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## FOCUS ON HEALTH CARE REFORM

### Trends in the Law: The Patient Protection and Affordable Care Act

Michael Lee, Jr. \*

#### INTRODUCTION

On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act (PPACA),<sup>1</sup> cited by *The New York Times* as “the most expansive social legislation enacted in decades”<sup>2</sup> and by opponents as “Obamacare.”<sup>3</sup> The bill has been subjected to wide-ranging support and criticism, but much of the discussion on both sides has been inaccurate, misleading, and highly partisan.<sup>4</sup> Between multiple published versions, extensive

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1. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) [hereinafter PPACA].

2. Sheryl Gay Stolberg & Robert Pear, *Obama Signs Health Care Overhaul Into Law*, N.Y. TIMES, Mar. 23, 2010, at A1.

3. See, e.g., Media Research Center, *The Truth About ObamaCare: What the Liberal Media Aren't Telling You About Obama's Healthcare Plans*, <http://www.obamacaretruth.org> (last visited Dec. 1, 2010).

4. See, e.g., Joan McCarter, *How Insurers Can Game the New System*, DAILY KOS, Apr. 1, 2010, <http://www.dailykos.com/storyonly/2010/4/1/853166/-How-Insurers-Can-Game-the-NewSystem> (listing several incorrect arguments while advocating that the bill be expanded, along with listing several complaints that have nothing to do with the bill); Rachel Weiner, *Palin: Obama's "Death Panel" Could Kill My Down Syndrome Baby*, HUFFINGTON POST, Aug. 8, 2009, [http://www.huffingtonpost.com/2009/08/07/palin-obamas-death-panel\\_n\\_254399.html](http://www.huffingtonpost.com/2009/08/07/palin-obamas-death-panel_n_254399.html); The Market Ticker, <http://market-ticker.org/akcs-www?singlepost=2139125> (Mar. 22, 2010, 13:23 EST) (“[T]his is the end of the health industry in America.”); Media Research Center, *supra* note 3 (displaying a segment titled “Busting Obamacare”); Andrea Santiago, *The Medicus Firm Physician Survey: Health Reform May Lead to Significant Reduction in Physician Workforce*, Jan. 2010, <http://www.themedicusfirm.com/pages/medicus-media-survey-reveals-impact-health-reform> (“What if nearly half of all physicians in America stopped practicing medicine?”). Comments on message boards are too numerous and too vicious to cite, but even CNN's relatively tame message boards are populated with bipartisan vitriol. See CNN Health, *How the Health Care Bill Could Affect You*, <http://www.cnn.com/2010/HEALTH/03/19/interactive.health.care.benefits/index.html>

internal revisions, and a companion bill,<sup>5</sup> this legislation is highly complex—together the bills total 2,562 pages—and confusing. It has also been subject to wide-ranging popular scrutiny. Under those conditions, it is not surprising that the bill has been so widely misunderstood: it has been criticized inaccurately as promoting government-mandated euthanasia<sup>6</sup> and a conspiracy to force the government takeover of health care.<sup>7</sup> It is our hope that the *Yale Journal of Health Policy, Law, and Ethics* can help to fill that gap, serving as legal scholarship's leading examination of this landmark legislation. In doing so, we hope to help satisfy the great curiosity—both global and national—that the bill has sparked.

In order to examine the goals of the bill, it is crucial for readers to understand PPACA's economic foundation. Despite its complexity, PPACA is *not* a hodgepodge of miscellaneous ideas; it is, perhaps surprisingly, a very coherent package. It revolves around one specific provision—the ban on discrimination against preexisting conditions—and each of the other major provisions of the bill is designed to protect that one central feature.

Underlying all of health reform is one fundamental question: what is the purpose of health insurance? Is it meant as an economic and actuarial tool or a social one?<sup>8</sup> PPACA seeks to push the second answer—to use health insurance to promote socioeconomic solidarity in which the healthy subsidize the sick.<sup>9</sup> Pure market insurance redistributes costs only on an ex post basis—it stratifies pools based on expected health status, and only shares risk based on unpredictable events. Solidarity insurance, by contrast, does away with this stratification and shares risk even on an ex ante basis.<sup>10</sup> The healthy will always subsidize the unpredictably sick, but market insurance does not ask them to subsidize the *predictably* and chronically ill; solidarity insurance does.

This is not a trivial difference. The United States is a nation in which 75% of all medical expenditures are devoted to chronic illness, which is usually

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(including comments such as “Health reform my butt” and “Pelosi needs to see a psychiatrist”).

5. Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010) [hereinafter HCERA].

6. See Weiner, *supra* note 4.

7. See The Market Ticker, *supra* note 4.

8. Mary Crossley, *Discrimination Against the Unhealthy in Health Insurance*, 54 U. KAN. L. REV. 73, 73 (2005).

9. *Id.*; Frank Pasquale, *The Three Faces of Retainer Care: Crafting a Tailored Regulatory Response*, 7 YALE J. HEALTH POL'Y L. & ETHICS 39, 41 (2007) (“Tiering in the health insurance market has already eroded the primary ‘end’ of health insurance: subsidizing the unhealthy, unlucky, and sick with funds from the healthy, lucky, and well.”).

10. For a discussion of ex ante versus ex post distinctions, see Posting of Uwe E. Reinhardt to Economix, <http://economix.blogs.nytimes.com/2010/01/01/is-community-rating-in-health-insurance-fair> (Jan. 1, 2010, 07:01 EST).

predictable.<sup>11</sup> The lowest-spending 49% of the population incurs only 3% of medical expenses, and the highest-spending 5% incurs 50% of the expenses.<sup>12</sup> For insurance to thoroughly redistribute that expense gradient, it requires an extraordinary amount of coercion—coercion that the markets, on their own, will not provide.

This is the first and central goal of the PPACA: to prevent health status discrimination. When it takes effect, insurers will no longer be able to charge different rates to the sick; they will no longer be able to exclude certain conditions from coverage; they will no longer be able to stratify premiums and coverage in accordance with actuarial tables. This ban on discrimination based on preexisting conditions is the bill's most famous component.

And yet such legislation, standing on its own, would open up a host of problems. The vast majority of PPACA is thus devoted to solving these created problems. If insurance companies use the healthy to subsidize the sick, then the economically rational response is for the healthy to simply drop coverage entirely.<sup>13</sup> PPACA thus imposes a mandate—a requirement that every citizen purchase and maintain health insurance or else pay a fine.<sup>14</sup> This solves the problem of dropping coverage, but it creates a new problem: the government can hardly force people to purchase something they cannot afford. And so PPACA thus grants a subsidy.<sup>15</sup> For those Americans who meet certain income qualifications, the government will pay a certain proportion of their health insurance premiums. This, of course, requires money—money that the government raises through a combination of new taxes,<sup>16</sup> Medicare and Medicaid

11. NAT'L CTR. FOR CHRONIC DISEASE PREVENTION & HEALTH PROMOTION, CTRS. FOR DISEASE CONTROL & PREVENTION, *THE POWER OF PREVENTION: CHRONIC DISEASE. . . THE PUBLIC HEALTH CHALLENGE OF THE 21ST CENTURY I* (2009), available at <http://www.cdc.gov/chronicdisease/pdf/2009-Power-of-Prevention.pdf>.

12. Mark W. Stanton, Agency for Healthcare Research & Quality, *The High Concentration of U.S. Health Care Expenditures*, RES. ACTION, June 2006, at 1, available at <http://www.ahrq.gov/research/ria19/expendria.pdf>.

13. David A. Hyman & Mark Hall, *Two Cheers for Employment-Based Health Insurance*, 2 YALE J. HEALTH POL'Y L. & ETHICS 23, 26 (2001) ("Commentators wax poetic about the social role of health insurance, and treat the decision to offer and purchase such coverage in morally weighted terms. However, the evidence is fairly clear that potential subscribers approach coverage decisions in *traditional economic terms*.") (emphasis added).

14. PPACA, Pub. L. No. 111-148, § 1501, 124 Stat. 119, 242-49 (2010), modified by § 10106; amended by HCERA, Pub. L. No. 111-152, § 1002, 124 Stat. 1029, 1032-33 (2010) (to be codified at 42 U.S.C. § 18091, 26 U.S.C. § 5000A).

15. PPACA § 1401, 124 Stat. at 213-20 (to be codified at 26 U.S.C. § 36, 26 U.S.C. § 280C); HCERA § 1001(a)(1)(A), 124 Stat. at 1030-31.

16. See, e.g., PPACA § 1501, 124 Stat. at 242-49, modified by § 10106, amended by HCERA § 1002, 124 Stat. at 1032-33 (to be codified at 42 U.S.C. § 18091, 26 U.S.C. § 5000A) (fines from

cuts,<sup>17</sup> and other financial provisions.<sup>18</sup> These four elements comprise the central provisions of PPACA. Each is devoted to the social solidarity model of health insurance and the economic difficulties that such a model presents, and thus PPACA expands access dramatically. CBO projects that it will reduce America's uninsured by thirty-two million Americans—no small feat.<sup>19</sup>

Still, PPACA does not provide universal coverage—some Americans will fall through the cracks. The first piece of our collection, Mark Hall's *Approaching Universal Coverage with Better Safety-Net Programs for the*

the individual mandate); PPACA § 1513(a), 124 Stat. at 253-55, *amended by* HCERA § 1003(b)(2), 124 Stat. at 1033 (to be codified at 49 U.S.C. § 4980H) (fines from the employer mandate); PPACA § 9001, 124 Stat. at 847-53, *amended by* HCERA § 1401, 124 Stat. 1059-60 (to be codified at 26 U.S.C. § 4980I) (excise tax on “Cadillac” plans); PPACA § 9015(a)(1), 124 Stat. at 870-71, *modified by* § 10906, *amended by* HCERA § 1402(b)(2), 124 Stat. at 1063 (to be codified at 26 U.S.C. § 3101) (additional 0.9% payroll tax); HCERA § 1402(a), 124 Stat. at 1060-63 (3.8% investment income tax); PPACA § 9008, 124 Stat. 859-62, *amended by* HCERA § 1404, 124 Stat. at 1064 (to be codified at 26 U.S.C. § 4001) (pharmaceutical industry fees); HCERA § 1405, 124 Stat. at 1064-65 (excise tax on medical devices); PPACA § 10907, 124 Stat. at 1020 (to be codified at 26 U.S.C. § 5000B and note) (indoor tanning tax, nullifying § 9017, a tax on cosmetic medical procedures); PPACA § 6301(e)(2)(A), 124 Stat. at 743-46 (\$2-per-enrollee insurance industry tax); PPACA § 9010, 124 Stat. at 865-68, *modified by* § 10905, *amended by* HCERA § 1406(a)(4), 124 Stat. at 1066 (to be codified at 26 U.S.C. § 4001 note prec.) (insurance industry fees); PPACA §§ 2501-2502, 124 Stat. at 306-10 (to be codified as amended in scattered sections of 42 U.S.C.) (increasing Medicaid reimbursement for prescription drugs).

17. *See, e.g.*, PPACA § 2551, 124 Stat. at 312-15, *modified by* § 10201(f) (to be codified at 42 U.S.C. § 1396r-4(f)) (reducing payments to Disproportionate Share Hospitals); PPACA § 3112, 124 Stat. at 421 (to be codified at 42 U.S.C. § 1395iii) (eliminating the “Medicare Improvement Fund”); PPACA § 3201(b), 124 Stat. at 444 (to be codified at 42 U.S.C. § 1395w-23(c)(6)) (specifying a spending freeze for 2011's Medicare Advantage Program); § 3201(d)(2), 124 Stat. at 445 (to be codified at 42 U.S.C. § 1395w-2(a)(6)(B)) (codifying a more competitive, actuarially-based bidding process for Medicare Advantage); PPACA § 3401, 124 Stat. at 480 (to be codified at 42 U.S.C. § 1395ww(b)(3)(B)) (implementing severe “market basket reductions” to reimbursement scales for providers).

18. *See, e.g.*, PPACA § 3023, 124 Stat. at 399-403, *modified by* § 10308 (to be codified at 42 U.S.C. § 1395cc-4) (a pilot program for payment bundling); PPACA § 10326, 124 Stat. at 961-62 (to be codified at 42 U.S.C. § 1395b-1 note) (a pilot program for pay-for-performance); PPACA § 2702, 124 Stat. at 156 (to be codified at 42 U.S.C. § 300gg-1) (reducing payments to hospitals which report too many hospital acquired conditions); PPACA § 6402(i), 124 Stat. at 760-62 (increasing funding to the Health Care Fraud Abuse and Control Fund); PPACA § 6002, 124 Stat. at 689-96 (to be codified at 42 U.S.C. § 1320a-7h) (mandating disclosure where physicians have some ownership in drug or device manufacturers).

19. Letter from Douglas W. Elmendorf, Dir., Cong. Budget Office, to Representative Nancy Pelosi, Speaker, U.S. House of Representatives (Mar. 20, 2010), *available at* <http://www.cbo.gov/ftpdocs/113xx/doc11379/AmendReconProp.pdf>.

*Uninsured*, explores the populations that will remain uninsured after PPACA's provisions are implemented and the "safety net" options through which they might continue to receive care. PPACA expands funding for such safety net programs—such as Federally Qualified Health Centers (FQHCs)<sup>20</sup>—but also presents a new challenge for those services. As Professor Hall argues, safety net programs must now also seek to prevent free-riding behavior, lest it undermine solidarity insurance. This element of PPACA—expanding the means and complicating the mission of the safety net—has been highly underappreciated, especially in comparison to the controversy surrounding the constitutionality of the mandate.<sup>21</sup> And yet for millions of Americans, it will be the only element of health reform that actually impacts their lives. It must not be overlooked.

Perhaps the largest elephant in the room, however, is the question of cost-control. In and of itself, the bill does not impose any surefire ways to control the nation's overall health expenditures.<sup>22</sup> Yet the mandate *absolutely* depends upon such control. If costs continue to escalate, then they will place the mandate in danger—and with it, the entire purpose of health reform. In a tentative January estimate, the Congressional Budget Office (CBO) estimated that the bronze family plan, already a low-benefits package, would probably average more than \$12,000<sup>23</sup>—approximately double the current national average.<sup>24</sup> Plans could rise by \$6,000 a year or more. And this estimate lines up well with the empirical evidence as seen in New York's insurance regulation<sup>25</sup> and the evidence regarding our nation's underlying health expense distribution.<sup>26</sup> Somehow, CBO's dire predictions have gone underappreciated by observers.

If excess premiums charged to the healthy are higher than the fine associated with the mandate, a rational actor will be motivated to drop coverage and simply

20. PPACA § 5601(a), 124 Stat. at 677; § 10503, 124 Stat. at 1004 (to be codified at 42 U.S.C. § 2546-2).

21. See, e.g., *Florida ex rel. McCollum v. U.S. Dep't of Health and Human Servs.*, 716 F. Supp. 2d 1120 (N.D. Fl. 2010) (denying motion to dismiss some counts of a lawsuit filed by the State of Florida and 19 other states challenging the constitutionality of the mandate).

22. For agreement with this assessment, see commentary from Atul Gawande, *Testing, Testing*, NEW YORKER, Dec. 14, 2009, at 34 ("But the legislation has no master plan for dealing with the problem of soaring medical costs.").

23. Letter from Douglas W. Elmendorf, Dir., Cong. Budget Office, to Senator Olympia Snowe, U.S. Senate (Jan. 11, 2010), available at [http://www.cbo.gov/ftpdocs/108xx/doc10884/01-11-Premiums\\_for\\_Bronze\\_Plan.pdf](http://www.cbo.gov/ftpdocs/108xx/doc10884/01-11-Premiums_for_Bronze_Plan.pdf).

24. See AMERICA'S HEALTH INSURANCE PLANS, INDIVIDUAL HEALTH INSURANCE 2009 4 (2009), available at <http://www.ahipresearch.org/pdfs/2009IndividualMarketSurveyFinalReport.pdf>.

25. AMERICA'S HEALTH INSURANCE PLANS, *supra* note 24, at 5; Anemona Hartocollis, *New York Offers Costly Lessons on Insurance*, N.Y. TIMES, Apr. 17, 2010, at A1.

26. See Stanton, *supra* note 12, at 1.

pay the fine.<sup>27</sup> Further, if premiums rise high enough, many families will fall into a built-in “hardship exemption” where the fine will not apply.<sup>28</sup> If many of the healthy drop coverage—one of Professor Hall’s concerns, especially if the safety net is robust—premiums will rise further, prompting yet more people to drop their insurance. Premiums will then rise again, sparking what is known as the “adverse selection death spiral” of insurance.<sup>29</sup>

The bill, therefore, absolutely depends upon controlling medical expenditures. Can it do so? There are no surefire, definitive cost-control mechanisms in the bill, and yet there is some reason for optimism.<sup>30</sup>

One prominent cost-control attempt is the Independent Payment Advisory Board (IPAB), established to make certain expenditure-reducing recommendations to Congress. Timothy Jost explores the philosophy, politics, and powers of this Board in his piece, *The Independent Medicare Advisory Board*. CBO does not expect much from the Board—CBO projects that it will create only \$15 billion in savings over ten years<sup>31</sup>—but concedes that there is room for wide variation. Professor Jost explores some of the ways in which the IPAB might accomplish its goals.

Nonetheless, it will be a tall order for any one panel, however expert, to resolve America’s health care cost troubles. To that end, it is possible—perhaps likely—that the issue of cost control will have to be revisited. What form might that revisiting take? When might it be necessary, and how strong will it have to be? For that matter, which of PPACA’s broader goals will be accomplished, and at what price?

None of these answers will come easily, but perhaps the most direct guidance will come from the prior Massachusetts health reform. Much of PPACA strongly resembles that state’s Chapter 58 reform from 2006, and so

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27. PPACA, Pub. L. No. 111-148, § 1501, 124 Stat. 119, 244-45, *modified by* § 10106 (2010); *amended by* HCERA, Pub. L. No. 111-152, § 1002, 124 Stat. 1029, 1032-33 (to be codified at 26 U.S.C. § 5000A) (establishing the fine as the *greater* of \$695 or 2.5% of the taxpayer’s income in excess of the threshold amount at which a tax return is required). *See* I.R.C. § 6012(a)(1) and § 151(d)(1) (indicating that no return needs to be filed for incomes below the exemption amount, and that that exemption amount is \$2,000, respectively, adjusted for inflation since 1989). *See* Internal Revenue Service, 1040 Instructions 2009, 8, chart A, <http://www.irs.gov/pub/irs-pdf/i1040.pdf> (listing updated threshold amounts).

28. PPACA § 1501(b), 124 Stat. at 246-47 (to be codified at 26 U.S.C. § 5000A) (establishing a hardship exemption if insurance costs more than 8% of a family’s income).

29. For usage of the term, see, for example, Hartocollis, *supra* note 25.

30. *See* Gawande, *supra* note 22, at 34 (“Which of these programs will work? We can’t know. That’s why the Congressional Budget Office doesn’t credit any of them with substantial savings . . . . But, in the end, it contains a test of almost every approach that leading health-care experts have suggested.”)

31. Letter from Douglas W. Elmendorf to Nancy Pelosi, *supra* note 19, at 6.

Massachusetts can provide an early look at what PPACA's results might be. Stephen Weiner's piece, *Payment Reform After PPACA: Is Massachusetts Leading the Way Again?*, explores the differences and similarities between Massachusetts's reform and the federal reform bill, as well as the successes and failures of Chapter 58. He helps us see which of Massachusetts's results might apply to the nation as a whole, and which were dictated by conditions specific to that state.

Perhaps most prominently, Massachusetts did *not* feel that its Chapter 58 was a complete and comprehensive reform. To the contrary, Massachusetts waited just two years before addressing the cost issue in greater depth with its Chapter 305 legislation. PPACA, like Chapter 58, focuses chiefly on access problems. But, as *Payment Reform After PPACA: Is Massachusetts Leading the Way Again?* explains, Massachusetts did not believe that this was a comprehensive solution to what ails health care today, and so undertook a second aggressive reform just two years later. Even as this issue goes to publication, Massachusetts is considering a third reform. Many of those ideas could be applied to federal health reform, especially if, as CBO projects, costs actually accelerate. The Comment examines the core ideas involved in Chapter 305, assesses their applicability to the federal level, and prepares us for what may perhaps prove to be the second round in the battle over health reform.

PPACA has many laudable intentions and will provide valuable services to many Americans who have previously been underserved. Many of these reforms, however, will not be sustainable if expenditures continue to grow as quickly as they have, much less if they accelerate. If costs continue to spiral, they will derail the mandate and, with it, the rest of PPACA's goals. Perhaps the IPAB will live up to its promise, innovating new payment mechanisms and solving the game theory problem that underlies so much of American health care, or perhaps other provisions of PPACA will prove more important than expected. But it seems more likely that Congress will have to follow the lead of Massachusetts by revisiting the issue of cost control and implementing bold new solutions itself. That option is not politically safe, but it would be safer than the too-alluring alternative of inaction.





## Approaching Universal Coverage with Better Safety-Net Programs for the Uninsured

Mark A. Hall\*

The Patient Protection and Affordable Care Act (PPACA) will extend public and private insurance to about thirty million people, which will cover more than half of those who currently are uninsured.<sup>1</sup> This is a monumental achievement, but it still will leave more than twenty million residents uninsured—or about 8% of the nonelderly population.<sup>2</sup> Therefore, the United States will continue to lag well behind peer industrialized nations in providing nearly universal access to a decent level of care. To approach universal coverage, additional efforts will be required to improve access to care for those who continue to lack insurance coverage. Insurance, after all, is not an end in itself; it is the best means of access to affordable care. But, if other means to minimally acceptable access exist, they may provide a form of non-insurance, direct-access coverage that helps to fill the remaining coverage gap for the uninsured.

Sources of care for the uninsured are referred to loosely as the health care “safety net.”<sup>3</sup> In general, health insurance obviously provides better access to care than is available to the uninsured. However, the uninsured do not have zero access.<sup>4</sup> Those with resources can pay for at least some care out-of-pocket at

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1. Letter from Douglas W. Elmendorf, Dir., Cong. Budget Office, to Representative Nancy Pelosi, Speaker, U.S. House of Representatives (Mar. 18, 2010), *available at* <http://www.cbo.gov/ftpdocs/113xx/doc11355/hr4872.pdf>.

2. *Id.*

3. See, e.g., ALISON SNOW JONES & PARSA S. SAJID, ROBERT WOOD JOHNSON FOUND., A PRIMER ON HEALTH CARE SAFETY NETS (2009), *available at* <http://www.rwjf.org/files/research/49869.pdf>.

4. Joseph D. Freeman et al., *The Causal Effect of Health Insurance on Utilization and Outcomes in Adults: A Systematic Review of US Studies*, 46 MED. CARE 1023 (2008) (comparing medical utilization of the insured versus uninsured); Caroline Roan Gresenz, Jeannette Rogowski & José J. Escarce, *Health Care Markets, the Safety Net, and Utilization of Care Among the Uninsured*, 42 HEALTH SERV. RES. 239, 240 (2007); Jack Hadley & Peter Cunningham, *Availability of Safety Net Providers and Access to Care of Uninsured Persons*, 39 HEALTH SERVICES RES. 1527, 1527 (2004) (“[U]ninsured persons can often obtain health services from providers who treat patients regardless of their ability to pay.”); Joseph S. Ross, Elizabeth H. Bradley & Susan H. Busch, *Use of Health Care Services by Lower-Income and Higher-Income Uninsured Adults*, 295

market rates as the need arises. Hospitals must screen patients who come to the emergency room and treat those who urgently need care regardless of their ability to pay.<sup>5</sup> Moreover, in many communities, government and nonprofit hospitals and community health centers will treat some low-income uninsured patients for free or for deeply discounted sliding-scale fees.<sup>6</sup>

Nevertheless, the inadequacy of safety-net access<sup>7</sup> is a major justification for Congress' recent expansion of public and private insurance coverage and for earlier efforts by Massachusetts and other states. Nationwide, the uninsured face substantially increased chances of death, disability, or impairment due to reduced access to care.<sup>8</sup> The exact magnitude of these health deficits is subject to dispute.<sup>9</sup> But the basic fact remains that, overall, the uninsured in this country have inadequate access to care.

What is generally true for the uninsured nationwide is not necessarily true, however, for each community. Some communities have gone to considerable lengths to improve access to care for the uninsured.<sup>10</sup> In various ways, they have constructed and funded programs that each provides tens of thousands of patients a primary care medical home and coordinates access as needed to prescription drugs, specialist referrals, and hospital services. This Essay argues that if all safety-net systems were to perform at the level of these well-structured model programs, then the uninsured would have a level of access that approximates that provided by conventional insurance coverage. It then points to various provisions in the new law that might facilitate the development of programs like these that

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JAMA 2027, 2027 (2006).

5. Emergency Medical Treatment and Active Labor Act, 42 U.S.C. § 1395dd (2006).

6. See MARION EIN LEWIN & STUART ALTMAN, AMERICA'S HEALTH CARE SAFETY NET: INTACT BUT ENDANGERED 47-70 (2000) (discussing the role of core safety-net providers in offering discounted care).

7. See J. Michael McWilliams, *Health Consequences of Uninsurance Among Adults in the United States: Recent Evidence and Implications*, 87 MILBANK Q. 443 (2009); Andrew P. Wilper et al., *Health Insurance and Mortality in US Adults*, AM. J. PUB. HEALTH 2289 (2009).

8. COMM. ON HEALTH INS. STATUS & ITS CONSEQUENCES, INST. OF MED., AMERICA'S UNINSURED CRISIS: CONSEQUENCES FOR HEALTH AND HEALTH CARE 116 (2009).

9. Richard Kronick, *Health Insurance Coverage and Mortality Revisited*, 44 HEALTH SERVICES RES. 1211, 1227 (2009); Helen Levy & David Meltzer, *The Impact of Health Insurance on Health*, 29 ANN. REV. PUB. HEALTH 399, 406 (2008).

10. See, e.g., CHRISTINA MOYLAN, NAT'L ASS'N OF PUB. HOSPS. & HEALTH SYS., MANAGING CARE FOR UNINSURED PATIENTS 1 (2005), available at <http://naph.org/Publications/managingcareforuninsuredpatients.aspx>; Lynn A. Blewett, Jeanette Ziegenfuss & Michael E. Davern, *Local Access to Care Programs (LACPs): New Developments in the Access to Care for the Uninsured*, 86 MILBANK Q. 459, 461 (2008); Lawrence D. Brown & Beth Stevens, *Charge of the Right Brigade? Communities, Coverage, and Care for the Uninsured*, 25 HEALTH AFF. W150, w150-51 (2006); Stephen L. Isaacs & Paul Jellinek, *Is There a (Volunteer) Doctor in the House? Free Clinics and Volunteer Physician Referral Networks in the United States*, 26 HEALTH AFF. 871, 872 (2007).

meet at least a standard of minimal adequacy.

## I. MODEL SAFETY-NET PROGRAMS FOR THE UNINSURED

For the sake of brevity, this Essay discusses only two safety-net prototypes. The first uses traditional safety-net providers, namely, public hospitals connected with medical schools and community health centers. This traditional model is found mainly in large cities or major metropolitan areas<sup>11</sup> such as Albuquerque,<sup>12</sup> Boston,<sup>13</sup> Dallas,<sup>14</sup> Denver,<sup>15</sup> Indianapolis,<sup>16</sup> New Orleans,<sup>17</sup> New York,<sup>18</sup> and the San Francisco Bay Area.<sup>19</sup> A second model is more adaptable to different community types since it pays or recruits volunteer providers throughout and is therefore suited for communities of any size with a full-service hospital. Examples can be found in places as diverse as Asheville, North Carolina,<sup>20</sup>

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11. See, e.g., MOYLAN, *supra* note 10; MARSHA REGENSTEIN ET AL., URGENT MATTERS, WALKING A TIGHTROPE: THE STATE OF THE SAFETY NET IN TEN U.S. COMMUNITIES 3 (2004), available at [http://urgentmatters.org/media/file/UrgentMatters\\_Walking\\_A\\_Tightrope.pdf](http://urgentmatters.org/media/file/UrgentMatters_Walking_A_Tightrope.pdf).

12. Arthur Kaufman et al., *Managed Care for Uninsured Patients at an Academic Health Center: A Case Study*, 75 ACAD. MED. 323, 323 (2000).

13. MARK A. HALL, ROBERT WOOD JOHNSON FOUND., THE COSTS AND ADEQUACY OF SAFETY NET ACCESS FOR THE UNINSURED: BOSTON, MASSACHUSETTS 7 (2010), available at <http://www.rwjf.org/files/research/safetynetmass201006.pdf>.

14. MOYLAN, *supra* note 10, at 42.

15. MARK A. HALL, THE COSTS AND ADEQUACY OF SAFETY NET ACCESS FOR THE UNINSURED: DENVER, COLORADO (2010), available at <http://www.rwjf.org/files/research/safetynetdenver201006.pdf>.

16. MOYLAN, *supra* note 10, at 28.

17. MICHELLE M. DOTY ET AL., THE COMMONWEALTH FUND, COMING OUT OF CRISIS: PATIENT EXPERIENCES IN PRIMARY CARE IN NEW ORLEANS, FOUR YEARS POST-KATRINA ix (2010), available at [http://www.commonwealthfund.org/~media/Files/Publications/Fund%20Report/2010/Jan/Coming%20Out%20of%20Crisis/1354\\_Doty\\_coming\\_out\\_of\\_crisis\\_new\\_orleans\\_clinics.pdf](http://www.commonwealthfund.org/~media/Files/Publications/Fund%20Report/2010/Jan/Coming%20Out%20of%20Crisis/1354_Doty_coming_out_of_crisis_new_orleans_clinics.pdf).

18. DOUGLAS MCCARTHY & KIMBERLY MUELLER, THE COMMONWEALTH FUND, THE NEW YORK CITY HEALTH AND HOSPITALS CORPORATION: TRANSFORMING A PUBLIC SAFETY NET DELIVERY SYSTEM TO ACHIEVE HIGHER PERFORMANCE vii (2008), available at [http://www.commonwealthfund.org/~media/Files/Publications/Fund%20Report/2008/Oct/The%20New%20York%20City%20Health%20and%20Hospitals%20Corporation%20%20Transforming%200a%20Public%20Safety%20Net%20Delivery%20System/McCarthy\\_nychlhospitalscorpstudy\\_1154%20pdf.pdf](http://www.commonwealthfund.org/~media/Files/Publications/Fund%20Report/2008/Oct/The%20New%20York%20City%20Health%20and%20Hospitals%20Corporation%20%20Transforming%200a%20Public%20Safety%20Net%20Delivery%20System/McCarthy_nychlhospitalscorpstudy_1154%20pdf.pdf); Eve Weiss, Kathryn Haslanger & Joel C. Cantor, *Accessibility of Primary Care Services in Safety Net Clinics in New York City*, 91 AM. J. PUB. HEALTH 1240, 1240 (2001).

19. EMBRY M. HOWELL ET AL., THE URBAN INST., A REPORT ON THE SECOND YEAR OF THE SAN MATEO COUNTY ADULT COVERAGE INITIATIVE AND SYSTEMS REDESIGN FOR ADULT MEDICINE CLINIC CARE 2 (2010), available at <http://www.urban.org/UploadedPDF/412103-san-mateo-clinic-care.pdf>; Mitchell H. Katz, *Golden Gate to Health Care for All? San Francisco's New Universal Access Program*, 358 NEW ENG. J. MED. 327, 327 (2008).

20. See MARK A. HALL & WENKE HWANG, ROBERT WOOD JOHNSON FOUND., THE COSTS AND ADEQUACY OF SAFETY NET ACCESS FOR THE UNINSURED: BUNCOMBE COUNTY (ASHEVILLE), NORTH

Hollywood, Florida;<sup>21</sup> Lansing, Michigan;<sup>22</sup> and Portland, Maine.<sup>23</sup> Several communities have programs that combine elements of each model.

In either model, uninsured individuals are screened for eligibility, given a membership card good for six to twelve months, and assigned a primary care medical home. Care managers help coordinate care and educate patients, especially those with chronic or recurring ailments. Prescription drugs, diagnostic testing, specialist referrals, and hospitalization are available as needed. However, members have little or no choice of providers, and there may be strict medical necessity controls for services that are covered. Also, some services may not be covered, such as routine dental care, specialized behavioral health, and expensive medical equipment.

Importantly, these programs usually do not commit to providing a specified level of service. Instead, they typically disavow any notion of providing insurance coverage, and they often qualify the range of services and providers offered as being subject to change or limitation based on fluctuations in funding and availability of providers. In short, the notion is one of *eligibility* for limited resources rather than an *entitlement* to a defined standard of care. An entitlement connotes individually enforceable rights arising from a legal commitment created by contract or statute. Safety-net eligibility arises from screening a person as qualified to receive available services, and so it is more of a social understanding than a legal standard.

This absence of an individually enforceable legal guarantee does not, by itself, negate a notion of minimally decent coverage. Similar constraints on legal entitlements exist in major European countries that fund their health care systems through fixed budgets or block grants for direct service, rather than through insurance. Under these countries' legal regimes, rights to health care and guarantees of access often are non-justiciable as individual claims since any meaningful adjudication requires balancing one individual's need for a particular service against the collection of expected needs from all other patients

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CAROLINA (2010), available at <http://www.rwjf.org/files/research/safetynetnc201006.pdf>.

21. See MEMORIAL HEALTHCARE SYS., ANNUAL REPORT (2009), available at [http://www.mhs.net/pdf/AnnualReport\\_2009.pdf](http://www.mhs.net/pdf/AnnualReport_2009.pdf).

22. See TERESA COUGHLIN ET AL., THE URBAN INST., THE MEDICAID DSH PROGRAM AND PROVIDING HEALTH CARE SERVICES TO THE UNINSURED: A LOOK AT FIVE PROGRAMS 29-38, 51 (2001), available at [http://www.urban.org/UploadedPDF/410976\\_ASPEIDSH.pdf](http://www.urban.org/UploadedPDF/410976_ASPEIDSH.pdf); Erin Fries Taylor, Peter Cunningham & Kelly McKenzie, *Community Approaches to Providing Care for the Uninsured*, 25 HEALTH AFF. (WEB EXCLUSIVE) w173, w175 (2006), available at <http://content.healthaffairs.org/cgi/reprint/25/3/w173>.

23. See MARK A. HALL, ROBERT WOOD JOHNSON FOUND., THE COST AND ADEQUACY OF SAFETY NET ACCESS FOR THE UNINSURED: SOUTH COASTAL MAINE (CARE PARTNERS) (2010), available at <http://www.rwjf.org/files/research/49869maine.pdf>; Jeffrey T. Kullgren, Erin Fries Taylor & Catherine G. McLaughlin, *Donated Care Programs: A Stopgap Measure or a Long-Run Alternative to Health Insurance?*, 16 J. HEALTH CARE FOR POOR & UNDERSERVED 421, 422 (2005).

throughout the remainder of the funding period. Therefore, constitutional or statutory commitments to provide coverage are often characterized in Europe as creating only social rights that are vindicated mainly through political institutions.<sup>24</sup> Nevertheless, these systems are regarded as providing universal coverage.

In the United States, some structured safety-net programs provide care that is virtually free, but others use sliding fee scales to charge significant amounts to patients who are not indigent. The programs that are virtually free typically cover people with incomes only up to 200% of the federal poverty level (FPL), but sliding scale programs go up to 300% FPL or more.<sup>25</sup>

When patients pay, the critical distinction is that they pay only for specific services received and usually not for membership in the program. Along with the absence of explicit guarantees of access, this explains why these programs do not constitute insurance. When membership fees are charged, they are only modest amounts covering administrative expenses, not prospective payment for expected services.

## II. PROGRAM ADEQUACY AND COST

Many studies profile the structure and funding of the safety net generally,<sup>26</sup> but prior research has done little to document the costs and adequacy of care provided by model programs. To help fill this void, I have reported elsewhere five in-depth studies of model programs in Asheville, Boston, Denver, Flint, and San Antonio.<sup>27</sup> Based on a variety of indicators, these studies conclude that these programs provide access to care that is similar to that provided by conventional insurance.<sup>28</sup> From a structural perspective, these programs enroll members in a

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24. Uwe E. Reinhardt, *Reforming the Health Care System: The Universal Dilemma*, 19 AM. J. L. & MED. 21, 22 (1993).

25. Mark A. Hall, *Rethinking Safety-Net Access for the Uninsured*, NEW ENG. J. MED. (forthcoming 2010) (manuscript at 5, on file with author).

26. DENNIS ANDRULIS & MICHAEL GUSMANO, N.Y. ACAD. OF MED., COMMUNITY INITIATIVES FOR THE UNINSURED: HOW FAR CAN INNOVATIVE PARTNERSHIPS TAKE US? (2000); LYNN QUINCY ET AL., MATHEMATICA POLICY RESEARCH, DESIGNING SUBSIDIZED HEALTH COVERAGE PROGRAMS TO ATTRACT ENROLLMENT: A REVIEW OF THE LITERATURE AND A SYNTHESIS OF STAKEHOLDER VIEWS (2008), available at <http://aspe.hhs.gov/health/reports/08/subenroll/report.pdf>; Lynn A. Blewett & Timothy J. Beebe, *State Efforts To Measure the Health Care Safety Net*, 119 PUB. HEALTH REP. 125 (2004); Peter J. Cunningham, *The Healthcare Safety Net: What Is It, What Good Does It Do, and Will It Still Be There When We Need It?*, HARV. HEALTH POL'Y REV., Fall 2007, at 5; Sheldon M. Retchin, Sheryl L. Garland & Emmanuel A. Anum, *The Transfer of Uninsured Patients from Academic to Community Primary Care Settings*, 15 AM. J. MANAGED CARE 245 (2009).

27. Mark A. Hall, Alison Snow Jones & Parsa S. Sajid, *Health Care Safety Nets*, <http://www.rwjf.org/healthpolicy/product.jsp?id=49869> (follow links to second through fifth publications on left sidebar).

28. Mark A. Hall, *Access to Care Provided by Better Safety Net Systems for the Uninsured*:

coordinated system that offers the basic range of services and providers that one expects from insurance. Program members use physicians with frequencies similar to insured groups. However, there is less use of hospitals than expected in the two programs (Flint and Asheville) that rely on uncompensated hospital charity care.

Also, these programs are not able to show improvements in the population-wide measures of access that commonly are used in national or state surveys. These measures include: having a usual source of care; an ability to receive care when needed; and having at least one medical visit each year.<sup>29</sup> Uninsured populations in most of the five study communities fare no better under these population-wide measures of access than uninsured elsewhere in the state or the nation, and they usually fare worse than people with insurance. However, these surveys fail to assess the exact target group of people who are both low-income and uninsured; instead, results typically are shown for uninsured at all income levels or for all low-income, including those on Medicaid.

Moreover, respondents may consider enrollment in a well-structured safety-net program to be equivalent to insurance. If so, population surveys may be *least* accurate in assessing uninsured rates within the target population in the very communities that have the *best* safety-net programs. In fact, there is evidence of underreporting of uninsured status in most of the case studies, which itself is an indicator of these programs' basic adequacy, since it means that some members do not even realize they are without coverage.

Measuring the value of the care received in terms of its institutional costs of delivery, these studies also estimated that, in 2008, the institutional costs of the services provided by these programs ranged from \$141 to \$200 a month for adults.<sup>30</sup> This was roughly one-quarter to one-half less than the estimated cost to cover these same populations with Medicaid or private insurance, even if that insurance were restricted to the same general range of benefits and the same set of providers.<sup>31</sup> Therefore, these programs are a more affordable means to increase coverage than expanding insurance.

These findings are not unique to these communities. Similar successes also have been documented in other communities,<sup>32</sup> and for federal programs that

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Measuring and Conceptualizing Adequacy (Aug. 30, 2010) (unpublished manuscript) (on file with author).

29. Jill Eden, *Measuring Access to Care Through Population-Based Surveys: Where Are We Now?*, 33 HEALTH SERVICES RES. 685, 699 (1998).

30. Mark A. Hall, Wenke Hwang & Alison Snow Jones, *The Costs of Caring for the Uninsured Under Well-Structured Safety Net Systems* (Aug. 30, 2010) (unpublished manuscript) (on file with author).

31. *Id.* at 20.

32. See *supra* notes 11-23; see also ALLISON COOK & BARBARA A. ORMOND, *THE URBAN INST., WHO HAS INSURANCE AND WHO DOES NOT IN THE DISTRICT OF COLUMBIA?* 3 (2007), available at [http://www.urban.org/UploadedPDF/411589\\_insurance\\_dc.pdf](http://www.urban.org/UploadedPDF/411589_insurance_dc.pdf).

serve safety-net functions for veterans and for Native Americans. The Veterans Health Administration (VA) is widely regarded as a successful direct care system.<sup>33</sup> The most thorough and sophisticated study to date concluded that it would have cost Medicare about 20% more if it had paid for the services that the VA provided in 1999.<sup>34</sup>

The Indian Health Service (IHS) provides direct care to tribal members on or near reservations.<sup>35</sup> The level of access they report is similar to that for insured groups. The leading study (which used 1997-1999 data), found that Native Americans “with only IHS access fared . . . as well as insured Whites for key measures” such as having a usual source of care and having had a medical or dental visit in the past year.<sup>36</sup> According to the government’s actuarial estimates, the IHS current spending provides roughly half of what it would cost to increase IHS coverage to its core population to the level of federal employees, adjusting for differences in demographics, health characteristics, and covered services.<sup>37</sup> IHS funding is widely regarded as inadequate for patients who require referral for advanced hospital and specialist services that are not immediately available from IHS providers.<sup>38</sup> But if funding for these outside referrals were increased to levels that program advocates testified are needed,<sup>39</sup> IHS costs would still be about 40% less than commercial insurance.<sup>40</sup>

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33. See CONG. BUDGET OFFICE, *THE HEALTH CARE SYSTEM FOR VETERANS: AN INTERIM REPORT* (2007), available at [http://www.cbo.gov/ftpdocs/88xx/doc8892/12-21-VA\\_Healthcare.pdf](http://www.cbo.gov/ftpdocs/88xx/doc8892/12-21-VA_Healthcare.pdf); PHILLIP LONGMAN, *BEST CARE ANYWHERE: WHY VA HEALTH CARE IS BETTER THAN YOURS* (2010); Anne E. Sales, *The Veterans Health Administration in the Context of Health Insurance Reform*, 46 MED. CARE 1020 (2008).

34. Gary N. Nugent et al., *Value for Taxpayers' Dollars: What VA Care Would Cost at Medicare Prices*, 61 MED. CARE RES. REV. 495, 502 (2004).

35. INDIAN HEALTH SERV., *THE FIRST 50 YEARS OF THE INDIAN HEALTH SERVICE: CARING & CURING* 15 (2006).

36. Stephen Zuckerman et al., *Health Service Access, Use, and Insurance Coverage Among American Indians/Alaska Natives and Whites: What Role Does the Indian Health Service Play?*, 94 AM. J. PUB. HEALTH 53, 56 (2004).

37. ROGER WALKER, *INDIAN HEALTH SERVICE: HEALTH CARE DELIVERY, STATUS, FUNDING, AND LEGISLATIVE ISSUES* 14-16, 19-21 (2008).

38. See U.S. GOV'T ACCOUNTABILITY OFFICE, *INDIAN HEALTH SERVICE: HEALTH CARE SERVICES ARE NOT ALWAYS AVAILABLE TO NATIVE AMERICANS* 18 (2005), available at <http://www.gao.gov/new.items/d05789.pdf>.

39. See *Access to Contract Health Services in Indian Country: Hearing Before the S. Comm. on Indian Affairs*, 110th Cong. 1-7 (2008) (statement of Hon. Byron L. Dorgan, Chairman, S. Comm. on Indian Affairs).

40. According to Senator Dorgan, outside referral services are “funded at about \$580 million at this point” and that “\$1.3 billion would be necessary to meet the current need.” *Id.* at 2. This infers that IHS is about 40% less than commercial insurance.

## III. SAFETY-NET PROGRAMS AFTER HEALTH INSURANCE REFORM

Recognizing that safety-net programs can provide the uninsured adequate access at reasonable costs, it remains to be seen how these programs can be adapted to fit the components of the population that will remain uninsured. Starting in 2014, many of the people safety-net programs have served will become eligible for Medicaid or highly subsidized private insurance. Nevertheless, substantial segments of uninsured will remain.

First, the reform law's subsidies are not available to undocumented immigrants.<sup>41</sup> These non-citizen residents will constitute roughly one-third of the remaining uninsured.<sup>42</sup> It is notable that most of the model safety-net programs profiled above are open to non-citizen residents. They adopt inclusive policies not only because undocumented immigrants are a major component of the needy population in some communities, but also as a matter of convenience to legal residents. Excluding illegal immigrants would require identifying them, which entails insisting that all applicants verify their legitimacy. Many citizens find it offensive and difficult to prove their legitimacy using birth records and the like. Thus, the more acceptable policy for everyone concerned is often simply to dispense with any documentation requirements other than showing local residence (such as with a utility bill).

Second, the reform law requires legal residents to purchase insurance only if they have decent coverage available to them that costs less than 8% of their income. Insurance subsidies that reduce premiums to approximately this level phase out at 400% of the federal poverty level. Some upper-middle-income people will face insurance premiums greater than the mandate threshold, especially older people for whom insurers may vary rates threefold based on age.<sup>43</sup> Legally, these higher-income people may decide to drop or avoid health insurance without penalty.

Also not subject to a mandate penalty are people who are uninsured for only three months or less. Observing the similar reform measures in Massachusetts, we learn that gaps in coverage are difficult to avoid when people switch from public to private coverage.<sup>44</sup> This is because private insurance, even when highly

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41. Nathan Cortez, *Embracing the New Geography of Health Care: A Novel Way To Cover Those Left out of Health Reform 7* (Aug. 30, 2010) (unpublished manuscript) (on file with author).

42. Mark A. Hall, *The Mission of Safety Net Organizations Following National Insurance Reform*, J. GEN. INTERNAL MED. (forthcoming 2010) (manuscript at 4, on file with author).

43. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1201, 124 Stat. 119, 155 (2010) (to be codified at 42 U.S.C. § 300gg) [hereinafter PPACA].

44. See HEALTH CONNECTOR, REPORT TO THE MASSACHUSETTS LEGISLATURE: IMPLEMENTATION OF HEALTH CARE REFORM FISCAL YEAR 2009 (2009), available at <https://www.mahealthconnector.org/portal/binary/com.epicentric.contentmanagement.servlet.ContentDeliveryServlet/About%2520Us/Executive%2520Director%2520Message/Connector%2520Annual%2520Report%25202009.pdf>; Sharon K. Long & Karen Stockley, *Sustaining Health Reform In*



subsidized, is not designed for immediate or retroactive enrollment. Instead, the process of filling out forms and paying the first month's premium in advance will usually entail a delay. Also, once the new insurance exchanges are operational, it is entirely possible that open enrollment will not be continuously available, but will instead be limited to certain times of the year. Insurance gaps caused by these transitions from public to private coverage will be fairly common, since the reform law requires that this switch occur each time a person's income increases above 133% FPL.<sup>45</sup>

A structured access system that allows the legally uninsured to pay for care as needed under a sliding fee scale would provide an alternative form of coverage. The programs in Denver and San Antonio are two notable examples of this approach.<sup>46</sup> If these sliding scale service payments are capped at a reasonable percent of income or assets, they may provide affordable access to a decent range of services.

The remaining component of the uninsured will consist of people who illegally forgo coverage, despite having an insurance option that costs less than 8% of income. A large portion of this group will be eligible for Medicaid,<sup>47</sup> which allows enrollment for free at the point people need treatment (or even retroactively in some circumstances). Therefore, people eligible for Medicaid will have virtual coverage when needed, even if they are not actually enrolled. This leaves only about a quarter of the uninsured (about 2% of the population) that safety nets will need to exclude.<sup>48</sup> In order to avoid "crowding out" the legal mandate to purchase insurance when it is affordable,<sup>49</sup> safety-net programs should not accept middle-income people (above, say, 250% FPL) who have subsidized or employer-sponsored insurance options that cost less than 8% of

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*A Recession: An Update on Massachusetts as of Fall 2009*, 29 HEALTH AFF. 1234 (2010).

45. See PAMELA FARLEY SHORT ET AL., COMMONWEALTH FUND, IMPLEMENTING NATIONAL HEALTH INSURANCE REFORMS: MAINTAINING AFFORDABILITY, SHARED RESPONSIBILITY, AND CONTINUITY WHEN LIFE CHANGES (forthcoming 2011) (manuscript on file with author).

46. MARK A. HALL, ROBERT WOOD JOHNSON FOUND., THE COSTS AND ADEQUACY OF SAFETY NET ACCESS FOR THE UNINSURED: BEXAR COUNTY (SAN ANTONIO), TEXAS 4 (2010), *available at* <http://www.rwjf.org/files/research/safetynettexas201006.pdf>. See HALL, *supra* note 15, at 5.

47. See RAND CORP, ANALYSIS OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT (H.R. 3950) 11 (2010), *available at* [http://www.rand.org/pubs/research\\_briefs/2010/RAND\\_RB9514.pdf](http://www.rand.org/pubs/research_briefs/2010/RAND_RB9514.pdf).

48. See Hall, *supra* note 25.

49. See generally GESTUR DAVIDSON, LYNN A. BLEWETT & KATHLEEN THIEDE CALL, ROBERT WOOD JOHNSON FOUND., PUBLIC PROGRAM CROWD-OUT OF PRIVATE COVERAGE: WHAT ARE THE ISSUES? (2004), *available at* [http://www.rwjf.org/pr/synthesis/reports\\_and\\_briefs/pdf/no5\\_researchreport.pdf](http://www.rwjf.org/pr/synthesis/reports_and_briefs/pdf/no5_researchreport.pdf); M. Susan Marquis & Stephen H. Long, *Public Insurance Expansions and Crowd Out of Private Coverage*, MED. CARE 344 (2003); ROBERT WOOD JOHNSON FOUND., UNDERSTANDING THE DYNAMICS OF "CROWD-OUT": DEFINING PUBLIC/PRIVATE COVERAGE SUBSTITUTION FOR POLICY AND RESEARCH (2001), *available at* <http://www.allhealth.org/briefingmaterials/hcfo-845.pdf>.

income. This portion hopefully will be small enough that, in theory, a comprehensive safety-net program for the legally uninsured would be capable of bringing us to nearly universal access.

#### IV. POLICY INITIATIVES FOR IMPROVING ACCESS FOR THE UNINSURED

It is wishful thinking, of course, to hope that model safety-net access programs will soon spread nationwide to encompass all of these major swaths of the legally uninsured. An important funding source for insurance expansion is to reduce and redirect funds previously aimed at safety-net care for the uninsured under the logic that there will be substantially fewer uninsured people.<sup>50</sup> Nevertheless, the potential for safety-net improvements exists in several critical pieces of this comprehensive legislation, even with the redirection of safety-net funds.

