40-2,153 (2000); MASS. GEN. LAWS ANN. ch. 176D, § 3B (West 2007 & Supp. 2012); MISS. CODE ANN. § 83-9-6 (2011); N.J. STAT. ANN. § 26:2J-4.7 (West 2007); S.D. CODIFIED LAWS § 58-18-37 (2004); TENN. CODE ANN. § 56-7-2359 (2008 & Supp. 2012).

275 ME. REV. STAT. ANN. tit. 22 § 2699 (2004 & Supp. 2010).