First, \$11 billion in new funding is directed to federally qualified community health centers (FQHCs),<sup>51</sup> which is expected to roughly double their capacity.<sup>52</sup> Second, although PPACA cuts existing federal payments to hospitals that serve a disproportionate share of uninsured and low-income patients, it does not eliminate these payments altogether. Instead, the reform law calls on the Secretary of Health and Human Services to devise a fairer approach to allocating Medicaid disproportionate share funds.<sup>53</sup> Rather than basing these payments entirely on hospital services, the new allocation criteria could give greater weight to investments in primary care delivery for the uninsured. Also, the allocation could favor hospitals that require specialist physicians on their medical staff to accept a fair allotment of uninsured safety-net patients at discounted rates.<sup>54</sup> Finally, the reform law provides for a series of demonstration projects or waiver programs that could support developing better safety-net access programs.<sup>55</sup>

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50. JOHN HOLAHAN & BOWEN GARRETT, *THE COST OF UNCOMPENSATED CARE WITH AND WITHOUT HEALTH REFORM 1* (2010), available at [http://www.urban.org/UploadedPDF/412045\\_cost\\_of\\_uncompensated.pdf](http://www.urban.org/UploadedPDF/412045_cost_of_uncompensated.pdf).

51. PPACA, Pub. L. No. 111-148, § 10503, 124 Stat. 119, 1004 (2010) (to be codified at 42 U.S.C. § 254b-2).

52. KAISER COMM'N ON MEDICAID & THE UNINSURED, *COMMUNITY HEALTH CENTERS: OPPORTUNITIES AND CHALLENGES OF HEALTH REFORM 7* (Aug. 2010), available at <http://www.kff.org/uninsured/upload/8098.pdf>.

53. § 2551, 124 Stat. at 313-14, *modified by* § 10201(f) (to be codified at 42 U.S.C. § 1396r-4 note).

54. *See* COUGHLIN ET AL., *supra* note 23, at iii. The reform law also requires increased transparency and scrutiny of the charity care policies and practices that justify nonprofit hospitals' tax exempt status, § 9007, 124 Stat. at 855-57, *modified by* § 10903 (to be codified at 26 U.S.C. § 501). This is another leverage point to encourage community hospitals to help coordinate more comprehensive safety-net access for the uninsured.

55. The PPACA states the option to establish a "basic health program," § 1331(a)(1), 124 Stat. at 199 (to be codified at 42 U.S.C. § 18051), for low-income people (up to 200% FPL) who are not

States and communities need not wait for federal support, however, to construct better safety-net access for the uninsured. The changing composition of the uninsured will require safety-net programs to be reconfigured in any event. Some current funding sources might diminish, but others, such as local property taxes or philanthropy, remain largely intact. In addition, Medicaid's expansion to 133% of poverty will free up existing funds by eliminating much of the need to serve truly indigent people. Finally, free care programs might consider adopting sliding scale fee schedules for middle-income people in need, which would generate new resources.

With this combination of support and through careful crafting, well-structured safety-net programs could be tailored to fit the major population segments that, legally, will remain uninsured. We may scoff at the phrase "Mission Accomplished." But reasonable insurance coverage for most of us and a decent safety net for the rest could at least allow the United States to hold its head higher among peer industrialized nations. Although decent safety-net access is inferior to comprehensive insurance, further expansions of insurance are highly unlikely any time soon. To refuse safety-net improvements out of compunction over ideal social equity is to hold the lives and welfare of the least advantaged among us hostage to the unachievable ransom demands of those who might prefer single-payer insurance for all. If good-enough safety-net programs were in place, no longer would we be the only advanced society that fails to provide decent access to care for almost all its people. That would be a remarkable accomplishment indeed.

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eligible for Medicaid, including legal immigrants who have not met Medicaid's five-year waiting period, § 1331(e)(1), 124 Stat. at 202-03, *modified by* § 10104(o) (to be codified at 42 U.S.C. § 18051). Through these basic health programs, states may contract directly with providers for discounted rates, creating in essence a state version of the much-debated public option that was rejected at the federal level. States that opt for this approach will receive 95% of the tax credits and cost-sharing reductions that the federal government would have paid for individuals enrolled in exchange-based health plans. *Id.* Somewhat more tentatively, sections 10333 and 10504 authorize, but do not appropriate, funds for two special programs related to better-structured safety-net programs. The first is for a "community-based collaborative care network program" that provides "comprehensive coordinated and integrated health care services" for low-income populations. § 10333, 124 Stat. at 970 (to be codified at 42 U.S.C. § 256i). These networks must include at least one hospital and all FQHCs in their area, and funding priority is given to networks with public hospitals or clinics. *Id.* The second special program is a three-year demonstration project authorized for up to ten "[s]tate-based, nonprofit, public-private partnership[s]" that provide "access to comprehensive health care services to the uninsured at reduced fees." § 10504, 124 Stat. at 1004 (to be codified at 42 U.S.C. § 256 note).



# The Independent Medicare Advisory Board

Timothy Stoltzfus Jost

It is a common realization that neither unconstrained markets nor our current political institutions are capable of governing our health care system. The cost of health care is spinning dangerously out of control, yet market forces alone cannot manage these costs because of a host of relatively well-understood market failures.<sup>1</sup> Moreover, our traditional political institutions—Congress and the executive administrative agencies—have also failed us in this respect. These institutions are too driven by special interest politics and too limited in their expertise and vision to control costs.<sup>2</sup> Both Medicare payment formulas and coverage determinations often seem to be driven by political, rather than scientific or economic, considerations.

Enter the Platonic Guardians. The governance of the health care system should, it is argued, be turned over to an impartial, independent “Federal Health Board” of experts who could make coverage and payment determinations based purely on evaluations of effectiveness and perhaps efficiency. The Federal Health Board became a central theme in the 2009 debate primarily through Tom Daschle’s book *Critical*,<sup>3</sup> but the idea of an impartial and independent board to govern the Medicare program goes back further to the 1999 report of the National Bipartisan Commission on the Future of Medicare.<sup>4</sup> Other experts, including Victor Fuchs and Ezekiel Emanuel along with Len Nichols have also proposed some form of national health care governing board.<sup>5</sup> The models of the Federal Reserve Board or the Base Closing Commission are often invoked as agencies that make difficult decisions largely insulated from political

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1. These include information and agency failures, moral hazard, misaligned incentives, and externalities. See BARRY FURROW ET AL., *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* 565-74 (6th ed. 2008).

2. See Timothy Stoltzfus Jost, *Governing Medicare*, 51 ADMIN. L. REV. 39 (1999).

3. Tom Daschle, Scott S. Greenberger & Jeanne M. Lambrew, *Critical: What We Can Do About the Health-Care Crisis* 169-80 (2008).

4. Nat’l Bipartisan Comm’n on the Future of Medicare, *The Medicare Board*, <http://thomas.loc.gov/medicare/3fmedbrd.htm> (last visited Nov. 3, 2010).

5. EZEKIEL J. EMANUEL & VICTOR R. FUCHS, THE BROOKINGS INST., *A COMPREHENSIVE CURE: UNIVERSAL HEALTH CARE VOUCHERS* 2 (2007), available at [http://www.brookings.edu/~media/Files/rc/papers/2007/07useconomics\\_emanuel/200707emanuel\\_fuchs.pdf](http://www.brookings.edu/~media/Files/rc/papers/2007/07useconomics_emanuel/200707emanuel_fuchs.pdf); Len M. Nichols, New Am. Found., *A Sustainable Health System for All Americans* 8 (2007), available at <http://www.policyarchive.org/handle/10207/bitstreams/8826.pdf>.

considerations and special interest pressure.<sup>6</sup> The Federal Health Board would be composed of experts in health policy, health economics, and health care delivery who would be appointed for long terms of office through an apolitical process, such as appointment by the Comptroller General. Its members would be subject to rigorous conflict of interest strictures and would make decisions based on the evidence rather than on politics.

The role of the Federal Health Board has varied from proposal to proposal. One function it could serve would be to establish a standard set of benefits and determine coverage for items and services through evidence-based evaluation of quality, performance, and effectiveness. Another function would be to set payment rates for providers, practitioners, and suppliers to maximize incentives to provide high-quality, coordinated, and effective care. Yet another would be to set the rules for promoting competition among insurers through health insurance exchanges. The jurisdiction of the Federal Health Board could encompass only the Medicare program, all federal programs, or the entire health care system.

As the health reform legislation moved through Congress during 2009 and the winter of 2010, the concept of an independent board with power to set Medicare payment policy took shape. President Obama mentioned the idea of giving additional authority to the Medicare Payment Advisory Commission (MedPAC) in a June 2, 2009 letter to Senators Kennedy and Baucus.<sup>7</sup> Peter Orszag, the Director of the Office of Management and Budget, followed up with a July 17 letter to Speaker Pelosi endorsing the creation of an Independent Medicare Advisory Council.<sup>8</sup> MedPAC is a legislative branch agency that currently advises Congress on the operation of the Medicare program. The Independent Medicare Advisory Board (IMAB) appeared in the Senate Finance bill<sup>9</sup> and in the combined Senate bill, HR 3590, introduced by Senator Reid in November.

The IMAB concept was generally supported by health economists, two dozen of whom sent a letter to Reid on December 7, 2009.<sup>10</sup> Indeed, the

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6. See PAUL N. VAN DE WATER, NAT'L ACAD. OF SOC. INS., *DESIGNING ADMINISTRATIVE ORGANIZATIONS FOR HEALTH REFORM* (2009), available at <http://www.rwjf.org/files/research/vandewater.pdf>; Joe White, *Getting the "IMAB" Proposal Right: Some Health Care Homework for the Recess*, ROLL CALL, Aug. 4, 2009, <http://www.rollcall.com/news/37522-1.html>.

7. Letter from President Barack Obama, to Senators Edward M. Kennedy & Max Baucus, U.S. Senate (June 2, 2009), available at [http://www.whitehouse.gov/the\\_press\\_office/letter-from-president-obama-to-chairmen-edward-m-kennedy-and-max-baucus](http://www.whitehouse.gov/the_press_office/letter-from-president-obama-to-chairmen-edward-m-kennedy-and-max-baucus).

8. Letter from Peter R. Orszag, Dir., Office of Mgmt & Budget, to Representative Nancy Pelosi, Speaker, U.S. House of Representatives (July 17, 2009) (on file with author).

9. America's Healthy Future Act of 2009, S. 1796, 111th Cong. § 3403 (2009).

10. Posting of David Leonhardt to Economix, <http://economix.blogs.nytimes.com/2009/12/08/rockefeller-the-economists-man-in-the-senate> (Dec. 8, 2009, 23:56 EST).

economists argued that the IMAB should be given greater power to recommend changes in Medicare payments for physicians and hospitals and even for Medicaid, and that its recommendations should be considered for “fast track” action in Congress. Commentators with an interest in health economics, including David Leonhardt and Ezra Klein, added their voices.<sup>11</sup> Klein argued that Congress was “too captured by special interests and too baffled by technical arguments and too paralyzed by partisanship” to do health care reform, and that what was needed instead was “an expert body able to continuously evaluate the data and make changes to Medicare that will increase the program’s effectiveness and decrease its costs.”

The concept, on the other hand, was vigorously opposed by provider groups, a coalition of whom sent a letter to Senator Reid and Speaker Pelosi attacking the idea on January 11, 2010.<sup>12</sup> They argued that the cuts imposed by agency could “jeopardize both access for Medicare beneficiaries and even infrastructure for the entire health care system” and that the body accountable to no one but the President would “greatly limit the ability of Medicare beneficiaries, advocates and providers to work with Congress to improve the [Medicare] program.” A few independent health policy experts, including Joe White, also questioned the Commission concept: White published an opinion piece in *Roll Call* in August asking whether the proposal would give too much power to the President to shape Medicare policy, whether its authority should be limited to Medicare, and whether it would be dominated by provider interests.<sup>13</sup> From the outset the provision included language prohibiting rationing or cutting of benefits to elide claims that had emerged over the summer that the reform law generally would cut Medicare benefits and impose rationing.<sup>14</sup>

The Senate extensively modified the IMAB provisions in the Senate bill through a manager’s amendment with language proposed by Senators Rockefeller, Lieberman, and Whitehouse. They were part of the final Senate bill enacted on December 23, 2009 and the House on March 21, 2010.<sup>15</sup> Among the

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11. See David Leonhardt, *Budget Hawks Have a Buffet of Options with Health Bill*, N.Y. TIMES, Nov. 25, 2009, at B1, available at <http://www.nytimes.com/2009/11/25/health/policy/25leonhardt.html>; Ezra Klein: Economic and Domestic Policy, and Lots of It, [http://voices.washingtonpost.com/ezra-klein/2009/07/the\\_dull\\_reality\\_of\\_change.html](http://voices.washingtonpost.com/ezra-klein/2009/07/the_dull_reality_of_change.html) (July 17, 2009, 17:10 EST).

12. Letter from AIDS Action Baltimore et al., to Senator Harry Reid, Majority Leader, U.S. Senate, & Representative Nancy Pelosi, Speaker, U.S. House of Representatives (Jan. 11, 2010), available at <http://www.aamc.org/advocacy/library/gme/corres/2010/011010.pdf>.

13. White, *supra* note 6.

14. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3403(a)(1), 124 Stat. 119, 489-506, modified by § 10320 (2010) (to be codified at 42 U.S.C. § 1395kkk) [hereinafter PPACA].

15. *Id.*

modifications included in the manager's amendment was the renaming of the IMAB to the Independent Payment Advisory Board (the IPAB or "the Board") with added authority to make recommendations to Congress affecting private insurance as well as Medicare. The budget reconciliation bill adopted by the House and Senate in late March did not modify the IPAB provisions of the Senate bill.

The IPAB is one of a number of boards, commissions, councils, and centers created by the Patient Protection and Affordable Care Act (PPACA).<sup>16</sup> Most directly relevant to the scope of earlier health board proposals, the Center for Medicare and Medicaid Innovation is responsible for designing, evaluating, and implementing innovative Medicare payment and service delivery models.<sup>17</sup> The Center also shares with the IPAB the responsibility for cutting Medicare costs and improving the quality of care through payment reform.<sup>18</sup> The IPAB is composed of fifteen members appointed by the President with the advice and consent of the Senate, supplemented by the Secretary of Health and Human Services (HHS) and the Administrators of the Center for Medicare and Medicaid Services and of the Health Resources and Services Administration.<sup>19</sup> The members are appointed to staggered six-year, one-time-renewable terms of office.<sup>20</sup>

The members are to be nationally recognized experts in health finance, payment, economics, actuarial science, health facility management, and health plan and integrated delivery systems.<sup>21</sup> The IPAB will also include: physicians or other health care providers;<sup>22</sup> experts in medicine, pharmacoeconomics, and drug benefit programs; representatives of employers, third-party payors, consumers, and the elderly; and persons skilled in the conduct and interpretation of biomedical, health services, health economics, technology assessment, and outcomes and effectiveness research.<sup>23</sup> According to section 3403, the Board should be composed of a mix of different professionals, broad geographic representation, and a balanced urban and rural mix.<sup>24</sup> In addition, the majority of the Board must not be persons directly involved in the provision or management

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16. *Id.*

17. § 3021(a), 124 Stat. at 389--94, *modified by* § 10306 (to be codified at 42 U.S.C. § 1315a).

18. *Id.*

19. § 3403(a)(1), 124 Stat. at 502, *modified by* § 10320 (to be codified at 42 U.S.C. § 1395kkk).

20. § 3403(a)(1), 124 Stat. at 503, *modified by* § 10320 (to be codified at 42 U.S.C. § 1395kkk).

21. § 3403(a)(1), 124 Stat. at 502, *modified by* § 10320 (to be codified at 42 U.S.C. § 1395kkk).

22. *Id.*

23. *Id.*

24. *Id.*



of health care items and services.<sup>25</sup> A separate ten-member consumer advisory board is supposed to be appointed by the Comptroller General of the United States.<sup>26</sup>

Service on the IPAB, unlike service on Medicare Payment Advisory Commission (MedPAC) or on other boards and commissions created by the PPACA, is a full-time job. The IPAB members, like members of federal regulatory boards such as the NLRB, FTC, or SEC, are forbidden from engaging in “any other business, vocation, or employment.”<sup>27</sup> Members will be compensated at a rate equal to the annual rate prescribed for Level III of the Executive Schedule (currently, \$165,300), while the Chairperson is compensated at the Level II rate (\$179,700), and the executive director at the Level V (\$145,700) rate.<sup>28</sup>

The basic task of the Board is to develop and implement specific detailed proposals to reduce Medicare spending in years when Medicare per capita spending is expected to exceed target levels.<sup>29</sup> These proposals must be implemented unless Congress acts following expedited procedures to implement alternative cost-cutting measures.<sup>30</sup> The Board is also charged with developing and submitting to Congress “advisory reports on matters related to the Medicare program.”<sup>31</sup> Finally, at least once every two years beginning in January of 2015, the IPAB is responsible for submitting to Congress and the President publicly available recommendations as to how to slow the growth in national health care expenditures (other than through federal programs) while preserving or enhancing the quality of care.<sup>32</sup> These recommendations are supposed to include proposals that could be addressed by federal legislation, as well as recommendations that could be implemented administratively or by state legislation or private action.

At the heart of the tasks of the IPAB is its responsibility for taking action to cut Medicare spending. Each year beginning with April 30, 2013, the Centers for

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25. *Id.*

26. § 3403(a)(1), 124 Stat. at 505, *modified by* § 10320 (to be codified at 42 U.S.C. § 1395kkk).

27. § 3403(a)(1), 124 Stat. at 503, *modified by* § 10320 (to be codified at 42 U.S.C. § 1395kkk).

28. See U.S. Office of Personnel Mgmt, Salary Table No. 2010-EX: Rates of Basic Pay for the Executive Schedule (Jan. 2010), <http://www.opm.gov/oca/10tables/pdf/ex.pdf> (listing 2010 executive schedule rates of pay).

29. See *infra* notes 33-34.

30. See *infra* notes 47-50.

31. § 3403(a)(1), 124 Stat. at 489, *modified by* § 10320 (to be codified at 42 U.S.C. § 1395kkk).

32. § 10320(a)(5), 124 Stat. at 952 (to be codified at 42 U.S.C. § 1395kkk).

Medicare and Medicaid Services (CMS) Chief Actuary will make a determination whether the projected per capita growth rate for the implementation year (the second year following the determination year, initially 2015) will exceed the per capita target growth rate for that year.<sup>33</sup> If the Actuary determines that for any given year the projected Medicare growth rate will exceed the target rate, the Board shall make proposals that will reduce Medicare spending overall by an amount established by the statute.<sup>34</sup>

The proposal, however, must fit within stringent constraints. First, the proposal may not “ration health care, raise revenues or Medicare beneficiary premiums,” increase the Part D based beneficiary premium percentage or full premium subsidies, “increase beneficiary cost-sharing . . . , or otherwise restrict benefits or modify eligibility criteria.”<sup>35</sup> Second, proposals submitted before 2019 for years before 2020 may not target particular providers and suppliers already singled out under section 3401 of the PPACA for cuts above those attributable to reductions based on constrained productivity increases.<sup>36</sup> This means that the Board cannot cut payments for inpatient or outpatient acute hospitals, long-term care hospitals, inpatient rehabilitation hospitals, psychiatric hospitals, and possibly hospice care prior to 2020 or clinical laboratories prior to 2016.<sup>37</sup> Third, proposals must take into account administrative expenditures that HHS will incur in carrying them out.<sup>38</sup> Finally, proposals may “only include recommendations related to the Medicare program.”<sup>39</sup> The Board is explicitly

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33. § 3403(a)(1), 124 Stat. at 493, *modified by* § 10320 (to be codified at 42 U.S.C. § 1395kkk). The Medicare per capita growth rate for the implementation year will be calculated as the projected five-year average rate of growth in per capita spending under Medicare ending in the implementation year (not considering negative updates in the physician sustainable growth rate and taking into account payment reforms enacted but not yet implemented). *Id.* The target growth rate is the projected five-year average ending in the implementation year of, prior to 2018, the average of the Urban Consumer Price Index (U.S. city average), and the medical care category of the Urban Consumer CPI (U.S. city average). § 3403(a)(1), 124 Stat. at 494, *modified by* § 10320 (to be codified at 42 U.S.C. § 1395kkk). After 2017, it will be set at nominal gross domestic product per capita growth plus one percentage point. *Id.*

34. The established amount is 0.5% in 2015, 1% in 2016, 1.25% in 2017, and 1.5% in 2018 and thereafter, or, if less, the projected excess of the growth rate over the target rate. § 3403(a)(1), 124 Stat. at 494, *modified by* § 10320 (to be codified at 42 U.S.C. § 1395kkk).

35. § 3403(a)(1), 124 Stat. at 490, *modified by* § 10320 (to be codified at 42 U.S.C. § 1395kkk).

36. *Id.*

37. § 3401, 124 Stat. at 480–88, *modified by* § 10319 (to be codified as amended in scattered sections of 42 U.S.C.).

38. § 3403(a)(1), 124 Stat. at 491, *modified by* § 10320 (to be codified at 42 U.S.C. § 1395kkk).

39. *Id.*

allowed to reduce payments to Part C Medicare Advantage plans and Part D prescription drug plans.<sup>40</sup> It is not precluded from cutting payments for physicians, but it is likely that its powers will be limited under a permanent, sustainable growth rate fix.

In addition to these requirements, the Board's proposals should: extend the solvency of the Trust fund; better coordinate care and improve quality, access, prevention, wellness, and efficiency; target reductions at areas of excessive cost growth; consider the effects of reductions in provider payment on beneficiaries; consider the effects on providers and suppliers with negative cost margins, and consider the unique needs of dual eligibles.<sup>41</sup> Proposals also may not increase the total amount of Medicare program spending over the ten-year period starting with the implementation year—costs may not simply be shifted to future years.<sup>42</sup> In other words, the Board should aim for everything that is good, true, and right.

By September 1 in a year in which the Board receives notice from the Actuary, it must submit a draft proposal to the HHS Secretary and to MedPAC.<sup>43</sup> By January, the proposal must be submitted to the President and then the Congress.<sup>44</sup> If the Board fails to submit a proposal by deadline, HHS must itself submit a proposal meeting statutory requirements.<sup>45</sup> The President will then forward the proposal to Congress.<sup>46</sup> The statute contains lengthy provisions for congressional consideration of a proposal from the Board or Secretary including consideration under an expedited procedure with limited debate.<sup>47</sup> Congress cannot consider any amendment to the proposal that does not achieve the cost-reduction requirements that the Board is required to meet unless both vote to waive this provision, the Senate by a three-fifths vote.<sup>48</sup> Congress may also adopt a Joint Resolution to abolish the Board, but must do so by a three-fifths vote not later than August 15, 2017.<sup>49</sup> The statute recognizes, however, that Congress has

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40. *Id.*

41. *Id.*

42. *Id.*

43. § 3403(a)(1), 124 Stat. at 491–92, *modified by* § 10320 (to be codified at 42 U.S.C. § 1395kkk).

44. § 3403(a)(1), 124 Stat. at 500, *modified by* § 10320 (to be codified at 42 U.S.C. § 1395kkk).

45. § 3403(a)(1), 124 Stat. at 493, *modified by* § 10320 (to be codified at 42 U.S.C. § 1395kkk).

46. *Id.*

47. § 3403(a)(1), 124 Stat. at 495–99, *modified by* § 10320 (to be codified at 42 U.S.C. § 1395kkk).

48. § 3403(a)(1), 124 Stat. at 496, *modified by* § 10320 (to be codified at 42 U.S.C. § 1395kkk).

49. § 3403(a)(1), 124 Stat. at 500–02, *modified by* § 10320 (to be codified at 42 U.S.C. § 1395kkk).

the constitutional power to change its rules to remove the three-fifths majority requirement.<sup>50</sup> If Congress fails to adopt a substitute provision to reduce Medicare spending complying with the statute by August 15, HHS must implement the Board's proposal.<sup>51</sup>

No judicial review is permitted of an HHS decision to implement the Board's recommendations.<sup>52</sup> Although provisions in Medicare laws limiting judicial review of specific legislative-type decisions, such as the setting of a conversion factor for a prospective payment scheme, are not uncommon, an across-the-board ban on judicial review of the implementation of a program is. It is unclear how any of the limitations on the power of the IPAB would be enforced absent judicial review. If, for example, the IPAB were to recommend a cut in benefits contrary to the law, would the decision be unreviewable? The courts have historically been reluctant to overturn executive policy decisions in the Medicare program,<sup>53</sup> but the complete removal of their oversight of the implementation of the IPAB proposals is problematic. On the other hand, Congress does have the power to limit the jurisdiction of the federal courts, and limitations on judicial review have been routinely upheld.<sup>54</sup> The PPACA appropriates \$15 million for the IPAB for 2012.<sup>55</sup> For each subsequent year this amount is increased by the percentage increase in the CPI. This is a standing appropriation and should further free the IPAB from political pressure.

The Congressional Budget Office (CBO) discussed the IPAB at some length in its December 19, 2009 report on the PPACA Manager's Amendment. The CBO concluded that the IPAB would reduce Medicare spending by \$28 billion over the 2010 to 2019 period, with most of the savings coming at the end of the period, and with significant savings continuing beyond 2019.<sup>56</sup> On December 20,

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50. § 3403(a)(1), 124 Stat. at 499, *modified by* § 10320 (to be codified at 42 U.S.C. § 1395kkk).

51. § 3403(a)(1), 124 Stat. at 499-500, *modified by* § 10320 (to be codified at 42 U.S.C. § 1395kkk).

52. § 3403(a)(1), 124 Stat. at 500, *modified by* § 10320 (to be codified at 42 U.S.C. § 1395kkk).

53. Jost, *supra* note 2, at 54.

54. *See* United States v. Fausto, 484 U.S. 439 (1988); *CardioSom v. United States*, 91 Fed. Cl. 659 (2010). Courts are reluctant, however, to construe review preclusion statutes to deny the courts jurisdiction to decide constitutional questions, which would seem to be necessary to protect the ultimate responsibility of the judiciary to interpret the Constitution. *See also* Bowen v. Mich. Acad. of Family Physicians, 476 U.S. 667 (1986); *Bartlett v. Bowen*, 816 F.2d 695 (D.C. Cir. 1987). If, therefore, a challenge were brought to the constitutionality of the IPAB litigation, the courts may permit review.

55. § 3403(a)(1), 124 Stat. at 506, *modified by* § 10320 (to be codified at 42 U.S.C. § 1395kkk).

56. Letter from Douglas W. Elmendorf, Dir., Cong. Budget Office, to Senator Harry Reid,

the CBO issued a correction noting that it had misunderstood the formula that the IPAB would apply after 2019, and that the IPAB could in fact be expected to decrease Medicare spending by between one-quarter and one-half of one percent of GDP going forward, instead of the one-half percent it had projected earlier. Still, it noted, this would reduce the annual growth rate of Medicare to six percent per year, as compared to average increases of eight percent over the past two decades.<sup>57</sup> In his report, however, the CMS Actuary questioned whether this goal was achievable, noting that, hypothetically, the IPAB target growth rates would have been met in only four of the past twenty-five years, and would have approximated the target growth rate in the Sustainable Growth Rate (SGR) formula, which Congress has routinely overridden.<sup>58</sup> The Chief Actuary expressed concern that health care providers would have difficulty remaining profitable and might leave the Medicare program when faced with these constraints. The Actuary concluded, however, that after 2019, further proposals from the IPAB would not be required as the other savings provisions in the bill, if permitted to continue, would achieve the spending goals set by the legislation.

Many questions remain about how and whether the IPAB will work. Staffing the IPAB with fifteen leading experts, who are willing face a congressional confirmation as well as give up research, practice, and teaching for six years for a relatively modest salary, will be a challenge. The relationship between the IPAB and other boards and commissions, most notably the Center for Medicare and Medicaid Innovation and MedPAC along with the enhanced Medicaid and CHIP Payment and Access Commission (MACPAC), will need to be worked out. The legislation does not anticipate that MedPAC's role will be diminished, but instead strengthened. But necessarily MedPAC will lack the authority given to the IPAB to implement recommendations without direct congressional authorization. The Center for Medicare and Medicaid Innovation would seem to have even greater power than the IPAB for implementing innovative approaches to Medicare payment. Although multiple entities pursuing the same tasks could stumble over each other, there are also real opportunities for synergy. In particular, shared staffing between the IPAB and the innovation center and regular communications between the IPAB and the MedPAC and MACPAC

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Majority Leader, U.S. Senate (Dec. 19, 2009), *available at* [http://www.cbo.gov/ftpdocs/108xx/doc10868/12-19-Reid\\_Letter\\_Managers\\_Correction\\_Noted.pdf](http://www.cbo.gov/ftpdocs/108xx/doc10868/12-19-Reid_Letter_Managers_Correction_Noted.pdf).

57. Letter from Douglas W. Elmendorf, Dir., Cong. Budget Office, to Senator Harry Reid, Majority Leader, U.S. Senate (Dec. 20, 2009), *available at* [http://www.cbo.gov/ftpdocs/108xx/doc10870/12-20-Reid\\_Letter\\_Managers\\_Correction1.pdf](http://www.cbo.gov/ftpdocs/108xx/doc10870/12-20-Reid_Letter_Managers_Correction1.pdf).

58. Memorandum from Richard C. Foster, Chief Actuary, Ctrs. for Medicare & Medicaid Servs. (Apr. 22, 2010), *available at* [http://www.politico.com/static/PPM130\\_oact\\_memorandum\\_on\\_financial\\_impact\\_of\\_ppaca\\_as\\_enacted.html](http://www.politico.com/static/PPM130_oact_memorandum_on_financial_impact_of_ppaca_as_enacted.html).

could strengthen all three.

The legislative requirement that the IPAB submit annual proposals will encourage recommendations for short-term payment fixes rather than long-term changes that might in fact “bend the cost curve.” If the IPAB is to be truly effective, it must consider not just cuts in provider payments but also changes in how providers are paid. It might even find a way to alter consumer incentives, although the law would seem to block most paths to achieving this. Although the statute prohibits reduction in “payment rates” for hospitals before 2020, it does not prohibit the IPAB from recommending changes in payment methods, which might have longer-term effects on cost. The statute does not seem to prohibit, for example, the IPAB from making proposals for bundled payment or shared-savings arrangements, which could change the wasteful incentives built into fee-for-service payment. These kinds of incentive changes will be the focus of the innovation Center, and this is another argument for close coordination between the IPAB and the Center. But the necessity of making year-to-year cuts is likely to focus the IPAB’s attention on short-term payment cuts rather than on changes in program incentives. In particular, it is likely to focus on further cuts in Medicare Advantage plans, which are already slated for deep cuts under the PPACA, or on finding ways to save money in the Part D outpatient prescription drug program. The IPAB’s success will also depend on Congress’s reactions to its recommendations. A three-fifths vote will be needed to override payment cuts, but Congress could increase Medicare funding through independent legislation, effectively negating the IPAB cuts. Critics have cited the fact that Congress has regularly evaded the Medicare physician SGR formula as proof that Congress cannot cut Medicare costs.<sup>59</sup> On the other hand, Congress left in place the vast majority of the Medicare-savings provisions in the 1990, 1993, 1997, and 2005 Budget Reconciliation Acts.<sup>60</sup> And our current fiscal crisis may sharpen lawmakers’ resolve to cut spending. It is quite possible that a Congress focused on deficit reduction will see the IPAB’s proposed cuts as offering relief rather than a challenge.

The delegation of authority by Congress to the IPAB may be challenged as violating separation of power principles. The IPAB is effectively granted the power to amend the Medicare statute subject only to congressional veto. Although there are in theory constitutional limits to the power of Congress to delegate its authority, the Supreme Court has rarely found that Congress has

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59. See Ezra Klein: Economic and Domestic Policy, and Lots of It, [http://voices.washingtonpost.com/ezra-klein/2009/11/can\\_congress\\_control\\_costs.html](http://voices.washingtonpost.com/ezra-klein/2009/11/can_congress_control_costs.html) (Nov. 6, 2009, 17:17 EST) (discussing this argument).

60. James R. Horney & Paul N. Van de Water, Ctr. on Budget & Policy Priorities, House-Passed and Senate Health Bills Reduce Deficit, Slow Health Care Costs, and Include Realistic Medicare Savings 10-11 (2009), available at <http://www.cbpp.org/files/12-4-09health.pdf>.

crossed these limits.<sup>61</sup> As long as Congress lays down an “intelligible principle” to guide the discretion of an administrative agency to which authority has been delegated, the nondelegation doctrine has not been violated. A court would probably hold the guidelines contained in the IPAB provisions<sup>62</sup> to give sufficient direction to survive a delegation challenge, if such a challenge were to survive the bar to judicial review. Nevertheless, the conscious abdication of congressional responsibility to the IPAB is striking. Moreover, the bar to judicial review calls into question the extent to which the intelligible principles found in the statute actually limit the IPAB’s discretion.

Another major question is whether it is possible to cut Medicare’s provider payments as long as private payers’ rates remain unconstrained. If the gap between private and Medicare rates continues to grow, health care providers may well abandon Medicare. Although the IPAB can make recommendations to Congress regarding private payments, these are nonbinding. In the long run, Congress may not be able to cap Medicare expenditures without addressing private expenditures as well. There is no reason to believe that Congress is ready to adopt price controls in the private sector, and thus the gap between Medicare and private payment is likely to continue to be an issue. At some point, however, the gap may become unacceptable, which may require Congress to take the private sector recommendations of the IPAB more seriously. If this leads to all-payer rate setting, this may be the most revolutionary contribution of the IPAB concept. If the IPAB plays a role in all-payer rate setting, it will truly have become the Platonic Guardian of our health care system.

In creating the IPAB, Congress is attempting to lash itself to the mast to keep the siren song of special interest lobbyists from distracting it from its task of controlling Medicare cost growth. For good measure, it has bound the courts to the mast as well. This attempt raises a host of questions involving law and policy. Has Congress violated separation of power principles by abdicating legislative responsibility and barring judicial oversight? Can any group of experts repeatedly create effective short-term cost control solutions year after year that do not cut benefits or ration care, and that focus on only a subset of Medicare providers? Can Medicare costs be cut while private sector costs grow unabated? Or will the IPAB simply become the conscience of Congress, forcing Congress itself to confront again and again each year the hard work of cost control, perhaps in the private sector as well as in Medicare? Only time will tell.

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61. See *Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457, 472-76 (2001); *Mistretta v. United States*, 488 U.S. 361, 371-79 (1989).

62. See *supra* notes 35-42.





# Payment Reform After PPACA: Is Massachusetts Leading the Way Again?

By: Stephen M. Weiner\*

The Congressional debate leading to the enactment of federal health care reform legislation (the Patient Protection and Affordable Care Act or the “PPACA”<sup>1</sup>) paid close attention to the structure and results of access reform legislation enacted in Massachusetts in 2006 in Chapter 58 of the Acts of 2006 (“Chapter 58”).<sup>2</sup> Many of the key access reform elements of the PPACA mirrored the most notable components of Massachusetts’s reform.<sup>3</sup>

In crafting the PPACA, the Administration and Congress had to consider the effect on the federal deficit of the coverage expansion and other benefits provided for under the legislation. Congressional Budget Office (CBO) scoring of each proposal during the legislative process became a focus of anticipation, debate, and controversy. Other, more political concerns became predominant,

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1. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) [hereinafter PPACA]. The PPACA refers to the Senate version of the Act as adopted without change by the House. Amendments to the PPACA have been adopted by the subsequent Health Care and Education Affordability Reconciliation Act of 2010, a week after passage of the PPACA, and are included in the references throughout.

2. Act of Mar. 23, 2010, ch. 58, 2006 Mass. Acts 77 (codified as amended in scattered sections of MASS. GEN. LAWS).

3. These include the individual mandate, Act of Mar. 23, 2010, ch. 58, sec. 12, § 2(b), 2006 Mass. Acts 94-95 (codified as amended at MASS. GEN. LAWS ch. 111M, § 2(b) (2010)); the concept of minimum creditable coverage that should be obtained and maintained by all qualifying individuals, sec. 12 § 1, 2006 Mass. Acts at 93 (codified as amended at MASS. GEN. LAWS ch. 111M, § 1 (2010)); the formation of state-level health care exchanges (the Commonwealth Health Insurance Connector in Massachusetts) to facilitate access to “affordable” health benefit policies, § 101, 2006 Mass. Acts at 134-45 (codified as amended at MASS. GEN. LAWS ch. 176Q (2010)); insurance reform, §§ 48-100, 2006 Mass. Acts at 117-35 (codified as amended in scattered sections of MASS. GEN. LAWS) (in Massachusetts, reform of insurance coverage had already proceeded substantially so was of less overall importance in the scheme of the Massachusetts reform); and government subsidies for low-income residents through the Commonwealth Care program to facilitate their obtaining affordable coverage, § 45, 2006 Mass. Acts at 113 (codified as amended at MASS. GEN. LAWS ch. 118H (2008)).

especially relating to increased federal spending on health care expected to accompany access expansion and subsidies so soon after the substantial deficit spending authorized in the American Restoration and Reinvestment Act of 2009.<sup>4</sup> To obtain an acceptable CBO score, the PPACA contained certain quantifiable effects on the federal budget. These included tax increases,<sup>5</sup> reductions in provider payments (especially Medicare inpatient hospital payments),<sup>6</sup> and a significant decrease in payments for disproportionate share hospitals.<sup>7</sup> These reductions assumed, presumably, that the affected hospitals would benefit from the anticipated increase in the number of previously uninsured patients who would access their services through non-Medicare benefit coverage. In addition the PPACA provided for other changes to Medicare payment policies that were intended to reduce costs while also improving quality, such as those relating to hospital-acquired conditions<sup>8</sup> and readmissions.<sup>9</sup>

The PPACA addressed efforts to achieve broader delivery and payment reform only in relatively limited ways,<sup>10</sup> in part due to the political compromises

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4. American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115.

5. *See, e.g.*, PPACA § 9001, 124 Stat. at 847-53, *amended by* Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 1401, 124 Stat. 1029, 1059-60 (to be codified at 26 U.S.C. § 4980I) [hereinafter HCERA] (excise tax on "Cadillac" plans); PPACA § 9015(a)(1), 124 Stat. at 870-71, *modified by* § 10906, *amended by* HCERA § 1402(b)(2), 124 Stat. at 1063 (to be codified at 26 U.S.C. § 3101) (additional 0.9% payroll tax); HCERA § 1402(a), 124 Stat. at 1061 (to be codified in scattered sections of 26 U.S.C.) (3.8% investment income tax); PPACA § 9008, 124 Stat. 859-62, *amended by* HCERA § 1404, 124 Stat. at 1064 (to be codified at 26 U.S.C. § 4001) (pharmaceutical industry fees); HCERA § 1405, 124 Stat. at 1064-65 (to be codified in scattered sections of 26 U.S.C.) (excise tax on medical devices); PPACA § 10907, 124 Stat. at 1020 (to be codified at 26 U.S.C. § 5000B and note) (indoor tanning tax, nullifying § 9017, a tax on cosmetic medical procedures); PPACA § 6301(e)(2)(A), 124 Stat. at 743-46 (to be codified at 26 U.S.C. §§ 4375-77) (\$2-per-enrollee insurance industry tax); PPACA § 9010, 124 Stat. at 865-68, *modified by* § 10905, *amended by* HCERA § 1406(a)(4), 124 Stat. at 1066 (to be codified at 26 U.S.C. § 4001 note prec.) (insurance industry fees); PPACA §§ 2501-2502, 124 Stat. at 306-10 (to be codified in scattered sections of 42 U.S.C.) (increasing Medicaid reimbursement for prescription drugs).

6. PPACA § 3401, 124 Stat. at 480-88, *modified by* §§ 10319, 10322, *amended by* HCERA § 1105, 124 Stat. 1047-49 (to be codified at 42 U.S.C. § 1395ww(b)(3)(8)).

7. PPACA § 3133, 124 Stat. at 432, *modified by* § 10316, *amended by* HCERA § 1104, 124 Stat. at 1047 (to be codified at 42 U.S.C. § 1395ww(r)).

8. PPACA § 3008(a), 124 Stat. at 376-77 (to be codified at 42 U.S.C. § 1395ww).

9. PPACA § 3025(a), 124 Stat. at 408-13 (to be codified at 42 U.S.C. § 1395ww).

10. These provisions include a national pilot program on bundled payments as an alternative to fee-for-service payment, PPACA § 3022, 124 Stat. at 395 (to be codified at 42 U.S.C. § 1395jjj); a "gainsharing" program encouraging the formation of accountable care organizations (ACOs), bringing together providers to accept payment based on various incentive models in order more effectively to coordinate the care of Medicare beneficiaries, *id.*; a "medical home" primary care and care coordination demonstration that would link primary care physicians and other primary care

needed to achieve enactment of such a broad and complex piece of legislation. But the PPACA also recognized that there are limits to seeking major changes in the overall structure of, and payment for, health services through using only Medicare.

By contrast, the political coalition that came together in 2005 and 2006 in Massachusetts to secure enactment of Chapter 58 made what seems to have been an intentional decision primarily to address access and to forego dealing with the necessarily concomitant issue of reducing cost increases likely generated by expanded access.<sup>11</sup> Supporting this political consensus was the already high level of per capita state spending on health care in Massachusetts prior to enactment of Chapter 58, and the then federal Administration's support for the reform's philosophical underpinning: to move people from reliance on the limited benefits available through the Commonwealth's uncompensated care pool to broader reliance on insurance coverage.<sup>12</sup>

The challenge in Massachusetts was whether access reform would in fact be followed by broader efforts to contain health care costs, for both the Commonwealth budget and the private system, through delivery system and payment reform. Failure to undertake such efforts on a broad basis would increase costs because of enhanced demand for services but without simultaneous efforts to restrain those increases.

Federal health care reform, in its preliminary phases, focuses principally on coverage reform and access, not dissimilar to the initial focus in Massachusetts

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practitioners to promote coordinated care with payment based on an alternative to fee-for-service, PPACA § 3024, 124 Stat. at 404-05 (to be codified at 42 U.S.C. § 1395cc-5); creation of a Center for Medicare and Medicaid Innovation to develop innovative approaches to payment and delivery in the federal programs, PPACA § 3021(a), 124 Stat. at 389-92 (to be codified at 42 U.S.C. § 1315a); and authorization for the formation of a Patient-Centered Outcomes Research Institute as a private, non-profit entity, to undertake comparative clinical outcomes research associated with effective and efficient treatment options, PPACA § 6301(a), 124 Stat. at 728-29 (codified at 42 U.S.C. § 1320e).

11. Chapter 58 did, though, contain provisions in addition to those relating to access that foreshadowed the efforts at more broad-based system reform discussed later in this Essay, including provisions relating to increased spending for prevention and screening programs, an initial investment in health information technology to help fund a pilot program on computerized physician order entry, the launching of a State-wide infection prevention program, the creation of the Massachusetts Quality and Cost Council and the Health Disparities Council and inclusion of wellness programs under insurance policies. The author wishes to thank Senator Richard T. Moore, Senate Chairman of the Joint Committee on Health Care Financing of the Massachusetts Legislature, for his insights on the scope of Chapter 58.

12. The approval of the Centers for Medicare & Medicaid Services, within the federal Department of Health and Human Services, was needed for a Medicaid waiver that would allow federal financial participation in the proposed subsidized program. The approval of this waiver was crucial to the economics of the overall program.

under Chapter 58. The debate over health care reform at the federal level included expressions of the need for broader reform of the delivery system and for changes in payment mechanisms to encourage a more organized and efficient system for delivering care. There were similar expressions of intent enunciated in Massachusetts as the coalition that successfully secured the enactment of Chapter 58 indicated a desire to move on to seek system delivery and payment reform. Just as Massachusetts was a leader in securing access changes, can the history of post-Chapter 58 initiatives in Massachusetts serve as a model for likely changes at the national level that could be leveraged from enactment of the PPACA? This Essay addresses the efforts made in Massachusetts to seek further reforms, and then considers whether the steps taken there may serve as a further model for national efforts, in other states or through the federal government.

### I. CHAPTER 305: A BLUEPRINT FOR REFORMS

What may be considered the second phase of Massachusetts's efforts to establish health care reform occurred two years following the enactment of Chapter 58, with passage of Chapter 305 of the Acts of 2008.<sup>13</sup> Chapter 305 is a blueprint for a broad array of reforms seeking improvements in the cost and quality of health care services.<sup>14</sup>

Of greatest significance for this Essay, Chapter 305 mandated studies and public hearings to promote a greater understanding of the factors that increase provider costs and insurance premiums, with the expectation that such an understanding could lead to recommendations to facilitate radical changes in the structure of, and payment for, health care services. This Essay examines three of these mandates and the response they have generated, to gain some insight into the potential outcome of similar efforts that might be undertaken either federally or in other States to address structural reforms to contain the cost of health care.

#### *A. Payment Reform Commission*

Chapter 305 mandated the formation of a Special Commission on the Health Care Payment System (the "Special Commission"), "to investigate reforming and

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13. Act of Aug. 10, 2008, ch. 305, 2008 Mass. Acts 697.

14. Chapter 305 addressed a broad set of topics in health care, including, as examples only: enhancement of quality and patient safety (§§ 9, 10, 17, 2008 Mass. Acts at 707, 708, 713); improvement in resources to respond to the increase in primary care demand following on implementation of Chapter 58 (§§ 8, 29, 31-34, 40, 2008 Mass. Acts at 705, 719, 719-721, 722); state-wide dissemination of interoperable electronic health records and requirements for proficiency in health information technology (§§ 4, 15, 36-37, 51, 2008 Mass. Acts at 701, 713, 713, 725); reducing the influence of pharmaceutical and device manufacturers on prescriber behavior (§§ 14, 15, 2008 Mass. Acts at 710-713); and improvement in the quality of life associated with end-of-life care (§§ 41-43, 2008 Mass. Acts at 723).

restructuring the [delivery] system to provide incentives for efficient and effective patient-centered care and to reduce variations in the quality and cost of care.”<sup>15</sup> The Commission was charged with examining alternatives to fee-for-service payment methodologies<sup>16</sup> and recommending a common, all-payer payment methodology intended to promote a number of public values (coordination of care, rewarding primary care, reducing waste, decreasing unnecessary hospitalizations, etc.).<sup>17</sup>

The Special Commission’s final report, released in July 2009,<sup>18</sup> recommended a five-year transition to a global payment system based on risk-bearing accountable care organizations.<sup>19</sup> The recommendations also included suggestions regarding an oversight agency<sup>20</sup> to oversee implementation of the new payment system during the five-year period, to monitor increases in the cost of care, and perhaps to intervene in the event that cost increases exceeded certain pre-determined benchmarks.<sup>21</sup>

The Special Commission’s recommendations require legislation in order to implement and have generated extensive discussion within Massachusetts regarding payment reform.<sup>22</sup> The recommendations anticipated legislative

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15. § 44(a), 2008 Mass. Acts at 723.

16. § 44(c)(i), 2008 Mass. Acts at 724.

17. §§ 44(c)(ii), 44(c)(iii), 2008 Mass. Acts at 724.

18. See MASS. SPECIAL COMM’N ON THE HEALTH CARE PAYMENT SYS., RECOMMENDATIONS OF THE SPECIAL COMMISSION ON THE HEALTH CARE PAYMENT SYSTEM (2009), *available at* [http://www.mass.gov/Eeohhs2/docs/dhcfp/pc/Final\\_Report/Final\\_Report.pdf](http://www.mass.gov/Eeohhs2/docs/dhcfp/pc/Final_Report/Final_Report.pdf).

19. *Id.* at 10, 13.

20. *Id.* at 17-18.

21. *Id.* at 63.

22. For example, the Massachusetts Hospital Association has issued a series of five reports exploring elements of the recommendations and their implications in depth. See MASS. HOSP. ASS’N, MASSACHUSETTS PAYMENT REFORM: AN OVERVIEW OF CRITICAL FOUNDATIONAL ISSUES (2009), *available at* [http://www.mhalink.org/AM/Template.cfm?Section=Cost\\_Containment\\_Payment\\_Reform&Template=/CM/ContentDisplay.cfm&ContentID=7664](http://www.mhalink.org/AM/Template.cfm?Section=Cost_Containment_Payment_Reform&Template=/CM/ContentDisplay.cfm&ContentID=7664); MASS. HOSP. ASS’N, MASSACHUSETTS PAYMENT REFORM: SUPPORT FOR SOCIETAL NEEDS: A CRITICAL ISSUE TO ADDRESS IN PAYMENT REFORM (2010), *available at* [http://www.mhalink.org/AM/Template.cfm?Section=Cost\\_Containment\\_Payment\\_Reform&Template=/CM/ContentDisplay.cfm&ContentID=9961](http://www.mhalink.org/AM/Template.cfm?Section=Cost_Containment_Payment_Reform&Template=/CM/ContentDisplay.cfm&ContentID=9961); MASS. HOSP. ASS’N, MASSACHUSETTS PAYMENT REFORM: BENEFIT DESIGN AND BEYOND: CONSUMER CHOICE AND THE ROLE OF EMPLOYERS IN PAYMENT REFORM (2010), *available at* [http://www.mhalink.org/AM/Template.cfm?Section=Cost\\_Containment\\_Payment\\_Reform&Template=/CM/ContentDisplay.cfm&ContentID=10372](http://www.mhalink.org/AM/Template.cfm?Section=Cost_Containment_Payment_Reform&Template=/CM/ContentDisplay.cfm&ContentID=10372); MASS. HOSP. ASS’N, MASSACHUSETTS PAYMENT REFORM: OVERSEEING THE TRANSITION (2010), *available at* [http://www.mhalink.org/AM/Template.cfm?Section=MHA\\_News1&template=/CM/ContentDisplay.cfm&ContentID=12553](http://www.mhalink.org/AM/Template.cfm?Section=MHA_News1&template=/CM/ContentDisplay.cfm&ContentID=12553); HAROLD D. MILLER, MASS. HOSP. ASS’N, MASSACHUSETTS PAYMENT REFORM: CREATING ACCOUNTABLE CARE ORGANIZATIONS IN MASSACHUSETTS (2009), *available at*

proposals aimed at long-term system reform. They did not address interim legislative steps, although, as is discussed later in this Essay,<sup>23</sup> this is the approach the Massachusetts legislature has chosen to use while the discussion on broader changes presumably continues.

### *B. Study of Insurer and Hospital Reserves*

Public policy concerns about provider costs include consideration of the levels of reserves that providers maintain. Theoretically, the accumulation of “excessive” reserves by hospitals, and specifically non-profit hospitals with no obligation to make equity holder distributions, could generate investment in plant and equipment that, regardless of merit, could put pressure on the underlying medical loss ratio of insurance premiums. Chapter 305 sought to explore this issue by authorizing the Massachusetts Division of Health Care Finance and Policy (the “Division”), working with the Division of Insurance (“DOI”), to “examine options and alternatives available to the Commonwealth to provide regulation, oversight and disposition of the reserves, endowments, and surpluses of health insurers and hospitals.”<sup>24</sup> Health insurer reserves are generally subject to regulation to promote insurer solvency. There is, however, much less analytical material supporting an understanding about the appropriate levels of reserves for hospitals or health care systems and how they might be regulated.

With regard to hospitals, Chapter 305 mandated the Division to examine existing regulatory schemes, recent hospital fiscal practices, and financial reporting; and to review the methods by which hospitals fund community benefit programs, including how such funding may be regulated elsewhere.<sup>25</sup>

In May 2010, the Division issued its “Study of the Reserves, Endowments, and Surpluses of Hospitals in Massachusetts.”<sup>26</sup> The study describes a number of financial and accounting rules relating to hospital and health system reporting, and identifies the lack of clear standards for measuring the adequacy of hospital reserves. It did, however, suggest indirectly that there might be a standard to measure “excessive” reserves through a series of tests that determine whether a hospital has “considerable accumulated financial resources.”<sup>27</sup> To date there has

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[http://www.mhalink.org/AM/Template.cfm?Section=Cost\\_Containment\\_Payment\\_Reform&Template=/CM/ContentDisplay.cfm&ContentID=9056](http://www.mhalink.org/AM/Template.cfm?Section=Cost_Containment_Payment_Reform&Template=/CM/ContentDisplay.cfm&ContentID=9056).

23. See *infra* text accompanying notes 62-75.

24. Act of Aug. 10, 2008, ch. 305, § 35, 2008 Mass. Acts 697.

25. § 35(b), 2008 Mass. Acts at 721.

26. MASS. DIV. OF HEALTH CARE FINANCE & POLICY, STUDY OF THE RESERVES, ENDOWMENTS, AND SURPLUSES OF HOSPITALS IN MASSACHUSETTS (2010), available at [http://www.mass.gov/EeoHHS2/docs/dhcfp/r/pubs/10/hospital\\_reserves\\_report.pdf](http://www.mass.gov/EeoHHS2/docs/dhcfp/r/pubs/10/hospital_reserves_report.pdf).

27. *Id.* at 3-4. The Massachusetts Hospital Association has criticized the report for leading to possible “erroneous conclusions” and for leading to the “mistaken assumption that Massachusetts

been no regulatory or legislative action as a result of the Division's report. But it did focus on the differences in reserve levels among hospitals in the Commonwealth, on the uses of unrestricted reserves, and on the potential for drawing a correlation between levels of unrestricted cash and prices for health care services.<sup>28</sup>

*C. Hearings on the Drivers of Provider Costs and Payer Premiums*

Chapter 305 expanded the existing authority of the Division to gather cost information from hospitals<sup>29</sup> in order to develop and implement regulations for uniform reporting of information from public and private health care payers. The data collected is intended to allow the Division to analyze changes over time—and compare public and private payers—with regard to insurance premium levels, benefit and cost-sharing designs, and plan cost and utilization.<sup>30</sup> Among the types of plan information the Division is authorized to gather is medical loss ratio, level of reserves and surpluses, and provider payment methods and levels.<sup>31</sup>

Chapter 305 requires the Division to hold annual public hearings based on the provider and payer information it gathers.<sup>32</sup> The hearings are to focus on provider and payer cost trends, “with particular attention to factors that contribute to cost growth” and “to the relationship between provider costs and payer premium rates.”<sup>33</sup> The statute also authorizes the attorney general to intervene in such proceedings, and grants her independent authority to “review and analyze any information” the Division derives from providers and payers.<sup>34</sup> Based on the information provided at the hearings, and other information the Division considers necessary, as defined in regulations, the Division is to prepare “an annual report concerning spending trends and underlying factors, along with any recommendations for strategies to increase the efficiency of the health care system.”<sup>35</sup>

In March 2010, the Division held four days of hearings in accordance with

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hospitals are awash in cash, when, in fact, the opposite is true.” See Press Release, Mass. Hosp. Ass'n, Study Reveals Hospitals Hold Inadequate Surpluses and Reserves; State's Narrow Focus Paints Inaccurate Picture of Hospital Finances (June 25, 2010), [http://www.mhalink.org/AM/Template.cfm?Section=MHA\\_News1&template=/CM/ContentDisplay.cfm&ContentID=11362](http://www.mhalink.org/AM/Template.cfm?Section=MHA_News1&template=/CM/ContentDisplay.cfm&ContentID=11362).

28. See MASS. DIV. OF HEALTH CARE FINANCE & POLICY, *supra* note 26.

29. MASS. GEN. LAWS ch. 118G, § 6 (2010).

30. *Id.*

31. *Id.*

32. *Id.* § 6 ½ (a).

33. *Id.*

34. *Id.* § 6 ½ (b).

35. *Id.* § 6 ½ (g).

the statute.<sup>36</sup> In conjunction with these hearings, the attorney general issued a report regarding health care cost drivers.<sup>37</sup> Her report emphasized the predominant role of market share over such other factors as case mix and quality, giving some providers leverage to secure preferential rates.<sup>38</sup> The report's stress on market share as the key factor in defining price differentials among providers generated significant controversy.<sup>39</sup> The responses to the report highlight the complexities of seeking to establish one predominant factor to explain variations in payer rates, but the report contributed valuable data to the health care cost discussion by displaying the relative rates paid to specific hospital and physician groups by the major private payers.

## II. EFFORTS AT SHORT-TERM FIXES: THE SMALL GROUP/NON-GROUP MARKET

While discussions commenced about seeking long-term systemic changes based on the studies and hearings that Chapter 305 initiated, more immediate political imperatives loomed in the Commonwealth. The financial burden posed by health insurance costs on small business has been a persistent bone of contention. While there are multiple causes for what seem like disproportionate increases in premiums for this class of insurance purchasers, with provider rates being only one factor, health care cost increases as reflected in insurance premiums is an issue of special sensitivity to small business. Recognizing this concern and also facing a re-election campaign in which his principal opponent was likely to be the former chief executive of one of the major health maintenance organizations (HMOs) in Massachusetts, Governor Deval Patrick decided to emphasize urgency in addressing health care costs, at least as reflected

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36. The preliminary report, the schedule of witnesses, and its final report based on the hearings may be accessed on its web site at <http://www.mass.gov/dhcfp/costtrends>.

37. OFFICE OF ATTORNEY GEN. MARTHA COAKLEY, EXAMINATION OF HEALTH CARE COST TRENDS AND COST DRIVERS (2010), *available at* [http://www.mass.gov/Cago/docs/healthcare/final\\_report\\_w\\_cover\\_appendices\\_glossary.pdf](http://www.mass.gov/Cago/docs/healthcare/final_report_w_cover_appendices_glossary.pdf).

38. *Id.* at 3-4.

39. Letter from Melinda Reid Hatton, Senior Vice President & Gen. Counsel, Am. Hosp. Ass'n, to Martha Coakley, Attorney Gen., Mass. (Apr. 29, 2010), <http://www.aha.org/aha/letter/2010/100429-cl-costs.pdf>. Partners HealthCare System, Inc., the largest health care system in the Commonwealth, commissioned a consultant study to critique the methodology used by the attorney general's office precisely for its failure to draw statistically more appropriate correlations with other factors that would explain price differences. *See* PAUL DREYER, ANALYSIS OF THE ATTORNEY GENERAL'S REPORT TITLED "EXAMINATION OF HEALTH CARE COST TRENDS AND COST DRIVERS" (2010), *available at* <http://multimedia2.heraldinteractive.com/misc/DreyerFinal.pdf>. In turn, the attorney general's office defended itself against this critique. Letter from Thomas O'Brien, Assistant Attorney Gen. & Chief, Health Care Div., Mass. Attorney Gen., to Brent L. Henry, Vice President & Gen. Counsel, Partners HealthCare Sys., Inc. (June 25, 2010), *available at* <http://www.boston.com/news/health/blog/jun29-partners/Partners%20Letters.6.25.pdf>.



in health insurance premiums for small business, and to propose what were explicitly intended to be short-term interventions while debate continued about longer-term systemic change.

### *A. Emergency Regulations*

On February 10, 2010, the Governor announced that DOI would adopt a set of emergency regulations under existing statutory authority, to address small business concerns about the cost of health care coverage. In announcing the emergency regulations, Governor Patrick explicitly related increases in small group premiums to underlying provider costs.<sup>40</sup> The connection seemed to reflect an assumption that the private sector would use its contracting authority vis-à-vis providers to undertake cost containment measures that the government could not directly institute, absent new legislative authority. That is, the Administration seemed to promote a substitution of private regulation for public regulation, notwithstanding the former's lack of due process constraints.<sup>41</sup>

Under existing authority at the time, HMOs were required to “submit proposed rates and benefits, or changes thereof, *on or before their effective dates*” and “are subject to the Commissioner’s disapproval if the benefits and rates do not meet” statutory requirements.<sup>42</sup> In practice, insurers filed proposed rates the day that they were to become effective. Following on Governor Patrick’s direction, DOI promulgated emergency regulations relating to HMO rate filings specifically for changes to premiums and rating factors for small groups, to be effective on April 1, 2010.

On April 1, 2010, DOI rejected 235 of the 274 rate filings on the grounds that they failed to meet the statutory requirement that rates not be excessive or unreasonable in relation to the benefits provided, and thus effectively froze the rates at their April 2009 level.<sup>43</sup> The Massachusetts Association of Health Plans and several HMOs brought suit and sought emergency injunctive relief to enjoin

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40. Governor Deval L. Patrick, Remarks to the Greater Boston Chamber of Commerce Regarding Small Business Jobs Bill (Feb. 10, 2010) (transcript available at [http://www.mass.gov/?pageID=gov3terminal&L=3&L0=Home&L1=Media+Center&L2=Speeches&sid=Agov3&b=terminalcontent&f=text\\_2010-02-10\\_jobs&csid=Agov3](http://www.mass.gov/?pageID=gov3terminal&L=3&L0=Home&L1=Media+Center&L2=Speeches&sid=Agov3&b=terminalcontent&f=text_2010-02-10_jobs&csid=Agov3)) (proposing “an oversight plan to screen provider rate increases”).

41. For a discussion of this point, see Stephen M. Weiner, *On Public Values and Private Regulation: Reflections on Cost Containment Strategies*, 59 MILBANK MEMORIAL FUND Q. 269 (1981).

42. 211 MASS. CODE REGS. 43.08 (2005) (emphasis added).

43. Press Release, Office of Consumer Affairs & Bus. Regulation, Patrick-Murray Administration’s Division of Insurance Announces Decision on Rate Increase Submissions from Health Insurers (Apr. 1, 2010), [http://www.mass.gov/?pageID=ocapressrelease&L=1&L0=Home&sid=Eoca&b=pressrelease&f=20100401\\_hirates&csid=Eoca](http://www.mass.gov/?pageID=ocapressrelease&L=1&L0=Home&sid=Eoca&b=pressrelease&f=20100401_hirates&csid=Eoca); MASS. GEN. LAWS ch. 176G § 16.

the Commissioner from prohibiting the plans from implementing their proposed rate increases.<sup>44</sup> The suit contended that the Commissioner had impermissibly disapproved the proposed rate increases based on a predetermined, arbitrary and inadequate rate increase limit that was not actuarially sound. It also challenged the requirement that rates remain at the April 2009 level.<sup>45</sup> The Superior Court denied the motion for injunctive relief on the grounds that the plaintiffs had not exhausted their administrative remedies and had not demonstrated entitlement to injunctive relief.<sup>46</sup> It later ordered two of the plans to continue to use the April 2009 base rates (as modified by approved adjustments) during the pendency of administrative hearings and appeals.<sup>47</sup>

One of the affected plans requested an administrative hearing. In order to prevail, it was obliged to demonstrate that each of the four independent bases for DOI's rate disapprovals was incorrect.<sup>48</sup> The administrative hearing was conducted by three DOI staff hearings officers, who, much to the surprise of most observers, unanimously overturned the Commissioner's decision and found in favor of the plan on all four grounds.<sup>49</sup>

The grounds and the rationale for the hearings officers' rejection of them are instructive with respect both to the current state of confusion regarding what drives health care costs and attendant premium increases (making the development of coherent public policy difficult) and to any expectation that insurers would be able to exercise regulatory authority over provider rates (notwithstanding contractual obligations and market realities). The four bases for the initial decision and the rationale for the decision being overturned are as follows:

- (1) The Commissioner found that the plan failed to demonstrate that it paid providers differing rates of reimbursement based solely on quality, patient mix, geographical location of care, and intensity of services, as

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44. *Massachusetts Ass'n of Health Plans v. Murphy*, No. 10-1377-BL52 (Mass. Sup. Ct. Apr. 12, 2010) (order denying preliminary injunction). The other named plaintiffs were Blue Cross and Blue Shield of Massachusetts, Inc., Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., Fallon Community Health Plan, Inc., Harvard Pilgrim Health Care, Inc., Health New England, Inc., Neighborhood Health Plan, Inc., and Tufts Associated Health Maintenance Organization, Inc.

45. *Id.*

46. *Id.*

47. *Massachusetts Ass'n of Health Plans v. Murphy*, No. 10-1377-BLS2, (Mass. Sup. Ct. Apr. 23, 2010) (order granting preliminary injunction). The two plans enjoined from raising rates were Harvard Pilgrim Health Care, Inc. and Fallon Community Health Plan, Inc.

48. *Harvard Pilgrim Health Care, Inc. v. Div. of Ins.*, No. R2010-02 (Mass. Div. of Insurance June 24, 2010), [http://www.mass.gov/Eoca/docs/doi/Legal\\_Hearings/R2010-02.pdf](http://www.mass.gov/Eoca/docs/doi/Legal_Hearings/R2010-02.pdf).

49. *Id.*

specified in the emergency regulations.<sup>50</sup> Reflecting the principal thrust of the attorney general's report cited above,<sup>51</sup> the hearings officers found that the variations were "due primarily to the market power of certain providers, which derives from size, brand reputation or geographic location," and determined that the plan had valid reasons to justify differential reimbursement beyond the four factors specified in the emergency regulation.<sup>52</sup>

(2) The Commissioner found that the plan's rates were unreasonable and excessive because it had failed to demonstrate that it had taken adequate steps to renegotiate rates with providers and had not demonstrated that it had decreased its provider costs by renegotiating those rates.<sup>53</sup> The hearings officers ruled that the plan had established that there were legal, practical and market place barriers to reopening existing provider contracts, but that it had nonetheless made efforts to renegotiate rates within the short time allowed by DOI.<sup>54</sup>

(3) The Commissioner had limited the plan's overall assumed trend rate to a range of 100% to 150% of the New England Regional Medical CPI ("CPI-M"). The hearings officers ruled that using the increase of the CPI-M for New England as the sole criterion for deciding whether to disapprove the plan's rates was incorrect.<sup>55</sup>

(4) The Commissioner found that the plan had failed to demonstrate that it was adequately controlling utilization.<sup>56</sup> The hearings officers found that the plan had "demonstrated its cost containment programs," documented its realized cost savings, and proved that its cost

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50. 211 MASS. CODE REGS. 43.08(10) (2010). The emergency regulations provided "If the HMO intends to pay similarly situated providers different rates of reimbursement, [it must include with its filing] a detailed description of the bases for the different rates including, but not limited to: (a) Quality of care delivered; (b) Mix of patients; (c) Geographic location at which care is provided; and (d) Intensity of services provided."

51. See OFFICE OF ATTORNEY GEN. MARTHA COAKLEY, *supra* note 37.

52. The DOI noted, "[t]he Emergency Regulation does not characterize the four articulated Regulatory bases as the *exclusive* bases for justifying differential reimbursement." *Harvard Pilgrim Health Care, Inc. v. Div. of Ins.*, *supra* note 48, at 5 (emphasis added).

53. *Id.* at 6.

54. *Id.* at 10.

55. *Id.* at 10-15. The hearings officers cited several reasons for this conclusion: (1) it was purely backward-looking and did not measure costs comparable to the plan's costs, (2) focusing on the *rate of increase*, to the exclusion of the actual premium number, would permit anomalous results, and (3) using a metric external to the plan as the sole factor to determine whether the plan's proposed rates were excessive violated actuarial and regulatory principles and contravened the statutory requirement that rates be adequate. *Id.*

56. *Id.* at 15-16.

containment programs were adequate.<sup>57</sup>

Following the hearings officers' rulings, based on further submissions, DOI reviewed the rates for 200 plans for which HMOs had submitted updated rate information for the July-September, 2010, period.<sup>58</sup> Taking a somewhat less aggressive approach, it approved single-digit rate increases for 63 plans, stating that the four insurers at issue had shown more restraint than other companies.<sup>59</sup> It also required three insurers to supply more data to justify proposed double-digit rate hikes for 137 plans before it would make a decision. It did not reject outright any rate proposals.<sup>60</sup> Further, it reached a settlement with the plan that had been the subject of the hearings officers' decision, with an agreement on rate increases for April 1, 2010, remarkably close to the level sought by the Commissioner initially.<sup>61</sup>

Traditional insurance regulation seeks to assure the fiscal solvency of the insurance industry in order to protect consumers. In the belief that underlying provider costs constituted the principal cause for increases in insurance premiums, the Patrick Administration sought to use existing standards focused on protecting solvency to address that concern. The brief history of the emergency regulations, the administrative appeal and the resolution of rate increase requests served to underscore the limitations of using existing statutory authority to restrain health care costs per se. It is no surprise, then, that, parallel to the regulatory efforts, the legislature itself moved to regulate health insurance premiums in its on-going effort to seek to restrain health care costs.

### *B. Legislative Developments: The Next Phase*

While the reports, hearings and analyses mandated by Chapter 305 pointed toward efforts for longer term systemic reform of the delivery and payment systems in Massachusetts, the political imperatives that resulted in the emergency regulations described above also led to further legislative action, intended to be of short-term effect while work continued on longer-term reforms. The next

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57. *Id.* at 17.

58. Robert Weisman, *State Retains 137 Rate Caps on Insurers*, BOSTON GLOBE, July 2, 2010, at A1. Some Massachusetts health insurers adjust their rate trends at regular increments during the year for actuarial accuracy, e.g., for the three-month period July-September 2010 in a contract covering the April 1, 2010 to March 31, 2011 year. For this purpose the HMOs submit updated information to DOI.

59. *Id.*

60. *Id.*

61. Robert Weisman, *Insurer, State in Surprise Accord: Harvard Pilgrim Will Limit Rates and Drop Suit*, BOSTON GLOBE, July 3, 2010, at A1. See also Press Release, Harvard Pilgrim Health Care, Inc., Harvard Pilgrim Health Care Settles Rate Dispute With Massachusetts Division Of Insurance (July 2, 2010), <https://www.harvardpilgrim.org/pls/portal/docs/PAGE/MEMBERS/ABOUT/NEWS/SETTLEMENTPR.PDF>.

legislative phase of Massachusetts reform was enacted in August 2010 as Chapter 288 of the Acts of 2010 (Chapter 288).<sup>62</sup>

While not taking concrete steps to implement the Special Commission's recommendations, Chapter 288 establishes a new special commission on provider price reform, with a general charge to "investigate the rising cost of health care insurance and the impact of reimbursement rates paid by health insurers to providers."<sup>63</sup> The commission is specifically directed to examine "the variation in costs of providers for services of comparable acuity, quality and complexity . . . the correlation between price paid to providers and (1) the quality of care, (2) the acuity of the patient population, (3) the provider's payor mix, (4) the provision of unique services, including specialty teaching services and community services, and (5) operational costs, including labor costs; . . . the correlation between price paid to providers and, in the case of hospitals, status as a disproportionate share hospital, a specialty hospital, a pediatric specialty hospital or as an academic teaching hospital; and . . . policies to promote the use of providers with low health status adjusted total medical expenses."<sup>64</sup> In developing its recommendations the commission is to consider the Special Commission's recommendations, and the new commission's recommendations must be consistent with those recommendations.

Also related to payment reform, Chapter 288 directs the Division to initiate activities to foster use by payers and providers of bundled payment arrangements in lieu of fee-for-service.<sup>65</sup> The legislation sets for the Division "as an objective, but not as a requirement, implementation of pilot bundled payment programs relating to payment for at least 2 acute conditions or procedures commencing by no later than January 1, 2011" and "for at least 2 chronic conditions commencing by no later than July 1, 2011."<sup>66</sup>

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62. Act of Aug. 10, 2010, ch. 288 (Mass.). Chapter 288 was enacted toward the end of the 2010 legislative session, a session that formally concluded at the end of July. In the debates leading up to it, there was a serious question as to whether any legislative action would be taken in this arena that year. See Liz Kowalczyk, *Health Payment Overhaul Shelved*, BOSTON GLOBE, July 4, 2010, at A1. On July 4, the *Boston Globe* reported that legislative cost containment efforts in Massachusetts were on hold for the balance of the calendar year, "largely because of disagreements among key officials, legislators, and providers over how best to control health care spending." *Id.* Senate President Therese Murray, an advocate of payment reform, said that she would not file legislation to change the system that year, as originally planned, "because of the logistical and political complexity of changing a system that has been in place for decades." At the time she expressed the hope that stakeholders would be able to reach a consensus on legislation to be filed in 2011. *Id.*

63. Act of Aug. 10, 2010, § 67(a).

64. *Id.* § 67(c).

65. *Id.* § 64.

66. *Id.*

Chapter 288's most significant provisions expand existing insurance regulatory authority, but not explicitly with the intent of reining in underlying provider costs. The legislation empowers the Commissioner to require that, effective October 1, 2010, carriers offering small group insurance plans are to file for any changes in small group product base rates or rating factors at least ninety days in advance of the proposed change's effective date.<sup>67</sup> The Commissioner is directed to disapprove a base rate change if it is "excessive, inadequate or unreasonable in relation to the benefits charged," and a rating factor change if the change is "discriminatory or not actuarially sound."<sup>68</sup>

While these standards are consistent with those of traditional insurance regulatory review, Chapter 288 establishes, temporarily, a novel approach to the Commissioner's review. The key regulatory change is the requirement that the Commissioner is to "presumptively" disapprove a base rate change filing on specified grounds, relating to the insurer's administrative expense and reserves and surplus.<sup>69</sup> The grounds reflect a more nuanced approach to discerning the factors driving premium increases, and do not directly seek to control underlying provider costs through premium regulation.<sup>70</sup>

With regard to payer contracting with providers, Chapter 288 does, however, promote one mechanism intended to provide better payer bargaining power: a mandate that any carrier offering a provider network and having five thousand or more enrollees in small group or individual plans must offer all small business and individuals in at least one geographic area at least one plan that contains either a limited network or a tiered network.<sup>71</sup> A limited network is one in which the carrier selects the hospitals that it will include in its products' networks; that is, it limits the access of its enrollees to only certain providers. A tiered network is one in which the cost share obligations of individuals accessing care are tiered

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67. Act of Aug. 10, 2010, § 29.

68. *Id.*

69. *Id.*

70. A filing will be "presumptively" disapproved as "excessive" if the administrative expense loading factor of the base rate, not including taxes and assessments, is projected to increase "by more than the most recent calendar year's percentage increase in the New England medical CPI," or if the aggregate medical loss ratio ("MLR") for all products the carrier offers to small groups is less than 88% (that percentage rises to 90% effective October 1, 2011). *Id.* However, if a filing does not meet the 88% or 90% MLR standard, and therefore would otherwise be presumptively disapproved, it could nonetheless be approved by the Commissioner if the carrier's aggregate MLR for all of its small group plans is at least 1% greater than it had been twelve months prior to the filing—an indication, presumably, that the carrier is making good faith progress to increase its overall MLR to the required minimum. *Id.* Further, a filing will also be "presumptively" disapproved as "excessive" if the carrier's reported contribution to surplus exceeds 1.9% (2.5% if the carrier's risk-based capital ratio falls below 300% for the most recently reported four quarters). *Id.*

71. Act of Aug. 10, 2010, § 32.

based on the hospital he or she chooses to access, with tiering generally based on a correlation of the cost and quality of the hospital.<sup>72</sup>

In order to obtain savings from this benefit design mandate, Chapter 288 requires that the base premium for a limited or tiered network product must be at least 12% lower than the base premium for the carrier's "most actuarially similar plan" that does not include such a network.<sup>73</sup> This differential can be achieved by means that include, as examples,<sup>74</sup> excluding providers with "similar or lower quality" (based on standard quality measures to be developed by the Massachusetts Department of Public Health) and with higher health status adjusted total medical expenses or relative price; or increasing cost share obligations for members who use providers for non-emergency services with "similar or lower quality" and with higher health status adjusted total medical expenses or relative prices.<sup>75</sup>

### III: LESSONS

In reflecting on the Massachusetts experience post-enactment of Chapter 305, certain observations come to the fore. First, health care is complex. There is no question that there are varying interests, that one person's cost saving, or "greater efficiency," is another's "income loss"<sup>76</sup> and that any approach to addressing the underlying costs of care must be cautious, incremental,<sup>77</sup> and take cognizance of potential secondary effects of ideas that seem on the surface good.

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72. Additional requirements applicable to limited or tiered network plans include the following: (a) variations among member cost-share obligations in a tiered plan must be "reasonable in relation to the premium charged as long as the carrier provides adequate access to covered services at lower patient cost share levels;" (b) the Commissioner is to determine "network adequacy" for each type of network "based on the availability of sufficient network providers" in the overall network; (c) in determining network adequacy, the Commissioner is to consider factors that include location of participating providers, the "employers or members that enroll in the plan; the range of services provided by providers in the plan; and any plan benefits that recognize and provide for extraordinary medical needs of members that may not be adequately dealt with by the providers within the plan network." *Id.*

73. Act of Aug. 10, 2010, § 32.

74. Through what appears to be a drafting error, while the limited or tiered network requirements are slated to go into effect on January 1, 2011, these examples of how the 12% may be achieved are technically effective as of the date of enactment of the Chapter, a date earlier than the effective date of the imposition of the 12% differential requirement.

75. Act of Aug. 10, 2010, § 33. Other provisions of Chapter 288 require the Division to elaborate on the definitions of "health status adjusted total medical expenses" and "relative prices." *Id.* §§ 11-12.

76. Should Health Benefits Be Taxed?, <http://economix.blogs.nytimes.com/2009/05/15/should-health-benefits-be-taxed> (May 15, 2009, 07:43 EST).

77. Atul Gawande, *Testing, Testing*, NEW YORKER, Dec. 14, 2009, at 34.

Second, regulation seems to be reemerging as a valid response to concerns about health care costs. Health care policy goes in cycles, and one may need to examine any lessons learned from efforts at provider rate regulation in the 1970s and 1980s to see whether there is any likelihood that such an approach can have salutary effects.

Third, insurers and providers need to be brought into a collaborative framework in which both can work together to achieve change in the system. Insurers were a little too quick to blame premium increases on providers.<sup>78</sup> The experience with the highly publicized Anthem increases proposed in California in the midst of the national health reform debate indicates that provider rates are not the only, and may not always be, the principal driver of premium increases.<sup>79</sup> Volume, price, underwriting, reserves, administrative expense and profit needs all have a role to play in varying degrees to produce proposed rates of increase that outstrip the CPI-M and provider price increases.<sup>80</sup> The key to collaboration should be a recognition that neither group really wants to be, or should be, seen as responsible for solving the challenge of rising health care costs by itself. Providers cannot do so without the ability to control volume of service, something that may be more readily achieved by insurers in the current environment; and a willingness to take on more service-related risk. Insurers cannot do so without greater ability to control providers through contract, but that leverage will vary by market conditions, and the use of private regulation, absent due process constraints that attend public regulatory authority, could put them in untenable legal, political and market positions. For payers, shifting service-related risk to providers, as distinct from underwriting risk, may be attractive.

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78. For example, when the DOI hearings officers' decision described *infra* was announced, the president and CEO of the plan that brought the administrative appeal was quoted as stating, "It is time to focus on what is truly driving health care expense, and that is the cost of care. We must address the prices charged by hospitals and physicians." Harvard Pilgrim Health Care, Inc., *supra* note 61. Further, in commenting on Chapter 288's impact and recent data regarding continuing high premium increases for small business, the president of the Massachusetts Association of Health Plans is quoted as saying that the "rate cap" under Chapter 288 is "a short-term, one hit kind of gimmick...It did nothing to deal with the underlying medical costs." Erin Ailworth, *Small Firms' Rates Soaring*, BOSTON GLOBE, Sept. 23, 2010, available at [http://www.boston.com/business/healthcare/articles/2010/09/23/small\\_firms\\_health\\_care\\_rates\\_soaring](http://www.boston.com/business/healthcare/articles/2010/09/23/small_firms_health_care_rates_soaring).

79. See, e.g., John Rogers, *Anthem Blue Cross Withdraws California Rate Increase*, HUFFINGTON POST, Apr. 30, 2010, [http://www.huffingtonpost.com/2010/04/29/anthem-blue-cross-withdra\\_n\\_557966.html](http://www.huffingtonpost.com/2010/04/29/anthem-blue-cross-withdra_n_557966.html).

80. In discussing the continuing increase in base price for small business premiums notwithstanding Chapter 288's enactment, the *Boston Globe* noted: "But the base price of a premium is frequently pushed higher by additional factors, including the size, age, and health of a company's workforce, and the type of work performed. Smaller businesses are especially vulnerable to such variables. For instance, one or two employees with serious injuries or long-term illnesses such as cancer can dramatically add to insurances expenses." Ailworth, *supra* note 78.



Rational cost control may very well lie in securing the political will to change both the payment system and the delivery system in a coordinated manner. That is, with a thoughtful implementation plan, the Special Commission may have gotten it more or less right. But the fact that Massachusetts has adopted only an interim step through Chapter 288 suggests the complexity of the task and the daunting political risks of undertaking such an effort without careful foresight.

Fourth, both Massachusetts and the federal experiences demonstrate what could be a truism about health care politics. Health policy and politics operate along a continuum, with access on one end and cost containment on the other. Each by itself is conceptually easy to achieve. Promoting access alone could be successful if no concern is given to the costs of care that will result. Improved access almost of necessity increases the overall costs of care even if it is possible to achieve efficiencies in one or more areas of the delivery system. Cost containment as the principal objective of health care policy can be advanced, at the other end of the continuum, by rationing care, an equally unlikely political outcome. Consequently policy is a continuous balancing, a shifting equilibrium between the poles of access and cost containment. Generally, when the two face off directly in the political commons, access wins and cost containment concerns are deferred.<sup>81</sup> It is much easier to deal with access, both politically and conceptually, than to tackle the hard realities—conceptual, political, and economic—of health care cost control. The Massachusetts experience has demonstrated that access improvement may be achieved without simultaneously addressing costs, but eventually the piper must be paid. While at the federal level Congress and the Administration paid attention to this issue in enacting the PPACA, especially in light of the attention given to CBO scoring, the federal government has barely begun to make serious efforts on the cost containment front. Perhaps Massachusetts's 2011 legislative session will provide more guidance based on the work done to date in the Commonwealth. Or perhaps we will continue to temporize around cost and hope that the piper never shows up.

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81. See as an example the enactment of the so-called TRICARE for Life program. Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001, Pub. L. No. 106-398, § 712, 114 Stat. 1654, 1654A-176 (2000). TRICARE for Life, which was enacted in a Presidential election year, extended TRICARE eligibility to persons age 65 and over who would otherwise have lost their TRICARE eligibility by virtue of becoming eligible for Medicare. That is, TRICARE for Life provides a Defense Department-funded Medicare supplement program for persons who previously had been responsible for securing their own supplemental payment coverage from private sources.



## ARTICLES

### **Saving Lives, Saving from Death, Saving from Dying: Reflections on ‘Over-Valuing’ Identifiable Victims**

**Mark Kelman\***

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## INTRODUCTION

The canonical case that psychologists, philosophers, and policy analysts reflect upon in considering how and why individuals and collective decision makers allocate resources that diminish the number of preventable death in seemingly irrational ways is the “Baby Jessica” case. The simple behavioral observation we make is that there was a generous, spontaneous outpouring of aid to save Baby Jessica, a young child trapped in a well.<sup>1</sup> At the same time, those people who sent checks and cash to save the trapped child seem to be willing to expend far fewer resources to *prevent* such accidents or other fatalities. The case raises at least two quite distinct descriptive and normative issues that are often conflated, though each is worth independent attention: First, how do and should we think about the ways we react to saving identifiable victims rather than “unknown persons”?<sup>2</sup> Second, how do and should we make decisions about

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1. Actually, little, if any, of the approximately \$700,000 in unsolicited funds that were sent to the McClure family back in 1987 while Baby Jessica was trapped for fifty-eight hours after falling into a well in Midland, Texas, went to defraying the costs of the rescue—or to pumping additional resources into an otherwise-underfunded rescue effort. Instead, the funds were put into a trust both to pay to treat Jessica’s injuries and for her education and long-term support. See Susan Schindehette & Anne Maier, *The Joy of Life Hard Won*, PEOPLE, Nov. 7, 1988, at 146, 151, available at <http://www.people.com/people/archive/article/0,,20100404,00.html>. The trust, in fact, was never really used even for those purposes, even though Jessica did sustain some quite serious injuries: Jessica (at age twenty-one) reported that the trust, which will be distributed to her at twenty-five, will go to her own child, Simon. See Mike Celizic, ‘Baby Jessica’ 20 Years Later, TODAYshow.com, June 11, 2007, <http://today.msnbc.com/id/19165433/?GTI=10056>.

2. Over the course of the paper, it will become clear that the term “identifiable victim” is by no means readily defined; certain explanations of *why* people apparently care more (or, to put it more normatively, unduly) about identifiable victims depend on distinct accounts of what the attitude-affecting traits of such victims might be. For now, I believe it will be helpful in considering these issues to emphasize a few distinctions that have not been made in precisely this fashion in the literature. A victim is *strongly* “identifiable” if she is a known, named person, at least modestly vividly described in terms of her particular attributes—she has at least a thin bio. She is a strong *victim* if we know that there are discrete steps we can take now that will save her from a particular short-term threat. Victims are *weakly* identifiable if no one is identified as a particular person but we know that *some* person or people could already be labeled as in need of action that will prevent their deaths. However, the distinction between weakly identifiable persons and “mere” statistical lives seems extraordinarily psychologically flimsy. While it is reasonably clear that 1) releasing a toxin that will increase mortality rates of a large group ordinarily merely threatens “statistical lives,” and 2) releasing a toxin that will imminently kill a particular family, vividly pictured, threatens “identifiable lives,” there are many intermediate and blurry cases. Imagine the toxin will kill all members of whatever geographically confined community it happens to “land on,” but we do not yet know where that community will be. The victims are plainly not strongly identifiable, but it is not obvious whether they are weakly identifiable in attitude-relevant ways or not; the answer to that question depends on whether one believes that a significant part of what drives the

expending resources to *cure* or *rescue* those who are already known to be in mortal danger rather than to *prevent* people from dying or developing fatal maladies?<sup>3</sup>

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effect is that people care more about a large proportion of a group, however defined, dying than they care about a smaller proportion of a large group dying. Moreover, if “identifiability” is in whole or in part a species of “salience” or vividness, it may well be that seemingly unambiguously statistical deaths strongly associated with some past set of focal, salient dying persons will be treated more like deaths of identifiable victims: I suspect, for instance, that most costly steps designed to reduce the risk of death-from-terrorism are in significant ways thought by many subjects to redound not to *mere* “unidentifiable victims” or statistical lives but to the projected-to-the-future and therefore psychologically vivid lives of iconic 9/11 victims.

It might matter, too, even if we are in the ex ante decision-making position (Can we release the toxin? Must we take expensive steps to avoid its release?), whether we believe that we *will* know, ex post, that some particular deaths were attributable to the toxin. Victims will obviously be more “identifiable” ex post if the autopsy clarifies what caused their death than if, even ex post, we must rely on epidemiological evidence to tell us that *some* of the deaths among a large number would almost surely not have occurred had we acted differently. Note, then, that yet another reason preventive measures to avert death-by-terrorist may involve saving semi-identifiable persons is that we know, ex ante, that if some do die, it will be known, ex post, to be a result of terrorism, though it will not so clearly be a result of terrorism that could have been averted by the steps we might have chosen to forego. But, once again, whether the foreknowledge that this will be the case makes us evaluate the initial decision to a greater extent as killing the identifiable victims depends in part on how one *explains* the psychological processes behind the so-called “identifiable victim” effect. See Karen E. Jenni & George Loewenstein, *Explaining the ‘Identifiable Victim Effect,’* 14 J. RISK & UNCERTAINTY 235 (1997). I am skeptical that we have especially good explanations of the identifiable victim effect. Thus, I am not at all certain how to classify all victims.

I point out that it is also not easy to tell whether a person, identifiable or not, is already a victim or is merely in jeopardy of becoming one. See *infra* note 3.

3. “Cure” and “prevention” are hardly clear, binary categories either, but I offer some thoughts about how they might be profitably distinguished. At core, we are most clearly engaged in “cure” or “rescue” when several conditions are simultaneously met. First, we must be “substantially certain” that the party at risk could die as a direct result of an injury already sustained or a disease already developed. Second, we must believe that the measures we are considering are intended to make the party’s death substantially less likely. We are engaged in prevention, in my view, when the person is not yet injured or sick with the disease that would be listed as the cause of death, and when it is merely risky that he will be injured or develop the dangerous disease that poses a risk of death. Why are the categories plainly not analytically binary? First, there is no bright line distinction between an event being “substantially certain” and “highly probable.” Second, the notion that we are preventing rather than curing until the party has developed the last fatal complication in a disease course is problematic: are we not plausibly engaged in life-saving “cures” when we try to treat already-developed diabetes even though the person will likely die more directly from a vascular disease that is a “complication” of diabetes? Also, while we might typically think that those we take steps to cure or to rescue are sunk without our help, this need not be the case: it is clear that we can try to rescue people who are plainly *not* otherwise certain to die. The lifeguard may jump into the pool to save someone who might have struggled to the side of the

The two distinct issues are indeed each at play in the Baby Jessica case: when we direct resources to save Jessica, we both know she is already in jeopardy (i.e., it is a rescue case) *and* know precisely who she is in the strongest or most vivid sense (she is personalized, pictured, and named). But the issues could be completely separated: we might choose to expend more money to reduce the prospective risks that a known person or known persons would have an accident or develop a fatal malady than we would spend to reduce the prospective risks faced by unknown persons. In this regard, consider a decision to install expensive safety devices for all of the named and known racers at a particular NASCAR event rather than highway dividers that will save some unknown drivers in the future. We might also expend more resources researching how to *cure* a disease, not knowing who will be cured, than we would spend to *prevent the development (or spread)* of the same or another equally fatal disease in other unknown persons. Consider, for example, spending more to research better anti-virals than to develop vaccinations, as well as spending more to develop better medications to limit the impact of Type II diabetes rather than devising public health measures to shift diet in such a way that fewer cases will emerge.

It is not simply a stickler's analytical point that we should differentiate the choice between "cure" and "prevention" from the choice between curing or preventing the development of disease in an "identified person" and an "unidentified person." In fact, this paper aims to show that the willingness to spend on saving those already in jeopardy rather than to prevent peril from developing is significantly, and perhaps even dominantly, a reflection of our distinct reactions to *death*, on the one hand, and to *dying* and the *dread of death*, on the other. I believe that many of us have these distinct reactions and might rationally manifest them, even in thinking about what we would want done in our own cases. The preference for "curing" or "saving" over "preventing" is not, then, merely about selective empathy for the "identified"—justified or not. Nor is it solely about mistaken perceptions of the effects of our actions on what some mistakenly see as the sole outcome variable of interest—actual premature mortality rates.<sup>4</sup> By contrast, I will argue that our comparatively strong sympathy

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pool without her aid. But once we see that those who are saved or cured might merely be at risk (it is substantially certain that they are already suffering from a fatal *vulnerability*, not that they will die without intervention), then we can more readily think of those who, for example, have a genetic predisposition to develop cancers if exposed to certain environmental carcinogens (classic "prevention" cases) as already-in-jeopardy.

4. Some mistakenly see actual premature mortality rates as the sole outcome variable of interest. See, e.g., George Loewenstein, Deborah A. Small & Jeff Strnad, *Statistical, Identifiable, and Iconic Victims*, in BEHAVIORAL PUBLIC FINANCE 32, 37 (Edward J. McCaffery & Joel Slemrod eds., 2006) (arguing that the identifiable victim effect may be properly exploited to increase aid that would not otherwise be forthcoming but the underlying "first best" goal is increase social welfare

for identified over unidentified persons predominantly arises from non-utilitarian *moral* views—whether justified or not—that are largely of interest in thinking about our reactions to others.<sup>5</sup>

Resolving these issues is certainly of practical significance. For one, public resource allocation decisions are sensitive to the resolution of these issues. Finite resources could be invested, at the margin, in safer highways, or they could be invested in better emergency rooms that save the inflated number of crash victims we generate by not making the roads safer in the first instance. Moreover, though there are obviously a host of empirical issues about the deterrent effect of the death penalty,<sup>6</sup> death penalty proponents could surely argue that policy debate in the area is “distorted” by the distinct reactions people have to killing an already identified convicted murderer rather than saving unidentified statistical lives who would never be killed if their potential murderers are deterred.<sup>7</sup> Moreover, we may even, in making our private judgments, overvalue the reduction of *identifiable symptoms* at the expense of accepting higher but unidentified, diffuse risks of mortality and morbidity for reasons that parallel—under certain but not all conceptions—our reactions to saving identifiable victims. Under some obviously medically contested views, hormone replacement therapy is just such a treatment.<sup>8</sup>

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by equalizing social benefits, e.g., lives saved, per aid dollar).

5. Because we invariably confront the decision to rescue in the context of rescuing a relatively identifiable person, it is possible that our “intuitions” about the choice between “rescue” and “prevention” are rules of thumb that build upon more basic feelings about some form or other of identifiability. (Even if we are saving a trapped earthquake victim whose name we do not yet know—thus he is not strongly or thickly identified—he will surely be known to be a particular person and we can plainly imagine his peril as a particularized sufferer.) Perhaps we would choose to expend resources on institutions that would cure rather than those that would prevent (e.g., emergency rooms rather than safer roads) because we know at some level that by the time the emergency room is “used,” it will be used on an identifiable victim, even though at the time we expend the resources, the party to be saved is not yet identified. We will never learn the identity of those who did not get killed because we built a safer road.

6. For a good summary of the literature—albeit a summary from the vantage point of authors skeptical that substantial deterrent effects exist, see generally John Donohue & Justin Wolfers, *Uses and Abuses of Statistical Evidence in the Death Penalty Debate*, 58 STAN. L. REV. 791 (2005).

7. This is precisely the sort of argument that is made in Cass R. Sunstein & Adrian Vermeule, *Is Capital Punishment Morally Required? Acts, Omissions, and Life-Life Tradeoffs*, 58 STAN. L. REV. 703, 710, 741 (2005), which argues that the capital punishment debate is affected by the saliency of persons sentenced to death compared to the namelessness and facelessness of statistical lives saved by capital punishment.

8. Hormone replacement therapy may alleviate both short-term symptoms of menopause (e.g., hot flashes, fat redistribution) and longer-term problems (e.g., osteoporosis, muscle aging). But it may be associated with increased risk of heart disease, stroke, breast cancer, and, when estrogen is administered without a progestin, endometrial cancer. The most significant piece in the public

But while I am quite interested in resolving these difficult practical problems, all I realistically hope to do in this piece is to make certain observations about the problems that will do no more than spur a more nuanced consideration of the practical options. Reflecting on these issues also raises far more widespread and general conceptual difficulties we face in evaluating both public policy formation and private decision making, forcing us to consider carefully certain disputes over the propriety or completeness of typical consequentialist methodologies.

My more specific goal is both to embrace, in part, and resist, in part, the mainstream intuition among fundamentally utilitarian “policy wonks” that subjects who spend more to save an identified life than they would choose to spend to prevent the death of an unidentified person are, at core, the poster children for the persistence of irrationality and error. This is the primary intuition of those schooled in the notion that rational decision making is *normative*, but that actors frequently are cognitively *incapable* of making rational choices, not simply because they lack information about the expected effects of their choices, but because their internal processing capacities are too limited to process the information that they do have. What lies just one baby step behind this intuition is the claim that we can impute only one sensible end to actors in these settings—a consequentialist commitment to minimize premature death. (It is critical to note that I am setting aside, now and for the remainder of this piece, issues that arise from the fact that differential physical morbidity might be associated with distinct deaths and paths to death. The fact that people might physically suffer more if we extend their lives once they are ill is clearly important to rational-choice (“rat-choice”) consequentialists. Obviously such consequentialists might have different value schemes, and thus make distinct trade-offs between extending the total number of years lived and the *quality-adjusted* number of years lived.)<sup>9</sup>

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health literature criticizing the therapy is Writing Group for the Women’s Health Initiative Investigators, *Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women: Principal Results From the Women’s Health Initiative Randomized Controlled Trial*, 288 JAMA 321 (2002).

9. For a lucid discussion of Quality Adjusted Life Years, a concept developed in significant part to facilitate various sorts of cost-benefit analyses of distinct medical interventions, see Erik Nord, *Methods for Quality Adjustment of Life Years*, 34 SOC. SCI. MED. 359 (1992); and John Broome, *Qalys*, 50 J. PUB. ECON. 149 (1993).

There are obviously a host of practical and conceptual difficulties inherent in trying to measure losses from different levels of morbidity or to measure morbidity at all relative to lost years of life, but these are all beside the point for the purposes of this piece. For one of the classic early discussions of how consequentialist policy analysts ought to make trades between longevity and quality-of-life, see Joseph S. Pliskin & Clyde H. Beck, Jr., *A Health Index for Patient Selection: A Value Function Approach with Application to Chronic Renal Failure*, 22 MGMT. SCI. 1009, 1010 (1976) (“The two factors, increments to longevity and quality of life, are the



If increasing the number of years people, including ourselves, live is the only rational goal to seek in this domain, then it follows readily that these actors could better meet this goal if they transferred an incremental dollar invested in death-decreasing projects from a death-decreasing project that saved fewer lives to one that saved more lives. If the subject is not following this policy, he must be making one of two forms of cognitive error: He might misperceive the effect of his actions, or to put the point more narrowly, he might misperceive the number of lives that will be saved by taking each action because he has a distorted understanding of the probabilities that particular outcomes follow from particular actions. Alternatively, he might not see that outcomes that are in fact the same are really the same because the outcomes are framed differently, or, perhaps more frequently, his views of the relative desirability of the options are elicited using particular methods that influence how desirable each outcome seems.

What I hope is manifestly clear is that this sort of critique of decision-maker capacity is at the heart of the heuristics and biases (hereinafter, H&B) literature in psychology,<sup>10</sup> associated with Nobel laureate Daniel Kahneman and his long-time collaborator, Amos Tversky. The H&B literature is significantly incorporated in the policy analytical world under the label “behavioral economics.”<sup>11</sup> People may try to compute expected values but they cannot estimate the probability that distinct outcomes will eventuate if they make certain concrete choices, and they have trouble coming to stable evaluations of the outcomes whose probabilities of eventuating they have already miscomputed. A subject *wants* to take risk-minimizing actions or to insure against risks that are more prevalent, but mistakenly perceives, for instance, that those risks readily “available” to him—that is, easily recalled or brought to mind (airplane crashes are the canonical example) are more commonplace than other risks, factually more prevalent, that are less salient and harder to recall (bathtub falls are the canonical example here).<sup>12</sup> A subject believes he can directly assess how much he values a nice pen, relative to a sum of money, but he values the pen more

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predominant dimensions when evaluating response to treatment....”). For my purposes here, though, it is sufficient to note that those who think subjects should have simple consequentialist ends would believe that caring about physical morbidity, however measured, was perfectly sensible, but would find it as senseless to care about the morbidity of the identifiable person rather than the statistical person as to care more about the identifiable person’s death.

10. The best summary of work in this tradition remains *HEURISTICS AND BIASES: THE PSYCHOLOGY OF INTUITIVE JUDGMENT* (Thomas Gilovich, Dale Griffin & Daniel Kahneman eds., 2002).

11. The most lucid single summary of the quite varied behavioral economics tradition, as applied to law, remains Christine Jolls, Cass R. Sunstein & Richard Thaler, *Behavioral Responses to Law and Economics*, 50 STAN. L. REV. 1471 (1998).

12. The canonical work on biased probability estimates that can grow out of using availability as a proxy for frequency is Amos Tversky & Daniel Kahneman, *Availability: A Heuristic for Judging Frequency and Probability*, 5 COGNITIVE PSYCHOL. 207 (1973).

highly when he is presented with an irrelevant third alternative—a pen that is far inferior to the pen whose value he is realistically assessing relative to the money.<sup>13</sup> I am quite sympathetic to the H&B literature,<sup>14</sup> but also try to remain aware of the standard problems within the tradition.

What *are* the standard problems I will need to deal with? The first problem is the problem I am most concerned with, and it is the topic of Part II. Even if our subjects are or should be simple consequentialists, it is possible that we are profoundly wrong when we say that they have failed to meet the simple end we have imputed to them. We may be ignoring the possibility that they are seeking alternative or supplementary ends efficaciously. What I will argue in this regard is that rational subjects may seek not only to minimize deaths or, to put it another way, maximize either their own or collective life expectancy, but that they seek to alter *how people die*. In discussing this point, recall that I am completely setting aside significant distinctions in physical pain and morbidity associated with distinct paths to death and will focus solely on the possibility that what they are trying to do is not simply to maximize how long they live but to dampen certain aspects of the existential despair associated with *dying*, rather than the quite distinct—and actually quite elusive, perhaps even non-existent—well-being losses associated with *being dead*.<sup>15</sup> It is possible to interpret what I am doing as merely *refining* or amending our conception of quality of life by noting that those who know they are dying suffer in ways we need to be cognizant of, even if they are not suffering in ways that those conventionally described as physically ill are suffering.

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13. The seminal works on this sort of context-dependent decision making are Itamar Simonson & Amos Tversky, *Choice in Context: Tradeoff Contrast and Extremeness Aversion*, 29 J. MARKETING RES. 281 (1992); and Amos Tversky & Itamar Simonson, *Context-Dependent Preferences*, 39 MGMT. SCI. 1179 (1993).

14. I started writing in this tradition more than thirty years ago, and I got my first job at Stanford on the basis of a third-year law school paper that independently worked through two of the issues that the early heuristics and biases researchers were working on: the endowment effect and problems of self-governance over time (and meta-preferences). See Mark Kelman, *Choice and Utility*, 1979 WISC. L. REV. 769; Mark Kelman, *Consumption Theory, Production Theory, and Ideology in the Coase Theorem*, 52 S. CAL. L. REV. 669 (1979). I give a sympathetic summary and reconstruction of some of the major themes in the literature in Chapter 2 of MARK KELMAN, *THE HEURISTICS DEBATE: ITS NATURE AND ITS IMPLICATIONS FOR LAW AND POLICYMAKING* (forthcoming Oxford University Press 2011) [hereinafter *THE HEURISTICS DEBATE*].

15. In this regard, I am trying to give more content to a rather casual observation made by Thomas Schelling in the first academic article that considered the identifiable victim effect, though the observation was never followed up on in any of the subsequent psychological literature. Schelling noted that “the pain associated with the awareness of death—with the prospect of death—is probably often commensurate with the costs of death itself.” T.C. Schelling, *The Life You Save May Be Your Own*, in PROBLEMS IN PUBLIC EXPENDITURE ANALYSIS 127, 144 (Samuel B. Chase, Jr. ed., 1968).

Next, I discuss in Part III that it is possible that we are wrong to assume that our subjects are bumbling consequentialists, or even consequentialists with a surprisingly complex array of goals, rather than *non-consequentialists*. They may be non-consequentialists because their moral or decisional code is agent-relative, rather than agent-neutral. They may be agent-relative in the sense that they are interested in what they as individuals *do* (and whether they cause certain outcomes purposely, knowingly, recklessly, or negligently), and in particular whether they violate the “rights” of other agents or treat each of them with the respect owed separate autonomous rational agents. They are not just interested in the results that are likely or necessary causal outcomes of their entire course of acts and omissions (sometimes, but not always, including the violation of rights by third parties). Think, in this regard, about the standard, if hardly uncontroversial, deontological intuition that an actor A could not justly “punish” an innocent V to save another set of innocent Victims X, Y and Z from a mob that would be satiated by V’s punishment, because A’s *conduct* in such a case would impermissibly violate rights, even though it would arguably causally prevent the violation of rights by others. Or think about the less commonplace Kantian intuition that one should not lie to another, even if doing so would deprive the lied-to person of information he would use to harm another.<sup>16</sup> Are

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16. There are a host of such dilemmas for strong deontologists. My intuition is that one can probably most readily assess just how strong a subject’s attraction to the view that one can never do anything “wrong” oneself, whether or not one’s “wrongdoing” might interfere with a separate moral agent’s plans to cause even really bad consequences, by whether he thinks it worth more than a second’s reflection to resolve the cherished Kantian dilemma of whether it is morally permissible to lie to a would-be killer about the whereabouts of his intended victim. Some neo-Kantians—like Korsgaard—ultimately argue that one can lie to the would-be murderer only on the supposition that he is trying to deceive you about his plans, but seem to feel that lying in other cases is always categorically impermissible, because doing so fails to show “respect” for his autonomous decision-making capacity, since one deprives him of the information he needs to make autonomous choices that meet his considered goals. See CHRISTINE M. KORSGAARD, *CREATING THE KINGDOM OF ENDS* 133-58, 335-62 (1996). Others, like Schapiro, believe that one is obliged to tell the truth only when the purposes of truth-telling are served: she argues that they may not be served when the person to whom one lies lacks the capacity to make autonomous choices in any case (this justifies paternalistic deception, not in any situation in which it could improve decision making and never with that goal in mind, but only in cases in which one is dealing with someone who lacks autonomous rational agency) or when, as in the case of the would-be murderer, he has betrayed the communicative relationship by “withdrawing” from a commitment to engage in joint legislative projects (“defensive deception”). See generally Tamar Schapiro, *Kantian Rigorism and Mitigating Circumstances*, 117 *ETHICS* 32 (2006).

For most of us, I suspect the hard question is whether anyone *giving* the true information about the victim’s whereabouts, knowing how it is to be used, is complicit with the murderer, or whether mere knowledge that one is aiding him—rather than a purpose to do so—is insufficient. The question of whether one is actually obliged to lie rather than to shut up simply reduces to a question

those who devote more resources and energy to saving identifiable lives parallel to, though not precisely like, those who believe that their duties to avoid harming or violating rights directly are considerably more extensive than their duties to save or prevent others from violating rights? If the failure to take precautions that decrease global risk is most like “failing to act” and killing a person is most like unambiguous rights-violating action, then perhaps failing to take steps to save an already-identified person occupies a moral midpoint, neither as “bad” as killing nor as “acceptable” as failing to save, for an agent relativist focused on his or her own conduct. I will make what I view as a very tentative argument to that effect in Part III. At core, the argument is that the clearest form of problematic conduct or rights violation involves a dyadic relationship between a uniquely situated identifiable perpetrator and an identifiable victim whom the perpetrator injures. One stays closer to the core case so long as there is identifiability on at least one side of the dyad.

But our decision makers might also be non-consequentialists because they make judgments that are agent-relative in a distinct sense. They might see no reason to treat all deaths as equally bad even if they accept the abstract moral equality of those who will die because they are entitled to demonstrate partiality and preference for some subset of persons who might die. Again, thinking about the canonical example should help. A father might act justly in saving his own child from drowning after a boating accident, even though he could have saved two other equally worthy children had he not devoted his energies to saving his own child. While obviously the relationships with identified strangers are weaker than with kin or friends, it is possible that we establish non-trivial “relationships” with those we know are dying merely by virtue of learning their identity—relationships that justify at least a weak form of partiality.<sup>17</sup>

I will return briefly, in Part IV, to consider whether the preference for prolonging the life of identifiable persons, separated out as much as possible

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of whether a stranger has an affirmative duty to save. But if she chooses to answer questions about the victim’s whereabouts at all, she may have no choice but to lie if knowing aid is a form of complicity.

There are also plainly those whose deontological intuitions are stronger in situations in which one set of unwanted consequences involves not only actor conduct but also impermissible rights violations by the actor-in-question while another does not. Thomson, for instance, believed at one point that the reason one cannot push the man off the drawbridge to block a trolley that will otherwise kill five innocents while one could divert a trolley about to run five people over so that it kills just one is that in the former case, the pushed party has a “right” to be free from the homicidal assault while none of the possible “accident victims” has such a right. Her view was that in the divert-the-trolley case, none of the six possible victims has a right be free from being accidentally run over. See Judith Jarvis Thomson, *The Trolley Problem*, 94 YALE L.J. 1395, 1403-06 (1985).

17. Sarah Clark Miller makes a more complete variant of this argument in relationship to the duty to rescue. See generally Sarah Clark Miller, *Need, Care and Obligation*, 80 ROYAL INST. PHIL. (Supp. 57) 137 (2005).

from the frequently associated question of whether we are *saving* those already in jeopardy rather than preventing jeopardy from developing, can be understood in some significant part by reference to this second form of agent relativity. I will briefly comment as well on whether we should foster this seeming consequentialist “error” if and perhaps only if it serves consequentialist ends to do so. In this regard, I will make note of empirical findings that indicate that even when people are alerted to the fact that many people expend more resources to save identifiable victims than statistical lives, they do not become more generous towards unidentified strangers. Instead, their altruistic concern for identified people diminishes.

# I. DO SUBJECTS MEET THEIR GOALS INEFFICACIOUSLY OR DO CRITICS MISCOMPREHEND THEIR GOALS?

## A. Conceptualizing Distinct Hesitations about Claims of Cognitive Error

Heuristics and biases (H&B) researchers claim that they have experimentally demonstrated that subjects are frequently unable to meet a set of stable ends because of cognitive distortions.<sup>18</sup> It is fruitful to begin by distinguishing two distinct sorts of arguments made by those suspicious of this claim. Those taking the first approach—most associated with Gerd Gigerenzer’s “fast and frugal heuristics” (hereinafter, F&F) school<sup>19</sup> and its critiques of Kahneman and Tversky’s work on biased judgment<sup>20</sup>—argue that subjects are and should be less conventionally rational. Instead, they typically use nonrational judgment and decision-making tools that take advantage of the readily available information in natural environments to make behavioral decisions that meet the organisms’ proximal goals. The theory is that subjects’ decisions are not conventional rat-

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18. It is easiest to conceive of H&B scholars as criticizing the descriptive realism, rather than the normative desirability, of expected utility theory: H&B theorists think we may both miscompute the probability of the events that might occur if we take any particular action and cannot consistently and stably evaluate how we would value the end-states whose probability we may well misconstrue. I discuss these points at length in Chapter 2 of *THE HEURISTICS DEBATE*. See *supra* note 14. A similar sort of argument about the most basic message of the H&B school can be seen in Richard Thaler, *Toward a Positive Theory of Consumer Choice*, 1 J. ECON. BEHAV. & ORG. 39 (1980).

19. Some of the classic works in this tradition are *BOUNDED RATIONALITY: THE ADAPTIVE TOOLBOX* (Gerd Gigerenzer & Reinhard Selten eds., 2002); *GERD GIGERENZER, ADAPTIVE THINKING: RATIONALITY IN THE REAL WORLD* (2002); *HEURISTICS AND THE LAW* (Gerd Gigerenzer & Christoph Engel eds., 2006).

20. There are many such critiques. Among the most prominent are Gerd Gigerenzer, *How To Make Cognitive Illusions Disappear: Beyond Heuristics and Biases*, 2 EUROPEAN REV. SOC. PSYCHOL. 83 (1991); and Gerd Gigerenzer, *On Narrow Norms and Vague Heuristics: A Reply to Kahneman and Tversky*, 103 PSYCHOL. REV. 592 (1996).

choice, logical decisions, meeting conscious goals that the H&B researchers simply failed to take into account. Rather, they are decisions that are ecologically rather than logically rational, meeting sensible, even obvious, ends whether or not they follow canons of rationality.<sup>21</sup> The second approach<sup>22</sup>—more associated with rat-choice resistance to the findings of H&B research that people fail to act rationally—is that subjects who seemingly fail to meet ends ascribed to them by experimenters actually are consciously or semi-consciously meeting a separate, less obvious end.<sup>23</sup>

Here is an example of the distinction between these two types of critiques of researchers who believe subjects are failing to pursue their ends: Assume that

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21. I discuss and critique this approach at length in *THE HEURISTICS DEBATE*, *supra* note 14, Chapters 3 and 5. I discuss the criticisms of H&B theory in Chapter 4.

Here is an example that should help illustrate the distinction between ecological and logical rationality: people often fallaciously believe that a player who has made many recent shots in a basketball game would continue to make them (the so-called “hot-hand fallacy”). See Bruce D. Burns, *Heuristics as Beliefs and as Behaviors: The Adaptiveness of the ‘Hot Hand,’* 48 *COGNITIVE PSYCHOL.* 295 (2004). Burns acknowledges at least for argument’s sake that conventional H&B researchers were correct to assert that people are mistaken to believe in the “hot hand” in basketball. That is to say, people are wrong to believe that the probability that a player will make his next shot is dependent on whether that particular player has made or missed his previous shots. For the initial statement of this finding, see Thomas Gilovich, Robert Vallone & Amos Tversky, *The Hot Hand in Basketball: On the Misperception of Random Sequences*, 17 *COGNITIVE PSYCHOL.* 295 (1985).

But Burns argues that it is nonetheless *ecologically rational* to take the action that belief in the hot hand “fallacy” suggests one should take: to pass the ball to the “hot shooter” and try to ensure that the shooter with the hot hand gets as many shots as possible. It is a rational belief because it entails adaptive action: Even if the *reason* that one does the right thing is that one mistakenly believes that his shooting percentage will be higher if he is “hot” than “cold,” so long as following the hot-hand heuristic meets the overarching rational ends of the team—to score more points—the “fallacy” is ecologically rational.

22. The second of the two arguments is much closer to the one I ultimately want to emphasize when I make an effort to distinguish between subjects seeking to avert death and those seeking to cushion the existential despair associated with the awareness that they are dying.

23. I emphasized that this sort of rat-choice critique of the findings of researchers who purported to demonstrate bias or incompetence was ubiquitous—and sometimes, though not always, credible—in Mark Kelman, *Law and Behavioral Science: Conceptual Overviews*, 97 *Nw. U. L. REV.* 1347, 1364-72 (2003). Many H&B experiments are subject to the critique that subjects may have sought to meet different ends than the experimenters believed they had pursued irrationally.

Many are subject to yet a different criticism; H&B researchers may claim that subjects evaluate the *same* option differently depending upon how preferences among options are elicited; rat-choice critics may respond that the subject is not really evaluating the same option in each setting, but that the option he rejects given one “elicitation mode” is actually more costly to pursue. *Id.* at 1370-71.

experimental subjects are shown an urn with seven red and three green balls and told that a ball will be drawn ten times, with replacement; each time the subject picks the color of the ball that is drawn, she wins \$5. A subject seeking to maximize the amount of money she wins would pick red all ten times, but most subjects engage in what is usually dubbed “probability matching”—picking red seven and green three times because this is the most likely aggregate outcome. They do so even though the expected value of that choice pattern is  $0.7 \times 7 + 0.3 \times 3$  or 5.8 correct guesses rather than 7 ( $0.7 \times 10$ ).<sup>24</sup>

Theorists who believe we make irrational decisions note that those who seek to maximize their winnings are not doing so—and are not doing so because they are miscomputing expected values. Rat-choice theorists making the sort of critique I am interested in here are prone to argue that the subjects simply have a more complicated utility function than the H&B researchers suggest: arguably, at least, the subjects want not only the money they can earn but want to keep the game-playing task amusing, and choosing red each time is a bore.<sup>25</sup> F&F theorists, on the other hand, note that probability matching—even if counterproductive to this specific task—evolved in the context of developing optimal foraging strategies. Strategies in which subjects select a mix of more and less probable “winners” have evolved to meet organism needs, even if the actors never *compute* the advantages of the strategy in either the foraging or the ball-selection context.<sup>26</sup>

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24. See, e.g., Amos Tversky & Ward Edwards, *Information Versus Reward in Binary Choices*, 71 J. EXPERIMENTAL PSYCHOL. 680 (1966); Richard F. West & Keith Stanovich, *Is Probability Matching Smart? Associations Between Probabilistic Choices and Cognitive Ability*, 31 MEMORY & COGNITION 243 (2003).

25. This is one interpretation of the finding that subjects engage in probability matching less frequently when the monetary stakes rise. Experiments finding that people engage in this behavior less frequently when the incentives to maximize expected return are stronger are summarized in Nir Vulkan, *An Economist's Perspective on Probability Matching*, 14 J. ECON. SURV. 101 (2000). At any rate, one could surely argue that the implicit price of keeping oneself amused rises as stakes rise, and people “buy” less amusement as its price goes up. Of course, it is possible that rising monetary stakes simply cause subjects to focus on a task that they otherwise do carelessly and without focus, not because the desire to act “carelessly” is best considered a genuine alternative end, but because attentiveness and care are always effortful.

26. The evolutionary advantage of the strategy in the foraging context is (purportedly) that one should not merely maximize current food gathering, but also learn more about environments in which finding food is less likely, so that one will have alternative sites to find food in the future. Thus, it is suboptimal in meeting the fuller set of goals to maximize expected current winnings. See William S. Cooper & Robert H. Kaplan, *Adaptive Coin-Flipping: A Decision-Theoretic Examination of Natural Selection for Random Individual Variation*, 94 J. THEORETICAL BIOLOGY 135 (1982); Morris P. Fiorina, *A Note on Probability Matching and Rational Choice*, 16 BEHAV. SCI. 158 (1971); Catrin Rode et al., *When and Why Do People Avoid Unknown Probabilities in Decisions Under Uncertainty? Testing Some Predictions from Optimal Foraging Theory*, 72

I do not mean to dismiss the F&F critique; to the contrary, I believe the F&F researchers have done a good job noting a number of significant problems in the H&B findings,<sup>27</sup> but have, at the same time, downplayed conceptual and empirical problems in their own work.<sup>28</sup> But, as I said, what I want to highlight

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COGNITION 269 (1999).

A mainstream rat-choice theorist would argue that the optimal forager—who genuinely learned information by “sampling” sites where the probability of success was lower—was not acting irrationally; instead, he simply had the foresight to maximize the discounted present value of the long-term income stream. Even if F&F theorists were willing to acknowledge that translation (which treats the behavior as logically rational, not just ecologically rational), he would argue that the strategy was not consciously chosen by a subject attempting to maximize discounted expected income.

27. I discuss some of the strengths and weaknesses of these critiques in Chapter 4 of *THE HEURISTICS DEBATE*, *supra* note 14. The most significant, basic critique that F&F theorists level at H&B research is that subjects *seem* to perform sub-optimally in H&B experiments only because they are given problems in these experimental settings that do not accurately mimic problems that they would confront in natural environments. What ultimately *causes* the gap between performance on “real world problems” and laboratory problems is that the mental capacities that evolved are the capacities to solve recurring problems that increase inclusive fitness, not the more diffuse capacity to be an abstractly better calculator (e.g., of expected values). In this view, what is wrong with H&B research is that the H&B investigators have fashioned lab problems that merely test formal problem-solving capacity and then interpret formal failures on these problems as functional failures of cognition.

Among the key works in the F&F literature that raise these concerns are GIGERENZER, *ADAPTIVE THINKING*, *supra* note 19, at 92-123; Gigerenzer, *On Narrow Norms*, *supra* note 20, at 593; Ralph Hertwig & Gerd Gigerenzer, *The ‘Conjunction Fallacy’ Revisited: How Intelligence Looks Like Reasoning Errors*, 12 J. BEHAV. DECISION MAKING 275 (1999). Strong versions of these critiques can also be found in Leda Cosmides & John Tooby, *Are Humans Good Intuitive Statisticians After All? Rethinking Some Conclusions from the Literature on Judgment Under Uncertainty*, 58 COGNITION 1 (1996); Gerd Gigerenzer & Klaus Hug, *Domain-Specific Reasoning: Social Contracts, Cheating and Perspective Change*, 42 COGNITION 127 (1992); and Catrin Rode et al., *When and Why Do People Avoid Unknown Probabilities*, *supra* note 26.

28. I detail some of the basic criticisms of F&F work in Chapter 5 of *THE HEURISTICS DEBATE*, *supra* note 14. The most contentious criticism leveled against F&F theorists is that they are simply wrong when they declare that their descriptions of the heuristics people use are more detailed and accurate than those that H&B theorists provide. Instead, the critics suspect, the heuristics the F&F people identify are frequently inaccurate idealizations of actual capacities or cognitive strategies—ungrounded both in behavioral observations and in neurobiology—that merely posit a solution to some imputed adaptive goals, as if these solutions were observed capacities. To put that point another way, H&B scholars arguably believe that the F&F theorist typically describes a cognitive process without regard to its real nature, but only as the projected solution to the adaptive problem the F&F theorist *imagines* the organism both needed to solve and must have solved in the fashion the theorist posits. This criticism of F&F scholarship is not widespread but can be seen to some extent in Ben R. Newell, *Re-Visions of Rationality?*, 9 TRENDS COGNITIVE SCI. 11 (2005).

Critics also note that F&F theorists cannot adequately account for the variability across



are situations in which the theorist examines researchers who posit that subjects are making irrational judgments because they do not appear to be meeting the ends the researcher has posited they are seeking, ignoring the possibility that they might be seeking other ends.

One more example might help: H&B researchers have identified multiple forms of hindsight bias—the problematic tendency to overestimate the *ex ante* probability that results that ultimately occurred would occur, the tendency to overestimate one’s own prior estimates of the probability that the actual outcome would occur, and the tendency to believe others should have known what actually occurred even when the outcome was not readily cognizable *ex ante*.<sup>29</sup>

H&B experimenters note, in this regard, that experimental jurors directed to judge whether police were justified in engaging in a search—in the experimental instructions, the propriety of the judgment to search is *explicitly* grounded only in the *ex ante* probability of finding relevant contraband or evidence—is altered by learning that contraband was found.<sup>30</sup>

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persons in the use of heuristics: variability is not especially readily reconciled with the claim that adaptive pressures dictate the use of relatively mandatory heuristics. This particular critique is made especially sharply in Keith E. Stanovich & Richard F. West, *Individual Differences in Reasoning: Implications for the Rationality Debate*, in *HEURISTICS AND BIASES: THE PSYCHOLOGY OF INTUITIVE JUDGMENT* 421–440 (Thomas Gilovich, Dale Griffin & Daniel Kahneman eds., 2002).

Finally, and most importantly, there is evidence in many settings that subjects who purportedly use lexical, non-compensatory “fast and frugal” heuristics in fact use additional cues in reaching judgments. Thus, for instance, Gigerenzer (and Goldstein) assert that people will *only* use information about whether or not they recognize a city in deciding that one city is more populous than another. Their assertion was best spelled out in Daniel C. Goldstein & Gerd Gigerenzer, *Models of Ecological Rationality: The Recognition Heuristic*, 109 *PSYCHOL. REV.* 75 (2002). It is rejected in Mark Kelman and Nicholas Richman Kelman, *Revisiting the City Recognition Heuristic* (unpublished working paper, 2008), much of which is repeated in Chapter 5 of *THE HEURISTICS DEBATE*, *supra* note 14. *See also* Ben R. Newell & David R. Shanks, *On the Role of Recognition in Decision Making*, 30 *J. EXPERIMENTAL PSYCHOL.: LEARNING, MEMORY & COGNITION* 923 (2004); Daniel M. Oppenheimer, *Not So Fast! (and Not So Frugal!): Rethinking the Recognition Heuristic*, 90 *COGNITION* B1–B9 (2003); Rudiger F. Pohl, *Empirical Tests of the Recognition Heuristic*, 19 *J. BEHAV. DECISION MAKING* 251 (2006); Tobias Richter & Pamela Spath, *Recognition Is Used as One Cue Among Others in Judgment and Decision Making*, 32 *J. EXPERIMENTAL. PSYCHOL.: LEARNING, MEMORY & COGNITION* 150 (2006).

29. The distinction among these three forms of hindsight bias—which are too often inadequately distinguished in the literature—was highlighted in Mark Kelman, David E. Fallas & Hilary Folger, *Decomposing Hindsight Bias*, 16 *J. RISK & UNCERTAINTY* 251 (1998). The seminal work on hindsight bias is Bernard Fischhoff, *Hindsight ≠ Foresight: The Effect of Outcome Knowledge on Judgment Under Uncertainty*, 1 *J. EXPERIMENTAL PSYCHOL.: HUM. PERCEPTION & PERFORMANCE* 289 (1975). A good summary of the literature can be found in Jay J.J. Christensen-Szalanski & Cynthia Fobian Willham, *The Hindsight Bias: A Meta-Analysis*, 48 *ORGANIZATIONAL BEHAV. & HUM. DECISION PROCESS* 147 (1991).

30. Jonathan D. Casper, Kennette Benedict & Jo L. Perry, *Juror Decision Making, Attitudes,*

The cognitive error explanation is that they overestimate the ex ante probability of finding contraband if it is indeed found. But, of course, it is possible that they are implementing an additional or substitute norm beyond the one they are explicitly directed to attend to and that the experimenters impute as their only conceivable end. They may believe, at least to some extent, that only the factually innocent—those without contraband—should be protected from intrusive searches.

### *B. Death and Dying*

The basic case I will deal with grows from my own experience as a cancer patient. In the spring of 2008, I was diagnosed, after an eight-month monitoring period, with a rare form of cancer, a retinal melanoma. The disease is more complicated than I will explain, in large part because it is considerably more complicated than I understand. I will also largely omit the details of the space-age treatment I received. Suffice it to say that a doctor looking suspiciously like the Wizard of Oz first implanted tiny metal balls in my eye. Having the little metal balls in one's eye permits the relevant radiologists to transform X-ray pictures of the tumor into something that seems awfully like an accurate 3D video game target. The target is briefly zapped by "external beam" proton radiation administered not in a medical facility but in a physics department building housing a mildly out-of-date linear accelerator that pretty closely resembles a warehouse in which terrorists on the TV show *24* would be assembling a suitcase bomb or Jack Bauer would be torturing these same terrorists off-site. What I want to account for is an intuition that helps illuminate the difference between dying and death. To simplify, I will assume completely counterfactually that there is a single follow-up visit in which one can not only learn that the treatment failed but also learn that it "succeeded." My intuition is that I would have readily made the following trade: Instead of facing my actual low odds of a "bad" follow-up (again, to simplify, treat them as 1 in 100), I would, if I could, have chosen to reduce those odds to zero in exchange for a substantially higher increase of, say 1 in 50, in my background global risks of dying suddenly and without warning (think lightning, think wayward buses, think an instantly fatal heart attack or stroke) during the same period in which the melanoma realistically could metastasize and kill me. If I am right that I would have made that trade,<sup>31</sup> the question that arises for me is whether I failed to meet

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and the Hindsight Bias, 13 L. & HUM. BEHAV. 291 (1989).

31. I am absolutely confident that I would have made the trade but for the fact that I have a wife and children. Death obviously affects third party survivors (one hopes a great deal in the case of wives or kids), whether or not it affects me (At all? A great deal?). But had I been acting wholly selfishly, it would have been easy to accept the trade-off I posit between a higher risk of death and avoiding the dread of death.

the only rational end one could attribute to me—the desire to maximize my life expectancy. I might have manifested this precise action preference (take the objectively higher risk) solely because cognitive bias led me to misapprehend what my actual life expectancy would be making each choice. Is it rational, though, to dampen the existential anguish of becoming a *dying person* by getting the diagnosis that my treatment had worked, even at the cost of increasing the still-low odds that I would soon be *dead*? It is crucial to note that I am *not* claiming that everyone would make the trade I claim I would make, or even that most people would; I am simply claiming that it reflects a comprehensible subjective “taste,” rather than a cognitive error.<sup>32</sup>

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32. It is worth noting as well that the subjective taste may be a product not of the form of error that I discuss at length in the text—that I am miscalculating the probability of death. It is also possible that I improperly estimate how badly I will feel if I indeed learn that I am dying relatively imminently, basically because I, like most subjects, underestimate the degree to which people hedonically adapt to most circumstances. Many researchers have argued that our affective forecasting is poor—we overestimate how good we will feel when something good happens (e.g., we think it will make us happier than it does to get tenure or win a lottery) and how bad we will feel if something bad happens (e.g., if we don’t get tenure or have a disabling accident). The standard account, with explanations and data-based support, is given in Daniel T. Gilbert et al., *Durability Bias in Affective Forecasting*, in *HEURISTICS AND BIASES*, *supra* note 10, at 292. See also Shane Frederick & George Loewenstein, *Hedonic Adaptation*, in *WELL-BEING: THE FOUNDATIONS OF HEDONIC PSYCHOLOGY* 302 (Daniel Kahneman, Ed Diener & Norbert Schwarz eds., 1999). If there are indeed “real” biases in affective forecasting, there may well be significant policy implications. For instance, non-disabled people may underestimate the actual quality of life of those with disabilities, mistakenly projecting how they think they would react to disability on to people whose actual reactions are far less adverse; this might lead those who implicitly or explicitly ration health care to undervalue life-saving steps that risk disability or extend the life-span of those with disabilities or lead juries to overcompensate those whose injuries result in disabilities. These implications are explored, for instance, in Samuel R. Bagenstos & Margo Schlanger, *Hedonic Damages, Hedonic Adaptation, and Disability*, 60 *VAND. L. REV.* 745 (2007).

Again, it is not by any means central to my point here, but there are reasons to be skeptical about the empirical findings of those who claim that people hedonically adapt to bad news: for a variety of reasons that I have explored at length in other writing, it is at least plausible that Daniel Kahneman is correct that seeming hedonic adaptation is a reporting error—that people’s moment-by-moment experiences really are worse when bad things have happened and better when good things have but that they *report* reasonably high “overall satisfaction” levels because they report such levels relative to a downward shifting baseline of expectations. Kahneman’s basic argument is laid out in Daniel Kahneman, *Objective Happiness*, in *WELL-BEING: THE FOUNDATIONS OF HEDONIC PSYCHOLOGY*, *supra* note 32, at 3, 11-12. For a somewhat critical discussion of his view, see Mark Kelman, *Hedonic Psychology, Political Theory, and Law: Is Welfarism Possible?*, 52 *BUFF. L. REV.* 1, 52-54 (2004).

What seems more bothersome to me, though, about the hedonic adaptation literature is that, taken seriously, it tells us very little about the impact of shifts in life circumstances, whether policy-sensitive or not; its sole lesson, it seems, is that nothing much matters. To the extent that we

### 1. *The Possibility of Cognitive Bias*

There are a number of reasons to believe that while I am able to say, “I would trade a 1 in 100 chance of death for a 1 in 50 chance”—that I actually subjectively processed the 1 in 100 chance of death I was discarding as *higher* than the 1 in 50 chance I was ostensibly trading for. It is not at all implausible that I miscomputed the relative probabilities of dying if I took option one (sure cure from melanoma) rather than two (increased sudden death vulnerability) and that it was miscalculation, and only miscalculation, that made the irrational trade seem sensible. Let me just touch on three of the many possible reasons, drawing on the H&B literature, that I might have miscomputed the probability of death. People might make the precise same mistakes when thinking about the more general question I am addressing. People might miscompute the relative death rates that will result from taking life-saving rather than peril-preventing steps, even when given bottom-line probabilities to work with:

*Availability heuristic:* Death from retinal melanoma, or from any source so well-defined that we are considering saving a person from the peril she is in, had become incredibly salient to me. The thought or prospect of dying in that particular manner was therefore readily “available” or easily retrieved from memory. Ordinarily, of course, judging the frequency of events by reference to their availability is not just quick and easy, but accurate. We typically recall things most readily when we have been exposed to them more frequently, and we have typically been exposed to things more frequently when they indeed occur more frequently. But we may *substitute* availability for more considered multi-cue judgments of frequency even when events are available solely because they are emotionally salient.<sup>33</sup> Thus, I may have thought that death from retinal melanoma was far more common than I purported to “know” it really was, because it was the most readily pictured and recalled form of death. Whether we make this cognitive error because we have directly come to confuse availability for frequency and rationally base predictive probability judgments on past frequencies or

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develop a measurement schema that tells us that all states are fundamentally the same (prison, cancer, good marriages, messy divorces, high income, squalor), it might be appropriate to question the schema—whether this entails moving from a focus on distinctions in hedonic states to a focus on distinctions in capabilities, for example, or to a focus on the satisfaction of preferences, or whether it requires us merely to do a better job reflecting on how hard it is to measure hedonic states.

33. The seminal work on the availability heuristic is Tversky & Kahneman, *supra* note 12. For a very good review essay on the pioneering work on availability, see Shelley E. Taylor, *The Availability Bias in Social Perception and Interaction*, in JUDGMENT UNDER UNCERTAINTY: HEURISTICS AND BIASES 190 (Daniel Kahneman, Paul Slovic & Amos Tversky eds., 1982).

because we compute frequencies by sampling events retrieved from memory is controversial.<sup>34</sup> Whatever the reason, it is surely possible that my actual, *working* subjective estimate of the probability of death from retinal melanoma was much higher than what I ostensibly learned it to be. That is to say, I “thought” that to be cured of the melanoma was to defuse a risk considerably higher than 1 in 100, and I judged the trade I had proposed based on these distorted subjective probabilities.

*Affect heuristic:* Both academic psychologists in the H&B tradition and clinicians who use “cognitive behavioral therapy” techniques believe that people’s cognitive judgments often reflect the strength of their emotional reactions to situations. Whether we call this an “affect heuristic” (following Slovic and the H&B researchers)<sup>35</sup> or “emotional reasoning” (following modern-day cognitive behavioral therapists like Burns),<sup>36</sup> the mechanism is much the same. We treat the intensity of our fear of an event as diagnostic of the actual danger of the event. Since we are often afraid when events are objectively scary, we come to think that events must be objectively scary if we are afraid, even though our emotional reactions may have a multiplicity of sources. Again, to take my own case, it is perfectly plausible that my focus on and fear of both the follow-up visit itself and death by melanoma (availability may do its work through its impact on affect) made me believe that there was an “objectively” higher probability of dying from the disease than I ostensibly “knew” there was.

*Distortions in Aggregating Alternatives:* People may have a great deal of trouble comparing probabilities of aggregated outcomes, rather than comparing the probabilities of the most salient members of groups. Let me take an example from experiments on lottery choices: consider two possible lotteries in which the objective probability of drawing a winning ticket is 20% (15 of 75). In each case, one wins if one draws one of the fifteen “blue” cards from the pile and loses if one draws one of the other sixty cards, which come in seven different colors, that one might draw. Most experimental

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34. For a fuller discussion of this controversy, concluding that ease of recall is the mechanism that dominates when subjects make “trivial” judgments and pseudo-sampling is the mechanism they use in making highly personally salient judgments, see Norbert Schwarz & Leigh Ann Vaughan, *The Availability Heuristic Revisited: Ease of Recall and Content of Recall as Distinct Sources of Information*, in *HEURISTICS AND BIASES*, *supra* note 10, at 103.

35. See Paul Slovic et al., *The Affect Heuristic*, in *HEURISTICS AND BIASES*, *supra* note 10, at 397. A similar argument is proffered in George F. Loewenstein et al., *Risk as Feelings*, 127 *PSYCHOL. BULL.* 267 (2001). An actor seeking to avoid health or safety risks might substitute his level of emotionally charged fear of X (rather than Y) for a (more relevant) considered judgment that X is actually the more serious threat.

36. DAVID D. BURNS, *WHEN PANIC ATTACKS* (2006).

subjects “feel” much better about entering a lottery with 15 winning blue tickets when the other 60 losing tickets come in bundles of 12 of one other color, 11 of another, 10, 8, 8, 8, and 3 rather than 29 of one other color, 10 of another, 10, 4, 4, 2, and 1.<sup>37</sup> Again, there are a variety of explanations for this phenomenon. I happen to be most drawn to the idea that we quickly compute the probability of drawing a winning ticket relative to the probability of drawing the single most probable alternative sort of ticket and then get “anchored” to the idea that we have a good or bad ticket, but the explanations for the finding are essentially beside the point.<sup>38</sup> The relevance to my case is fairly straightforward: all the “losing tickets” associated with death from retinal melanoma were of a single sort while the increased odds of death I was willing to take on were diffused across many, many alternative forms of “losing tickets,” none of which seemed common enough to be judged as especially probable relative to death from retinal melanoma. A single event with a 1 in 100 probability might seem more probable than a diffuse group of events with an aggregated probability of 1 in 50—internally labeled or constructed as the “alternative event”—so long as none of the constituent events constituting the alternative has a probability nearly as high as 1 in 100.

At the same time, it is possible that I not only misapprehended the actual relative probability of dying from the melanoma and dying from “increased diffuse risk”—even though I had stated the trade in terms that explicitly referred to the higher probability of dying from increased diffuse risks—but that I was subject to rationally indefensible framing effects. These framing effects arguably made me evaluate freedom from risk of my melanoma differently than I evaluated freedom from the hypothetically equivalent or greater risks I would voluntarily choose to take on.

So, again, here’s one of many plausible framing mechanisms I might have used that has been identified in the H&B literature that might account for this: subjects are told that a disease has been discovered that will kill 600 persons if

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37. See Paul D. Windschitl & Michael E. Young, *The Influence of Alternative Outcomes on Gut-Level Perception of Certainty*, 85 ORG. BEHAV. & HUM. DECISION PROCESS 109 (2001).

38. One could argue that this phenomenon is not radically different from selections made in accordance with “contrast effects.” Subjects asked to pick between a Mark Cross pen and \$6 are more likely to pick the pen if also offered a markedly inferior pen (thus violating a cardinal principle of rational choice—that the presence of irrelevant alternatives should not impact a decision between two relevant ones). My intuition has always been that such contrast effects also arise from the fact that one judgment is easy—the Mark Cross pen is preferable to the cruddy pen—and that subjects then anchor to the choice of the Mark Cross pen when they have to make the more difficult choice between the pen and the cash. See Tversky & Simonson, *Context-Dependent Preferences*, *supra* note 13; Mark Kelman, Yuval Rottenstreich & Amos Tversky, *Context-Dependence in Legal Decision Making*, 25 J. LEGAL STUD. 287 (1996).

untreated, and asked to select between two alternative treatment programs. Most pick a program that will *save* 200 lives over one with a 1/3 chance of saving 600 and a 2/3 chance of saving none. At the same time, they pick a program with a 1/3 chance that no one will die and a 2/3 chance that 600 will die over a program in which 400 will surely die.<sup>39</sup> They make these distinct choices even though the programs are substantively identical; the outcomes are merely framed differently.<sup>40</sup> People may indeed be risk seekers when it comes to avoiding deaths (losses) and risk avoiders when it comes to being saved (gains). I may have construed myself as already dying from melanoma and constructed freedom from that form of death as a gain, as a form of being saved, and I was risk averse when it came to being saved, while I was a risk-seeker when thinking about dying from *new* diffuse risks, events that I would construe as losses.

In thinking about the conventional literature on the identifiable victims effect, it is important to realize that individuals who thought that those who would willingly devote some sum \$X to save the identified person rather than, say, 50 unidentified persons, were making just these sorts of computational errors. Thus, for instance, in their first set of experiments—which they subsequently substantially disclaimed for reasons I will return to in the discussion of whether our subjects are non-consequentialists rather than failed consequentialists—Loewenstein and various colleagues dominantly attributed the identifiable victims effect either to a computational error or an irrational projection from an individually rational decision to one that is irrational when

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39. This well-known problem was originally presented in Amos Tversky & Daniel Kahneman, *The Framing of Decisions and the Psychology of Choice*, 211 *SCI.* 453 (1981).

F&F theorists believe that the finding is a perfect exemplar of misleading H&B experiments. The claim, at core, is that experimental subjects are interpreting the instructions with a better ear for the conversational implications of the words the experimenter utters than the experimenter have: When we tell the subjects that 200 people will be saved by treatment 1, it leaves open the possibility that more than 200 people will live even though they have the disease. When we say that 400 people will be dead after treatment 2, those 400 people are once-and-for-all goners. A program that “saves” 200 (and leaves open the possibility that others will not die) really is better than one that certainly results in 400 deaths. See Anton Kuhberger, *The Framing of Decisions: A New Look at Old Problems*, 62 *ORG. BEHAV. & HUM. DECISION PROCESSES* 230, 231 (1995).

The critique is certainly not implausible, a priori, but it is probably wrong: the fact that experimental subjects with generally superior cognitive skills more typically give the “rational choice normative” answer rather than the answer subject to “framing effects” makes it seem unlikely that subjects are interpreting the instructions in a more nuanced way than the experimenters intended. See, e.g., Keith E. Stanovich & Richard F. West, *Individual Differences in Reasoning: Implications for the Rationality Debate*, in *HEURISTICS AND BIASES*, *supra* note 10, at 421, 436-39.

40. In each case, one is deciding between a 1/3 chance that all 600 people will live and a 100% chance that 200 people, or 1/3 of the people at risk, will live. In the first case, we *frame* the certain outcome as a gain (*saving* 200), while in the second, we frame it as a loss (400 *dying*).

made for a group.<sup>41</sup> It might seem, at first blush, that people would recognize that one saves more lives with an \$X investment if one saves 50 people from developing a fatal malady or dying in an accident than if one saves a smaller number of known persons in peril. Most people reason, however, about the efficacy of their actions by looking at the *proportion* of good results they achieve.<sup>42</sup> A public health preventative measure might save 50 of 5 million lives (a high number, but a very low proportion) while saving Baby Jessica saves “one of one.”<sup>43</sup>

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41. See Jenni & Loewenstein, *supra* note 2.

42. This point is also made, without reference to the identifiable victims effect, in James Friedrich et al., *Psychophysical Numbing: When Lives Are Valued Less as the Lives at Risk Increase*, 8 J. CONSUMER PSYCHOL. 277 (1999). When asked to indicate how many lives they felt must be saved to justify an \$850 million investment in improved braking systems, 62% of respondents required more lives to be saved when the number of lives at risk was larger. *Id.* at 285. See also David Fetherstonough et al., *Insensitivity to the Value of Human Life: A Study of Psychosocial Numbing*, 14 J. RISK & UNCERTAINTY 283 (1997).

43. “According to the proportion of the reference group at risk explanation, there is not a strict dichotomy between identifiable and statistical lives. Instead, identifiable victims lie at one end of a continuum running from low probability risks spread over the entire population (statistical deaths) to certain deaths for every member of the population ‘identifiable deaths.’” See Jenni & Loewenstein, *supra* note 2, at 239.

Thinking in terms of proportions might be a simple cognitive error in one of two ways. Jenni and Loewenstein highlighted the degree to which individuals find it rational to spend more to reduce risks in their own cases by a fixed amount from a higher baseline rate than from a lower baseline—perhaps echoing Weinstein et al.—because doing so involves the loss of bequest-directed rather than own-consumption-directed income. See, e.g., Milton C. Weinstein, Donald S. Shepard & Joseph S. Pliskin, *The Economic Value of Changing Mortality Probabilities: A Decision Theoretic Approach*, 94 Q.J. ECON. 373, 374-75, 385-89 (1980). But in spending to save others, one is spending own-consumption-oriented income in either case, so the projection from self-interested certainty effects to outward-directed ones would be problematic. It is also possible that people simply overestimate probabilities close to one relative to more modest probabilities.

What is striking, too, regarding the possibility that we are dealing with cognitive error in thinking about proportions, rather than that there is something special about the salience or affect-provoking qualities of the identifiable is that psychophysical numbing—the tendency to value some fixed number of lives X to be saved as more valuable when X is a high proportion of the lives at risk—seems to closely parallel a well-known phenomenon in marketing: people react less to the absolute number of dollars they will save when offered a discount than they react to the percentage discount they will receive. These parallels are explored in detail in James Friedrich et al., *Psychophysical Numbing*, *supra* note 42, at 279-80, 296. For the standard study on the perception of price discounts, see Timothy B. Heath, Subimal Chatterjee & Karen R. France, *Mental Accounting and Changes in Price: The Frame Dependence of Reference Dependence*, 22 J. CONSUMER RES. 90 (1995). Similarly, people value *time* inconsistently in discount-shopping: Far more people will spend a half hour to get a 50% discount on a \$100 item (worth \$50) than will spend the same half hour to get a 5% discount on a \$1000 item (also worth \$50). See, e.g., Richard



Similarly, while the identifiable victims effect seems to persist even in cases in which the victims are not described vividly (no thick identifiability), it is possible that the effect is often created in part by a miscalculation of risk based on either the affect heuristic (vividly described persons evoke strong emotions that create a sense that we are responding to something urgent) or availability (the peril of vivid people is pictured most readily).<sup>44</sup>

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Thaler, *Mental Accounting Matters*, 12 J. BEHAV. DECISION MAKING 183, 186 (1999); Amos Tversky & Daniel Kahneman, *The Framing of Decisions and the Rationality of Choice*, 211 SCI. 453 (1981).

It is also possible that we care about the deaths of high proportions of reference groups for reasons that are wholly rational—if, for instance, the reference group that would be wiped out is not defined by simple identifiability but by virtue, say, of its cultural heritage. Jenni and Loewenstein acknowledge this point, but do not seem to realize that if one pushes it hard enough, one might become skeptical of the significance of identifiability per se:

Given that reference group size is often a matter of framing—a reference group of arbitrary size can be specified for virtually any hazard—a blanket endorsement of a policy that treats fatalities differently based on what proportion of the reference group they compose is normatively dubious. For example, it probably makes no sense to treat a disease that kills 100% of the 10% of the population susceptible to it differently from one that kills 10% of the 100% of the population susceptible to it. *However, some reference groups may be more normatively defensible than others. Thus, even after careful consideration, one might be more upset about a disease that kills an entire family or people in a small geographic area than one that kills a similar number of victims from around the country.*

See Jenni & Loewenstein, *supra* note 2, at 239-40 (emphasis added).

But then think about whether we would and should be more upset about a rare, fatal hereditary disease that will kill half the population of a small, culturally endangered tribe; even though the victims are not strongly identified, at least if identification requires *individuation* (we don't know which tribe members will die), we might rationally spend more to prevent those deaths than to prevent a similar number of deaths diffused over the nation's population, even if we could identify the diffuse victims because the death of a high proportion of some groups rather than the death of a high proportion of a wholly arbitrary "group" might have effects beyond the sum of the personal tragedies.

44. Jenni and Loewenstein raised the possibility that the identifiable victim effect is caused by the vividness of the identifiable victims, though they did not think the early experimental evidence strongly supported this explanation. See Jenni & Loewenstein, *supra* note 2, at 235, 237. Loewenstein (and colleagues) largely reject the explanation even more thoroughly in a set of later experiments that I discuss in talking about agent-relative judgments (*see infra* note 48); the gist of the experiments is that people will give more to a certain number of charitable beneficiaries selected from a pool of potential beneficiaries (because the pool remains the same size, the proportion-of-saving explanation drops out) *merely if they are told that the persons who will receive their gifts have already been selected, without any further information about them.* (They are thus—at least seemingly—no more vivid, as well.) See Deborah Small & George Loewenstein, *Helping a Victim or Helping the Victim: Altruism and Identifiability*, 26 J. RISK & UNCERTAINTY 5 (2003).

Loewenstein and his colleagues do not explore one last possible explanation, explicitly grounded in the H&B literature on scope neglect. Subjects making use of the representativeness heuristic typically neglect the scope of a problem. They are willing to pay little more to save 10,000 birds from an oil spill than to save one, because their view of the severity of the problem is grounded in thinking only about the representative instance, the bird pictured as stuck in the oil.<sup>45</sup> If that is right, we should not be surprised to find that people are willing to spend less *per life saved* on large-scope statistical deaths. If 1000 drowning deaths caused by the failure to shore up the levees seem no worse than 1 drowning death caused by the failure to save the representative victim—say, an elderly, immobile flood victim stuck up on the roof of her rapidly disappearing building—then it is no great shock that people would be willing to spend the same amount on each. If they do that, though, they will spend far less per life in the former case.

## 2. *The Possibility of Unacknowledged Goals: Death, Dying and Dread*

I acknowledge, then, that it is absolutely *possible* that my intuitive sense—that I would voluntarily choose to lower my life expectancy—was grounded in the very same sorts of irrationality that H&B researchers have always highlighted. But at the same time, I want to note the strong possibility that I had an entirely separate end. There are, in this view, two distinct things that I sought to eliminate, and they are not equally present in the situation I was willing to accept and the situation I was eager to put an end to. The one that we have already focused on, of course, is death, and the intuition that the trade I claim I would have made is irrational is grounded in the idea that it seems to reveal that I would have preferred a higher chance of undesired death to a lower chance. What I want to argue, though, is that there is an entirely separate, and conceivably more significant harm that I was trying to avert by accepting my imaginary trade: a focused awareness that I had tipped over into the world of persons who were

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I am not fully convinced that identifiability can ever be experimentally dissociated from vividness, or at least I am not convinced that it has been in the existing experiments that purport to do so. As soon as we believe individuals are identified, we may fill in details of their lives and doing so makes them vivid, even though we are making them more vivid on the basis of imagined traits. (Recall, too, in this regard the problem I raised earlier—of whether we can think about the lives that might be saved by expensive counter-terrorism measures as purely statistical. I am dubious that we can know, first, whether those evaluating such expenditures treat these saved lives as purely abstract and statistical or as identifiable and vivid, because they may first project past well-known deaths from terrorism—Flight 92 victims, World Trade Center victims—to the purportedly abstract lives, and then give the putative victims—projection of past victims—vivid, if imaginary mini-biographies.)

45. See William Desvousges et al., *Measuring Resource Damages with Contingent Valuation: Tests of Validity and Reliability*, in *CONTINGENT VALUATION: A CRITICAL ASSESSMENT* 91 (Jerry Hausman ed., 1993).

*dying*. I sought to fight off the awareness that I had become a person who would be unable to escape the dread of death, unable to maintain the reassuring fantasy that we typically maintain until we confront the strong possibility of fairly imminent death that life stretches out, if not precisely infinitely, at least indefinitely.

First, let me emphasize the point that death and dying are *different* negative experiences. I need not believe, nor convince anyone else, that death itself is of no moment psychologically. Still, one should acknowledge that there is a perfectly defensible, if controversial and stunningly counterintuitive, position, dating back to Epicurus, that at least for those who do not believe in an afterlife, death is neither bad nor good, in welfarist terms at all. This is fundamentally true because, unlike dying, no subject ever experiences it.<sup>46</sup> Note that one of the many disquieting implications of this view is that killing causes no harm to anyone but grieving survivors.<sup>47</sup>

The view that death has no welfare consequences is powerful. To the extent that one's intuitions about welfare are fundamentally Benthamite—a person's welfare is measured by the sum of his positive pleasures and his negative pains,

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46. Here is one of many versions of the position typically associated in the metaphysics-of-death crowd with Epicurus, the source of this quote:

Death is nothing to us. For all good and evil consists in sensation, but death is deprivation of sensation. And therefore a right understanding that death is nothing to us makes the mortality of life enjoyable, not because it adds to an infinite span of time, but because it takes away the craving for immortality. For there is nothing terrible in life for the man who has truly comprehended that there is nothing terrible in not living. [Death] does not . . . concern either the living or the dead, since for the former it is not, and the latter are no more.

The position associated with Epicurus is defended in Stephen E. Rosenbaum, *Epicurus and Annihilation*, in *THE METAPHYSICS OF DEATH* 267 (John M. Fischer ed., 1993).

47. The legal implications of this view are explored in considerable detail in Matthew D. Adler, *Risk, Death and Harm: The Normative Foundations of Risk Regulation*, 87 MINN. L. REV. 1293, 1299-1301, 1389-1444 (2002-03). Adler also reviews defenses and critiques of the claim that death is not a harm to the person who dies, concluding ultimately that death does harm the person who dies, so long as we think of a policymaker or the person P who might die herself comparing P's lifetime well-being to the lifetime well-being of some P' who is just like P but for the fact that P dies at an earlier age. It is less obvious to Adler that we can make any meaningful statements about whether the *momentary* well-being of P' is lower, higher, or the same as the momentary well-being of P at some point in time when P is still alive and P' is dead because it is inaccurate to describe P' as having some hedonic state at all. Her state is not "neutral;" rather, it does not exist. Nonetheless, Adler thinks P' is worse off whether we think of the party's welfare hedonically (defining hedonically superior states as desired states rather than as states that give rise to a single preferred emotion like "pleasure," but without regard to whether the desired states are experienced) in terms of her as having superior objective capacities or in terms of satisfying her preferences. *Id.* at 1303-10, 1321-40.

each of which must be experienced—it takes some not entirely easy or satisfactory work to get to the view that death “harms” the once-living person. Being dead is obviously neither painful nor pleasurable.<sup>48</sup> While a hedonic utilitarian trying to maximize *aggregate social welfare* could readily recommend a policy that minimized death if living people, on average, had lives that delivered more pleasure than pain, since doing so would improve the aggregate pleasure/pain balance, this sort of preference for death-averting practices would have no distinct force from the dubious utilitarian case for pro-natalist policies.<sup>49</sup> Dead S is not really distinct from never-born S. While replacing dead S with some alive S could increase social welfare, it is simply by virtue of creating a placeholder for a relativistic utility calculus that must be performed by others, rather than by virtue of his or her “own” hedonic state.<sup>50</sup> Moreover, even if all we

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48. The most prominent attack on the position associated with Epicurus is an attack by Nagel, who argues that a person is harmed if he is deprived of the opportunity to have positive experiences. See Thomas Nagel, *Death*, in *THE METAPHYSICS OF DEATH*, *supra* note 46, at 67. It is clear that the aggregate quantity of social welfare is reduced if a positive experience does not occur. It is unclear, however, that any individual is harmed if he does not have an experience since there is no such thing as an individual incapable of having experiences with whom one could compare an individual who has them.

49. I hope the arguments in the text are clearly distinct from familiar arguments about whether a utilitarian should maximize total utility rather than average utility. For discussions of this distinction, see, for example, JOHN RAWLS, *A THEORY OF JUSTICE* 22, 161-64 (1971). Obviously, killing a person or preventing the birth of a person with below-average utility would increase average utility, but so long as she had positive utility, her birth or survival would increase total utility. I am assuming in the text for simplicity's sake that encouraging birth or survival as social welfare aggregative policies would increase both total and average utility. I mean merely to question whether a hedonic utilitarian can readily conclude from that fact alone that the once-embodied individual S who dies or the hypothetical S who was never conceived is “better off” hedonically, in some morally significant sense, than S who survived or some arbitrarily selected person S, matched as the never-conceived non-S's “comparison partner.” The question in some sense goes to whether aggregate utilitarianism requires giving moral meaning to an imaginary reified collective entity, and that it is not really possible to think morally about anything but real entities. The argument in the text can be partly translated in the following terms: we could know that a policy of “conceiving S” improves total or average utility but still have little idea what it would mean to say that “unconceived S” would be better off if he were conceived, since assigning him a comparison person is wholly arbitrary. It is similarly not clear that once-living S is any more rightly paired with still-living S; dead and never-conceived S may well be indistinguishable non-subjects.

Still, it is worth noting that from the vantage point of the individual, death will always lower his average and total utility if living hedonic states are positive, while if one is merely toting up social welfare functions, the death of someone who we conceive of as harmed by death could still *increase* average utility.

50. It would seem inadequate to say that death is precisely like (neither better nor worse than) never having been born in hedonic utility terms even if the only way we can understand each is that

are attempting to do is to make aggregate social welfare judgments, policy may be indeterminate in a fashion that reveals that the dead and never-born have no particular utility level. What if we could only increase the number of births by allowing some to die? Would we have any way of ascertaining whether death is worse or better than non-birth from a hedonic welfarist viewpoint when neither the dead nor the never-born feel anything?<sup>51</sup>

At the same time, the view that death does not harm is powerfully unpersuasive and almost gallingly paradoxical for those whose most fundamental utilitarian intuitions are framed by preference utilitarianism. When the hold-up man says, “your money or your life,” nearly everyone eagerly chooses to hand over his money and almost surely thinks he has never cared nearly so much about getting what he prefers. What we learn from that decision, though, is that death seems worse than the loss of money, and we certainly treat *this* as a substantial harm.

But the paradox is not so readily resolved for the sub-set of preference utilitarians who believe, at core, that satisfying preferences is not an intrinsic source of utility, but instead that our preferences are merely better or worse predictions about the hedonic satisfaction we will gain from the end-states we choose to achieve rather than those we choose to forego. In this view, preference utilitarianism is not so much a theory of the sources of or the definition of utility; rather, it emerged merely as a reactive response to the obvious flaws of early hedonic utilitarianism. The Benthamite hedonic utilitarians had not given a satisfactory response to the primary accusation against them: the charge that they assumed a very narrow, non-catholic set of plausible tastes. Here was the basic problem: Why should every subject care only about pleasure or pain? What about the dutiful? What about the masochistic?<sup>52</sup> At the same time, preference

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each state is less “utility-producing” than living. Surely we cannot explain the sorts of preferences we will soon explore about dying by comparing them to preferences about never having been born; as difficult as it may be to contemplate the *cessation* of one’s subjectivity and consciousness, the notion that we can contemplate a particular pre-conscious or pre-subjective “being” seems even more strained. What the comparison misses is precisely what is hard to capture in the hedonic utility framework, the need to associate sensations with subjects. I will not do more than avert here to the more uncompromising aggregative hedonic utilitarian position, best articulated by Parfit, that we ought to care dominantly about experiences—rather than who has the experiences—because subjects are far thinner and more fleeting than we typically imagine, that the sense of subjectivity/personal identity is significantly illusory. See DEREK PARFIT, *REASONS AND PERSONS* 346 (1984). Not surprisingly, Parfit finds it easy to think of non-existent people as fit place markers for a welfare calculus.

51. It is hard to avoid, at this point, contemplating the old joke in which a group of Talmudic scholars ruminate on whether it is better to have been born or never to have been born before the wisest one settles the argument with the pronouncement, “Gentlemen, I think we would all agree that it is better never to have been born. But how many are so lucky: one in a thousand?”

52. See JAMES GRIFFIN, *WELL-BEING: ITS MEANING, MEASUREMENT AND MORAL IMPORTANCE*

utilitarianism, defined once again as a mere negative reaction to the problems of Benthamite thinking, was not only more catholic about tastes (pleasure is good only insofar as a subject desires it more than, say, duty fulfillment), but was also not subject to the criticism that utilitarians could not say whether option 1 was “better” than option 2 because the pleasure and pain that would result from each option were not tractable, commensurable, nor measurable constructs. Hedonic utilitarians require unavailable cardinal utility measures. The preference utilitarian, however, could extol one option so long as subjects could provide ordinal rankings.

Still, preference utilitarianism, again, defined negatively and reactively, remains conceptually wedded to a more catholic, less pain-and-pleasure centered form of hedonism, or at least what might be better dubbed “experientialism.” Satisfying preferences is not necessarily intrinsically utility-enhancing. It is just the best way of guessing or estimating what made people satisfied, given their catholic attitudes about what ends are desirable. Understood negatively or reactively, it did not eliminate the requirement that utility must be experienced by a sentient subject. I may gain utility from the *prospect* that the money I direct in my will to be used for a particular purpose will get used this way, and other living people may gain utility from seeing that decedents’ wishes are respected, but there is no subject who gains utility when my preference that the money be used in a particular way is satisfied after my death.<sup>53</sup>

Assume, then, that one believes that preferences are merely predictors of future hedonic states. Assume further that one is sensitive to the fact that preferences might be poor predictors,<sup>54</sup> particularly if one is under-informed or imprudent. One could then readily argue that the manifest preference for life over death is merely an imprudent or under-informed preference. This would be a hard conclusion to avoid unless it is indeed true that in *some* sense, we could reasonably say that good or even bad experiences turn out to be preferable to no experience. It is not obvious, though, from the vantage point of a hedonic

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8 (1996), for one of the most lucid of many statements of this critique of hedonic utilitarian thought.

53. See generally L.W. SUMNER, WELFARE, HAPPINESS AND ETHICS (1996) (explicating this negative or reactive view of preference utilitarianism).

54. The fact that people may predict hedonic outcomes poorly drove some philosophers and the “new hedonic psychologists” back to hedonic utilitarianism. See, e.g., RICHARD BRANDT, A THEORY OF THE GOOD AND THE RIGHT 246-53 (1979) (expressing one such resulting philosophical position); Daniel Kahneman, Peter O. Wakker & Rakesh Sarin, *Back to Bentham? Explorations of Experienced Utility*, 112 Q.J. ECON. 375 (1997) (presenting one such resulting psychological view emphasizing not only that predictive error was possible, but that it was likely to be ubiquitous given our cognitive limitations). For an excellent summary of the psychological literature explaining how poorly people predict the affective outcomes of their choices, see George Loewenstein & David Schkade, *Wouldn't It Be Nice? Predicting Future Feelings*, in WELL-BEING: THE FOUNDATIONS OF HEDONIC PSYCHOLOGY 85 (Daniel Kahneman, Ed Diener & Norbert Schwarz eds., 1999).

utilitarian what it would mean to say that “no experience” is “less pleasurable” than any sort of experience, good or bad. It is also not obvious for a utilitarian interested in attainment of objective goods, one who believes people are better off when they maximize their “capacity” to achieve whatever ends they happen to seek rather than to maximize their enjoyment of experiences, that a person who is dead is less capable in the relevant sense than someone who is alive because she cannot clearly meet her ends more readily. Once again, though, if preferences are merely predictors of hedonic states, then they are of little moment if they are just bad guesses. Naturally, it is more likely that they are just bad guesses, in relationship to this particular choice, because we are unable to choose between options in a fashion that mimics our typical choice pattern at all (deciding which of two end-states is likely to be more desirable or satisfying along whatever dimensions we care about).<sup>55</sup>

Certainly, it is plausible that when we make the choice between life and death, we have no information or real basis for making a prudent judgment; for the secular, at least, death is a state that is utterly beyond our concrete contemplation. Presumably, the fact that our own death is so incomprehensible is part of what triggers our dread of death. It is almost surely the case that when we contemplate our deaths, we are doing so in a fashion we would acknowledge is significantly grounded in error. As Herbert Fingarette put it, “[S]ince I can’t imagine being dead, I imagine, unwittingly, that I am conscious, a presence in that future world, conscious of it and yet utterly cut off from participation in it. That way of imagining my ‘death’ is confusion because in reality I would not be there to suffer such alienation and longing.”<sup>56</sup> Even if we could contemplate what our own death is “like” to some extent, it is plainly a state we have not learned much about through repeated trial choices, nor—given dread and anxiety about

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55. It might be instructive to return for a moment to note that certain sorts of anti-consequentialists might claim that our “choices” are not made by a utility-computing brain, but by a modularized brain that manifests certain choice or action tendencies because such tendencies are the ones that increased inclusive fitness. In this sense, say, if death-avoidance were instinctive (those who didn’t seek to avoid death would not have reproduced as successfully as those who did), it would be odd to describe death-avoidance as utility-maximizing (or as “normative” in any sense) rather than as merely an inevitable proclivity that each member of our species has. The idea that it is daffy to think about the taste for life over death as a preference—rather than as something more like a central biological defining feature of beings, the pre-desiring core that makes preference possible or meaningful—far pre-dates not only modern evolutionary psychologists, but even Darwin. See, e.g., Arthur Schopenhauer, *The World as Will and Idea*, reprinted in HERBERT FINGARETTE, *DEATH: PHILOSOPHICAL SOUNDINGS* 143-44 (1996) (“[T]he fear of death is independent of Reason. Animals have the fear; yet they do not know death. Every creature born into the world brings this fear with it. This a priori fear of death is simply the other face of the Will to Live, which is what we all are. Just as the concern for self-preservation is innate, so too, therefore is the fear of one’s own destruction.”).

56. See FINGARETTE, *supra* note 55, at 9.

death—is the choice to avert it likely to be one that we would make in a calm, detached, and prudent way.

No matter how one resolves the thorny question of whether death is a welfare-reducing harm at all, it is clear that the desire not to be dying in the perceptible short-term reflects a wish to avoid a *distinct* loss of welfare. The desire not to experience an intense and focused dread of death—an experience that I felt I would have if my particular follow-up visit went badly—is simply *different*. While it may well be the case that the existential dread is itself imprudent unless death is itself a bad outcome, that need not be the case. The person who dreads knowing she is dying soon may dread the life one leads and *plainly* experiences once one knows that.

We may powerfully and prudently dread a period of time in which long-term plans seem pointless, and believe that the experience of recognizing that planning is pointless strips us of central aspects of our identity.<sup>57</sup> Furthermore, we may dread the inability to think that days hold the possibility of significant favorable surprises or variation, and may dread dealing with the discomfort of those around us who know that we are dying. We may dread the loss of the recalcitrant fantasy of indefinite life; the incapacity to imagine or make sense of what nothingness is may be profoundly disquieting. There are reasons that existential psychiatrists press patients to try to recognize that they have all “experienced” nothingness before, in the infinitely long period *before* they were born.<sup>58</sup> But it is hardly

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57. Fingarette argues that what most defines us as people *in the present* is how we exist given a particular conception of both the past and, even more significantly, the future. While we cannot but “live in the present” (in the sense that it is all we experience), it is hardly paradoxical to be focused on plans:

“[L]ive in the moment.” How odd that advice is. Taken literally, it’s utterly superfluous. As if there were any alternative! But what about the future? It’s our nature to live with purpose, to have goals. Shouldn’t we be seriously committed to these? It seems a contradiction to say: Be whole-heartedly committed to the goals you set yourself—but live in the moment.

The paradox is resolved when we examine the inward experience of time. The goals I set for myself, and the future as I see it ahead of me, are present to me now. The past, too, insofar as it exists for me, insofar as it registers in my consciousness, is present to me now.

*Id.* at 73. “[T]o be without purpose is to lack something essential to the fully human mind.” *Id.* at 70.

58. See IRVING YALOM, *STARING INTO THE SUN* 81-2 (2008). Many philosophers who write about the metaphysics of death recognize that if death is merely non-experience, there is no interesting distinction between the time after we die and the time before we are born. Schopenhauer put it elegantly: “Were it the thought of our nonbeing that made death seem so frightening, we ought to shudder, too, at the thought of the time before we ever came to be.” Schopenhauer, *supra* note 55, at 144. But it is plain that as a matter of fact, people dread the loss of experiences they either expect or can at least imagine, not the simple absence of experience. Trying to account for



intuitive to do so, nor is it obvious that it is helpful to describe pre-birth as an experience at all. Freud famously argued it was simply impossible.<sup>59</sup> Above all, perhaps, what is almost surely the most powerful aspect of our dread of death—the dread that we will miss events and people, that something like a magnified version of “curiosity” will go unsatisfied—is something we can experience, in the present, once dying. Take the familiar, illustrative paradigm case: the parent who dreads that she will not be alive for her child’s wedding next summer. The pain that one *knows* one’s curiosity won’t be satisfied is experienced while *dying*: it is neither experienced when dead nor when one does not strongly fear imminent mortality. If I know I will die before my kid gets out of high school, I *know* right now, that there are a host of questions I am anguished to know I won’t have answers to; this is a concrete lived experience.<sup>60</sup> It is likely that a good deal

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that distinction between lost and absent experience preoccupies those who think death is in some ways harmful. For attempts to explore or explain the distinction, see, for example, FINGARETTE, *supra* note 55, at 10-11, which emphasizes that one has a more detailed sense of the events that one will miss in the future—they involve people and situations you can picture in detail—while not having experienced periods of history one can only vaguely imagine is relatively painless; PARFIT, *supra* note 50, at 165-85; and Anthony L. Brueckner & John Martin Fischer, *Why Is Death Bad?*, in *THE METAPHYSICS OF DEATH* 221-22 (John Martin Fischer ed., 1993), which argues that there are situations in which it is rational to care more about what will happen than what has happened.

Plainly, these are very difficult issues to get one’s head around: it seems plain that even if the harm of death somehow involves lost opportunities, we need to account for distinctions between lost opportunities that the subject herself was able to imagine having but for death (death of a competent adult with a sense of her future versus, for example, the death of a baby) and the loss of opportunities that a competent adult realistically imagines she might have in the “ordinary course” of events. (Are we able to muster as much sadness at dying at all as we are at dying young, even though, hypothetically, we could imagine experiences stretching out into the indefinite future if we were not to die?)

59. “We cannot, indeed, imagine our own death; whenever we try to do so we find that we survive ourselves as spectators . . . [A]t bottom no one believes in his own death, which amounts to saying: in the unconscious every one of us is convinced of his immortality.” SIGMUND FREUD, *REFLECTIONS ON WAR AND DEATH* 114 (A.A. Brill & Alfred B. Kuttner trans., 1918).

Yalom argues—on behalf of existential psychiatry—that Freud so radically underestimated the centrality of death anxiety in the intra-psychic lives of patients precisely because he thought neurosis arose from the conflict between the conscious and unconscious mind. Since Freud thought the unconscious mind did not fear death, he thought it unlikely that the “buried” or “repressed” fear of death produced intra-psychic distress. See YALOM, *supra* note 58, at 18-19.

60. Fingarette makes this familiar point well, but makes it in the context of arguing that the preference for life over death is rational, even if death is not a (good or bad) experience.

The truth is that appraisal should depend on how I feel *now* about any particular future, not how I’ll feel then . . . suppose I look into the distant future and see my little grandson, John, as an adult, mature and in mid-life. Since my grandson is only a five-year-old now . . . I can have only the faintest and most uncertain glimpses of what he will be like as an adult. But I hunger to know—and I know I never will. Yet it makes sense for me to

of our dread of death—not dying—comes from falsely projecting that same sense of longing for more knowledge, more experiences, more contact into some post-death future where such longing is not really possible.

I do not mean to downplay the possibility that *positive* hedonic states may also be uniquely available to those who know they are dying soon: capacities to reflect on what gave one's life meaning, to garner sincere honor from others, to get one's practical affairs in order, to say proper goodbyes and to reconcile and accept for instance. I merely need to assert that it is not irrational to believe that those gains could be outweighed by the negative experiences for at least some non-trivial sub-set of subjects. Some people might well prefer to die more slowly and knowingly than simply to be dead, having died quickly and without significant consciousness of impending death, but so long as *this* taste is not universal, my point remains unaltered.

To try to explore further how we might react to *dying*, and to distinguish reactions to dying from those to death, I think it is helpful to reflect on the familiar paradoxes that Broome, among others, has raised in criticizing how policy analysts conventionally value lives.<sup>61</sup> Generally, economists and cost-benefit analysts value lives by measuring the inverse of the shadow price placed on accepting increased or foregoing decreased ex ante risks of death. If we will pay only X dollars more for a product that reduces the risk of death by 1/100, or demand only a Y dollar wage premium to tolerate an increased risk of 1/100, we value life, if risk-neutral, by 100X or 100Y.<sup>62</sup> If “not dying” were like winning a prize in a lottery, this would seemingly be a perfectly reasonable procedure. Broome noted that this valuation method seemed paradoxical since if we knew we were just about to die unless we took some costly step, we would pay so much more than 100X to prevent our death that it would be difficult to explain

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wish now that I'd still be alive to see and be with him. My death means to me now that I will never know his future . . . . All such doomed wishes are real elements of the present subjective meaning of my future death. They are a source of legitimate *present* sadness.

Fingarette, *supra* note 55, at 69. And Fingarette recognizes, to some degree, what I argue in the text: that until one is dying, one maintains a somewhat false belief that planning is always sensible: “As a practical matter, I have always assumed an indefinite period ahead in which life will continue as usual. I *must* assume this. I must look to tomorrow and tomorrow as days of life, even though I know that at some unspecifiable point there will be no tomorrow.” *Id.* at 72.

61. The two basic works are John Broome, *Trying To Value a Life*, 9 J. PUB. ECON. 91 (1978); and John Broome, *Trying To Value a Life: A Reply*, 12 J. PUB. ECON. 259 (1979).

62. For more sophisticated versions of this basic procedure see, for example, Kevin M. Murphy & Robert H. Topel, *The Value of Health and Longevity*, 114 J. POL. ECON. 871, 884-88 (2006), which accounts for distinctions in the value of additional years of life over the life cycle; and W. Kip Viscusi, *The Value of Life: Estimates with Risks by Occupation and Industry*, 42 ECON. INQUIRY 29 (2004), which attempts to account for distinctions in fatality rates within industries and occupations in assessing wage premia that workers must be offered to accept greater risk.

the ex ante prices in terms of conventional attitudes towards risk.<sup>63</sup> Broome's narrow argument, in terms of public cost-benefit analysis, was that the acceptability of public plans was unduly held hostage to random exigencies if one employed the conventional policy analytical procedure: we would accept or reject the precise same program depending on an informational accident. Were victims identifiable? Did we have limited or fuller information about the mortality impact of our proposed action? More particularly, could we find individuals who would know the project would kill *them*, in particular, so that we would have to ask them what they would need to be paid to tolerate the project going forward? Would few, if any, projects pass muster then? But more profoundly, his point was that all estimates of the value of life based on risk tolerance are inadequately informed. In a world where we were smarter and had more determinate information, we could arguably always identify the people who would die from projects now described as merely risky. So either the ex post measures were the apt ones, or we needed to rethink the issue of how to value a life.

I think there are two related points worth raising here, the second perhaps more closely tied to explicating the importance of attending to existential dread. The first, though, is that *neither* the ex ante risk-averting nor the ex post saving perspective are the only ones to take on the value of life. We may better think of the problem as a problem of evaluating *extra time*. We could at least *imagine* taking a whole life utility-maximizing perspective in which people trade off additional lifetime consumption and additional bequests for a defined and certain increase in life years, and make them stick to their judgments. What is critical to note is that the hypothetical trade we are making is *not* between a certain defined long life and lower income, but between lower income and a particular certain *increase* in life years, added incrementally to a still-unknown base life expectancy. That is to say, we can imagine—conceptually if not practically—trading off extra income for one extra year of life without knowing whether that extra year will mean we live for 81 rather than 80 years or for 51 rather than 50 years. What is certain in making the trade-off is the incremental *increase* in time;

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63. See Weinstein, Shepard & Pliskin, *The Economic Value of Changing Mortality Probabilities*, *supra* note 43, at 373-96 (arguing that people rationally spend more to save their own lives when they are at higher risk of death because they are more likely to be “merely” spending money they will bequeath to others, rather than money they would be spending themselves, which they value more highly). This “rational choice” explanation, I suspect, has a germ of truth to it even though, at first blush, it seems rather daffy: to keep safe from all low-level risks would be to change one’s lifetime consumption pattern a great deal. But I am not sure it is wholly right to characterize the person who would spend a lot when she faces a high probability of death as feeling free to do so because she is “only” spending money she no longer cares about rather than that she is suddenly unable to evaluate alternative spending plans as anything but trivial and small and/or that she is unable to spend in the way that people able to maintain the fantasy of indefinite life are able to.

what remains uncertain is life expectancy. (If we imagine instead a trade in which life span were made certain at a particular income cost, the trade would permit us not only to extend the amount of time we spent alive—to trade consumption goods and bequests for time—but to eliminate the anxiety that we might die over a prolonged period in which we now must suffer that anxiety.)<sup>64</sup>

As I noted, I do not believe as a practical matter that any actual market judgments mimic this procedure. The point is that it is distinguishable from attempting to assess whether our distinct reaction to the *risk of death* is more “authentic” or “revealing” than our reaction to *certain death*. Such judgments of the value of extra time were they possible, likely would not reveal a constant dollar value for additional life years at every point in the life cycle. The marginal value of incremental years would almost surely decline quite dramatically—adding years as a younger or middle-aged person (i.e., not dying “young”) would likely seem radically more valuable than adding years in old age. This would almost surely be the case not merely because old age years are likely less enjoyable but, perhaps more significantly, because to the degree most of us intuitively resist Epicurus’s claim that our own death does not harm us,<sup>65</sup> we do so, above all, because we yearn to experience conventionally expected life cycle markers.<sup>66</sup> What is perhaps most critical to recognize is that is quite plausible if this is right that neither the conventional *ex ante* nor conventional *ex post* procedures give us much information about the “value of life.” Judgments about *ex ante* risk-acceptance do not so much measure the value of living (i.e., the value of extra time alive, measured in terms of foregone consumption and bequests) as they measure the value of modest reductions in death-anxiety. And

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64. The fact that anxiety over the possibility of death—the psychically costly fear that any terribly bad headache could be a brain tumor or aneurism, that one must check one’s body for potentially fatal lumps—is different still, distinct both from death and dying—can be seen readily by “playing” an introspective game. Consider whether the following set of life expectancy lowering preferences (that I find totally comprehensible) are coherent: would you prefer an 85-year life expectancy with risk of death at any point in your life to an 83-year life expectancy with 77 years certain and uncertainty thereafter?

But lest you think that dying does not matter, that the concern is *only* about the reduction of mortality *anxiety* (from our normal existential state “indefiniteness” to an unimaginably superior one, “non-anxiety” for some period of certain survival), think about whether you would, like me, pick the 83-year expectancy with 77 years of certain life over an 84-year life expectancy with a certain date of death at 84. (In this scenario, as one approaches 84, one is not *anxious* out of uncertainty—one knows what is coming—but one shifts existential frames from living in denial to dying.)

65. See *supra* notes 47–48.

66. Those with children, for instance, might especially dread not seeing what becomes of them as grown-ups, or seeing grandchildren. Perhaps because we have no models around us of people who live more than eight to ten decades, we don’t have a standard set of experiences in mind that would be wiped out by death in old age.

ex post judgments (especially hypothetical ones in which people give honest responses to what they would now pay—if they only could, by going back and saving what they did not save by taking expensive precautions—to cure them of the incurable diseases or rescue them from the hopeless situations their prior risk-taking caused) are typically merely attempts to have one's cake and eat it too. It is far too easy to say one would now undo choices to consume more or live a more exciting, risky life that may indeed have been perfectly reasonable.<sup>67</sup>

But here is the second point—the point closer to the one I have emphasized throughout Part II about the death/dying distinction. The risk of death is ubiquitous in our lives. We are typically able to background it if we are to avoid paralyzing despair. At most times, our futures are indefinite: a shift within the domain of diffuse, reasonably low risk simply does not alter the sense that our lives still stretch out *indefinitely*. This sense that life stretches out indefinitely has many correlative benefits. We can still care about planning for the future, care about the trivial present without contrasting it with the weightiness of soon-arriving death, feel a rush from the sense of invulnerability or freedom that days are not so finite and precious that any particular day can be badly misspent. We may believe that we will learn the answers to the typically small and personal questions about which we are most curious, that we will not have to soon experience the rupture of relationships. From the ex ante low-risk perspective, it is even plausible to me that most of us truly believe in some hazy, not fully cognized sense that we are immortal: we have only experienced consciousness and a sense of the self, and simply cannot imagine what it would mean for that to end.<sup>68</sup> The ex post perspective kicks in when we have shifted existential frames, when nothing but our death seems of any moment. When we shift existential frames, we would do nearly anything for life chances to appear meaningfully indefinite again.

If it is right that we are rational to dread dying at least as much as we seek to avoid death, then we can readily comprehend a whole range of private and public decisions that seem to increase or do little to decrease the *risk* of death at any point in “normal” time, but try at great cost, to eliminate or dampen the experience of having to shift existential frames.<sup>69</sup>

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67. I have articulated the perspective that it is worth thinking about the value of extra time, not of “life.” This perspective is not enormously distinct from the perspective articulated—in quite different form—by Allan Feldman in a series of unpublished working papers in the late 1990s that I became aware of after I had written this section. See, e.g., Allan Feldman, *The Value of Life Revisited* (Brown Univ. Dep’t of Econ., Working Paper No. 96-2, Jan. 1997).

68. Whether we are maintaining the infantile fantasy that Freud describes, *supra* note 59, that our lives stretch out infinitely, that we are immortal in our unconscious, in part because we cannot imagine what it would be like to be dead, is a separate question. The sense that life’s end is not on the table, not worth thinking about, seems *distinct* from the sense that one is truly immortal.

69. The first social scientist who highlighted the “identifiable victim effect,” Thomas

And now think back to our public policy problems: Isn't it plausible that seemingly excessive investment in life-saving cures rather than prevention is in significant part an effort to reduce the number of occasions in which diagnosis switches people into the state of thorough existential dread? Developing cures, or treatments that make cure seem more possible can at least frequently delay dread until it is accompanied by a level of morbidity that makes the existential dread secondary to physical pain and morbidity. This is definitely *not* to say that the trade-offs we observe *in fact* serve the more complex ends. If we look at the standard sorts of lists of life-saving government programs that note we spend far more money to save lives in some distinct contexts than in others, one does not exactly discover the hidden rationality that I seek. Instead, it appears that a variety of perceptual problems and political pathologies drive death-averting spending levels: undue attention to highly publicized and available death-causing practices<sup>70</sup> and interest group politics.<sup>71</sup>

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Schelling, seems to be the last one who intuitively recognized (though did not pursue) the point that our reactions to identifiable victims invoke our anxieties about our own deaths and dying, as well as feelings of responsibility for the death of others (an issue we will return to in discussing anti-consequentialism), while we could face increases in statistical risk while remaining in the world in which we are largely in denial of death. See Schelling, *supra* note 15. Here was Schelling's basic, canonical take on the identifiable victim's effect:

Let a 6-year-old girl with brown hair need thousands of dollars for an operation that will prolong her life until Christmas and the post office will be swamped with nickels and dimes to save her. But let it be reported that without a sales tax, the hospital facilities of Massachusetts will deteriorate and cause a barely perceptible increase in preventable deaths—not many will drop a tear or reach for their checkbooks.

*Id.* at 129.

To evaluate an individual death requires attention to special feelings. Most of those feelings, though, involve some connection between the person who dies and the person who has the feelings; a marginal change in mortality statistics is unlikely to evoke these sentiments. Programs that affect death statistically . . . need not invoke these personal, mysterious, superstitious, emotional, or religious qualities of life and death.

*Id.* at 131. And here is yet another of Schelling's remarks on the difficulty of thinking about death: "Death is an awesome and indivisible event that goes but one to a customer in a single large size . . . . For many people it is a low-probability event except on special occasions when the momentary likelihood becomes serious." *Id.* at 158.

Schelling was also quite aware that the reduction of anxiety over death could lead people to take steps that would increase their chances of dying. The example he gives is someone who knows a life-saving operation will become necessary at some point, and that the operation itself has some risk of being fatal. He will sometimes prefer to undergo the operation immediately; he thus "raises the stakes against himself" (lowers his life expectancy) to avoid the anxiety associated with the non-trivial, already-present risk of death in the future. *Id.* at 145. It is thus clear, once more, that he recognizes that the dread of death and the harms of death itself were separate.

70. Obviously, the reaction to Baby Jessica herself reflected not just an "identifiable victim" effect—the outpouring for her exceeded the outpouring for other identifiable victims—but the high

Why do we pour so many resources into saving those who are trapped in mines or drifting at sea? Is it in some significant part because there is scarcely anything more dreadful than the acute awareness of imminent, preventable death unaccompanied by other forms of morbidity and suffering? Or, to put the more significant health policy point more provocatively, can we explain our desire to cure rather than prevent illness (to eliminate “diagnosis shock”) but think we do not do enough to insure that most people die from heart attacks, strokes, and accidents, the sorts of deaths that occur without people having to experience a time where they are *dying*? If we could dissociate mortality and morbidity enough to do that, should we? Is the real problem of under-spending on prevention rather than cure that we can’t raise cure rates enough to make it rational to spend less on preventing the development of incurable disease, not that we spend too little on preventing death? To put that last point another way, is it possible current policy is irrational not because it does not focus exclusively on maximizing life expectancy, but because it does not focus enough on preventing lingering, foreseen deaths?<sup>72</sup>

The chief problem, looked at through this lens, is that we cannot realistically hope to funnel far more deaths into sudden unexpected death, and people typically discount—or fail to imagine—the possibility that the steps they take now will put them in the position of *dying*, not just being dead, later. The problem is not that it is irrational to want to avoid life after a grim diagnoses, it is the failure to realize there are preventative measures we can take to reduce the number of such diagnoses. Conceivably, we could better funnel deaths towards “sudden death” by reducing the number of people who *develop* cancer (e.g., by reducing the presence of environmental carcinogens) than we do by developing as many cures for cancer as we are capable of developing. At the same time, though, the fact that typical public opinion poll subjects are willing to spend roughly four times as much to prevent a death from cancer as they are willing to

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degree of media attention devoted to her case (and the associated extreme salience of her particular jeopardy). *See supra* notes 1-2.

71. The canonical list of selected regulations with wildly disparate costs/death averted is presented in CASS R. SUNSTEIN, *RISK AND REASON* 30-31 (2002). Generally speaking, though, the list does reveal something of the pattern I suggest in the text is rational though it may well reveal it to an irrational extent: far more is spent preventing lingering fatal illnesses—by and large—than is spent preventing sudden accidental deaths. (But the variation within the “avert lingering illness” regulations is still enormous.)

These lists are partly difficult to interpret, too, because it is unclear in each case what the marginal efficacy of increasing death-averting expenditures would be: it is not implausible, for instance, that some of the cheap death-averting programs are set at the technologically maximally feasible levels.

72. This could be done by spending more to develop either successful or plausible cures for diseases that patients will otherwise know are incurable or by spending more to prevent the development of diseases known to be incurable, rather than diseases that kill suddenly.

spend to prevent a sudden accidental death<sup>73</sup> (a pattern that seems to understate the value placed on averting cancer deaths in our actual regulations<sup>74</sup>) strikes me as reflecting wholly rational decision processes, even without regard to the hardly trivial fact that cancer deaths will almost surely be preceded by substantial *physical* morbidity.<sup>75</sup>

## II. CONSEQUENTIALISM AND AGENT-RELATIVITY (A): CONDUCT V. CAUSE

I will discuss only briefly whether our attitudes about identifiable lives reflect a more wholesale rejection of conventional consequentialist reasoning. I am almost wholly unsympathetic toward one of the two standard forms of anti-consequentialism: the one in which subjects are morally bound above all to evaluate their own conduct and/or mental states, to determine whether the conduct itself accords due respect to the rights or interests of others rather than to evaluate the expected value impact of their action or inaction on all those affected by that action or inaction.<sup>76</sup>

Some of us find this sort of focus on the virtue of a particular actor-in-question puzzling or infuriating. Why should I care only about what I do—or want, or know I will cause, or self-consciously or carelessly risk causing—rather than what states of the world will exist, or are more likely to exist, given alternative courses of action I might take? Isn't this just infantile, narcissistic ego-centrism masking as morality? Others find it incomprehensible to think

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73. See Richard L. Revesz, *Environmental Regulation, Cost-Benefit Analysis, and the Discounting of Human Lives*, 99 COLUM. L. REV. 941, 962-74 (1999).

74. See SUNSTEIN, *supra* note 71, at 30-31. It is almost surely the case, too, that data on per death prevention costs are hard to interpret because we don't know, looking at the raw data, whether incremental spending on those risks we spend little on would be as efficacious as spending on those risks we currently spend a lot on. There is no reason to believe there is a linear relationship between spending and deaths prevented: while we might save two people at \$10 million per life saved to eliminate exposure to a carcinogen, we may save two people by spending \$1 million on avoiding an industrial accident and no more by spending \$19 million more.

75. Of course, even if it would be rational for "first parties"—those who can elect between their own sudden death and "dying" before being dead—to funnel mortality towards sudden deaths, this would not inevitably be the right social policy. Surviving family and loved ones might *gain* in significant ways if they had the chance to come to terms with the loss of the person who passes away and might thus prefer slow deaths to sudden ones. If this is right, there is a purely "utility-based" argument against funneling deaths towards sudden deaths.

76. Recall the Kantian reluctance to countenance lying about the whereabouts of a would-be killer's potential victim: all the putative liar can attend to is whether she "shows respect" for the autonomy of the person she might deceive. Lying invariably shows disrespect for another's autonomy since it contributes to that rational agent's inability to direct his own choices appropriately, with good information about the effects of his choices. The fact that the party one does not deceive may well use the information to interfere with another's autonomy, as killing him surely will, does not affect the own-conduct centric's obligations. See *supra* note 16.



about ethical behavior without staying focused on what our appropriate *obligations* might be, obligations consistent with establishing a social order giving adequate reign both to our own autonomy and our consideration for others' autonomy. Individuals are separate entities; gains to one do not necessarily counterbalance losses to another. We rightly tolerate only a certain sort of "loss" or "restriction" on our own freedom; the sorts of losses we and those around us should accept are those consistent with our *recognition* of others as similarly and equally autonomous agents. While our interests cannot in the final analysis ever be fully protected—suffering is ubiquitous; bad stuff happens; we all die at some point—we *can* live in a world in which we are all respected as equally autonomous beings. But I have absolutely nothing to add to the familiar and well-worn debate on that issue. Thus, my far more modest goal is simply to highlight that the debate over why subjects seem to care so much more about identifiable lives and whether it is irrational or immoral to do so might implicitly invoke the debate over why people focus more on what they directly do than what they either diffusely cause or "merely" allow to happen.

The preference to save "identifiable" lives doubtless has many roots. In addition to those widely discussed in the existing literature,<sup>77</sup> it might track the commonplace preference to avoid harmful acts and more direct harm causing by the agent herself, rather than harmful omissions thought to lead to equivalent or worse consequences through a more diffuse causal chain or only in conjunction with the conduct of others. This might be true even in cases in which we are considering failing to save either the identifiable person or an unidentified person. I am not saying that in the identifiable victim experiments, researchers have carelessly conflated cases in which subjects are comparing scenarios where they actively harm identifiable persons with situations in which they merely fail to protect unidentified persons. Nor am I claiming that the standard deontological distinctions many experimental subjects act upon are the same as the distinctions drawn between failing to rescue identifiable persons and failing to take steps that prevent the death of as-yet unidentified ones. This is true whether we are considering distinctions between acts and omissions, between rights-violating acts and non-rights-violating acts that result in identical bad effects, or between intended and merely known negative effects of conduct.<sup>78</sup>

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77. See *supra* notes 41–45.

78. These are all distinctions that might be drawn in the standard Trolley Problems. In one of the canonical Trolley Problems, generally dubbed "Fat Man" in the literature, subjects embracing standard deontological positions refuse to push a heavy person off a bridge to stop a trolley that will otherwise kill five people, though they will pull a switch to direct a trolley off-course, knowing it will kill one, but save five. In the first case, they (a) *directly* act upon the person who is killed, rather than allowing an intermediating agent, the trolley, to do all the direct dirty work; (b) they arguably violate bodily integrity *rights*—the right of the person pushed off the bridge not to be killed by another agent is purportedly distinguished, in a non-circular fashion, from the absence of

The argument I want to make instead is one I offer quite tentatively: This is true in part because I am not convinced it would prove to describe accurately subjects' reactions to distinct cases if it were appropriately experimentally tested. It is also true because even if it were descriptively accurate that subjects are responding as they do for the reasons I suggest, this would not affect my views of the *acceptability* of the identifiable victim effect. That is the case because the effects I am describing strike me as arising from the use of difficult-to-justify moral heuristics that would aptly frame morality only in a world in which harm-causing was invariably simple (X batters/kills Y) but would serve us poorly in a world in which harm is caused in a more complex fashion (X makes Y more vulnerable to a host of environmentally present toxins that might kill Y even if X had not acted as he did, though his actions hurt Y's *chances* of surviving exposure to the toxins). In our ancestors' world—when we presumably developed some of our most readily accessible heuristic intuitions—we neither had the post-agrarian technology to cause diffuse increases in the risk of harm on a regular basis, rather than to damage another identifiable person directly, nor did we understand in any sophisticated ways probabilistic epidemiological inference.<sup>79</sup>

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a right not to be hit by a diverted trolley since neither the five victims nor the single victim on the side-track have any trumping right to be free from accident; (c) they arguably create a novel risk rather than merely redistributing something like a pre-existing risk; and (d) it is their *purpose* that the victim suffer injury or death though their *motive* might be to save others. Similarly, killing necessarily temporally precedes saving in the "Fat Man" case but comes after the multiple victims have been saved in the case in which the trolley is diverted. Thus, in the "divert-the-trolley" case, it is at least arguably merely a known side-effect of their direct decision to save the five in jeopardy that someone else will die. To put the double effects issue in more conventional Kantian terms, the person who pushes the Fat Man over the bridge "uses" him as a means to save the others while the person who merely diverts the Trolley onto a track where a person happens to be would be thrilled if no victim were there and (arguably) does not use him in any ways to help others: it is using someone as a means that demonstrates the particularly troublesome form of disrespect.

For some, of many, classic deontological defenses of drawing a distinction between these cases, see, for example, Michael J. Costa, *The Trolley Problem Revisited*, 24 S. J. Phil. 437 (1986); F.M. Kamm, *Harming Some To Save Others*, 57 PHIL. STUD. 227 (1989); John Mikhail, *Universal Moral Grammar: Theory, Evidence, and the Future*, 11 TRENDS COGNITIVE SCI. 143 (2007); James A. Montmarquet, *On Doing Good: The Right and the Wrong Way*, 79 J. PHIL. 439 (1982); and Judith J. Thomson, *Killing, Letting Die, and the Trolley Problem*, 59 THE MONIST 204 (1976).

79. Cass Sunstein has forcefully made the argument that we frequently use problematic moral heuristics. See generally, e.g., Cass Sunstein, *Hazardous Heuristics*, 70 U. CHI. L. REV. 751 (2003); Cass Sunstein, *Moral Heuristics*, 28 BEHAV. & BRAIN SCI. 531 (2005); Cass Sunstein, *Moral Heuristics and Moral Framing*, 88 MINN. L. REV. 1556 (2004).

Sunstein self-consciously analogizes the "moral heuristics" he describes to the often-mistaken heuristics H&B theorists argue that people use in making factual judgments, especially judgments about the probability that certain events will occur. He is also fairly explicit that the sorts of framing/elicitation effects that H&B theorists have argued are in play when people evaluate end-

Here, though, is the descriptive hypothesis that I want to suggest is plausible. People might intuitively conflate judgments of identifiability in situations in

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states generally are operative when we try to elicit considered moral judgments, which are, in this respect, merely a particular variety of evaluative judgment.

In each sort of case in which a subject makes use of a heuristic, the agent has some limited set of goals—to assess the probability of an outcome, to judge the permissibility of certain conduct—and the rule of thumb will be “accurate enough” to assess probability or to make the judgment about permissibility most of the time. Thus, the agent substitutes the “heuristic attribute” for the true “target attribute” in making a judgment. What can often be problematic about the use of heuristics is that these heuristics are, like any rule, inapt to the full range of situations to which they may apply. Thus, to return to the canonical case of judgment bias, the availability heuristic, it indeed is *usually* the case that one will judge probability accurately if one follows the “rule” that events that are readily available to memory have occurred more frequently than unavailable events, but sometimes one will not because one occasionally recalls events because they are salient rather than frequently encountered. Similarly, in the realm of “moral heuristics” it will usually be the case, for instance, that omissions are less culpable than commissions. For instance, those who omit to take steps are less likely to intend harm and intending harm is relevant; one cannot discern whether or not omissions are deliberate or not and placing blame without “proof” is a poor idea; or because when X omits to save Y, some Z or Zs may still do so while when X aggresses against Y, harm is more certain. Sometimes, though, omissions are not less culpable. *See, e.g.,* Sunstein, *Moral Heuristics*, *supra*, at 540.

Sunstein is not especially clear whether he thinks of the moral heuristics as consciously adopted rules designed to meet known ends; whether he believes instead that they are essentially the sort of cognitive routines that we develop because in trying consciously to meet a particular end over a range of situations, we subconsciously develop a habit of substituting one or a small number of attributes that we see often in analyzing a situation for a fuller analysis of the situation; or whether individuals are predisposed to process the simpler heuristic cues, completely unaware that they might be predisposed to do so because, somewhere in our evolutionary history, processing these simple cues was sufficient to meet our ends in most “similar” situations. Another way of putting this point is that he is not clear whether people consciously know the “target attribute” at all, and if they do, whether they are consciously aware that they are substituting a “heuristic attribute” for the target attribute because they know it is easier to do so.

Thus, for instance, it is not enormously clear whether Sunstein believes that those who distinguish omissions from commissions ever think that, say, discerning the intention of the party whose course of conduct they are evaluating is their true purpose. It is likewise ambiguous whether he thinks that they did so before developing a conscious rule of thumb that they would merely ascertain whether they were dealing with an act or failure to act or whether the “rule of thumb” simply developed as an increasingly automatic reaction because in a large number of situations in which they were attempting to discern intention, they unconsciously noted that they so rarely found it in omissions cases that the simpler search for an act became a habit. It seems that he is more drawn to a different story: People have no conscious idea of why they distinguish omissions from commissions. Doing so is not a method of meeting a purpose (e.g., to ferret out intentional actors) that they have consciously developed nor does doing so remain as a residue of having gone through many iterations of trying to ascertain intent and settling on an economical way of getting there. Rather, it is a “rule” whose connection to its original purpose is unrecoverable.

which we merely fail to act to prevent a death with judgments about causation and, in a related fashion, judgments about the presence or absence of independent conduct. This is true of both situations in which we are failing to save and situations in which we are failing to avert the development of peril. More specifically, they might conflate judgments of identifiability with judgments about whether causation is “relatively direct” rather than “relatively diffuse” and with judgments about whether other actors are more or less likely to be seen as “superseding,” not necessarily because they are temporally causal interveners, but because their causal roles are thought of as more central. The familiar way in which one form of “identifiability” matters is that we find it more natural to think of omissions as causes when we can *single out* and thus identify the actor-in-question from some mass of actors who are either equally able or equally duty-bound to take affirmative steps to prevent peril or to rescue. In one view, duty or obligation (which might flow simply from being uniquely situated to avert harm but more readily flows from status or contract) is primary. Once we decide that a party is independently duty-bound to avert a harm, only then do we attribute causal power to that party, and only then with some discomfort.

But it is also possible that, at least to an extent, making intuitive judgments about which sorts of parties are the more direct cause of an outcome pushes us away from consequentialism (a focus on the net result of any course of action or inaction). It pushes us towards a focus on actor-centered moralism, focusing merely on avoiding taking steps that more directly cause harms. If, though, it is not the judgment that the actor-in-question owes some prior duty to the victim driving the conclusion that he is the “cause,” but identifiability or relative uniqueness of at least some actors in the story that drives the judgment that the actor-in-question is the cause, then *victim identifiability* may increase the sense that the actor-in-question causes harm as well.

In this view, the “prototype” causal story has both readily identifiable perpetrators and identifiable victims: X shoots Y, and Y dies. The claim I am making here is that causal/conduct salience can be preserved in part either by singling out an X *or* a Y. When neither is singled out, and all we observe is an increase in the number of dead or injured Ys, and some diffuse group of Xs who might have stopped those bad outcomes from happening, conduct/cause-centered anti-consequentialists will be least moved to condemn.

Judgments that omissions are “conduct” and can “cause” results are made most readily in situations in which the actor-in-question is singled out from the mass of potential life-savers by the fact that he has an independent duty to prevent harm. But I think most people would believe that an omission is also more conduct-like and more apt to be thought of as causally relevant if the party has a unique or at least distinguishable *identity* as more readily able to avert harm than unnamed others, even in the absence of duty. The first distinction—between those with duties and those without—is raised clearly in a hypothetical offered by

Patricia Smith, who implies that our intuitions about cause are not strongly parasitic on prior judgments of duty. She implies that in the context of arguing that omissions are never comfortably considered causes:

Suppose that a train switchman, Charlie, and his buddy, Frank, are about to watch a playoff basketball game when Charlie says to Frank, "I have to pull that switch at 9:02. Don't let me forget or the L&W will crash straight into the Boston Flyer." The game is riveting, and at 9:03, the L&W crashes straight into the Boston Flyer. Charlie is responsible for the crash . . . . But what should be said about cause?

One possibility is that Charlie didn't really cause the wreck . . . . So we just say he caused it because we want to hold him responsible . . . .

So, the second possibility is that Charlie did cause the crash . . . . But if that is admitted, then it should be noticed that there is no causal difference between Charlie and Frank.<sup>80</sup>

To the degree that observers are agent-centric only in the sense that they focus solely on breaches of legal duties or failure to respect the rights of others, not on conduct or cause, then (1) what distinguishes Charlie from all other persons is simply and exclusively that he alone has a duty to save (in this case established by contractual assumption of the duty to save) and that he has breached the rights of those who benefited from that contractual assumption of a duty to care and (2) *no* legal stranger's failure to save—whether it is a failure to save an identifiable or non-identifiable victim—is problematic. But to the degree that observers distinguish Charlie from his friend Frank in part because they single out or identify him as a unique perpetrator (active and causal) and that identifying him makes us especially revolted by his conduct, we would also expect that his friend Frank would seem more active, causally relevant, and therefore culpable than the typical person: Frank is more readily able to stop the wreck without much change in his life plans than one of an unidentified mass of persons who might have learned about the possibility of the wreck but failed to take similar steps to go out of her way to avert it.<sup>81</sup>

Assume then that we think Frank is more culpable than unidentifiable persons who might have the same opportunity to stop the disaster. The question, at that point, becomes whether the classic unidentified bystander who must go out of his way to save seems more active or causally relevant if he knows whom he might save by taking steps than if the people to be saved are also abstract and unidentified. Do we single out a bystander from a world of bystanders simply because they have been entwined in a particular relationship by *knowing* precisely whom they might save? So we are all bystanders to, say, a failure to install barriers or warning signs that might save some kids in general from

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80. Patricia Smith, *Legal Liability and Criminal Omissions*, 5 BUFF. CRIM. L. REV. 69, 101-02 (2001).

81. For instance, any one of many people who walks by a switchman's office and sees the switchman has had a fatal heart attack and is not able to deal with the trains.

drowning, but if one of us knows the identity of a particular child we could save from drowning, does he—by virtue of that fact alone—become distinct from the rest of us? In becoming distinct, does he get thought of as more causal and more directly active in the death if the child indeed drowns?

It is conceivable that we could test this account experimentally. If my point is right, we would expect experimental subjects to differentiate between Neighbor 1's failure to install a fence around his pool, which might protect unnamed kids in the neighborhood, from some Neighbor 2 who fails to build the fence when he is or could be concerned with a particular identified neighborhood toddler, even holding constant the probabilities that a child will drown. I am fairly certain that the ultimate moral judgments would be different—that is merely a restatement of the identifiable-victims effect, in the prospective harm, rather than rescue, case. I am radically less confident that one could tease out whether they are different *because* subjects construct Neighbor 2 either as more active or causally direct. One would need to ascertain whether they are more likely to use the word “kill” instead of the phrase “fail to save” in Neighbor 2's case *and* that using that word *drives* their judgment, rather than being the word they use because they have made a harsh moral judgment. To test for “causal salience,” one would also have to test whether they are less likely to recognize the causal contributions of others—the drowning child herself, that child's caretakers, etc.—when the jeopardized child is named.

As I said, though, I would be unmoved normatively by learning that Neighbor 2 is more frequently harshly judged by experimental subjects: conduct-centric anti-consequentialism is no more compelling if it is intuitive or easily mentally accessible.<sup>82</sup> (Unless we believe that our moral reactions are so

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82. For a clear version of the familiar argument that intuitions are of little moment since they are framed in response to evolutionary pressures that may now seem irrelevant, see, for example, Peter Singer, *Ethics and Intuition*, 9 J. ETHICS 331, 331-51 (2005). The following quote expresses a quite commonplace reaction relevant both to Trolley Cases and cases in which we seem more forgiving of those who “kill” by raising global death rates:

For most of our evolutionary history, human beings have lived in small groups . . . . In these groups, violence could only be inflicted in an up-close and personal way—by hitting, pushing, strangling, or using a stick or stone as a club. To deal with these situation, we have developed immediate, emotionally based responses . . . . The thought of pushing the stranger off the footbridge elicits these emotional responses. Throwing a switch that diverts a train that will hit someone bears no resemblance to anything likely to have happened in the circumstances in which we and our ancestors lived . . . the standard trolley case describes a way of bringing about someone's death that has only been possible in the last century or two, a time too short to have any impact on our inherited patterns of emotional response.

*Id.* at 347-48.

Singer's argument that we can condemn certain moral arguments by learning of their provenance, and more particularly by discovering that they developed as useful rules of thumb in

modularized that we simply *cannot* subject them to scrutiny and self-critical reflection, it is not clear that we should make much of initial intuitions or ease of cognition.) And, of course, as Sunstein and Vermeule noted, collective bodies cannot use a conduct-centric moral metric to judge policy in any case: *everything* the state does or fails to do is, at core, an action taken by the relevant “agent” relative to some alternative policy.<sup>83</sup>

### III. CONSEQUENTIALISM AND AGENT-RELATIVITY (B): PARTIALITY

People may believe they “know” identifiable people to some limited extent. They may be more drawn to saving these identifiable people than they are drawn to saving unidentified people for some of the same reasons that they are drawn towards saving those whom they know *best*, like most, and care most deeply about (such as kin and friends) rather than identifiable persons who they like less, feel less attached to, and spend little time thinking about. Consider the canonical case: a parent manifests what many see as a legitimate preference to save his own child rather than to save a larger number of strangers. The purest act-utilitarian may believe that, at least at first blush, the parent is acting improperly. Assuming that each stranger’s life and his child’s life are of equal intrinsic value, he is taking a step that diminishes overall utility. Most respond to the example either by noting that “pure” utilitarianism is either too stringent a moral code or that it is a defective one.

We expect two conventional utilitarian responses to the accusations that utilitarianism cannot cope with the legitimacy of this sort of “partiality.” Partiality can be understood as valuing the interests of some more than the interests of others without denigrating their abstract moral worth or the claim that their interests, as a general matter, should be considered no less significant. First, we might expect the response that the anti-utilitarians are misconstruing the *domain* of utilitarianism. It is arguably not meant to govern all personal morality, but merely public policy-making. It may be right for me to care more about my kids than I care for people generally, but for the state, it is best to presume that everyone is equally special to someone.<sup>84</sup>

Second, we expect utilitarian theorists to argue that *nurturing* this sort of agent-relative partiality has beneficial consequences. If we demanded that each party act as an impersonal consequentialist in each of her decisions, it would

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an environment in which a different set of moral problems typically arose, has been sharply criticized. See Selim Berker, *The Normative Insignificance of Neuroscience*, 37 PHIL. & PUB. AFF. 293, 319-21 (2009).

83. See Sunstein & Vermeule, *supra* note 7, at 705, 707, 719-24.

84. An argument that utilitarianism was historically meant as a guide to policy-making, rather than as a more inclusive set of ethical rules, is made in Guyora Binder & Nicholas J. Smith, *Framed: Utilitarianism and Punishment of the Innocent*, 32 RUTGERS L.J. 115 (2001).

weaken utility-promoting institutions like families. The argument takes two subtly distinct, though not mutually exclusive, forms. One could argue that if we nurture deep, utility-maximizing ties to our family members, we will simply be stuck with partiality in the life-saving decision. As a matter of psychological fact, then, we cannot expect people encouraged to form special bonds to ignore them when it might maximize utility on a particular occasion to do so. Alternatively, one could argue that partiality-in-saving is not just an *inevitable* side effect once we nourish a helpful institution, but also that encouraging such partiality affirmatively fosters the utility-increasing institution.

These arguments, of course, resonate in typical rule-utilitarian—as opposed to act-utilitarian—understandings of the dictates of utilitarian philosophy.<sup>85</sup> It might be good to abjure an act-utilitarian decision on a particular occasion if following a rule that lowers utility on the particular occasion will increase utility overall. Thus, we may promote *rules* such as “care most for your kids even when doing so will result in a loss of utility” or “don’t take others’ property even when you value it more highly than they do” because doing so will solidify crucial institutions like the family or secure private property. Obviously, this is not one of those situations in which the most powerful argument for *rule* utilitarianism is present—where there are utility gains to be had simply from following a practice without exception because it is “costly” for people either to decide when to make or to deal with others who make exceptions. Thus, in the canonical case, the rule utilitarian could argue it might well be worthwhile to follow a rule that one will tell the truth *always*, even if lying on a particular occasion would seem to increase utility, because if people know that all that they hear is true, at least as best as the speaker knows, it will increase overall utility. One might say that it would increase the utility-promoting institution of “trust,” or, to put the point in more conventional economic terms, it will reduce the costs of information-acquisition because one will never have to expend resources to verify that what others tell you reflects their actual beliefs. Following the “rule” that one should save those one is partial to rather than figure out on each occasion whether that is utility-maximizing does not increase utility by virtue of its being a “rule” (i.e., easily followed by the decision maker herself, or followed without exceptions that force others to absorb the costs of the presence of exceptions, etc.). But it might be a good rule to follow because doing so promotes other good attitudes or because it is the only rule we can realistically follow if we have developed the attitudes that utility-generating institutions promote.

What is crucial to highlight in this regard is that one of the most robust findings of the literature on the identifiable victim effect is that it is fragile in a

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85. For some seminal, standard accounts of the distinction between act and rule utilitarianism, see, for example, John C. Harsanyi, *Rule Utilitarianism and Decision Theory*, 11 *ERKENNTNIS* 25 (1977); John Rawls, *Two Concepts of Rules*, 64 *PHIL. REV.* 3 (1955); and J.J.C. Smart, *Extreme and Restricted Utilitarianism*, 6 *PHIL. Q.* 344 (1956).



very particular way. When people are told that people generally exhibit it, they *will* stop spending *more* to save or aid identifiable victims than they will spend to save or aid statistical lives. But the sad truth is that they do so not by increasing their altruistic outpourings towards statistical lives but by cutting back on their generosity to identifiable victims.<sup>86</sup> One might, in a precisely parallel fashion, believe that if parents are directed to show no more concern for their drowning kids than for others, they will show little or no concern for anyone. The permission of partiality frees up the manifestation of a utility-increasing practice that would simply not exist if we demanded a less partial, more neutral practice.

Altruistic concern may not depend *directly* on identifiability so much as it depends on the putative altruist having a strong affective reaction to the victim's suffering. Generally, we are more prone to have affective reactions when we react to named individuals. When we deliberate more, we lose affect as we see that we are over-reacting to a person who is merely representative of a larger group. But the claim here is not the rather depressing one that deliberation always breeds callousness. It might well be the case, for instance, that our typical low-affect reactions to distant strangers (whether they be distant physically, ethnically distinct, or socioeconomically) may be emotionally intensified when we deliberate more, and see the plight of these strangers as more compelling.<sup>87</sup> More generally, while high cognitive load—which reduces deliberation and increases the significance of affect in decision making—makes both self-identified political liberals and conservatives less prone to be generous in offering subsidies to those AIDS patients who they believe are more responsible for being sick than they offer those they believe are not responsible, liberals, but not conservatives, who deliberate more because under less cognitive load are just as generous to those they judge as blameworthy in acquiring the disease.<sup>88</sup>

Still, what seems fairly clear is that we may purchase a certain version of rational consistency—equality of spending on preventing statistical deaths and saving identifiable lives—only by driving altruistic spending levels towards zero. If doing so would decrease aggregate utility—as it would if the utility costs of altruistic actions are lower than the utility gains to the objects of altruism—then merely wiping out the distinction in the ways we treat identifiable and statistical victims might not be a good thing. Whether we should try, though, to justify non-consequentialist judgments solely by reference to their consequences is another very thorny question. But it is not a question that I have any novel thoughts

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86. See Deborah A. Small, George Loewenstein & Paul Slovic, *Sympathy and Callousness: The Impact of Deliberative Thought on Donations to Identifiable and Statistical Victims*, 102 *ORG. BEHAV. & HUM. DECISION MAKING PROCESSES* 143 (2007).

87. *Id.* at 151.

88. See Linda J. Skitka et al., *Dispositions, Scripts, or Motivated Correction? Understanding Ideological Differences in Explanations for Social Problems*, 83 *J. PERSONALITY & SOCIAL PSYCHOL.* 470 (2002).

about: I merely thought it important to note that one could imagine justifying a seemingly non-consequentialist partiality towards the identified in broadly rule-utilitarian terms.

### CONCLUSION

People typically manifest a willingness to pay a good deal more to save an identifiable person in jeopardy than to prevent the deaths of persons not yet known. It is possible that, in so doing, they are failing to meet their considered ends. Perhaps our only goal is to achieve the best end states or consequences that we can, and the only end-state we should seek is higher life expectancy.

While it is important to recognize that people do not always rationally evaluate whether the steps they choose to take best meet their ends, it is also important to recognize that we, as observers, may both improperly assess what their ends are and may also underestimate the degree to which they resist making judgments that are exclusively sensitive to the consequences of their conduct. These two general observations are critical in thinking about whether the “identifiable victim” effect is unambiguously troubling, representing a clear breakdown in rational decision making.

It is not at all clear that people do or should seek to maximize their own or others’ life expectancy, even setting aside issues of morbidity and physiological life quality. Death is likely a bad consequence (in very complicated ways), but *knowing one is dying* is *different* hedonically (and arguably a good deal worse). It might be fully rational to trade additional years of life for a reduction in periods in which the dread of death is pronounced; preferring cures and rescues over prevention or preferring accidental deaths over cancer deaths may imperfectly manifest a rational preference to avoid acute death-dreading periods of life, rather than to maximize life expectancy. While it is certainly possible that we miscompute the life-expectancy-extending efficacy of cure compared to prevention, miscalculation might not be all that drives the preference for cure and rescue.

At the same time, decisions either to save or prevent the imperilment of identifiable victims might be grounded in two forms of agent-relativity. We may simply not be as concerned with any sort of consequences—reduction of mortality, reduction of the experience of death dread—as we are concerned with either the appropriateness of our own conduct or with protecting a subset of persons to whom we are more connected. I expressed both descriptive and normative hesitations about the first form of agent-relativity. I am not at all sure that deontologists in fact believe that they are something more akin to rights violators or that they have failed to manifest appropriate respect for other autonomous agents only when they fail to save those they can identify; even if they do, I argue that the belief is grounded in an inapt moral heuristic. I am more sympathetic to the idea that in the absence of a social rule or practice that we are

entitled to attend more to the identified, we will simply reduce altruism excessively so that partiality is justified as a practice, even if any particular act of partiality seems to violate precepts against maximizing utility.

We may indeed mistakenly and irrationally overvalue rescues compared to prevention and identifiable lives to statistical ones. Given the complexity of attitudes both about the distinction between death and dying and the proper scope of consequentialist ethics, though, I am reluctant to conclude so readily that what we are observing is straightforward confusion and error.



# Improving Antibiotic Markets for Long Term Sustainability

Aaron S. Kesselheim, M.D., J.D., M.P.H. and Kevin Outterson, J.D., LL.M.\*

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## INTRODUCTION

The widespread introduction of antibiotics was one of the greatest medical accomplishments of the twentieth century, but our success in treating infectious diseases has led to a new public health challenge—the emergence and proliferation of microorganisms resistant to standard antibacterial therapy.<sup>1</sup> Unfortunately, legal and market structures in the United States have created a substantial gap between the private and social value of antibiotics, leading to problematic supply and demand incentives and increasingly resistant infections. Both hospitals<sup>2</sup> and community settings<sup>3</sup> report growing resistance problems.

Multidrug resistant bacteria are a grave public health concern because they put patients at risk for serious illness and possibly death,<sup>4</sup> and they place increased demand on already strained health care resources.<sup>5</sup> Patients with resistant infections can lead to increased inpatient hospital costs,<sup>6</sup> outpatient treatment costs,<sup>7</sup> and long-term care spending.<sup>8</sup> Life in a post-antibiotic era would be remarkably different and less healthy.

Leading academic groups, public health organizations, and governments have recently become more vocal about the problem of drug-resistant infections. The Infectious Diseases Society of America (IDSA) reported that “[i]nfections that were once easily curable with antibiotics are becoming difficult, even impossible, to treat, and an increasing number of people are suffering severe

1. We use the term “antibacterial” or “antibiotic” throughout, with full recognition that many of the concepts discussed herein also apply to the broader category of antimicrobial agents. We focus on the narrower category because antivirals and antiretrovirals may present novel resistance and incentive issues that require separate treatment. For example, as discussed below, entry of low-cost, generic antiretrovirals has saved millions of lives in the battle against AIDS, but similar outcomes from generic entry have not been reported in the antibiotic market.

2. See John P. Burke, *Infection Control—A Problem for Patient Safety*, 348 NEW ENG. J. MED. 651 (2003); L. Silvia Munoz-Price & Robert A. Weinstein, *Acinetobacter Infection*, 358 NEW ENG. J. MED. 1271 (2008); Melinda M. Neuhauser et al., *Antibiotic Resistance Among Gram-Negative Bacilli in US Intensive Care Units: Implications for Fluoroquinolone Use*, 289 JAMA 885 (2003).

3. See J. Patrick Powell & Richard P. Wenzel, *Antibiotic Options for Treating Community-Acquired MRSA*, 6 EXPERT REV. ANTI-INFECTIVE THERAPY, 299 (2008).

4. See Yehuda Carmeli et al., *Health and Economic Outcomes of Vancomycin-Resistant Enterococci*, 162 ARCH. INT. MED. 2223 (2002).

5. Rebecca H. Sunenshine et al., *Multidrug-Resistant Acinetobacter Infection Mortality Rate and Length of Hospitalization*, 13 EMERGING INFECTIOUS DISEASES 97 (2007).

6. Heather L. Evans et al., *Cost of Gram-Negative Resistance*, 35 CRIT. CARE MED. 89 (2007).

7. See Carl Asche et al., *Treatment Costs Associated with Community-Acquired Pneumonia by Community Level of Antimicrobial Resistance*, 61 J. ANTIMICROBIAL CHEMOTHERAPY 1162 (2008).

8. See Blair Capitano et al., *Cost Effect of Managing Methicillin-Resistant Staphylococcus Aureus in a Long-Term Care Facility*, 51 J. AM. GERIATRIC SOC’Y 15-16 (2003).

illness—or dying—as a result.”<sup>9</sup> The Alliance for the Prudent Use of Antibiotics has been focused for many years on resistance stemming from the misuse of antibiotics.<sup>10</sup> Government agencies in the United States<sup>11</sup> and other countries have given increasing attention to the topic; as the Select Committee on Science and Technology in the United Kingdom House of Lords noted:

“[T]he inevitable rise and spread of resistance will render existing drugs progressively less useful. In the absence of new drugs, this leaves us increasingly at the mercy of infections. We cannot eliminate resistance. We can however slow it down, by using antibiotics only when necessary, and by rigorous infection control and basic hygiene, both informed by thorough surveillance.”<sup>12</sup>

Many groups, including the Center for Global Development,<sup>13</sup> the London School of Economics,<sup>14</sup> Resources for the Future,<sup>15</sup> and the Swedish Presidency of the European Union,<sup>16</sup> have recently published reports on global antibiotic resistance. Despite this focused attention, few concrete, affirmative steps have been taken, and the threat of resistance grows.

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9. INFECTIOUS DISEASES SOCIETY OF AM., BAD BUGS, NO DRUGS: AS ANTIBIOTIC DISCOVERY STAGNATES . . . A PUBLIC HEALTH CRISIS BREWS 9 (2004), *available at* <http://www.idsociety.org/10x20.htm> [hereinafter BAD BUGS].

10. Stuart B. Levy, *Antibiotic and Antiseptic Resistance: Impact on Public Health*, 19 PEDIATRIC INFECTIOUS DISEASE J. S122 (2000).

11. *See generally* FDA TASK FORCE ON ANTIMICROBIAL RESISTANCE: KEY RECOMMENDATIONS AND REPORT (2000), *available at* <http://www.fda.gov/oc/downloads/ForConsumers/ConsumerUpdates/UCM243458.pdf>

12. SCI. AND TECH. SELECT COMM. OF THE HOUSE OF LORDS, THIRD REPORT: RESISTANCE TO ANTIBIOTICS para. 3 (2001), *available at* <http://www.publications.parliament.uk/pa/ld200001/ldselect/ldstech/56/5602.htm>.

13. RACHEL NUGENT, EMMA BACK & ALEXANDRA BEITH, CTR. FOR GLOBAL DEV., THE RACE AGAINST DRUG RESISTANCE (2010), *available at* <http://www.cgdev.org/content/publications/detail/1424207>. Professor Outtersson was a member of the Working Group on Drug Resistance at the Center for Global Development.

14. ELIAS MOSSIALOS ET AL., LONDON SCH. OF ECON., POLICIES AND INCENTIVES FOR PROMOTING INNOVATION IN ANTIBIOTIC RESEARCH (2010), *available at* [http://www.se2009.eu/polopoly\\_fs/1.16814!menu/standard/file/LSE-ABI%20F-Final.pdf](http://www.se2009.eu/polopoly_fs/1.16814!menu/standard/file/LSE-ABI%20F-Final.pdf). This monograph was funded by a grant from the Swedish government.

15. RAMANAN LAXMINARAYAN ET AL., EXTENDING THE CURE: POLICY RESPONSES TO THE GROWING THREAT OF ANTIBIOTIC RESISTANCE (2007), *available at* <http://www.extendingthecure.org/report>.

16. SWEDISH PRESIDENCY OF THE EUROPEAN UNION, INNOVATIVE INCENTIVES FOR EFFECTIVE ANTIBACTERIALS (2009), *available at* [http://www.se2009.eu/polopoly\\_fs/1.25861!menu/standard/file/Antibacterials5.pdf](http://www.se2009.eu/polopoly_fs/1.25861!menu/standard/file/Antibacterials5.pdf).



We believe that one of the primary contributors to the problem of antibacterial resistance lies in the market for antibiotics, and specifically how markets reimburse for drug development and use in this field. Current legal structures and market incentives unwittingly accelerate resistance in several ways, all rooted in the mismatch between private and social value. First, Medicare and U.S. private payor reimbursement<sup>17</sup> create certain market incentives without adequate concern for the potential social impact on resistance. For example, for many years, federal reimbursement under Medicare has rewarded hospital-associated infections with additional payments, while failing to reimburse for conservation and infection control. While hospitals have significant non-financial reasons to control hospital-acquired infections, this policy paradoxically rewards bad behavior by paying for hospital infections.<sup>18</sup> Or take the example of infection control, which experts have lauded as an effective public health measure that also conserves antibiotics. Medicare does not have a billing code for infection control practices. Because it is not reimbursed, infection control does not directly generate revenue.

Second, some well-intentioned efforts work at cross-purposes, undermining effectiveness at a population health level. For instance, the patent system helps spur innovation of new drugs, but pending patent expiration may lead antibiotic manufacturers to waste their products by promoting drug use for a broad array of minor clinical conditions rather than trying to assure that their products are limited to the most urgent cases.<sup>19</sup> This is a classic example of social value exceeding private value.<sup>20</sup> Another example of antagonistic incentives involves

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17. While our analysis has broader implications, we draw many of our market examples from the United States.

18. Kevin Outterson, Germ Shed Management, in *ANTIBIOTIC POLICIES: CONTROLLING HOSPITAL-ACQUIRED INFECTION* (Ian M. Gould & Jos M.N. van der Meer, eds., forthcoming 2011).

19. The “patent holder waste” hypothesis posits that the patent holder of an antimicrobial will tend to over-market (and thereby waste) the product as patent expiry approaches, delivering an exhausted antimicrobial to the public domain when generic entry looms. See Eric Kades, *Preserving a Precious Resource: Rationalizing the Use of Antibiotics*, 99 NW. U. L. REV. 611, 648-52 (2005). But see Kevin Outterson, *The Legal Ecology of Resistance: The Role of Antibiotic Resistance in Pharmaceutical Innovation*, 31 CARDOZO L. REV. 613 (2010) [hereinafter *Legal Ecology of Resistance*] (developing the theory of patent holder waste); Kevin Outterson, *The Vanishing Public Domain: Antibiotic Resistance, Pharmaceutical Innovation and Intellectual Property Law*, 67 U. PITT. L. REV. 67, 78-80 (2005) [hereinafter *Vanishing Public Domain*] (critiquing Kades’ approach).

20. Some policy experts claim that the social value of pharmaceuticals generally exceeds their private value. See, e.g., J.D. Kleinke, *The Price of Progress: Prescription Drugs in the Health Care Market*, 20 HEALTH AFF. 43 (2001). For a contrary example of the private value of information exceeding the social value, see Jack Hirshleifer, *The Private and Social Value of Information and the Reward to Inventive Activity*, 61 AM. ECON. REV. 561, 565-66 (1971).

antibiotic conservation and infection control programs. These initiatives reduce the inappropriate demand for antibiotics, prevent unnecessary infections, and therefore preserve the drugs for more valuable uses. Society benefits, but drug companies point out that these programs undercut antibiotic sales.<sup>21</sup> Citing the lack of appropriately sized and predictable markets, some drug companies have fled from antibiotic research, despite the significant clinician demands for additional effective therapies. The interactive and dynamic effects among these policy options must be mapped and addressed.

Finally, we must evaluate the cost-effectiveness of potential interventions on a population level. From society's perspective, the NIH severely underfunds basic research into antibacterial resistance.<sup>22</sup> Private markets are unlikely to pick up the slack in basic antibiotic research because private actors undersupply products with common pool or public goods characteristics. On the other hand, some research programs, such as additional antibiotics for self-resolving minor infections, appear to be privately valuable, but unnecessary at a population level. Some recent proposals could generate private financial gains for companies, though they might be counterproductive or cost-ineffective at the population level. One example is the proposal to grant wild-card patents for antibiotics, rewarding drug companies for antibiotic innovation by granting a longer patent on any other drug in the company's portfolio.<sup>23</sup> Wildcard patent proposals may cost many billions of dollars, with doubtful social value.<sup>24</sup> Essentially, wildcard patents tax drugs for heart disease to pay for antibiotic research and development. We should not pursue such options without adequately modeling the potential gaps between private and social cost, as well as the opportunity cost.

In previous work, we have described some of the policy options available to promote continued antibiotic effectiveness.<sup>25</sup> Table 1 displays these options graphically, dividing the policy options into eight Sectors. The columns in Table 1 are the two intermediate policy goals: conservation of existing antibiotics and

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21. See Steven J. Projan, *Why is Big Pharma Getting Out Of Antibacterial Drug Discovery?*, 6 CURRENT OPINION MICROBIOLOGY 427, 428-30 (2003).

22. N. Kent Peters et al., *The Research Agenda of the National Institute of Allergy and Infectious Diseases for Antimicrobial Resistance*, 197 J. INFECTIOUS DISEASE 1087, 1087 (2008).

23. See *infra* Section III.B for a critique of patent-based incentives for antibiotic development.

24. Kevin Outterson, Julie Balch Samora & Karen Keller-Cuda, *Will Longer Antimicrobial Patents Improve Global Public Health?*, 7 LANCET INFECTIOUS DISEASES 559, 559 (2007) [hereinafter *Longer Antimicrobial Patents*].

25. Aaron S. Kesselheim & Kevin Outterson, *Fighting Antibiotic Resistance: Marrying New Financial Incentives to Meeting Public Health Goals*, 29 HEALTH AFF. 1689, 1692-94 (2010) [hereinafter, *Fighting Antibiotic Resistance*]; Outterson, *supra* note 19, at tbl.1 (outlining six possible policy sectors for addressing continued antibiotic effectiveness, using property, regulation and contract to improve antibiotic conservation and production).

the production of new ones. While we have conceptually separated conservation and production into columns, the ultimate policy goal remains continued antibiotic effectiveness. Policymakers will need to balance both conservation and production to achieve that goal over time. The rows represent the four primary legal tools that can be deployed to achieve these goals: property, regulation, contract, and tort.<sup>26</sup> With Table 1, one can see a broad array of policy options, eight Sectors in all.

**TABLE 1: CONCEPTUAL LEGAL APPROACHES TO CONTINUED ANTIBIOTIC EFFECTIVENESS**

	<b>Conservation</b>	<b>Production</b>
<b>Property</b>	Patents used as conservation tools to privately constrain demand. (Sector 1)	Patents used as incentives to bring new antibiotics to market. (Sector 2)
<b>Regulation</b>	Public health infection control and antibiotic stewardship programs regulate demand for antibiotics. (Sector 3)	FDA regulations relaxed to speed approval of new antibiotics. Tax subsidies support R&D. (Sector 4)
<b>Contract</b>	Prizes, grants, and value-based reimbursement support antibiotic conservation. (Sector 5)	Prizes, grants, and value-based reimbursement support new antibiotic production. (Sector 6)
<b>Tort</b>	Patients sue for hospital-associated infections, increasing institutional incentives to promote safety through antibiotic conservation. (Sector 7)	Federal law designed to preempt state tort law, waiving drug company tort liability for antibiotics, similar to the national vaccine injury compensation program. (Sector 8)

This Article builds on our previous work by describing in-depth a range of integrated policy solutions that address the problem of antibiotic resistance. Our guiding premise is that society's primary goal should be continued antibiotic effectiveness on a population level by giving proper incentives to various institutions and actors. We emphasize a balanced approach between production of new products and conservation of existing drugs, mirroring a similar shift that

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26. For examples of legal and health policy scholarship in Sectors 1-6, see Outtersson, *supra* note 19, at 621-26.

is currently underway in energy policy.

Our approach departs from the conventional wisdom in several ways. Most dramatically, we focus economic incentives for conservation on the drug companies themselves, since we believe they are best positioned to act on superior information, if only their economic incentives were realigned. While supporting conservation incentives for providers and others, our primary contribution to the literature is to ensure that drug companies fully embrace antibiotic conservation. Secondly, we focus our efforts on Sectors 5 and 6 – voluntary contracts whereby governments reward patent owners for managing their resources for long-term public health. Our approach is novel in the legal literature. Legal scholarship on drug development has traditionally focused on property-based tools, especially the production of new drugs through patents (Sector 2).<sup>27</sup> With the notable exceptions of work by Eric Kades<sup>28</sup> and the “Extending the Cure” project by Ramanan Laxminarayan and Anup Malani,<sup>29</sup> legal scholarship has generally overlooked property-based conservation incentives designed to prolong antibiotic effectiveness for existing drugs, as well as other contract-based production incentives.<sup>30</sup> Some authors have descriptively catalogued the application of tort law to infections, but without a larger theoretical framework that includes production incentives.<sup>31</sup> Other legal scholars have described regulatory tools in Sectors 3 and 4, as well as cultural and

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27. See Outtersson, *supra* note 19, at 620.

28. See Eric Kades, *supra* note 19, at 643-53 (2005).

29. LAXMINARAYAN ET AL., *supra* note 15.

30. Outtersson, *supra* note 19, at 622. In recent years, several scholars have discussed the potential for value-based reimbursement or pay-for-performance as an antidote for hospital-associated infections. See, e.g., Rachel Deutsch, *The Federal Role in Reducing Hospital-Acquired Conditions: Are Medicare Reimbursement Incentives Enough?*, 42 COLUM. J.L. & SOC. PROBS. 1 (2008); David A. Hyman & Charles Silver, *You Get What You Pay For: Result-Based Compensation for Health Care*, 58 WASH. & LEE L. REV. 1427 (2001) (briefly discussing nosocomial infections).

31. Several authors have described tort-based approaches that would fit in Sector 7 (see Table 1). See, e.g., Jennifer M. Miller, *Liability Relating To Contracting Infectious Diseases in Hospitals*, 25 J. LEGAL MED. 211 (2004) (finding few effective tort remedies against hospitals and suggesting tort liability against health insurers as the better approach); Pamela Nolan, *Unclean Hands: Holding Hospitals Responsible for Hospital-Acquired Infections*, 34 COLUM. J.L. & SOC. PROBS. 133 (2000); William M. Sage & David A. Hyman, *Combating Antimicrobial Resistance: Regulatory Strategies and Institutional Capacity*, 84 TUL. L. REV. 781 (2010); Robert Steinbach, *Dirty Business: Legal Prophylaxis for Nosocomial Infections*, 97 KY. L.J. 505 (2008) (describing the positive role tort law can have to promote hospital safety against acquired infections). For an example of a related Sector 8 approach, see Lincoln Mayer, *Immunity for Immunizations: Tort Liability, Biodefense, and Bioshield II*, 59 STAN. L. REV. 1753 (2007).

professional influences on antibiotic prescribing practices.<sup>32</sup> A recent article by William Sage and David Hyman takes a broader approach, cataloguing many possible regulatory strategies.<sup>33</sup> The medical literature has often focused on Sector 3 conservation programs in isolation, without adequate analysis of the dynamic effects of multiple interventions and the legal and reimbursement environments. In the United States, most conservation and infection control studies focus on single hospitals, missing the positive externalities generated when multiple institutions cooperate across a region.<sup>34</sup> Recent proposals to weaken antibiotic clinical trial requirements are Sector 4 initiatives.<sup>35</sup> In short, legal and medical scholarship has not adequately focused on antibiotic issues in the remaining Sectors, especially contract law (5 and 6)<sup>36</sup> and the complex interactions between conservation and production.

To remedy this gap in the literature, we offer an overview of medical, legal, and market forces that affect antibiotic production and conservation. Furthermore, we present a novel cluster of integrated solutions, centered in contract law,<sup>37</sup> which we call the Antibiotic Conservation and Effectiveness (ACE) program. The ACE program emphasizes: (1) value-based reimbursement of antibiotics from public payors such as Medicare and Medicaid, with spillover participation from private payors, in order to improve private markets for antibiotic effectiveness by providing financial incentives to promote continued antibiotic effectiveness; (2) making these payments conditional on meeting realistic public health and conservation goals, including a Strategic Antibiotic Reserve; (3) market-enhancing regulatory changes, including limited waivers of antitrust as well as fraud and abuse laws, to permit market coordination for conservation (supporting efforts in multiple Sectors); and (4) increased public grant support for basic antibiotic research, including both conservation and new production.

32. Richard S. Saver, *In Tepid Defense of Population Health: Physicians and Antibiotic Resistance*, 34 AM. J.L. & MED. 431 (2008).

33. See Sage and Hyman, *supra* note 31, for a discussion on the regulatory institutions relating to antibiotic resistance.

34. See Outtersson, *supra* note 18.

35. BAD BUGS, *supra* note 9; Cecilia H. Burke & Geoffrey M. Levitt, *A Manufacturer's Perspective: Recent Challenges in Antibiotic Drug Approval*, 2 UPDATE: FOOD & DRUG L. REG. & ED. 12 (2008); Steven J. Projan & David M. Shlaes, *Antibacterial Drug Discovery: Is It All Downhill From Here?*, 4 CLINICAL MICROBIOLOGY & INFECTION. 18 (2004).

36. But see Sage & Hyman, *supra* note 33, at 799-803 (discussing improvements to information and public reporting of nosocomial infections).

37. We treat health insurance reimbursement as a form of contract law, even though the market includes some elements of monopolies and monopsonies, as well as significant government regulation. Similarly, we treat grants as contracts, voluntarily entered into by the parties. Issues of tort law will be saved for another day.

The first element of the ACE program is value-based reimbursement for antibiotics, increasing the private value of these drugs to more closely resemble the social value. Changes in reimbursement can have a remarkable impact on how antibiotics are created and used. For too long, antibiotics have been seen as cheap drugs, when in fact they are valuable exhaustible goods.<sup>38</sup> Improved systems of reimbursement can support usage patterns more in tune with the intrinsic value of these drugs, as well as support the rational development of new ones. Our proposal includes prizes to promote antibiotic innovation as a form of reimbursement. James Love has posited prizes and reimbursement as conflicting choices for antibiotic innovation,<sup>39</sup> but we tend to see them as complementary, so long as prices at the point of care do not increase. In our proposal, the price paid by patients is not directly affected by value-based reimbursement. We focus on how the patent holders are reimbursed by private and public health plans. One mechanism might be a voluntary contract between the federal government and the patent holder, promising a significant financial prize in line with the public health impact of the drug, akin to James Love and Tim Hubbard's extensive proposals for drug R&D prizes<sup>40</sup> or Thomas Pogge and Aiden Hollis' Health

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38. Recently, antibiotics have been featured prominently in low-cost generic drug dispensation programs by many national retail pharmacies. For example, Wal-Mart's low-cost program allows patients to buy twelve different varieties of the antibiotic amoxicillin for \$4 per month. See Wal-Mart \$4 Medication List, <http://www.usatoday.com/money/industries/health/drugs/walmart-druglist.pdf> (last visited Dec. 3, 2010). While such generic drug programs have been rightly extolled for helping promote access and adherence to essential medicines, low-cost antibiotic access has been linked to overuse of these drug, particularly in lower-income settings. Beatriz Espinosa Franco et al., *The Determinants of the Antibiotic Resistance Process*, 2 INFECTIOUS DRUG RESISTANCE 1 (2009); see also Karen Caffarini, *Antibiotic Giveaways Stoke Fear of Patient Pressure*, AM. MED. NEWS, Jan. 29, 2009, <http://www.ama-assn.org/amednews/2009/01/26/bisc0128.htm>. For a recent empirical analysis finding increased antibiotic consumption with free programs, see Shanjun Li & Ramanan Laxminarayan, *Are Physicians' Prescribing Decisions Sensitive to Drug Prices? Evidence from a Free-Antibiotics Program* (May 1, 2010) (working paper, available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1598804](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1598804)).

39. James Love, *Prizes, Not Prices, To Stimulate Antibiotic R&D*, SCI. & DEV. NETWORK, Mar. 26, 2008, <http://www.scidev.net/en/opinions/prizes-not-prices-to-stimulate-antibiotic-r-d.html>.

40. James Love & Tim Hubbard, *The Big Idea: Prizes To Stimulate R&D for New Medicines*, 82 CHI.-KENT L. REV. 1519 (2007); James Love & Tim Hubbard, *Prizes for Innovation of New Medicines and Vaccines*, 18 ANNALS HEALTH L. 155 (2009); see also LAXMINARAYAN ET AL., *supra* note 15; MOSSIALOS ET AL., *supra* note 14; SWEDISH PRESIDENCY OF THE EUROPEAN UNION, *supra* note 16; Amy Kapczynski, *Innovation Policy for a New Era*, 37 J.L. MED. & ETHICS 264 (2009) (suggesting prizes for antibiotic development); Kesselheim & Outtersson, *supra* note 25. But see Donald W. Light, *Making Practical Markets for Vaccines*, 2 PLOS MED. e271 (2005), available at [http://www.who.int/intellectualproperty/submissions/CGD-PLOS-Light-10%1371\\_journal%pm](http://www.who.int/intellectualproperty/submissions/CGD-PLOS-Light-10%1371_journal%pm)

Impact Fund.<sup>41</sup>

The second element of the ACE program makes these payments conditional: sponsors obtain enhanced financial rewards only if antibiotic conservation targets are met. With this condition in place, a financial incentive would be created for the first time to manage antibiotics for public health rather than just private gain. This second element is necessarily linked to the first: absent this conditionality, increased reimbursement for antibiotics would simply accelerate the patent holder's incentives to aggressively sell the drugs. Taken together, our goal is to pay more for fewer pills consumed. For a simplified example, if a company currently sells one-hundred million antibiotic pills for \$1 each, their total revenue is \$100 million. Under ACE, assume that actual clinical needs with conservation are only fifty million pills. At this point, the company has lost \$50 million in decreased unit sales. But if the company meets the conservation targets, an ACE prize of perhaps \$150 million will be paid—essentially quadrupling the unit price while halving the unit sales. The companies will profit significantly by achieving public health goals.

This conditionality also offers interesting opportunities for special prizes for a few particularly valuable antibiotics. For example, the United States could create a Strategic Antibiotic Reserve to reward the conservation of important antibiotics. Under the present patent-based system, companies turn a profit only if they sell vast quantities of an antibiotic. For drugs in the Strategic Antibiotic Reserve, companies would be rewarded today for *not selling* the antibiotic, preserving a precious resource for dire future needs.<sup>42</sup>

Third, the biology of resistance creates unique horizontal and vertical coordination problems, even with perfect information and improved incentives at the individual company level. Overuse of antibiotics can create resistance to other drugs within and beyond their class. If multiple drug companies hold the patents for these drugs, the companies will need to coordinate some of their

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%200020271-p-L.pdf (arguing against advanced market commitments in vaccine R&D).

41. AIDAN HOLLIS & THOMAS POGGE, *THE HEALTH IMPACT FUND: MAKING NEW MEDICINES ACCESSIBLE FOR ALL* (2008); Thomas Pogge, *Human Rights and Global Health: A Research Program*, 36 *METAPHILOSOPHY* 182 (2005); Aidan Hollis, *An Efficient Reward System for Pharmaceutical Innovation* (Jan. 17, 2005) (working paper, available at <http://econ.ucalgary.ca/fac-files/ah/drugprizes.pdf>).

42. We articulate the Strategic Antibiotic Reserve separately because the unit sales might be extremely low in the first decade after introduction, swamping the insurance reimbursement system with pills with an imputed unit cost in the millions of dollars. In this case, a direct payment mechanism is indicated. The concept of compensating developers for better managing their public good products has a long and complicated history in American markets, particularly in agriculture. See, e.g., *Agricultural Adjustment Act of 1933*, Pub. L. No. 73-10, 41 Stat. 31 (1933) (seeking to decrease supplies of crops during the New Deal era by paying farmers to produce less).

market activities for long-term sustainability. For these horizontal coordination activities, limited antitrust waivers will permit efficient market coordination, without some of the monopolistic concerns ordinarily addressed by antitrust law. Limited waivers in other aspects of the law, such as the Stark anti-self-referral legislation, may be required to permit vertical coordination with hospitals, physicians, and other providers in implementing infection control measures.

Finally, public funding through the National Institutes of Health (NIH) and other agencies is necessary because for-profit companies do not invest in certain types of research that are essential for public health, including investments in human infrastructure to build research capacities in infectious diseases.

This Article proceeds in six sections. Section I briefly reviews the medical literature on antibacterial resistance. Section II examines the current state of antibiotic research and development. Section III reviews existing legal paradigms for creating and managing antibiotics. Section IV presents our core proposals, the Antibiotic Conservation and Effectiveness (ACE) program. In Section V, we take up critiques of ACE incentives, including the difficulties in fine-tuning financial and reimbursement incentives and the increased investment necessary to make ACE a reality. One key to this proposal is that the patent system remains unchanged; any alternatives offered are contractual and voluntary at the discretion of the companies. We then offer our conclusions in Section VI. The ACE program is designed to improve antibiotic markets, using government contracts to create a long-term and sustainable balance between the supply and demand for antibiotics. The ACE program will better align private and social values in this important sector. Otherwise, we cannot be certain that effective antibiotics will be available when infections strike.

## I. ANTIBIOTIC RESISTANCE

The first commercial use of penicillin in the 1940s signaled the birth of the antibiotic era.<sup>43</sup> Despite the efficacy of these new antibiotics, the medical community observed the emergence and spread of antibiotic-resistant bacteria within a few years of the introduction of penicillin.<sup>44</sup> Microorganisms have been found to exhibit a number of biological adaptations, including natural selection of new mutations and the passage of elements carrying resistance genes between species.<sup>45</sup> Resistant microorganisms pass readily among people, and even more

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43. Charles M. Grossman, *The First Use of Penicillin in the United States*, 149 ANNALS INTERNAL MED. 135 (2008).

44. See Mary Barber, *Staphylococcal Infection Due to Penicillin-Resistant Strains*, 2 BMJ 863, 864 (1947) (noting that the first report of penicillin-resistant staphylococcal infections came shortly after the widespread use of penicillin).

45. See generally Marc Lipsitch & Matthew H. Samore, *Antimicrobial Use and Antimicrobial*



readily among the sickest people in hospitals or other health care delivery institutions.<sup>46</sup> Antibiotic use can also spur infection by clearing commensal species that serve as natural limits on the overgrowth of deadly bacteria such as *Clostridium difficile*.<sup>47</sup>

Over the past decades, however, we have learned that the way antibiotics are used facilitates the development and spread of resistance.<sup>48</sup> Sir Alexander Fleming, who shared the Nobel Prize for the discovery of penicillin, first noted the role that antibiotic misuse plays in resistance, reporting, “It is not difficult to make microbes resistant to penicillin in the laboratory by exposing them to concentrations not sufficient to kill them.”<sup>49</sup> Misuse of antibiotics occurs in a number of ways, including prescription of antibiotics when they are not needed, prescription of the wrong type of antibiotic, and improper use of antibiotics by patients. All of these factors have direct biological ramifications; one model is that as the most susceptible bacteria are killed, microbes that may have developed resistance mutations can flourish in an environment with fewer competitors.<sup>50</sup>

There is a large literature on factors contributing to the social misuse of antibiotics.<sup>51</sup> One driver is physicians’ prescribing practices. Studies show that physicians vary broadly in their antibiotic prescription practices,<sup>52</sup> and may not be aware of or adhere to clinical practice guidelines addressing proper use of antibiotic agents.<sup>53</sup> For example, studies have shown that generalists and

*Resistance: A Population Perspective*, 8 EMERGING INFECTIOUS DISEASES 347 (2002).

46. See J. Kristie Johnson et al., *The Role of Patient-to-Patient Transmission in the Acquisition of Imipenem-Resistant Pseudomonas Aeruginosa Colonization in the Intensive Care Unit*, 200 J. INFECTIOUS DISEASE 900 (2009).

47. See Outtersson, *supra* note 18, for a full discussion of the pathogenesis of *Clostridium difficile*.

48. See generally Saver, *supra* note 32.

49. A. Mark Joffe, *Desperate Therapies and the Amazing Race for Antimicrobial Alternatives*, 17 CAN. J. INFECTIOUS DISEASES MED. & MICROBIOLOGY 285 (2006) (quoting Sir Alexander Fleming, Nobel Prize Acceptance Speech, 1945).

50. See Lipsitch & Samore, *supra* note 45, at 349.

51. See, e.g., McDonnell Norms Group, *Antibiotic Overuse: The Influence of Social Norms*, 207 J. AM. C. SURGEONS 265 (2008). This is true of both pediatric and adult patients. See, e.g., Howard Bauchner et al., *Parents, Physicians, and Antibiotic Use*, 103 PEDIATRICS 395 (1999); see also John Macfarlane et al., *Influence of Patients’ Expectations on Antibiotic Management of Acute Lower Respiratory Tract Illness in General Practice: Questionnaire Study*, 315 BMJ 1211 (1997).

52. Ethan A. Halm et al., *What Factors Influence Physicians’ Decisions to Switch from Intravenous to Oral Antibiotics for Community-Acquired Pneumonia?*, 16 J. GEN. INTERNAL MED. 599 (2001).

53. Galen E. Switzer et al., *Physician Awareness and Self-Reported Use of Local and National Guidelines for Community-Acquired Pneumonia*, 18 J. GEN. INTERNAL MED. 816 (2003).

infectious disease specialists were more likely to prefer newer, broader-spectrum drugs for the treatment of community-acquired pneumonia compared to older, more narrowly tailored agents still recommended by national guidelines.<sup>54</sup> Use of broad-spectrum antibiotic agents in patients whose infections are susceptible to a narrower-spectrum product can promote resistance and ultimately impede management if a more severe multidrug-resistant infection develops that requires the broad-spectrum agent.<sup>55</sup>

Patient behavior also contributes substantially to the development of antibiotic resistance. Patients may demand antibiotic agents in inappropriate clinical situations.<sup>56</sup> Patient demand for antibiotics in the setting of viral or non-infectious diseases can promote resistance, as studies have shown that prescription of multiple courses of the same antibiotic selects for more resistant organisms<sup>57</sup> and clears ecological space for transmission and growth of resistant pathogens.<sup>58</sup> Yet patient demand is a leading predictor of whether physicians provide an antibiotic prescription.<sup>59</sup> In addition, studies have shown that patients are insufficiently aware of the important ramifications of antibiotic overuse in the development of resistance.<sup>60</sup> Patients also may not always adhere to full treatment lengths,<sup>61</sup> which might be better if the prescription was inappropriate in the first instance. For some infections with particularly dangerous public health implications, such as multidrug-resistant tuberculosis, directly observed therapy (DOT) programs have been employed to ensure patient adherence to a full course of treatment.<sup>62</sup>

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54. See, e.g., Joel Lexchin, *Promoting Resistance?*, 28/29 ESSENTIAL DRUGS MONITOR 11 (2000); Joshua P. Metlay et al., *Tensions in Antibiotic Prescribing: Pitting Social Concerns Against the Interests of Individual Patients*, 17 J. GEN. INTERNAL MED. 87 (2002).

55. Carlos G. Grijalva et al., *Antibiotic Prescription Rates for Acute Respiratory Tract Infections in US Ambulatory Settings*, 302 JAMA 758 (2009).

56. Samuel Coenen et al., *Antibiotic Prescribing for Acute Cough: The Effect of Perceived Patient Demand*, 56 BRIT. J. GEN. PRAC. 183 (2006).

57. Céire Costelloe et al., *Effect of Antibiotic Prescribing in Primary Care on Antimicrobial Resistance in Individual Patients: Systematic Review and Meta-Analysis*, 340 BMJ c2096 (2010).

58. See Phillip Toltzis et al., *Impact of Amoxicillin on Pneumococcal Colonization Compared with Other Therapies for Acute Otitis Media*, 24 PEDIATRIC INFECTIOUS DISEASE J. 24 (2005).

59. See Coenen et al., *supra* note 56.

60. See Jodi Vanden Eng et al., *Consumer Attitudes and Use of Antibiotics*, 9 EMERGING INFECTIOUS DISEASES 1128 (2003); see also Edward A. Belongia et al., *Antibiotic Use and Upper Respiratory Infections: A Survey of Knowledge, Attitudes, and Experience in Wisconsin and Minnesota*, 34 PREVENTATIVE MED. 346 (2002).

61. See Diana I. Brixner, *Improving Acute Otitis Media Outcomes Through Proper Antibiotic Use and Adherence*, 11 AM. J. MANAGED CARE S202 (2005).

62. A. M. Nyamathi et al., *A Randomized Controlled Trial of Two Treatment Programs for Homeless Adults with Latent Tuberculosis Infection*, 10 INT'L J. TUBERCULOSIS & LUNG DISEASE

External social pressures also contribute to antibiotic overuse and resistance. Direct-to-physician advertising of antibiotics is one such factor. One study of advertisements related to antibiotics in medical journals showed that these advertisements, in promoting use of their products, rarely mentioned the risk of antibiotic resistance.<sup>63</sup> The power of such advertising to affect physician-prescribing practices is well documented and will be discussed in more detail in Section IV below. The example of free antibiotic programs combines elements of physician, patient and social pressures to prescribe. As Li and Laxminarayan have recently shown, free antibiotic programs at large U.S. pharmacies, such as Wal-Mart, influence physician prescribing patterns in statistically significant ways.<sup>64</sup> These market forces are barriers to optimal antibiotic use, but are also important potential levers for the proposed ACE Program. If drug companies were properly incentivized for public health goals, their influence and financial resources could be deployed to counteract many of the clinically inappropriate uses described above. At the very least, the companies would no longer have strong financial incentives to oppose public health conservation measures.

## II. THE LIMITATIONS OF NEW ANTIBIOTIC DEVELOPMENT

In recent years, infectious disease experts have expressed concern over the diminishing pipeline of additional antibiotics available to manage resistant disease.<sup>65</sup> In this Section, we examine the evidence and conclude that new production alone is unlikely to meet clinical needs unless a strong emphasis is also placed on antibiotic conservation.

The Infectious Diseases Society of America (IDSA) has described a consistent decline in the total number of new antibacterial agents approved in the last twenty-five years, and has reported that since 2004, only five systemic agents were actively being developed by the largest pharmaceutical companies.<sup>66</sup> This is

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775 (2006).

63. Jacob Gilad et al., *Antibiotic Drug Advertising in Medical Journals*, 37 SCANDINAVIAN J. INFECTIOUS DISEASE 910 (2005).

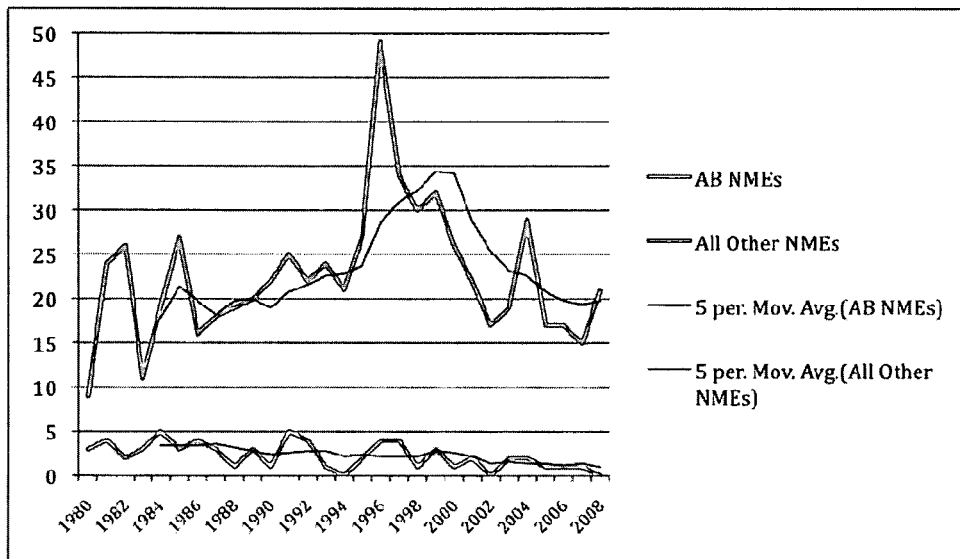
64. Shanjun Li & Ramanan Laxminarayan, *Are Physicians' Prescribing Decisions Sensitive to Drug Prices? Evidence from a Free-Antibiotics Program* (May 1, 2010) (working paper, available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1598804](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1598804)); see also Caffarini, *supra* note 38; Franco et al., *supra* note 38, at 1.

65. See, e.g., BAD BUGS, *supra* note 9; Brad Spellberg et al., *Trends in Antimicrobial Drug Development: Implications for the Future*, 38 CLINICAL INFECTIOUS DISEASES 1279 (2004).

66. David M. Livermore, *Has the Era of Untreatable Infections Arrived?*, 64 J. ANTIMICROBIAL CHEMOTHERAPY i29 (Supp. 1, 2009) (noting that we may have exhausted all therapeutic options); Brad Spellberg et al., *The Epidemic of Antibiotic-Resistant Infections: A Call to Action for the Medical Community from the Infectious Diseases Society of America*, 46 CLINICAL INFECTIOUS DISEASES 155, 158 (2008). But see Julian Davies, *The Garden of Antimicrobial*

partially a secular trend, especially since 1995, as FDA approvals in general have declined in recent years as well, as shown in Figure 1. Part of the problem lies with drug innovation in general, not antibiotics in particular.

**FIGURE 1: NUMBER OF ANTIBACTERIAL (AB) AND ALL OTHER NEW MOLECULAR ENTITIES (NMEs) APPROVED BY THE FDA, BY YEAR OF APPROVAL**<sup>67</sup>



According to the European Society of Clinical Microbiology and Infectious Diseases (ESCMID), the oxazolidinone class of antibiotics, which includes linezolid (Zyvox), is the only class with a completely novel mode of action that has been developed in the past three decades.<sup>68</sup> This claim, however, depends on how the term “class” is defined and the time period selected for comparison.<sup>69</sup>

*Delights*, 2 F1000 BIOLOGY REPORTS 26 (2010) (suggesting that additional antibiotic development should not be too difficult).

67. Rosa Rodriguez-Monguio, Enrique Seoane-Vasquez, John H. Powers, and Kevin Outtersen, Analysis of Systemic Antibiotics Approved in the U.S. Between 1980 and 2009 (2010) (abstract for 138th APHA Annual Meeting, on file with author).

68. Ragnar S. Norrby et al., *Lack of Development of New Antimicrobial Drugs: A Potential Serious Threat to Public Health*, 5 LANCET INFECTIOUS DISEASES 115, 116 (2005). Linezolid is the first member of the oxazolidinone family to be marketed in the United States.

69. *Longer Antimicrobial Patents*, *supra* note 24.

Since 2000, two new antibiotic classes (or analogues of classes)<sup>70</sup>—ketolides<sup>71</sup> and glycylcyclines<sup>72</sup>—have been approved that comprise important variations on old classes with improvements in their activity against resistant organisms. The FDA has also approved daptomycin (Cubicin) and quinupristin/dalfopristin (Synercid) in the last decade. Both of these products feature relatively novel mechanisms of action and could be considered new classes in humans, although prior animal use of virginiamycin has potentially affected quinupristin/dalfopristin. Several researchers have suggested that the proper category is not chemical class, but “functional resistance groups,” drugs for which certain species exhibit patterns of cross-resistance.<sup>73</sup> On that basis, the FDA has approved 2-5 new functional resistance groups in the past decade, depending on whether a narrow or expansive definition is used.

A more clinical way to view the success of antibiotic development may be to look at whether we are able to treat patients fighting serious resistant infections. From that perspective, current treatments are improving against some pathogens but worsening against others.<sup>74</sup> An IDSA task force surveyed the literature and identified six particularly dangerous groups of microorganisms displaying increasing resistance rates that pose important threats to patient care: extended-spectrum beta-lactamase (ESBL)-producing *Enterobacteriaceae*, methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant *Enterococcus faecium* (VRE), *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, and *Aspergillus*.<sup>75</sup> The IDSA concluded that among these six priority groups of

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70. Many independent industry experts would not consider ketolides and glycylcyclines as new classes, but as “analogues of existing classes.” Interview with Ursula Theuretzbacher, Founder, Ctr. for Anti-Infective Agents (July 27, 2010) (on file with Kevin Outterson).

71. Telithromycin (Ketek) is a novel derivative of the class of macrolide antibiotics that was designed with side-chain modifications intended to overcome antibiotic resistance to other macrolides. Kimberly D. Clay et al., *Severe Hepatotoxicity of Telithromycin: Three Case Reports and Literature Review*, 142 ANNALS INTERNAL MED. 415 (2006). Notably, telithromycin was not demonstrated to be more effective than other antibiotics in treating the infectious diseases for which it was indicated. It is also currently available only in oral form, which limits its utility in the sickest of patients with multidrug resistant infections.

72. Tigecycline (Tygacil) is derivative of the class of tetracyclines with microbiological activity against intra-abdominal and skin and soft tissue infections caused by susceptible or multidrug-resistant staphylococci, enterococci, or streptococci as well as most *Enterobacteriaceae* and anaerobic pathogens. Ethan Rubinstein & David Vaughan, *Tigecycline: A Novel Glycylcycline*, 65 DRUGS 1317 (2005).

73. LAXMINARAYAN ET AL., *supra* note 15, at 20, 40-41; MOSSIALOS, *supra* note 14, at 7, 113.

74. Livermore, *supra* note 66.

75. George H. Talbot et al., *Bad Bugs Need Drugs: An Update on the Development Pipeline from the Antimicrobial Availability Task Force of the Infectious Diseases Society of America*, 42 CLINICAL INFECTIOUS DISEASES 657, 657 (2006).

pathogens, MRSA has the largest current clinical impact and also the largest market for drugs.<sup>76</sup> Not surprisingly, a number of potentially useful MRSA drugs are in late-stage development.<sup>77</sup> The other five priority pathogens with smaller potential markets have fewer new agents in the pipeline,<sup>78</sup> which is not unexpected given market incentives.

The primary reason that pipelines for some priority pathogens can be so small is that for-profit companies with very high revenue expectations have dominated pharmaceutical research and development (R&D). The average funding for pharmaceutical R&D by the National Institutes of Health (NIH) has risen more slowly over time<sup>79</sup> as compared to pharmaceutical manufacturers.<sup>80</sup> More significantly, for-profit companies control approximately 90% of drug-related patents,<sup>81</sup> which often cover underlying research performed in academic institutions supported by public funds.<sup>82</sup> Though these companies have contributed to important progress in development of new medical treatments,<sup>83</sup> they also are beholden to their shareholders. Data from the Securities and Exchange Commission and the Department of Health and Human Services in the late 1990s suggest that the largest pharmaceutical manufacturers invest about one-third of their revenues in sales and general administration (including advertising), another 20% in return to shareholders, and about 15% in R&D in 2000<sup>84</sup> (industry estimates report 17% in 2009).<sup>85</sup> More recent data suggest that

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76. *Id.*

77. *Id.*

78. *Id.*

79. See NAT'L SCI. FOUND., *FEDERAL FUNDS FOR RESEARCH AND DEVELOPMENT: FISCAL YEARS 2007-09* (2010), available at <http://www.nsf.gov/statistics/nsf10305>.

80. CONG. BUDGET OFFICE, *RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY* (2006), available at <http://www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf>.

81. Aaron S. Kesselheim & Jerry Avorn, *Using Patent Data To Assess the Value of Pharmaceutical Innovation*, 37 J.L. MED. & ETHICS 176, 179 (2009).

82. Aaron S. Kesselheim & Jerry Avorn, *University-Based Science and Biotechnology Products: Defining the Boundaries of Intellectual Property*, 293 JAMA 850 (2005).

83. JOHN L. LAMATTINA, *DRUG TRUTHS: DISPELLING THE MYTH ABOUT PHARMA R&D* (Wiley 2008).

84. FAMILIES USA, *OFF THE CHARTS: PAY, PROFITS AND SPENDING BY DRUG COMPANIES* (2001), available at [www.familiesusa.org/assets/pdfs/offthecharts6475.pdf](http://www.familiesusa.org/assets/pdfs/offthecharts6475.pdf); KAISER FAMILY FOUND., *PRESCRIPTION DRUG TRENDS: A CHARTBOOK* 65, 70 fig. 4.5, 71 fig. 4.6 (2000), available at <http://www.kff.org/rxdrugs/3019-index.cfm>; Press Release, Public Citizen's Congress Watch, *Drug Industry Most Profitable Again* (April 11, 2001), available at <http://www.citizen.org/pressroom/release.cfm?ID=819> (noting that in 2000 Fortune 500 drug companies devoted 30% of revenues to marketing and administration and 12% to R&D).

85. PHARM. RESEARCH AND MFRS. OF AM., *PHARMACEUTICAL INDUSTRY PROFILE 2009* (2009), available at <http://www.phrma.org/files/attachments/PhRMA%202009%20Profile%20FINAL.pdf>

pharmaceutical manufacturers still spend 31%-50% of sales on marketing.<sup>86</sup> While industry supporters offer slightly different numbers,<sup>87</sup> the essential point is clear: increased sales of pharmaceuticals translate into only a limited increase in R&D after accounting for other expenses and R&D costs bear little relationship to prices. As Professor Scherer notes: “Sunk research-and-development costs are bygones and are therefore irrelevant in current pricing decisions.”<sup>88</sup>

As a result, projected revenue, rather than other factors such as morbidity of a disease or perceived public health need, can become the most important determinant of new drug development.<sup>89</sup> Antibiotics face unique reimbursement challenges in part because of their history of low unit prices, but also because the total unit sales may be smaller than other drug markets.<sup>90</sup> From a financial point of view, drug companies disparage antibiotics as poor sellers due to the short courses of therapy, which limit the ability to earn revenues over a long period of time.<sup>91</sup> “Blockbuster” drugs are usually defined as those producing revenues in excess of a billion dollars per year,<sup>92</sup> but in antibiotics, companies would

(citing 17.4% of total sales into R&D).

86. Marc-André Gagnon & Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, 5 PLoS MED. 29, 32 (2008), <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pm.ed.0050001>. (finding that the actual amount of promotional expenditures “could range from a low of US\$27.7 billion to a high of US\$57.5 billion”).

87. See *R&D Investment by US Biopharma Remains Strong Despite Ongoing Economic Challenges, Reaching a Record \$65.3 Billion*, THE PHARMA NEWS, Mar. 17, 2010, available at [http://www.phrma.org/news/news/rd\\_investment\\_us\\_biopharmaceutical\\_companies\\_remains\\_strong\\_despite\\_ongoing\\_economic\\_chall](http://www.phrma.org/news/news/rd_investment_us_biopharmaceutical_companies_remains_strong_despite_ongoing_economic_chall) (reporting that the pharmaceutical industry trade group estimates that “the USA’s pharmaceutical research companies have consistently invested around 18% of domestic sales on R&D activities”).

88. F.M. Scherer, *The Pharmaceutical Industry – Prices and Progress*, 351 NEW ENG. J. MED. 927, 929 (2004).

89. As Roin has pointed out, this perspective has a substantial effect on decisions regarding whether to continue to invest in “pipeline” drugs. Companies have preferentially invested in research on products whose intellectual property ownership is clear (or solidly under their control), excluding research on other approaches or agents that could be better suited to address unmet public health needs. Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503 (2009). But see Kevin Outterson, *Death from the Public Domain?*, 87 TEXAS L. REV. SEE ALSO 45 (2009), <http://www.texaslrev.com/seealso/volume-87/roin/death-from-the-public-domain.html> (challenging the example of an unpatentable drug given by Roin).

90. Richard P. Wenzel, *The Antibiotic Pipeline—Challenges, Costs, and Values*, 351 NEW ENG. J. MED. 523 (2004).

91. Roger Finch & Pamela A. Hunter, *Antibiotic Resistance—Action To Promote New Technologies: Report of an EU Intergovernmental Conference Held in Birmingham, UK, 12-13 December 2005*, 58 J. ANTIMICROBIAL CHEMOTHERAPY, i3, 17 (2006).

92. Bruce Booth & Rodney Zimmel, *Quest for the Best*, 2 NATURE REV. DRUG DISCOVERY.

consider \$200 million in annual sales to be a successful market.<sup>93</sup> And while some large pharmaceutical companies are moving away from the blockbuster drug development model,<sup>94</sup> manufacturers still focus on diseases that may provide a higher return on investment.<sup>95</sup> Even when drug companies decide to invest in R&D for antibiotics, they are drawn to the largest markets, such as the multibillion-dollar MRSA market. Large multinational drug companies have not deeply invested in finding drugs for the other five priority pathogens identified by the IDSA.<sup>96</sup> The ACE program redirects company R&D incentives by instituting value-based reimbursement. Companies will be paid for the health impact of their antibiotic, not the historically weak markets prevalent today.

Other peculiar factors also may disincentivize investment in new antibiotic development by for-profit companies. Increasing resistance makes the antibiotic less effective over time, which might limit the ability of pharmaceutical manufacturers to use standard “life-cycle management” strategies, such as the creation of variant dose or extended-release formulations.<sup>97</sup> Existing evidence suggests that commercially significant resistance does not occur during the patent term, so this effect may be modest.<sup>98</sup>

The market for new antibiotic products in the United States and other wealthy countries is limited by public health efforts to prevent infections and restrict the prescription of antibiotics in order to prevent the acceleration of bacterial resistance.<sup>99</sup> Pharmaceutical companies are concerned that important

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838, 838 (2003).

93. Interview with Ursula Theuretzbacher, Founder, Ctr. for Anti-Infective Agents (July 27, 2010) (on file with Kevin Outterson).

94. See David M. Cutler, *The Demise of the Blockbuster?*, 356 NEW ENG. J. MED. 1292 (2007); see also Matthew Goodman, *New Boss Andrew Witty Revamps GlaxoSmithKline*, THE TIMES, Jul. 27, 2008, [http://business.timesonline.co.uk/tol/business/industry\\_sectors/industrials/article4405862.ece](http://business.timesonline.co.uk/tol/business/industry_sectors/industrials/article4405862.ece).

95. Steven J. Projan, *Why Is Big Pharma Getting Out of Antibacterial Drug Discovery?*, 6 CURRENT OPINION IN MICROBIOLOGY 427, 428 (2003).

96. Fortunately, smaller pharmaceutical companies have taken the lead in research and development where larger manufacturers have stepped out. Andriy Luzhetskyy et al., *The Future of Natural Products as a Source of New Antibiotics*, 8 CURRENT OPINION INVESTIGATIVE DRUGS 608 (2007). For example, daptomycin was shepherded to approval in 2004 by the Boston-based biotech company Cubist seven years after Eli Lilly closed development of the product. Lilly outlicensed daptomycin early in its clinical trials owing to reports of side effects, but Cubist later determined that the side effects were related to suboptimal dosing strength and intervals. John F. Barrett, *Can Biotech Deliver New Antibiotics?*, 8 CURRENT OPINION IN MICROBIOLOGY 498 (2005).

97. See Edward Power, *Impact of Antibiotic Restrictions: The Pharmaceutical Perspective*, 12 CLINICAL MICROBIOLOGY & INFECTION 25, 27 (2006).

98. See *Legal Ecology of Resistance*, *supra* note 19, at 637-41.

99. See Spellberg et al., *supra* note 65; Spellberg et al., *supra* note 66.



new antibiotic drugs may be subject to aggressive restrictions on use, price controls, and copying by unlicensed generic manufacturers in developing countries.<sup>100</sup> These programs may greatly improve public health, but they reduce the demand for antibiotics and thus shrink the market for the companies that sell them. Antibiotic conservation directly threatens the commercial market for new antibiotics.<sup>101</sup> Similarly, the production of multiple new antibiotics promoted by for-profit companies directly threatens conservation. The ACE program directly addresses this problem by reimbursing for conservation.

Finally, drug companies sometimes claim that antibiotics face uniquely higher research costs that discourage development.<sup>102</sup> For example, critics claim that FDA regulatory requirements have been overly burdensome in the field of infectious diseases, where placebo-controlled studies can be infeasible and alternative study designs, such as non-inferiority studies, can be challenging and costly to organize.<sup>103</sup> While these claims about clinical study designs are plausible, they are not universally accepted.<sup>104</sup> Antibiotic clinical trials are often less expensive than many other types of drug trials because many “predictive animal models [are] available and the late attrition rate due to ineffectiveness is low for antibiotics.”<sup>105</sup> In addition, speeding up antibiotic approvals may increase the risk that antibiotics reach the market with unknown safety risks.<sup>106</sup> In the past three decades, drug companies have withdrawn numerous antibiotics with safety concerns from the U.S. market, more than any other drug class.<sup>107</sup> This is not a record that supports a call for weaker safety standards. Enhanced conservation under ACE will diminish the urge to rush antibiotics through trials prematurely.

In recent years, many groups have suggested proposals to address the problem of serious disease from resistant pathogens.<sup>108</sup> Some proposals focus on reducing demand for antibiotics, for example, through conservation, appropriate

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100. Projan, *supra* note 95, at 428.

101. *Legal Ecology of Resistance*, *supra* note 19, at 642-45.

102. David M. Shlaes, *The Abandonment of Antibacterials: Why and Wherefore?*, 3 CURRENT OPINION PHARMACOLOGY 470 (2003).

103. Cecilia H. Burke & Geoffrey M. Levitt, *A Manufacturer's Perspective: Recent Challenges in Antibiotic Drug Approval*, 2 UPDATE: FOOD & DRUG L. REG. & ED. 12 (2008).

104. GOVERNMENT ACCOUNTABILITY OFFICE, NEW DRUG APPROVAL: FDA'S CONSIDERATION OF EVIDENCE FROM CERTAIN CLINICAL TRIALS (2010), *available at* <http://www.gao.gov/new.items/d10798.pdf> (discussing issues with non-inferiority trials for antibiotics); Kevin Outterson, John H. Powers III, Ian M. Gould & Aaron S. Kesselheim, *Questions About the 10 X '20 Initiative*, 51 CLINICAL INFECTIOUS DISEASES 751 (2010).

105. Interview with Ursula Theuretzbacher, Founder, Ctr. for Anti-Infective Agents (July 27, 2010) (on file with Kevin Outterson).

106. *Id.*

107. Rodriguez-Monguió et al., *supra* note 67.

108. See *supra* notes 9-16 and accompanying text.

use, antibiotic stewardship and infection control (see Sector 3 in Table 1).<sup>109</sup> Others focus on the supply side (Sectors 2, 4 and 6), generally suggesting additional property rights or financial incentives to encourage for-profit pharmaceutical industry investment in new drug development.<sup>110</sup> The better discussions, in our view, integrate both conservation and production into a coherent policy analysis.<sup>111</sup> In the next Part, we analyze the most prominent conservation and production proposals and consider how they align financial incentives with public health goals. Our proposals borrow from many existing ideas, but integrate them simultaneously to address both conservation and production.

### III. EXISTING PARADIGMS TO PROMOTE CONTINUED ANTIBIOTIC EFFECTIVENESS

Proposals to address the growing problem with resistant microorganisms have emerged from a number of different perspectives. In many cases, these proposals come from different academic disciplines, often operating independently of each other. Patent lawyers suggest patent extensions; epidemiologists suggest infection control; clinicians demand new antibiotics; drug companies want to maximize revenue; and regulators suggest new regulations. These disciplines must break their isolation and integrate their perspectives into a comprehensive solution.

First, many researchers have emphasized conservation of currently available antibiotics through strategies such as infection control, as well as limitations on the use of antibiotics to clinically appropriate situations. One institutional champion of this Sector 3 (see Table 1) approach is the Alliance for the Prudent Use of Antibiotics (APUA). Other strategies focus on developing new drugs rather than conservation of existing ones. For example, the IDSA has prominently aligned itself with a call for new financial incentives to support the development of new antibiotic pharmaceutical products. These Sector 2 proposals include additional patent-based exclusivity for sponsors.<sup>112</sup> Some academics and think tanks have suggested non-patent-based incentive proposals, including guaranteed purchase contracts or cash prizes<sup>113</sup> for successful

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109. See, for example, the work of the Alliance for the Prudent Use of Antibiotics, *supra* note 10.

110. See, for example, the report by the Infectious Diseases Society of America, *supra* note 9.

111. See, e.g., LAXMINARAYAN ET AL., *supra* note 15; MOSSIALOS ET AL., *supra* note 14; NUGENT, BACK & BEITH, *supra* note 13

112. See BAD BUGS, *supra* note 9. But when IDSA supported legislation in the 111th Congress, the proposed legislation did not include the controversial patent language. See Strategies To Address Antimicrobial Resistance Act, H.R. 2400, 111th Cong. (1st Sess. 2009).

113. See, e.g., LAXMINARAYAN ET AL., *supra* note 15; MOSSIALOS ET AL., *supra* note 14;

development of a new antibiotic.<sup>114</sup> These are Sector 6 proposals, focused on contract rather than property rights. The IDSA and others have proposed reducing costs of antibiotic research and development (Sector 4), which can include changing regulatory parameters that guide new drug approval.<sup>115</sup> IDSA has also supported increasing government grants to build the infrastructure and help promote better understanding of basic biology and drug targets (Sector 6).<sup>116</sup> Tort law could also be used, either as a liability threat to promote conservation (Sector 7) or as a shield to promote production of new drugs by preempting state tort law (Sector 8). We will first examine the major existing efforts before we turn to our novel proposals.

### A. Antibiotic Conservation

Environmental infection control<sup>117</sup> and programs designed to promote rational use of antibiotics (also called “antibiotic stewardship”)<sup>118</sup> are the primary mechanisms through which antibiotic conservation is currently implemented.<sup>119</sup> Infection control is a public health measure that can help slow the spread of all infections, including particularly virulent or resistant microbes.<sup>120</sup> Examples of infection control mechanisms include tuberculosis testing for healthcare professionals,<sup>121</sup> environmental cleaning,<sup>122</sup> screening of high-risk patients for

SWEDISH PRESIDENCY OF THE EUROPEAN UNION, *supra* note 16; Kapczynski, *supra* note 40 (suggesting prizes for antibiotic development); Love & Hubbard, *The Big Idea*, *supra* note 40, at 1519; Love & Hubbard, *Prizes for Innovation*, *supra* note 40, at 155; Kesselheim & Outtersen, *supra* note 25. *But see* Light, *supra* note 40, at e271 (arguing against advanced market commitments in vaccine R&D).

114. Love, *supra* note 40.

115. BAD BUGS, *supra* note 9; Projan & Shlaes, *supra* note 35.

116. *Id.*

117. M. Lindsay Grayson et al., *Significant Reductions in Methicillin-Resistant Staphylococcus Aureus Bacteraemia and Clinical Isolates Associated with a Multisite, Hand Hygiene Culture-Change Program and Subsequent Successful Statewide Roll-Out*, 188 MED. J. AUSTRAL. 633 (2008).

118. Allison E. Aiello et al., *Ethical Conflicts in Public Health Research and Practice: Antimicrobial Resistance and the Ethics of Drug Development*, 96 AM. J. PUB. HEALTH 1910 (2006).

119. See *Fighting Antibiotic Resistance*, *supra* note 25, at 1691.

120. Rajesh K. Malik et al., *Epidemiology and Control of Vancomycin-Resistant Enterococci in a Regional Neonatal Intensive Care Unit*, 18 PEDIATRIC INFECTIOUS DISEASE J. 352 (1999).

121. Sharon F. Welbel et al., *Protecting Health Care Workers from Tuberculosis: A 10-Year Experience*, 37 AM. J. INFECTION CONTROL 668 (2009).

122. Lynn Eaton, *Hand Washing Is More Important than Cleaner Wards in Controlling MRSA*, 330 BMJ 922 (2005).

resistant microbes,<sup>123</sup> and isolating high-risk patients in special rooms or wards.<sup>124</sup>

Antibiotic stewardship can involve physician education or active management of physicians' prescription of antibiotics to encourage the appropriate selection, dosing, route, and duration of therapy.<sup>125</sup> The goal is to optimize clinical outcomes while minimizing unintended consequences of antibiotic use like the emergence of resistance.<sup>126</sup> Academic detailing programs<sup>127</sup> and antibiotic prescription guidelines<sup>128</sup> teach physicians about evidence-based prescribing without formal restrictions on their prescribing behaviors. Active management of prescription choices is usually a top-down process organized at the level of the payor or practice organization. The most interventionist programs involve formal restrictions on prescribing and can exclude certain antibiotics from clinical use.<sup>129</sup> Other less restrictive types of active management include requiring heightened justification from physicians before prescribing certain antibiotics. Prior authorization requirements, for example, have been shown to change prescribing patterns in other drug classes.<sup>130</sup>

Some stewardship tactics, particularly formulary restriction and preauthorization requirements, have demonstrated ability to affect antibiotic resistance rates; one study found that six months after restricting prescribing of vancomycin, colonization by vancomycin-resistant *Enterococcus* (VRE)

123. Walter E. Pofahl et al., *Active Surveillance Screening of MRSA and Eradication of the Carrier State Decreases Surgical-Site Infections Caused by MRSA*, 208 J. AM. C. SURGEONS 981 (2009); Stephan Harbarth et al., *Universal Screening for Methicillin-Resistant Staphylococcus Aureus at Hospital Admission and Nosocomial Infection in Surgical Patients*, 299 JAMA 1149 (2008).

124. Susan A. Maloney et al., *Efficacy of Control Measures in Preventing Nosocomial Transmission of Multidrug-Resistant Tuberculosis to Patients and Health Care Workers*, 122 ANNALS OF INTERNAL MED. 90 (1995).

125. See Saver, *supra* note 32.

126. Timothy H. Dellit et al., *Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America Guidelines for Developing an Institutional Program to Enhance Antimicrobial Stewardship*, 44 CLINICAL INFECTIOUS DISEASE 159 (2007).

127. Daniel H. Solomon et al., *Academic Detailing To Improve Use of Broad-Spectrum Antibiotics at an Academic Medical Center*, 161 ARCHIVES OF INTERNAL MED. 1897 (2001).

128. Kristin Schaffer et al., *Do Educational Interventions Improve Management of Patients with Community-Acquired Pneumonia?*, 28 J. HEALTHCARE QUALITY 7 (2006).

129. This is otherwise known as an "exclusive formulary." See Muhammad Mamdani et al., *Impact of a Fluoroquinolone Restriction Policy in an Elderly Population*, 120 AM. J. MED. 893 (2007).

130. Michael A. Fischer et al., *Medicaid Prior-Authorization Programs and the Use of Cyclooxygenase-2 Inhibitors*, 351 NEW ENG. J. MED 2187 (2004).

decreased from 47% to 15% in one hospital.<sup>131</sup> Stewardship programs can also be cost-effective for hospitals<sup>132</sup> and health care systems.<sup>133</sup>

Despite these successes, studies have also shown that stewardship programs are not fully effective against the emergence of antibiotic resistance.<sup>134</sup> Recent systematic reviews concluded that inpatient stewardship programs can reduce antibacterial resistance,<sup>135</sup> but that similar outcomes are much harder to achieve in the outpatient realm.<sup>136</sup> MRSA has been documented to circumvent patient isolation in different rooms or across separated cohort bays.<sup>137</sup> Other stewardship programs, such as educational tools aimed at teaching proper antibiotic use to physicians and disseminating expert-developed clinical guidelines, have varied effects on prescribing practices and have not been shown to have a substantial impact on development of resistance.<sup>138</sup> Formulary restrictions on certain antibiotics have led to over-prescription and increased resistance to other non-restricted antibiotics.<sup>139</sup> Finally, some studies have shown that even rigorous antibiotic restriction practices that result in short-term improvements and slower overall rates of resistance growth have not fully deterred antibiotic resistance.<sup>140</sup> Conservation buys more time, but is only a partial solution.

The scientific literature on stewardship programs thus suggests that certain sensible and well-coordinated programs can be effective against antimicrobial resistance. However, social factors related to the pharmaceutical and health delivery markets have limited the implementation of effective stewardship and

131. John M. Quale et al., *Manipulation of a Hospital Antimicrobial Formulary To Control an Outbreak of Vancomycin-Resistant Enterococci*, 23 CLINICAL INFECTIOUS DISEASE 1020 (1996).

132. Philippe Lesprit & Christian Brun-Buisson, *Hospital Antibiotic Stewardship*, 21 CURRENT OPINION INFECTIOUS DISEASE 344 (2008).

133. Belinda E. Ostrowsky et al., *Control of Vancomycin-Resistant Enterococcus in Health Care Facilities in a Region*, 344 NEW. ENG. J. MED. 1427 (2001).

134. Jeroen A. Schouten et al., *Barriers to Optimal Antibiotic Use for Community-Acquired Pneumonia at Hospitals: A Qualitative Study*, 16 QUALITY & SAFETY HEALTH CARE 143 (2007).

135. Peter Davey et al., *Interventions To Improve Antibiotic Prescribing Practices for Hospital Inpatients*, 4 COCHRANE DATABASE SYSTEMATIC REVIEWS CD003543 (2005).

136. Sandra R. Arnold & Sharon E. Straus, *Interventions To Improve Antibiotic Prescribing Practices in Ambulatory Care*, 4 COCHRANE DATABASE SYSTEMATIC REVIEWS CD003539 (2005).

137. Jorge A. Cepeda et al., *Isolation of Patients in Single Rooms or Cohorts To Reduce Spread of MRSA in Intensive-Care Units: Prospective Two-Centre Study*, 365 LANCET 295 (2005).

138. Paula Wilton et al., *Strategies To Contain the Emergence of Antimicrobial Resistance: A Systematic Review of Effectiveness and Cost-Effectiveness*, 7 J. HEALTH SERVICES, RES. & POL'Y 111 (2002).

139. James J. Rahal et al., *Class Restriction of Cephalosporin Use To Control Total Cephalosporin Resistance in Nosocomial Klebsiella*, 280 JAMA 1233 (1998).

140. David Livermore, *Can Better Prescribing Turn the Tide of Resistance?*, 2 NATURE REVIEWS MICROBIOLOGY 73 (2004).

infection control strategies. In particular, we have identified two primary ways that the financial incentives of important actors in this market are misaligned.

First, formulary restrictions and preauthorization requirements can be effective stewardship tools, but pharmaceutical manufacturers generally disfavor such measures since they dampen demand for their products. These managed-care techniques restrict access to their products through tiered formularies or as part of step therapy.<sup>141</sup> The industry has fought these restrictions in many ways, including litigation in the highest courts.<sup>142</sup> Since pharmaceutical companies are such powerful institutional actors, any public health program that faces strident drug company opposition will have difficulty succeeding. Our ACE proposals are designed to align private financial incentives with public health goals in a way that makes the drug companies full partners in antibiotic conservation efforts.

Second, hospitals and physicians do not have a billing code for conservation. The lack of both direct reimbursement for infection control and upfront resources to implement stewardship measures effectively have limited infection control measures at hospitals and ambulatory surgical centers.<sup>143</sup> Budgets for infection control continue to tighten—according to recent Medicare guidelines, hospitals will not be reimbursed for the additional costs of treating inpatients who develop urinary or vascular catheter-associated infections, whether or not the infection

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141. Pharmacy benefit managers (PBMs), which implement formularies for public and private health insurance plans, are a primary target of manufacturers in this regard. Manufacturers use a combination of rebates and fees to secure more favorable placement on a formulary, including access rebates for placement of products on the PBM formulary and market share rebates for garnering higher market share than established targets. John Carroll, *When Success Sours: PBMs Under Scrutiny*, MANAGED CARE MAGAZINE, Sept. 2002, available at <http://www.managedcaremag.com/archives/0209/0209.pbms.html>.

142. For example, state Medicaid programs offer insurance coverage for low-income patients, but in recent years Medicaid programs have struggled with rising spending on pharmaceutical products. When a number of states experimented with formulary restrictions aimed at reducing drug costs, pharmaceutical manufacturers sued to prevent their implementation. The case ultimately reached the Supreme Court, which held that the states' actions were legal. *Pharm. Research & Mfrs. of Am. v. Walsh*, 123 U.S. 1855 (2003). The drug industry recently lost a similar case before the European Court of Justice, involving formulary tools in the English National Health System. *Case C-62/09, Ass'n of the Brit. Pharm. Indus. v. Med. Healthcare Prod. Regulatory Agency*, 2010 E.C.R. (holding that public authorities may offer financial incentives to physicians who prescribe generics and cheaper therapeutic substitutes).

143. Michael Edmond & Theodore C. Eickhoff, *Who Is Steering the Ship? External Influences on Infection Control Programs*, 46 CLINICAL INFECTIOUS DISEASES 1746 (2008); Eli N. Perencevich et al., *Raising Standards While Watching the Bottom Line: Making a Business Case for Infection Control*, 28 INFECTION CONTROL & HOSPITAL EPIDEMIOLOGY 1121 (2007); Outtersson, *supra* note 18.

was avoidable.<sup>144</sup> Increased financial strain on individual institutions and their budgets for infectious disease programs assures that such programs remain chronically underfunded and underperforming. While some studies have claimed that infection control is cost effective, these studies generally compare hospital costs or charges rather than actual reimbursement.<sup>145</sup> Under Medicare and many private payor reimbursement systems, even these supposedly cost-effective programs probably lose money for the hospital.<sup>146</sup> Infection control is not a revenue center for U.S. hospitals. The U.S. system offers billions of dollars in tax and patent incentives for new antibiotic production, but virtually no market incentives for conservation. Under the ACE program, providers would be rewarded for conservation, either directly through the Medicare reimbursement system or indirectly from drug companies wanting to achieve their own conservation targets.

Finally, hospitals and other health care institutions have little incentive to cooperate regionally to support infection control. Infections pass between hospitals and long-term care facilities, and between rival institutions as patients and other populations circulate. Just as water pollution control is more effective when managed for the entire watershed, infections should be managed on a public health basis, a concept we call *germ shed management*.<sup>147</sup> The Netherlands provides clear evidence that a coordinated approach yields good results.<sup>148</sup> The ACE program facilitates coordination by giving significant financial incentives to the patent holders who operate globally.

In short, infection control and antibiotic stewardship programs sometimes succeed even in the face of the daunting financial incentives and institutions currently standing in opposition. If maintaining antibiotic effectiveness is a public good, then coordination should be facilitated among actors in a position to implement effective conservation, especially the drug companies and health care providers.<sup>149</sup> This is where we believe that the ACE program we propose in Part IV can have a significant impact.

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144. See Heidi L. Wald & Andrew M. Kramer, *Nonpayment for Harms Resulting From Medical Care: Catheter-Associated Urinary Tract Infections*, 298 JAMA 2782, 2782-84 (2007).

145. See, e.g., Phillipe Lesprit & Christian Brun-Buisson, *Hospital Antibiotic Stewardship*, 21 CURRENT OPINION INFECTIOUS DISEASES 344 (2008) (summarizing a number of studies showing cost savings from antibacterial conservation programs).

146. Outtersson, *supra* note 18.

147. Outtersson, *supra* note 18.

148. Heiman F. Wertheim et al., *Low Prevalence of Methicillin-Resistant Staphylococcus Aureus (MRSA) at Hospital Admission in the Netherlands: The Value of Search and Destroy and Restrictive Antibiotic Use*, 56 J. HOSPITAL INFECTIONS 321 (2004).

149. Benjamin M. Althouse et al., *A Public Choice Framework for Controlling Transmissible and Evolving Diseases*, 107 PNAS 1696, 1699 (2010).

*B. Property-Based Incentives*

Apart from efforts at infection control and stewardship, some have called for additional patent initiatives intended to increase the supply of antibiotics by encouraging investment in R&D,<sup>150</sup> even though patents as production incentives (Sector 1)<sup>151</sup> are only one of eight possible policy solutions to the problem of antibiotic resistance.<sup>152</sup> The patent system, which provides periods of market exclusivity for drug products, has long been the primary mechanism used to encourage for-profit companies to invest in new drug discovery and development in the pharmaceutical field.<sup>153</sup> Pharmaceutical manufacturers use their market exclusivity period to earn extraordinary revenues on their products.<sup>154</sup> Under the patent system, many important new drug products have been developed and marketed, leading to substantial public health gains, while the research-based pharmaceutical industry has remained a leader in earnings growth and return-on-equity for its shareholders.<sup>155</sup>

However, recent studies have revealed important problematic effects of the patent system incentives on public health,<sup>156</sup> and have even questioned whether this system contributes positively to the U.S. economy.<sup>157</sup> The fixed patent term begins when the patent is filed, usually not long after the initial isolation of a new antibiotic molecule. As a result, manufacturers are incentivized to move their products to market as quickly as possible, and regulatory authorities such as the FDA are pressured to approve products as quickly as possible—both of which can lead to missed signals for emerging safety problems.<sup>158</sup> After marketing

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150. See, e.g., BAD BUGS, *supra* note 9.

151. See Table 1.

152. See *supra* Table 1.

153. See generally J. H. Barton & E. J. Emanuel, *The Patents-Based Pharmaceutical Development Process: Rationale, Problems, and Potential Reforms*, 294 JAMA 2075 (2005).

154. Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y L. & ETHICS 193 (2005).

155. CONG. BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY (2006), available at <http://www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf>.

156. Aaron S. Kesselheim, *Intellectual Property Policy in the Pharmaceutical Sciences: The Effect of Inappropriate Patents and Market Exclusivity Extensions on the Health Care System*, 9 AAPS J. E306, art. 33 (2007).

157. JAMES BESSEN & MICHAEL J. MEURER, *PATENT FAILURE: HOW JUDGES, BUREAUCRATS AND LAWYERS PUT INNOVATORS AT RISK* (Princeton Univ. Press 2008).

158. Studies have shown that New Drug Applications approved on an accelerated time frame as artificial regulatory deadlines approach are more likely to have safety problems after they are on the market. See Daniel Carpenter et al., *Drug-Review Deadlines and Safety Problems*, 358 NEW ENG. J. MED. 1354 (2008); see also Mary K. Olson, *Are Novel Drugs More Risky for Patients than Less Novel Drugs?*, 23 J. HEALTH ECON. 1135 (2004). Notably, these findings remain controversial.



approval, the fixed patent term encourages manufacturers to maximize their return on investment by promoting rapid uptake of the product. Drug companies have recently paid hefty fines for promoting drugs for conditions not supported on the drug label approved by the FDA.<sup>159</sup> With the patent clock ticking, companies have a clear incentive to maximize revenues before generic competition appears.<sup>160</sup> Such overuse is financially wasteful and can expose patients to risks of adverse events without providing them with the benefits of the drug.<sup>161</sup> In the case of antibiotics, overuse is potentially even more troublesome, because it can speed the development and spread of antibiotic resistance.<sup>162</sup> One of us has previously characterized this behavior as “patent holder waste” if the patent holder’s overzealous marketing degrades the usefulness of the antibiotic before the patent expires.<sup>163</sup>

With these general comments in mind, we consider a number of different proposals that have been recommended for adjusting the patent-based market exclusivity system to make investment in antibiotic R&D more lucrative to for-profit companies. In large part, we remain critical of these patent-based approaches.<sup>164</sup>

### *1. Patent Extensions*

A number of Sector 2<sup>165</sup> (patents as production incentives) proposals offer to extend patent or data exclusivity periods for newly approved antibiotics. Patents last for twenty years from the filing date, but due to development and regulatory

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Clark Nardinelli et al., *Letter to the Editor: Drug-Review Deadlines and Safety Problems*, 359 NEW ENG. J. MED. 95 (2008).

159. See Aaron S. Kesselheim, David M. Studdert & Michelle M. Mello, *Whistle-Blowers’ Experience in Major Fraud Litigation against Pharmaceutical Companies*, 362 NEW ENG. J. MED. 1832, 1833 (2010) (describing nine cases of illegal off-label marketing leading to over \$3.5 billion in recoveries). See generally Aaron S. Kesselheim & David M. Studdert, *Whistleblower-Initiated Enforcement Actions Against Health Care Fraud and Abuse in the United States, 1996-2005*, 149 ANNALS INTERNAL MED. 342 (2008) (finding increasing numbers of pharmaceutical-related fraud cases).

160. William H. Shrank et al., *State Generic Substitution Laws Can Lower Drug Outlays under Medicaid*, 29 HEALTH AFF. 1383 (2010).

161. JERRY AVORN, *POWERFUL MEDICINES: THE BENEFITS, RISKS, AND COSTS OF PRESCRIPTION DRUGS* (2004).

162. John B. Horowitz & H. Brian Moehring, *How Property Rights and Patents Affect Antibiotic Resistance*, 13 HEALTH ECON. 575 (2004); Eric Kades, *supra* note 19, at 611-12.

163. See, e.g., *Legal Ecology of Resistance*, *supra* note 19; *Vanishing Public Domain*, *supra* note 19.

164. See Kesselheim & Outterson, *supra* note 25.

165. See Table 1.

approval times, the effective market exclusivity life of a newly approved small-molecule drug is usually on the order of eight to fifteen years.<sup>166</sup> The U.S. Government Accountability Office at one time suggested that patents could be lengthened “to 25 or 30 years” for important drugs with “high therapeutic potential,” which would include certain antibiotic products.<sup>167</sup> An alternative proposal that would accomplish similar goals involves starting the patent or market exclusivity term at the time of FDA regulatory approval, rather than when the patent is filed.<sup>168</sup> Longer market exclusivity terms would provide sponsors with more time in which to earn revenues on their products. A few commentators recommend extremely long patent terms as a production incentive and also as a Sector 1<sup>169</sup> conservation device.<sup>170</sup> They suggest that excessive use of antibiotics occurs when the owner of the intellectual property rights does not bear the cost of increased resistance in the future.<sup>171</sup> Some of these theorists suggest that if patents’ lengths are increased, it is in the intellectual property owner’s financial interest to maintain low resistance rates so that demand for the product does not diminish over time. This is a variant of the patent holder waste hypothesis, known as the “patent holder conservation” hypothesis.<sup>172</sup>

Patent-based initiatives seek to solve the antibiotic crisis by improving the potential revenues of the manufacturers, but it is unclear whether the financial prospects offered will encourage for-profit manufacturers to re-energize their antibiotic development. Using patents as a demand-rationing device is cumbersome, given the existing health care reimbursement systems in the United States.<sup>173</sup> While companies with existing products will always welcome the financial windfall from a patent extension, the impact on R&D decisions is less

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166. Most estimate an effective patent life for small-molecule drugs at around twelve to thirteen years. F. M. Scherer, *The Pharmaceutical Industry — Prices and Progress*, 351 NEW ENG. J. MED. 927 (2004). Biologic drugs, which do not face competition from follow-on products after patent expiration, have substantially longer effective market exclusivity, even before the recent legislation granting twelve years of data exclusivity.

167. GOVERNMENT ACCOUNTABILITY OFFICE, NEW DRUG DEVELOPMENT: SCIENCE, BUSINESS, REGULATORY, AND INTELLECTUAL PROPERTY ISSUES CITED AS HAMPERING DRUG DEVELOPMENT EFFORTS 36 (2006), available at <http://www.gao.gov/new.items/d0749.pdf>.

168. Livermore, *supra* note 140.

169. See Table 1.

170. Kades, *supra* note 19.

171. Otto Cars et al., *Meeting the Challenge of Antibiotic Resistance*, 227 BMJ a1438 (2008); Horowitz & Moehring, *supra* note 162; Kades, *supra* note 19; Stéphane Mechoulam, *Market Structure and Infectious Diseases*, 40(2) CAN. J. ECON. 468 (2005). But see *Longer Antimicrobial Patents*, *supra* note 24.

172. *Legal Ecology of Resistance*, *supra* note 19, at 164-165. Neither hypothesis has been empirically tested thus far.

173. *Vanishing Public Domain*, *supra* note 19; *Legal Ecology of Resistance*, *supra* note 19.

clear. The financial incentive offered by longer patents is likely to be quite modest since the additional funds come from exclusive years at the end of the original exclusivity period, which translates to only a small additional net present value.<sup>174</sup> Finally, simply lengthening patent terms does not provide manufacturers with an active incentive to change their behavior and delay profit-making. Since future spending on pharmaceutical products is unpredictable, owners of longer patents may choose to maximize revenues in the short term rather than promote conservation of the antibiotic resource.<sup>175</sup> If there are other manufacturers with antibiotics in the same or related classes, this pressure will be more acute, because bacteria can develop cross-resistance among drugs with similar mechanisms of action.<sup>176</sup>

We are also concerned about the ancillary effects of extensions in patents. Such initiatives frequently produce unintended consequences, and in order to achieve socially desirable outcomes, careful attention must be paid to the mechanisms employed.<sup>177</sup> For example, there might be global public health implications for antibiotic patent extensions in the United States, because the patent system on pharmaceutical products has been partially globalized through the World Trade Organization's Trade-Related Aspects of Intellectual Property (TRIPs) Agreement and the increasingly complex network of TRIPs-plus bilateral and regional trade agreements.<sup>178</sup> Paul Hunt estimates that the globalized patent system has priced two billion people out of the market for patented medicines.<sup>179</sup> If applied to the field of antibiotics, a new product might

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174. *Longer Antimicrobial Patents*, *supra* note 24.

175. See *Longer Antimicrobial Patents*, *supra* note 24; *Vanishing Public Domain*, *supra* note 19. However, some theorists suggest the opposite might occur. Horowitz & Moehring, *supra* note 162; Kades, *supra* note 19.

176. Anna Maria Ferrara, *New Fluoroquinolones in Lower Respiratory Tract Infections and Emerging Patterns of Pneumococcal Resistance*, 33 *INFECTION* 106 (2005). Resistance can develop across different classes, which widens the scope of the coordination problem.

177. For an example of using substantial financial incentives to achieve a socially desirable outcome that is rife with unanticipated consequences, see Aaron S. Kesselheim, *Encouraging Drug Development for Neglected Diseases — The Trouble with FDA Review Vouchers*, 359 *NEW ENG. J. MED.* 1981 (2008).

178. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 33 I.L.M. 81 (1994), available at [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips.pdf](http://www.wto.org/english/docs_e/legal_e/27-trips.pdf); Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 UNTS 154; 33 ILM 1144, at Annex 1C, art. 31(b) (1994), available at [http://www.wto.org/english/docs\\_e/legal\\_e/legal\\_e.htm](http://www.wto.org/english/docs_e/legal_e/legal_e.htm); Legal Instruments—Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994). Prior to the TRIPs Agreement, low-income countries could obtain low-cost copies of medicines under patent in the United States that were produced in places like India and Brazil, where patents on pharmaceutical products were not permitted.

179. See Paul Hunt, *Human Rights Guidelines For Pharmaceutical Companies in Relation to*

be less available to patients who need it in low-income settings.<sup>180</sup> In addition to the basic health effects, any modifications to U.S. law would have to account for the difficulties inherent in proposing modifications to the global structure. Many would oppose such changes with respect to low- and middle-income countries given this concern that existing intellectual property laws can hinder access to patented drugs. Purportedly global solutions to resistant infections should also address the needs of these countries, where the majority of infectious disease mortality occurs.

ACE incentives can be globalized by simply making the conservation and health impact goals global in focus. This can be achieved in the United States and Europe without regard to the quality of governance institutions in the developing world. The companies have extensive relationships with providers, institutions and governments around the world and would have a financial incentive to use those levers to achieve the public health goals articulated by ACE.

## 2. *Transferable Intellectual Property Rights*

“Transferable intellectual property rights” (TIPRs) have been proposed as an alternative to patent extensions. TIPRs, or “wildcard” patent extensions, would be earned upon development of new antibiotic agents and can be transferred to other drugs to extend their market exclusivity periods.<sup>181</sup> In the past, the IDSA has suggested applying them to the field of new antibiotic development.<sup>182</sup> Wildcard patents permit the sponsor to extend market exclusivity for a significant period of time for the most profitable drug in its portfolio, or to sell the right to the highest bidder. Such a market exclusivity extension, if applied to a blockbuster cholesterol-lowering drug such as atorvastatin (Lipitor), whose market exclusivity is due to expire in 2011, could be worth billions of dollars. Advocates of this proposal predicted that if a new antibiotic were developed that fully treated resistant *Pseudomonas aeruginosa*, and if a two-year wildcard patent were applied to a blockbuster drug, the incentive would achieve cost-

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Access to Medicines (2007) (draft for consultation, on file with authors); see also Oxfam, *Investing For Life: Meeting Poor People's Needs for Access to Medicines Through Responsible Business Practices 2* (Oxfam, Briefing Paper No. 109, 2007).

180. This problem is currently being seen in the case of tenofovir disoproxil fumarate (TDF, or Viread), a newer medication used to treat resistant HIV infections, as countries are facing growing demand but high prices supported by TRIPs-based intellectual property regimes. See, e.g., Tahir Amin et al., *Expert Review of Drug Patent Applications: Improving Health in the Developing World*, 28 HEALTH AFF. w948 (2009).

181. See Jorn Sonderholm, *Wild-Card Patent Extensions as a Means To Incentivize Research and Development of Antibiotics*, 37 J.L. MED. & ETHICS 240 (2009). But see Kapczynski, *supra* note 40, at 264 (attacking the wild-card proposal).

182. BAD BUGS, *supra* note 9, at 26.

neutrality within ten years.<sup>183</sup>

There are a number of important public health problems with wildcard patents. The first is cost. Ten wildcard patents have been estimated to cost more than \$40 billion.<sup>184</sup> Even supporters peg the cost of the first wildcard at \$7.7 billion.<sup>185</sup> The opportunity costs of an expenditure of this magnitude must be carefully considered: what other health programs could be underwritten for such a sum? We suggest the ACE program as one alternative.

Second, decoupling of patents from the innovative product is likely to cause hardships for patients taking the drug to which the TIPR is applied.<sup>186</sup> The emergence of generic drugs and the resulting decrease in cost that occur after patent expiration have been shown to significantly increase access to drugs and adherence by patients to therapeutic regimens.<sup>187</sup> Wildcard patents change this dynamic by delaying expiration of market exclusivity and derive their value by increasing costs on patients and payors of that other product.<sup>188</sup> If applied to an essential drug that helps reduce the risk of recurrent cardiovascular disease, a wildcard patent may end up harming millions—a far greater number of patients than a new drug for a rare multidrug-resistant bacterium may help. If companies are permitted to sell their wildcard patents to other manufacturers, public health authorities are unlikely to scrutinize such transfers, which may include concurrent payments or transfers of other intellectual property rights that can further increase costs or limit access to pharmaceutical products. Since changes in U.S. patent law often have global implications, wildcard patents (and patent length extensions) also may extend the waiting time for patients in resource-poor settings seeking access to the product at marginal cost.<sup>189</sup>

Third, the decoupling of patent rewards from the underlying invention is

183. See Brad Spellberg et al., *Societal Costs Versus Savings From Wild-Card Patent Extension Legislation To Spur Critically Needed Antibiotic Development*, 35 *INFECTION* 167 (2007). Notably, this cost estimate assumes that the drug would not have been developed absent the special incentive and ignores the opportunity cost of the proposal.

184. See *Longer Antimicrobial Patents*, *supra* note 24, at 561; see also Kapczynski, *supra* note 40, at 265-66; Kevin Outterson, *Antibiotic Resistance and Antibiotic Development – Author’s Reply*, 8 *LANCET INFECTIOUS DISEASES* 212-13 (2008).

185. Spellberg et al., *supra* note 183.

186. *Longer Antimicrobial Patents*, *supra* note 24 (“Wildcard patents would operate as a more than US\$40 billion annual tax on heart disease, hypertension, chronic obstructive pulmonary disease, asthma, and depression to inefficiently cross-subsidize antimicrobial research and development.”).

187. William Shrank et al., *The Implications of Choice: Prescribing Generic or Preferred Pharmaceuticals Improves Medication Adherence for Chronic Conditions*, 166 *ARCHIVES INTERNAL MED.* 332 (2006).

188. *Longer Antimicrobial Patents*, *supra* note 24.

189. *Vanishing Public Domain*, *supra* note 19. See *supra* discussion in Subsection III.b.1.

troubling on constitutional and policy grounds. An important potential constitutional objection maintains the novel, plausible claim that the patents clause requires the exclusion right to apply to the underlying invention.<sup>190</sup> On policy grounds, the intimate connection between the exclusion right and the invention are important to the economic efficiency of the mechanism. The market for the invention itself should determine the value of the patent; likewise, patents on inventions with little utility can be disciplined by a low market return. Decoupling the invention from the reward through the TIPRs mechanism thus unhinges patent exclusions from the key market test of their value, and substitutes an untested administrative process.<sup>191</sup> As Amy Kapczynski noted, “wild-card extensions embrace the most difficult aspect of a prize design without offering the benefits that a prize system could provide.”<sup>192</sup> The ACE program will certainly face prize design issues – discussed below – but the payoff is clear because companies are paid only if public health goals are met.

Despite these concerns, a few members of the pharmaceutical industry consider wildcard patents to be the incentive mechanism “most likely to successfully stimulate new antibiotic development.”<sup>193</sup> Other industry leaders have said privately that they do not support the proposal.<sup>194</sup> Wildcard patents have been considered (and rejected) by Congress as a way of encouraging the creation of countermeasures for bioterrorism agents.<sup>195</sup> At the time of this writing, it appears that the political prospects for applying wildcard patents to the antibiotic market are not great, perhaps in part because their policy and legal obstacles are formidable.

### *C. Reimbursement Incentives Based on Medical Need*

Some proposals to enhance potential revenues for antibiotic drug

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190. A “wildcard” patent that gives an inventor market exclusivity in a different product may not meet the language of the Constitution that permits Congress to provide market exclusivity rights in “their respective . . . discoveries.” See U.S. CONST. art. I, § 8, cl. 8. As a counterexample, the pediatric market exclusivity provision applies to drug manufacturers who conduct clinical trials on the use of their products in children and provides six months of additional market exclusivity *to that product*. See Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (1997). This supplementary exclusivity mechanism is directly connected to the invention in a way that is more consistent with the Constitutional language.

191. TIPRs are really a variant on the prize proposals discussed in Part C below, but with the prize amount based on the value of another, unrelated patent.

192. Kapczynski, *supra* note 40, at 266.

193. Spellberg et al., *supra* note 183.

194. Interview by Kevin Outterson with anonymous source.

195. Biological, Chemical, and Radiological Weapons Countermeasures Research Act, S. 666, 108th Cong. (2003).

development work primarily outside the patent system. A fundamental characteristic of market-based reimbursement of patented drugs is that the companies receive revenues based on their ability to sell drugs rather than actual improvement in human health. In countries with insurance coverage for drugs, the market is further disconnected from actual medical need. Where strong government health plans dominate, effective healthcare technology assessment can provide better information to the market. For example, in Australia, England, and Germany, coverage for pharmaceuticals is nearly universal and the government exercises significant control over pharmaceutical reimbursement. But if purchaser market power is fragmented for pharmaceuticals (as in the United States) or if the patients are too poor to be salient consumers (as in low-income countries), then the patent-based system can be significantly disconnected from medical need.

Several prominent proposals tie research incentives directly to medical need. James Love and Tim Hubbard have been leaders in delineating prize-based proposals geared to medical need. Love and Hubbard argue that significant prizes can create incentives for engaging in needed research. The public health payoff comes when the ultimate product is dissociated from its development costs and can enter the public domain immediately.<sup>196</sup> As a result, a plan for distribution of the drug can be undertaken without the revenue-related concerns that can prevent dissemination to lower-income settings. These prize fund proposals could provide financial rewards that increase with the estimated social value of the drug, with the largest rewards going to developers of drugs or vaccines for neglected or undertreated diseases.<sup>197</sup> Though still politically novel, and with a number of logistical and theoretical hurdles to overcome, these proposals have gained increased traction in recent years. In 2005, Vermont legislator Bernie Sanders first proposed a bill setting up an \$80 billion prize fund when he was in the U.S. House of Representatives,<sup>198</sup> and he introduced it again in 2007 as a senator.<sup>199</sup> In the 2008 Presidential campaign, candidate John Edwards discussed a prize system alternative to drug patents,<sup>200</sup> and in 2008 a proposal for prize funds was submitted by Bolivia and Barbados to the World Health Organization in response to a request by the Intergovernmental Working Group to develop a sustainable global health plan of action for research into essential medicines.<sup>201</sup>

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196. See Love & Hubbard, *The Big Idea*, *supra* note 40.

197. Joseph E. Stiglitz, *Scrooge and Intellectual Property Rights*, 333 BMJ 1279 (2006).

198. Medical Innovation and Prize Fund Act of 2005, H.R. 417, 109th Cong. (2005).

199. Medical Innovation and Prize Fund Act of 2007, S. 2210, 110th Cong. (2007).

200. James Love, *John Edwards Calls for Prizes To Replace Monopolies as Innovation Incentive for New Drugs*, KNOWLEDGE ECOLOGY INT'L, June 15, 2007, <http://keionline.org/content/view/87/1..>

201. WORKING DOCUMENT PROPOSED BY BARBADOS AND BOLIVIA (2008), *available at*

In 2010, the World Health Organization's governing body kept this issue on the table in the ongoing work of an expert working group on research and development.<sup>202</sup>

Two other prominent proposals follow similar tracks. Thomas Pogge and Aiden Hollis have proposed a global Health Impact Fund (HIF). The HIF would give companies the option to obtain reimbursement for drugs based on the actual health impact of the drug. The program would be voluntary and contractual, with payments coming from a multi-billion dollar global fund. Payments would be allocated among the qualifying drugs based on the global health impact of the intervention, as measured statistically in Quality-Adjusted Life Years (QALYs) of the target population.<sup>203</sup> Neglected and undertreated diseases would then have a significant blockbuster market without regard to the wealth or poverty of the patients. Drug companies would also receive financial rewards for marketing to maximize health impact rather than sales. The Health Impact Fund differs from some prize proposals in that it would operate as a complement to the patent system, at the election of the company. As a contract-based legal tool, the Health Impact Fund also falls into Sector 6.<sup>204</sup> More controversially, the HIF would allow the sponsor to retain their intellectual property. James Love in particular has been critical of this aspect of the Health Impact Fund, as he claims it would undermine generic markets.<sup>205</sup>

A third variation on this theme is the Advance Market Commitment (AMC), whereby countries, in concert with international aid organizations, commit to purchase a product meeting certain specifications as a production incentive.<sup>206</sup> AMC supporters argue that providing guaranteed demand can help interested manufacturers budget appropriately in the clinical development process, and can encourage companies to pursue promising late-stage products that might otherwise be abandoned for lack of demand.<sup>207</sup> In 2007, Canada, Italy, Norway,

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[http://www.keionline.org/misc-docs/b\\_b\\_igwg/working\\_document\\_barbados\\_bolivia.pdf](http://www.keionline.org/misc-docs/b_b_igwg/working_document_barbados_bolivia.pdf).

202. SIXTY-THIRD WORLD HEALTH ASSEMBLY, ESTABLISHMENT OF A CONSULTATIVE EXPERT WORKING GROUP ON RESEARCH AND DEVELOPMENT: FINANCING AND COORDINATION, (2010), available at [http://apps.who.int/gb/ebwha/pdf\\_files/WHA63/A63\\_R28-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R28-en.pdf).

203. Thomas Pogge, *Human Rights and Global Health: A Research Program*, 36 METAPHILOSOPHY 182 (2005); HOLLIS & POGGE, *supra* note 41; Hollis, An Efficient Reward System, *supra* note 41.

204. See Table 1.

205. James Love, *Open Licensing vs. Monopoly Controlled Supply*, KNOWLEDGE ECOLOGY INT'L, Apr. 27, 2008, <http://keionline.org/node/88>.

206. MICHAEL KREMER & RACHEL GLENNERSTER, STRONG MEDICINE: CREATING INCENTIVES FOR PHARMACEUTICAL RESEARCH ON NEGLECTED DISEASES (2004); Cars et al., *supra* note 171.

207. Ernst R. Berndt et al., *Advance Market Commitments for Vaccines Against Neglected Diseases: Estimating Costs and Effectiveness*, 16 HEALTH ECON. 491 (2006).



Russia, the United Kingdom, and the Bill & Melinda Gates Foundation modified this strategy by announcing a \$1.5 billion AMC for vaccines aimed at pneumococcal pneumonia.<sup>208</sup> This AMC is less ambitious than the original proposal, since almost all of the research and development work had been completed.<sup>209</sup> AMCs are also Sector 6<sup>210</sup> approaches, but must be negotiated piecemeal, with high transaction costs and the opportunity for process capture by drug companies.<sup>211</sup>

All three proposals are readily applicable to the field of antibiotic research, but have limitations that require adjustments. Only the AMC is close to being operational, but the first test is limited to a product nearing the end of development. It has been criticized as resembling little more than a purchase contract for products already launched.<sup>212</sup> Prize proposals face significant financing and implementation barriers.<sup>213</sup> Nevertheless, these proposals may someday shift the current paradigm in global pharmaceutical development, and may be a fruitful area for research and policy articulation. Their application to antibiotics seems especially promising, as any movement towards value-based prizes or reimbursement will dampen company incentives to excessively market antibiotics. The first prong of our ACE program is explicitly an extension of these ideas to antibiotics, by paying prizes or increasing reimbursement to more closely reflect the social need or health impact of the drug. In all three proposals, we would add explicit conditionality, requiring the drug companies to meet antibiotic conservation goals if they are to receive additional funds.

#### *D. Reducing Financial Hurdles for Antibiotic Innovation*

Patent modifications and prize-based approaches increase the rewards for innovation. Another strategy is to lower the costs of innovation, through grant support for basic science research (Sector 6) and efforts to reduce regulatory hurdles to successful drug product launches (Sector 4).<sup>214</sup> If costs are reduced, then perhaps the supply of new drugs can be increased. The Orphan Drug Act is an example of a legal mechanism to reduce costs to the drug sponsor during

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208. Theresa Braine, *Controversial Funding Mechanism To Fight Pneumonia*, 86 BULL. WORLD HEALTH ORG. 325 (2008).

209. *Id.*

210. See Table 1.

211. See Light, *supra* note 40.

212. Donald W. Light, *Is G8 Putting Profits Before the World's Poorest Children?*, 370 LANCET 297 (2007).

213. Marlynn Wei, *Should Prizes Replace Patents? A Critique of the Medical Innovation Prize Act of 2005*, 13 B.U. J. SCI. & TECH. L. 25 (2007).

214. See Table 1.

development, while also increasing potential revenues after marketing.<sup>215</sup> As in previous work, we support expanded public support for basic antibiotic research,<sup>216</sup> but here we also raise questions about any expansion of the Orphan Drug Act. We also review safety concerns with efforts to reduce regulatory standards in antibiotic clinical trials.<sup>217</sup>

### *1. Enhanced basic science funding*

Basic research funding in infectious diseases<sup>218</sup> can help to better categorize the biology of infectious diseases and the nature of resistance development and can also establish potential targets for antibiotic products. Such scientific investigation into the mechanisms of resistance can lead to more effective conservation programs.<sup>219</sup> Current investments are remarkably sparse, with the NIH spending about \$200 million per year on antibacterial resistance research.<sup>220</sup> Admittedly, upstream scientific investigation may take time to be developed into viable antibiotic end-products,<sup>221</sup> but this way of supporting innovation is still critical, especially given the permanent need for new antibiotic development. Enhanced basic science funding should be an integral complement to any potential programs focused on the downstream drug development process. The funding opportunities provided by the American Recovery and Reinvestment Act

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215. See *infra* Subsection III.D.2.

216. See Kesselheim & Outtersen, *supra* note 25, at 1692.

217. *Id.* at 1692.

218. Though such increased funding could come from any source, the greatest prospect for increased basic research funding comes from public sources. The NIH has maintained a commitment to basic science research over the past few decades, while the pharmaceutical industry has dedicated ever-increasing amounts of its research to later-stage clinical trials. Hamilton Moses III et al., *Financial Anatomy of Biomedical Research*, 294 JAMA 1333 (2005). Notably, the US is currently the worldwide leader in funding of basic science; the US directs about 6% of its total health care spending to biomedical research, far surpassing all other countries in relative and absolute terms. *Id.*

219. Lipsitch & Samore, *supra* note 45.

220. N. Kent Peters et al., *The Research Agenda of the National Institute of Allergy and Infectious Diseases for Antimicrobial Resistance*, 197 J. INFECTIOUS DISEASE 1087 (2008). The modesty of this funding is striking when compared to the cost of the wild-card patent proposal at \$7.7 billion for the first drug: imagine the possibilities if the NIH research budget was quadrupled over the next five years, with sustained funding thereafter.

221. Time from identification of receptors or pathways that can serve as the basis for new antibiotic targets to approval of a new product can take a decade or more. However, there is reason for optimism that this process can be accelerated due to recent developments in translational research, including high-throughput screening. Bernhard A. Müller, *Imatinib and Its Successors – How Modern Chemistry Has Changed Drug Development*, 15 CURRENT PHARMACEUTICAL DESIGN 120 (2009).

of 2009 are welcome steps in the right direction.<sup>222</sup>

## 2. Antibiotics under the Orphan Drug Act

Investment can also come in the form of more direct savings to pharmaceutical manufacturers interested in pursuing antibiotics. For example, the Orphan Drug Act (ODA) template includes tax incentives and research grants, both of which decrease the cost to the pharmaceutical company of up-front investment in research and development.<sup>223</sup> The ODA could be considered a form of federal cost-sharing for qualifying research projects. Under this legislation, however, the pharmaceutical manufacturer retains full control of the profits of any end product developed with the use of these government funds. In these cases, patients are arguably paying twice for drugs: first through the public funds supporting development of the innovative products, and second through the high prices that orphan drugs command from patients and public payors.<sup>224</sup> An

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222. Gardiner Harris, *Specter, A Fulcrum of the Stimulus Bill, Pulls Off a Coup for Health Money*, N.Y. TIMES, Feb. 13, 2009, at A15, available at <http://www.nytimes.com/2009/02/14/health/policy/14specter.html?em>.

223. The actual cost of drug development is a widely debated figure. Most pharmaceutical industry sources refer to figures from DiMasi, Grabowski, and others, that suggest that the estimate exceeds \$800 million in 2004 dollars. See Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003). Other consultants for the pharmaceutical industry report the value is as high as \$1.7 billion for a “blockbuster” drug. See Ashish Singh et al., *Healthy Convergence*, IN VIVO (2004), [http://www.bainlab.com/bainweb/publications/publications\\_detail.asp?id=17177&menu\\_url=publications\\_results.asp](http://www.bainlab.com/bainweb/publications/publications_detail.asp?id=17177&menu_url=publications_results.asp). But these figures are likely overestimates, particularly for drugs developed with initial investment from public research funding. These values have been criticized for including the cost of capital in their research estimates. See Arnold S. Relman & Marcia Angell, *America's Other Drug Problem*, 16 NEW REPUBLIC 27 (2002). Other estimates have suggested the real cost of new drug development averages closer to \$240 million. See RUTH RUTTENBERG & ASSOCIATES, INC., NOT TOO COSTLY, AFTER ALL: AN EXAMINATION OF THE INFLATED COST ESTIMATES OF HEALTH, SAFETY, AND ENVIRONMENTAL PROTECTIONS (2004), available at <http://www.citizen.org/documents/ACF187.pdf>. Still, these remain high figures, with substantial risk involved. Whatever the value, reducing unnecessary costs in drug development remains a worthy goal. See Michael Rawlins, *Cutting the Cost of Drug Development?*, 3 NATURE REVIEWS DRUG DISCOVERY 360 (2004).

224. See MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT (Random House 2004); see also Diana Porter, AARP Policy Brief, *Pharmaceutical Companies Maintain Huge Profits with High-Priced Pills* (2003), available at [http://www.retiredamericans.org/docs/G1/profpills\\_issuebrief\\_final.pdf](http://www.retiredamericans.org/docs/G1/profpills_issuebrief_final.pdf). This point is a subject of substantial debate, of course. See Frank R. Lichtenberg, *Are the Benefits of Newer Drugs Worth Their Cost? Evidence from the 1996 MEPS*, 20 HEALTH AFF. 241 (2001). But see Yuting Zhang & Stephen B. Soumerai, *Do Newer Prescription Drugs Pay for Themselves? A Reassessment of the Evidence*, 26 HEALTH AFF. 880 (2007). Most opponents of this view argue that manufacturer input

alternative system would seek better public returns on such investment in corporate research, either through limitations on prices from drugs arising from publicly funded research or a requirement that the ultimate manufacturer contribute a share of its revenues on these products to the basic science research commons.<sup>225</sup> In the ACE program, the conditionality is unrelated to prices or revenues, but linked to public health goals.

The FDA Amendments Act of 2007 set aside financial support for a conference intended to identify whether the incentives contained in the ODA might be extended to certain antibiotics developed to treat “serious and life-threatening infectious diseases, such as diseases due to gram-negative bacteria and other diseases due to antibiotic-resistant bacteria.”<sup>226</sup> Other groups have made similar recommendations.<sup>227</sup> The ODA was passed in 1983 to encourage research focused on therapeutic agents for the treatment of rare conditions, for which a limited patient pool could otherwise prevent recovery of the investment made in product development.<sup>228</sup> It is usually applied to diseases that affect less than two hundred thousand people in the United States, although companies can apply for diseases affecting more than two hundred thousand if they can establish that developing a drug for the condition is uneconomic because there is “no reasonable expectation” that U.S. sales could support development of the drug.<sup>229</sup> The ODA provides manufacturers with three primary incentives: 1) federal funding of some grants and contracts to perform clinical trials of orphan products; 2) a research tax credit of 50% of clinical testing costs; and 3) an exclusive right to market the orphan drug for seven years from the date of marketing approval. Through 2010, over three hundred and fifty products with orphan designations have received marketing authorization in the United States.<sup>230</sup>

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is integral to the drug development process. We do not disagree with this point; however, we believe that the role of government-funded basic research is not fully accounted for in these estimates.

225. Kesselheim & Avorn, *supra* note 82.

226. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 1112, 121 Stat. 823, 976 (2007).

227. Spellberg et al., *supra* note 183.

228. For a history of the Orphan Drug Act, see Henry A. Waxman, *The History and Development of the Orphan Drug Act*, in ORPHAN DISEASES AND ORPHAN DRUGS 135-45 (I. Herbert Scheinberg & J.M. Walshe eds. 1986).

229. 21 U.S.C. § 360ee(b)(2) (2006). Manufacturers rarely use this option because it involves displaying their financial projections and business strategy to regulators and others who might seek to obtain the information through a Freedom of Information Act request.

230. FOOD AND DRUG ADMINISTRATION, LIST OF ORPHAN DESIGNATIONS AND APPROVALS (2010), available at <http://www.fda.gov/orphan/designat/list.htm>; M. Miles Braun et al., *Emergence of Orphan Drugs in the United States: A Quantitative Assessment of the First 25 Years*,

Some commentators suggest “extending the Orphan Drug Act to antibiotics,”<sup>231</sup> but the Act already applies to emerging products in this market. While the greatest number of orphan products treats cancer, many target infectious diseases caused by viral and bacterial pathogens.<sup>232</sup> In the first half of 2008, two of the sixty-one new orphan drug designations related to antibiotics. For example, one of the orphan drug designations was granted to Mpex Pharmaceuticals for an IDSA-designated priority pathogen, specifically for the “[t]reatment of pulmonary infections due to *Pseudomonas aeruginosa* and other bacteria in cystic fibrosis patients.”<sup>233</sup> The designation was achieved without new legislation.<sup>234</sup>

Thus, the emphasis on the ODA is curious, and it is unclear how modifying it for antibiotics might be implemented. It should not be necessary to loosen the ODA’s population limits for antibiotics because the two-hundred-thousand-U.S.-person limit is not an absolute barrier. As described above, companies can gain orphan designation for larger groups if they can establish economic necessity. Empirical evidence suggests that this limit has not been a factor in marketing approvals under the ODA generally.<sup>235</sup> The campaign to apply the ODA to antibiotics appears to ignore the history of FDA approvals under the Act.

We also caution against any plan that calls for antibiotic orphan drugs to receive longer than the ODA-designated seven-year exclusivity term. The ODA has been hailed for promoting drug development for rare conditions,<sup>236</sup> but to our knowledge no studies have demonstrated its overall cost-effectiveness.<sup>237</sup> Some designated orphan drugs are used for broader purposes, which belies the rhetoric of orphan drugs. For example, the anemia drug epoetin alfa (Epogen) was originally approved in 1989 as an orphan product for anemia associated with end-stage renal disease, but it has been used for many other indications, such as

9 NATURE REVIEWS: DRUG DISCOVERY 519, 519-22 (2010).

231. A. Bruce Montgomery, *Reply to the Antibiotics Pipeline—Challenges, Costs, and Value*, 351 NEW ENG. J. MED. 2019-20 (2004).

232. Braun et al., *supra* note 230.

233. *Id.*

234. Critics may note that the designated drug (levofloxacin) is not new, but this is hardly a warrant for the extension of the ODA. Many of the approved designations under the ODA are for new uses of existing products. For example, in March 2004, Merck received an orphan drug designation for rofecoxib (Vioxx) for “[t]reatment of juvenile rheumatoid arthritis.” *Id.*

235. See Braun et al., *supra* note 230 (“The most common patient population size for orphan designations and approvals was fewer than 10,000 patients . . .”).

236. Marlene E. Haffner, *Adopting Orphan Drugs—Two Dozen Years of Treating Rare Diseases*, 354 NEW ENG. J. MED. 445, 445-47 (2006).

237. David Duffield Rohde, *The Orphan Drug Act: An Engine of Innovation? At What Cost?*, 55 FOOD & DRUG L. J. 125, 125-43 (2000).

cancer-related anemia, as well as in patients with mildly low red blood cell counts but without symptoms of anemia.<sup>238</sup> The manufacturer's annual revenue for Epogen grew to \$1.4 billion by 1996 and continues as a blockbuster more than a decade later,<sup>239</sup> with sales exceeding \$2.4 billion in 2008.<sup>240</sup> Many other products originally protected by the orphan designation are used off-label and provide substantial returns for their sponsor, which calls into question the necessity of the ODA in these circumstances.<sup>241</sup> One logical counterargument is that these off-label uses cannot be predicted at the time of drug development, but this misunderstands the relationship between the ODA and drug marketing. Qualifying for ODA status does not commit a company to apply for any particular label, but they will receive the additional incentives only for the specific ODA uses. With new drugs with sufficient patent life remaining, the ODA gives companies an incentive to apply for a narrow use affecting less than two hundred thousand patients per year to obtain the tax credits and grants. When finally approved by the FDA, the company can sell the drug to a much wider group, whether on- or off-label. Facing patent expiry in a few years, companies can take existing popular drugs and look for narrower clinical indications as a new orphan use. This latter group would also include drugs for which the patents have expired: the additional seven years of marketing exclusivity will block sales of rival generic drugs for that use, despite the absence of a valid patent.

Rather than implementing an expansion of orphan market exclusivity for antibiotics, we recommend a thorough and independent review of the cost-effectiveness of the ODA, including an evaluation of possible limits on the current ODA exclusivity term that ends when a new product is used for additional indications and becomes more profitable than anticipated. In particular, any modification of the ODA for antibiotics should be supported by careful empirical evidence of cost-effectiveness of the intervention, including opportunity costs. More fundamentally, an expansion of the ODA to include antibiotics targeting more than two hundred thousand people directly conflicts with conservation goals. The ACE program is designed to be a more carefully

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238. Surrey M. Walton et al., *Prioritizing Future Research on Off-Label Prescribing: Results of a Quantitative Evaluation*, 28 PHARMACOTHERAPY 1443, 1450 (2008).

239. Geeta Anand, *How Drugs for Rare Diseases Became Lifeline for Companies*, WALL ST. J., Nov. 15, 2004, at A1.

240. Press Release, Amgen, Amgen's Fourth Quarter 2008 Adjusted Earnings Per Share Increased 6 Percent to \$1.06; Full Year 2008 Adjusted Earnings Per Share Increased 6 Percent to \$4.55 (2009), available at [http://www.amgen.com/media/media\\_pr\\_detail.jsp?year=2009&releaseID=1248352](http://www.amgen.com/media/media_pr_detail.jsp?year=2009&releaseID=1248352).

241. This is particularly true of oncology-related drugs. See Paolo G. Casali on behalf of the Executive Committee of ESMO, *The Off-Label Use of Drugs in Oncology: A Position Paper by the European Society for Medical Oncology (ESMO)*, 18 ANNALS ONCOLOGY 1923 (2007).

designed response to the unique needs of the antibiotic market.

### 3. Reducing the costs of regulation

Before new pharmaceutical products can be legally sold, they must pass approval by the relevant drug regulatory agency. However, representatives of the pharmaceutical industry have attributed the decline in new product development in part to the overly rigorous evaluative process required by the FDA, locating this proposal in Sector 4.<sup>242</sup> For most drugs, the FDA allows placebo-controlled trials to support drug approval.<sup>243</sup> However, ethics rules would forbid the use of placebos in people with serious infections.<sup>244</sup> These studies utilize an active control, generally an approved antibiotic. Such trials are most frequently organized to demonstrate that the experimental antibiotic is not significantly inferior to the standard treatment; the relevant difference is referred to as the “delta.”<sup>245</sup> A non-inferiority trial design can be controversial depending on the

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242. See Martin L. Katz et al., *Where Have All the Antibiotic Patents Gone?*, 24 NATURE BIOTECHNOLOGY 1529 (2006); see also Alexander T. Tabarrok, *Assessing the FDA via the Anomaly of Off-Label Prescribing*, 5 IND. REV. 25 (2000). This argument was the intellectual underpinning for the *Abigail Alliance v. Von Eschenbach* case, involving a claim that there was a constitutional right for terminally ill patients to access unapproved prescription drugs. Peter D. Jacobson & Wendy E. Parmet, *A New Era of Unapproved Drugs: The Case of Abigail Alliance v. Von Eschenbach*, 297 JAMA 205 (2007). The argument found initial support in a three-member panel in the District of Columbia Court of Appeals before being overturned in an en banc hearing. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 445 F.3d 470 (D.C. Cir. 2006), *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007).

243. The placebo-controlled trial is generally considered to be the gold standard for proving efficacy in clinical trials, but it can have numerous flaws. The FDA has long considered two pivotal placebo-controlled trials as serving as a reasonable basis for a drug approval decision. Alan Davies & Peter D. Stonier, *Development of Medicines: Full Development*, in TEXTBOOK OF PHARMACEUTICAL MEDICINE 310, 310-31 (5th ed. 2006). It has been criticized because the placebo can be an improper comparator that does not provide any useful information about a drug as compared to other therapies for a particular disease. Jerry Avorn, *FDA Standards — Good Enough for Government Work?*, 353 NEW ENG. J. MED. 969, 970 (2005).

244. Robert J. Temple, *When Are Clinical Trials of a Given Agent vs. Placebo No Longer Appropriate or Feasible?*, 18 CONTROLLED CLINICAL TRIALS 613 (1997). Once treatment for a disease has progressed usefully, then it may no longer be reasonable to randomly assign someone in need of therapy to a placebo arm. David Knopman et al., *Clinical Research Designs for Emerging Treatments for Alzheimer Disease: Moving Beyond Placebo-Controlled Trials*, 55 ARCHIVES OF NEUROLOGY 1425 (1998).

245. Larry L. Laster & Mary F. Johnson, *Non-Inferiority Trials: The ‘At Least as Good as’ Criterion*, 22 STAT. MED. 187 (2003). The non-inferiority trial, as with other facets of clinical trials, has been the subject of much investigation intended to make it more efficient for drug developers in the antibiotic field. Kem F. Phillips, *A New Test of Non-Inferiority for Anti-Infective Trials*, 22

level of the delta required by regulators to prove the drug's utility.<sup>246</sup> Demonstrating non-inferiority with a low delta in a comparison with an active control means that more patients must be included in a Phase III study of an antibiotic to show a statistically significant difference.<sup>247</sup> Studies with large numbers of patients are more expensive to conduct.

Regulatory requirements directly relate to clinical trial costs, which are among the largest investments in drug development.<sup>248</sup> As a result, some commentators have suggested that lower regulatory hurdles may encourage for-profit pharmaceutical manufacturers to return to the field of antibiotics.<sup>249</sup> Such a move would both decrease the direct costs in premarketing studies and increase the expected returns from longer effective market exclusivity due to shorter regulatory preparation and review times. Norrby and colleagues recommend placing a greater emphasis on studies showing the properties of the drug and allowing extrapolations from data generated in one type of infection to others.<sup>250</sup> Baquero and colleagues suggest awarding limited marketing authorization based on earlier Phase II studies and beginning the Phase III studies while the antibacterial agent is already available for use.<sup>251</sup> Livermore contends that historical controls can provide effective comparisons and proposes that approval be extended to related indications (such as infections or types of microbes) based on microbiological data, rather than additional human trials.<sup>252</sup>

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STAT. MED. 201 (2003). For a recent review by the GAO, see GOVERNMENT ACCOUNTABILITY OFFICE, *supra* note 104, at 1-32 (discussing issues with non-inferiority trials for antibiotics).

246. Norrby et al., *supra* note 68. Recently, pharmaceutical manufacturers have expressed concern that the FDA is tightening the delta and clinical even further by tightening the statistical parameters. David M. Shlaes & Robert C. Moellering Jr., *The United States Food and Drug Administration and the End of Antibiotics*, 34 CLINICAL INFECTIOUS DISEASES 420 (2002).

247. Mark Rothmann et al., *Design and Analysis of Non-Inferiority Mortality Trials in Oncology*, 22 STAT. MED. 239 (2003).

248. Clinical trial costs are currently the largest driver of drug development costs. According to Moses et al., *supra* note 218, "the proportion of total pharmaceutical research and development expenditures (including those outside the United States) that has gone to clinical trials (phases 1-3) has increased from 28% in 1994 to 41% in 2003. In addition, the proportion of research and development funds that has supported phase 4 trials has increased from 5% in 1994 to 11% in 2003." One response from many pharmaceutical manufacturers is to move more clinical trials overseas to countries where patients can be accrued for lower costs. Seth W. Glickman et al., *Ethical and Scientific Implications of the Globalization of Clinical Research*, 360 NEW ENG. J. MED. 816 (2009).

249. See Shlaes & Moellering, *supra* note 246.

250. *Id.*

251. Fernando Baquero et al., *Antibiotic Clinical Trials Revisited*, 46 J. ANTIMICROBIAL CHEMOTHERAPY 651 (2000).

252. Livermore, *supra* note 140.



Despite these proposals for adjustments to the regulatory process, the effects of such adjustments are far from clear. Approved antibiotics usually have short mean and median clinical development times, as compared to other drug classes.<sup>253</sup> In the United States, the FDA already has programs to speed its regulatory evaluation of important new antibiotics. First, the “fast track” program begins early in the clinical trial process.<sup>254</sup> It is designed to facilitate the development of a New Drug Application (NDA) and expedite the review of drugs to treat serious diseases that fill an unmet medical need.<sup>255</sup> Second, novel antibiotics aimed at multidrug resistant pathogens would also certainly qualify for the FDA “priority review” program, under which the FDA completes its regulatory review within six months after full NDA submission.<sup>256</sup> For example, the antibiotic tigecycline (Tygecil), the first glycylcycline, received the benefit of both the fast track and the priority review systems.<sup>257</sup> The FDA has also taken a number of steps in the last few years to streamline the regulatory process for approval of antibiotics, including publishing guidelines to help manufacturers design trials with less uncertainty about FDA expectations, allowing smaller sample sizes for individual studies, and actively working with sponsors during the early development phase.<sup>258</sup>

There are also important disadvantages to loosening regulatory requirements. Premarketing drug trials can help determine the efficacy of a product, but are often underpowered to detect important adverse effects.<sup>259</sup> Such

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253. Joseph A. DiMasi, *Success Rates for New Drugs Entering Clinical Testing in the United States*, 58 CLINICAL PHARMACOLOGY THERAPIES 1 (1995); Janice M. Reichert, *Trends in Development and Approval Times for New Therapeutics in the United States*, 2 NATURE REVIEWS DRUG DISCOVERY 695 (2003).

254. Janice M. Reichert et al., *A Decade of the Fast Track Programme*, 7 NATURE REVIEWS DRUG DISCOVERY 885 (2008).

255. Food and Drug Administration Modernization Act of 1997, *supra* note 190.

256. SUSAN THAUL, CRS REPORT FOR CONGRESS: FDA FAST TRACK AND PRIORITY REVIEW PROGRAMS(2008), available at <http://www.nationalaglawcenter.org/assets/crs/RS22814.pdf>.

257. FOOD AND DRUG ADMINISTRATION, NME DRUG AND NEW BIOLOGIC APPROVALS IN 2005 (2009), available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/NMEDrugandNewBiologicApprovals/ucm081676.htm>.

258. John H. Powers, *Antimicrobial Drug Development—The Past, the Present, and the Future*, 10 CLINICAL MICROBIOLOGY & INFECTION (Supp. 4) 23 (2004).

259. The “power” of a trial is related to the number of patients enrolled. For example, randomized controlled trials are designed with the appropriate power to test the primary outcome. If a randomized controlled trial is powered to test a primary efficacy endpoint, not enough patients may be enrolled to demonstrate adequately whether other secondary outcomes, such as safety-related endpoints, are reached. Bruce M. Psaty, *Clinical Trial Design and Selected Drug Safety Issues for Antibiotics Used To Treat Community-Acquired Pneumonia*, 47 CLINICAL INFECTIOUS

adverse effects only arise after the drug has been approved. However, in a number of recent cases, overly aggressive drug promotion has led many people to receive unnecessary prescriptions for dangerous prescription drug products that were later withdrawn from the market.<sup>260</sup> The chance that an important safety concern with a product will be missed in pre-approval testing rises as regulatory requirements are lowered.<sup>261</sup> There may also be risks to speedy regulatory review. Carpenter and colleagues recently showed that approvals of new drugs by the FDA made in the two months before a regulatory deadline were associated with more subsequent safety problems, suggesting negative consequences to imposing such deadlines on FDA drug review.<sup>262</sup> Any proposal to loosen regulatory requirements, then, must be considered with a critical eye and with an appropriate view of the potential safety risks.<sup>263</sup> Several of the recently approved antibiotics have demonstrated some important safety issues after marketing approval by the FDA.<sup>264</sup> In fact, more than half of all antibiotics approved by the U.S. FDA in the two decades following 1980 were subsequently removed from the market, although not all explicitly for safety-related concerns.<sup>265</sup>

Drug safety is a significant concern, which argues against weakening the antibiotic approval process. For some of the most essential antibiotics, it may be worth taking on these additional risks. At the same time, systems such as active post-marketing surveillance should be in place to assure that a product's safety is being actively monitored.<sup>266</sup> Provisional approval of antibiotics for a few years

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DISEASE (Supp. 3) S176, S177-78 (2008).

260. Aaron S. Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 JAMA 308, 308 (2007).

261. For example, orphan drugs are nearly all approved on an accelerated basis in small numbers of patients. While such parameters may be reasonable for orphan drugs, because the diseases these drugs treat are only found in small populations of patients, there are clinical implications for permitting accelerated approval based on testing in fewer numbers of patients (both proxies for less stringent pre-marketing regulatory requirements). An early government-led analysis suggested that 31% of orphan drugs on the market had demonstrated more pronounced side effects during pre-approval clinical testing than non-orphan drugs, and following FDA approval, 13% produced more side effects than anticipated. See Susan F. Scharf, *Orphan Drugs: The Question of Product Liability*, 10 AM. J. LAW & MED. 491, 504-05 (1989).

262. See generally Carpenter et al., *supra* note 158.

263. See Outtersson et al., *supra* note 104.

264. See Outtersson et al., *supra* note 67.

265. *Id.* Notably, this risk of subsequent removal from the market presents another limitation to prize funds that reward development of new products upon their approval. Our ACE proposal accounts for the possibility of needing supplemental prizes, but the primary rewards are incremental, as certain public health outcomes are met. Thus, a drug that is later withdrawn for safety reasons would not waste ACE incentive resources.

266. Wendy Brewster et al., *Evolving Paradigms in Pharmacovigilance*, 1 CURRENT DRUG

under close post-marketing surveillance is a possible compromise position that dovetails nicely with the ACE incentives described below. More broadly, the ACE program takes the financial pressure off companies seeking a speedy and possibly premature approval of an antibiotic. Under ACE, the companies will also have an incentive to act on their private knowledge of safety and efficacy issues for the benefit of public health.

### *E. Summary*

The proposals that have been offered to address antibiotic drug development are limited by concerns related to their implementation (see Table 2). None of these alternatives sufficiently addresses the underlying trouble with the antibiotic market: that conservation and innovation incentives might negatively interact. In the next section, we describe in detail the ACE incentives, a panel of market changes that can help bring these incentives in better alignment.

**TABLE 2: SUMMARY OF CURRENT POLICY PROPOSALS TO ADDRESS RISING ANTIBIOTIC RESISTANCE**

<b>Policy category</b>	<b>Strategy</b>	<b>Examples</b>	<b>Benefits</b>	<b>Concerns</b>
Conservation	Infection control	Isolation beds, hand-washing, “search and destroy” programs	Most direct tool to limit infection and resistance	May slow but not stop resistance, limited funding, reduces drug company revenues
	Rational antibiotic use	Academic detailing, clinical treatment guidelines, formulary restrictions, prior authorization requirements	Addresses antibiotic misuse, some very successful implementation	Programs are often hospital-specific rather than system-wide, limited funding, reduces drug company revenues
Property-based incentives	Patent length extension	Start patent at regulatory approval, extend patent term to more than twenty years	Financial costs are indirect, valuable to some drug companies	High costs for patented drugs, non-transparent, rewards the wrong companies, may damage conservation
	Transferable Intellectual Property Rights (TIPRs)	Proposals range from six months to two years	Valuable to large pharmaceutical companies, financial costs are indirect	Transfers costs to other fields, non-transparent, may damage conservation
Value-based reimbursement	Prizes	Global prize funds, Health Impact Fund, Advance Market Commitments (AMC)	Rewards selected based on public health gains. In some proposals, drug enters public domain	Barriers to implementation and financing, questions about AMC capture by industry

## IMPROVING ANTIBIOTIC MARKETS

Reducing drug development costs	Enhanced funding for basic science	National Institutes of Health, private foundations	Develops basic tools and human capital which can lead to new antibiotics and better conservation	No substantial concerns, though funding may take time to achieve results
	Specific development programs	Orphan Drug Act (ODA)	ODA has been credited with producing numerous drugs for rare diseases	Already applies to antibiotic field, cost-effectiveness not known, does not support conservation
	Alters the regulatory review process	Loosen FDA standards, accelerate review time, allow access to drugs before completion of regulatory review	Reduce clinical trial costs, a potential barrier to antibiotic investment	Safety concerns, accelerated resistance from early marketing of new antibiotics

### IV. THE ANTIBIOTIC CONSERVATION AND EFFECTIVENESS (ACE) PROGRAM

The essential concept of the ACE program is to rationalize private incentives more closely to the ultimate public health goals. Our favored legal tool in the ACE program is contract: deploying insurance reimbursement, prizes, and grants for both conservation (Sector 5) and production incentives (Sector 6).<sup>267</sup> We articulate the primary objective to be continued antibiotic effectiveness, which requires a balanced pursuit of both conservation and new production. A significant question is which institutions to target with ACE incentives. Ideally, the target would be able to internalize all of the negative costs from antibiotic misuse and the positive benefits from antibiotic conservation. The target should also have ready access to private information about antibiotic use. As we describe below, the drug companies appear to be best positioned to successfully integrate the disparate economic incentives in this field. The companies can act directly to induce conservation and can also influence others (such as doctors and hospitals) to follow suit.

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267. See Table 1.

The ACE program emphasizes: (1) value-based reimbursement of antibiotics from public payors such as Medicare and Medicaid, with spillover participation from private payors (Sectors 5 and 6). These reimbursement changes will improve private markets for antibiotic effectiveness by giving significant institutional actors financial incentives to promote conservation and continued antibiotic effectiveness; (2) making these payments conditional on meeting realistic public health and conservation goals, including a Strategic Antibiotic Reserve (Sectors 5 and 6),<sup>268</sup> (3) regulatory changes, including limited waivers of antitrust as well as fraud and abuse laws, to permit market coordination for conservation (supporting efforts in multiple Sectors), and (4) increased public grant support for basic antibiotic research, including both conservation and new production (Sectors 5 and 6).<sup>269</sup> In this section, we discuss the details of these proposals in further depth and show how ACE incentives can be instituted without wholesale changes to the current drug approval, patent, and market exclusivity systems.

#### *A. Value-Based Reimbursement of Antibiotics*

The first plank of the ACE program is value-based reimbursement<sup>270</sup> for antibiotics.<sup>271</sup> The market undervalues antibiotics. The gross sales of antibiotics in the United States in 2008 were approximately \$11.2 billion.<sup>272</sup> Expressed as a percentage of the U.S. pharmaceutical market,<sup>273</sup> antibiotics represent about 3.9% of United States drug sales. Given that low percentage, it is understandable that antibiotics accounted for about 3.6% of all U.S. drug approvals since 2000.<sup>274</sup> Antibiotic innovation is delivering about the number of new drugs that its market size suggests. The market places a modest private value on this important class of drugs and companies respond appropriately. With present

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268. See Table 1.

269. See Table 1.

270. This reimbursement could take many forms, including increased ex-manufacturer pricing or prizes awarded under contract. If reimbursement mechanisms were chosen, care would have to be taken to isolate patients and perhaps plan sponsors from the increased costs, perhaps through a reverse rebate directly from the government to the patent holder. If the goal were to minimize changes to insurance reimbursement systems, then a prize system is preferred. Prizes have the disadvantage of requiring separate financing, while reimbursement is built into the health care insurance system.

271. Kesselheim & Outtersen, *supra* note 25, at 1692.

272. IMS Midas Database (2008 USD\_MFN) (\$11,195,825,230) (manufacturers' sales prices).

273. IMS Health, Top Therapeutic Classes by U.S. Sales (Apr. 6, 2010), [http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top\\_Line\\_Data/Top%2520Therapy%2520Classes%2520by%2520U.S.Sales.pdf](http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top_Line_Data/Top%2520Therapy%2520Classes%2520by%2520U.S.Sales.pdf).

274. See Outtersen et al., *supra* note 67.

spending patterns, antibiotics are not in the top fifteen global therapeutic drug classes, ranked by market size.<sup>275</sup> To demonstrate that the market undervalues antibiotics, we must compare the private value with some other referent. One possibility is the social burden of infectious disease in high-income countries. We calculate this value from the World Health Organization estimates of the disability-adjusted life year (DALY) burden of infectious diseases in various WHO regions. To translate DALYs to dollars, we provide a range of assumptions on the social value of a DALY, assuming that an additional healthy year of life is worth from \$50,000 to \$125,000 each. Table 3 (below) presents the results, suggesting that the unmet social burden of infectious diseases in the United States and Canada is worth \$73-\$183 billion per year. Providing \$10 billion per year in ACE incentives would still be a terrific bargain for society if it reduced these DALYs by an even greater amount.

**TABLE 3: UNMET SOCIAL BURDEN OF INFECTIOUS DISEASES IN SELECTED HIGH-INCOME COUNTRIES**<sup>276</sup>

Assumed DALY Value (in '000s)	\$50	\$75	\$100	\$125
Social cost (US/CAN) (in billions of USD)	\$73.3	\$110	\$146.7	\$183.3
Social cost (High Income Europe) (in billions of USD)	\$66.3	\$99.5	\$132.6	\$165.8
Total social cost (US/CAN & High-Income Europe) (in billions of USD)	\$139.6	\$209.5	\$279.3	\$349.5

A second possible referent is the social value of the current health impact of antibiotics. The calculations in Table 3 are limited to the current unmet health

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275. IMS Health, Top 15 Global Therapeutic Classes, 2009, Total Audited Markets, *available at* [http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top\\_Line\\_Data/Top%2015%20Global%20Therapeutic%20Classes\\_2009.pdf](http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top_Line_Data/Top%2015%20Global%20Therapeutic%20Classes_2009.pdf).

276. Underlying burden of disease data from WHO 2008. Estimates by Outterson (2009). These estimates do not include the social value of averted infectious diseases in high-income countries. The cost of resistant infections is a much smaller subset, reaching approximately \$30 billion per year in the United States.

need and do not include the current health impact delivered by today's antibiotic treatments. Life in a post-antibiotic world would be remarkably more dangerous, with profound impacts on human health. If ACE incentives were able to merely preserve the current level of antibiotic effectiveness, this success would be worth tens of billions of dollars, if not more. The estimates in Table 3 might be far too low, underestimating the true social value of antibiotics.

In short, the market as it currently operates places an inappropriately low private value on antibiotics and infection control.<sup>277</sup> The reimbursement price for both should more closely track their social value. But the U.S. health care markets have many dysfunctional aspects; thus some therapies receive too much reimbursement,<sup>278</sup> while others receive too little.<sup>279</sup> Antibiotics have historically been priced relatively cheaply. Whatever the precise cause, a process for refashioning this system must begin with modeling the health impact of new antibiotics and pricing accordingly. For example, if a new drug led to a reduction in length of hospital stay for patients with a certain kind of bacterial pneumonia, a value-based reimbursement plan will return a percentage of these savings to the company. When used in conjunction with the conservation-based exclusivity discussed below,<sup>280</sup> the company's immediate financial success will be conditioned on the continued effectiveness of the drug. Conversely, as resistance builds on a drug, ACE payments will automatically taper. This approach begins to remedy the mismatch between social value and private value, which we identify as a central problem in antibiotic markets. Make no mistake: we are proposing a very substantial increase in payments for antibiotics, driven by the social value of these important drugs. The total monetary value of ACE incentives might be a net increase of several billion dollars a year in the United States, even as unit sales decline. In fact, declining unit sales would be an expected result as antibiotic conservation techniques received full stakeholder support with financial incentives. Reimbursement for the value provided by infection control and antibiotic stewardship activities undertaken by providers and public health authorities should similarly increase.

Expert groups from a myriad of disciplines have suggested that drugs be reimbursed in accordance with their value to society.<sup>281</sup> In the United States, the

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277. Matthew E. Falagas et al., *A Comparative Study of the Cost of New Antibiotics and Drugs of Other Therapeutic Categories*, PLoS ONE e11 (2006).

278. Deborah Schrag, *The Price Tag On Progress—Chemotherapy For Colorectal Cancer*, 351 NEW ENG. J. MED. 317 (2004).

279. Robert A. Steinberg, *Easing the Shortage in Adult Primary Care—Is It All About Money?*, 360 NEW ENG. J. MED. 2696 (2009).

280. See *infra* notes 275-287

281. See, e.g., OFFICE OF FAIR TRADING, THE PHARMACEUTICAL PRICE REGULATION SCHEME (2007), available at [http://www.oft.gov.uk/shared\\_oftrreports/comp\\_policy/oft885.pdf](http://www.oft.gov.uk/shared_oftrreports/comp_policy/oft885.pdf); HOLLIS &



American Recovery and Reinvestment Act created a federal agency to organize comparative effectiveness studies.<sup>282</sup> The process of modeling the health impact of antibiotics and rating their utility is a logical task for such a body to undertake, with assistance from experts at Medicare and others familiar with large patient databases. The U.S. pharmaceutical industry has been critical of comparative effectiveness research, expecting that total reimbursements will decline and thus undermine innovation incentives.<sup>283</sup> In the specific case of antibiotics, we think these concerns are misplaced, as the purpose of the ACE program is to increase the private value of these drugs to more closely mirror social value.

### *B. Conditioning Reimbursement on Meeting Conservation Targets*

The second leg of the ACE incentive program links these enhanced financial rewards to appropriate use and successful conservation of the antibiotic. In addition to higher prices to the manufacturer (but not the patient), cash prizes can be used as incentives. The key concept here is conditionality, making the enhanced payments only if conservation goals are met at a population level.

Insurance reimbursement and cash prizes are favored over patent extensions and additional marketing exclusivity<sup>284</sup> because they operate directly and immediately with less discounting to present value. Insurance reimbursement and cash prizes significantly change the cash flow stream in all years and substantially alter the net present value of conservation management by the antibiotic sponsor. Unlike traditional R&D pull incentives, the time lag between company action and financial reward could be quite short with ACE reimbursement and prizes.<sup>285</sup> By contrast, patent modifications may be more uncertain from a company's view since they provide projected rewards,

POGGE, *supra* note 41; Hollis, *supra* note 41; Love & Hubbard, *The Big Idea*, *supra* note 40, at 1519; Joseph E. Stiglitz, *Scrooge and Intellectual Property Rights*, 333 BMJ 1279 (2006).

282. Jerry Avorn, *Debate About Funding Comparative-Effectiveness Research*, 360 NEW ENG. J. MED. 1927 (2009).

283. See, e.g., John A. Vernon, Joseph H. Golec & Steadman Stevens, *Comparative Effectiveness Research (CER) and the Potential Threat to Pharmaceutical Innovation* (2010), available at <http://ssrn.com/abstract=1579442>.

284. Our proposal does not rely on patent-term extensions, but rather on FDA-administered periods of marketing exclusivity while conservation targets continue to be met, coupled with greatly improved reimbursement or cash prizes after regulatory approval of the antibiotic. *Fighting Antibiotic Resistance*, *supra* note 25.

285. Unlike patent term extension proposals, which must influence company R&D behavior years before actual cash flow, ACE incentives can provide immediate cash flow for meeting conservation targets. If the time lag between company actions and significant resistance is quite long, then a time-lag discounting problem may also arise for ACE, necessitating a range of measures such as unit sales in addition to pathogen susceptibility.

discounted to net present value, and only if future sales materialize. In addition to being a weaker production incentive, patent modifications do not give strong incentives for conservation.

Unlike other regulatory exclusivity proposals,<sup>286</sup> the ACE program would condition payment to the continued effectiveness of the antibiotic. The sponsor can thus forecast a return on investment from managing antibiotic effectiveness for the long term. This incentive is likely to be much more cost-effective than patent modifications, because the amount of the additional incentive will be conditioned on meeting public health goals. Patents do not employ this condition. ACE incentives could also be tailored to individual drug-bug pairings and various levels of resistance, in order to prevent the antibiotic sponsor from losing financial rewards all at once. For a drug treating MRSA, for example, one target could be working to ensure that morbidity from MRSA in a representative sample of U.S. healthcare institutions remains below a set percentage.<sup>287</sup> This proposal would give the drug companies stronger financial incentives to promote conservation tools in hospitals and otherwise manage antibiotics for population-level public health.

ACE relies on drug companies to rationalize this market characterized by asymmetrical information and irrational economic incentives. Focusing ACE incentives at the pharmaceutical company allows the company to internalize and address the dynamic cross-purposes that characterize existing battles between conservation and new production. One objection is that the company does not fully control the utilization of antibiotics, making ACE incentives a partially effective policy lever. We concede that drug companies cannot achieve conservation alone, but we see value in co-opting these companies to the cause of public health. The companies control the patents, possess significant private information on antibiotic markets, and control significant resources to influence prescription patterns. No other private actor can claim so much. There is substantial empirical evidence that pharmaceutical manufacturers actively direct drug product use through marketing. Pharmaceutical manufacturers devote over \$50 billion dollars per year to promotional and advertising practices in the U.S. pharmaceutical market alone.<sup>288</sup> These efforts include direct physician contact

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286. See, e.g., Roin, *supra* note 89.

287. These targets could be designed by a roundtable of experts led by government, but also including representatives from academia, non-profit research groups, and industry. Sensible organizations to lead this target-setting group include the FDA, Centers for Medicare and Medicaid Services (CMS), and the Centers for Disease Control. Models for this type of cooperation and medical evaluation abound at the government level. One example is the Medicare Evidence Development and Coverage Advisory Committee, which provides independent guidance and expert advice to CMS on specific clinical topics.

288. Marc-André Gagnon & Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of*

through sales representatives, advertising to consumers and physicians via the media, lay press, and industry publications, provision of free samples of products, distribution of consulting fees or other payments that may act as inducements to prescribers, and development of sponsored Continuing Medical Education conferences touting the benefits of their product that are required of physicians by state medical licensing boards. Studies have shown the impact that these tactics can have on physician prescribing behaviors.<sup>289</sup> Promotional and advertising practices can lead physicians to prescribe more expensive, though less effective, drug products against expert recommendations.<sup>290</sup> This effect has been shown to be especially prevalent among prescribers of antibiotics.<sup>291</sup>

Currently, private financial incentives reward companies for promoting the sales of their antibiotics. As a result, pharmaceutical marketing efforts are exclusively directed towards increasing prescriptions of the company's antibiotic. Companies can increase the sales of their antibiotic in two primary ways: (1) increase the overall sales of antibiotics (grow the market); or (2) shift demand to their drug from a rival drug (increase market share). Growing the market produces positive externalities for other antibiotic manufacturers, as the benefits from a growing market may spill over to rival producers. Growing the market also produces unclear health effects. If the additional use is not clinically rational, growing the market creates negative public health externalities through resistance. Antibiotic conservation directly threatens the market growth model.

The second strategy entails several different characteristics. Increasing market share is positive for the company (additional sales, with fixed costs spread over a larger revenue base) and directly negative to rivals, who lose sales in a zero-sum game. Shifting market share from one drug to another may also have unclear health effects. If the better drug gains more market share, health should be positively impacted. The opposite is also possible: a company may convince physicians to prescribe and patients to take a less effective drug. Market shifts with negative public health externalities are perhaps more likely when the older, more effective drug is generic and lacks a company champion with a large marketing budget to defend market share. Many of these questions are empirical, and the companies themselves control much of the relevant data. We emphasize that rational policy making in drug innovation will be difficult without either the cooperation of the companies or careful empirical analysis of the data they control. Under the ACE program, the companies will have significant financial

*Pharmaceutical Promotion Expenditures in the United States*, 5 PLOS MED. e1 (2008).

289. Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is A Gift Ever Just a Gift?*, 283 JAMA 373 (2000).

290. Avorn, *supra* note 161.

291. John D. Cleary, *Impact of Pharmaceutical Sales Representatives on Physician Antibiotic Prescribing*, 8 J. PHARMACY TECH. 27 (1992).

incentives to use their private information and marketing resources for the benefit of public health goals.

The companies may also be formidable opponents to new conservation programs. In recent years, a number of pharmaceutical manufacturers have been cited for aggressive over-promotion of their drugs.<sup>292</sup> The efforts to encourage rational prescribing and develop evidence-based prescription guidelines have been limited because the investment in these public health efforts has been dwarfed by the pharmaceutical industry's investment in marketing, which is not necessarily aligned with public health goals. Under the ACE program, pharmaceutical industry promotional practices (such as physician detailing by pharmaceutical sales representatives and Continuing Medical Education) would be refocused for a purpose more in line with public health needs. The ACE incentives would encourage drug companies to target clinically rational use of their products in patients where the drugs would reduce morbidity, while at the same time encouraging the sponsor to restrict resistance-inducing overuse of the product. Industry promotional practices would also be incentivized to encourage efforts aimed at promoting rational prescribing practices and infection control. For example, manufacturers might consider cooperating with hospitals in restricting formularies, rather than seeking agreements or other mechanisms to undermine the practice.<sup>293</sup> The pharmaceutical industry marketing departments possess remarkable tools to influence physician prescribing practices. Under the ACE program, they would be turned into a mechanism for helping encourage proper use, not overuse, of new antibiotic agents. The government selects the public health goals, then the companies privately manage the process to achieve those goals.

Other levels of the market could be considered for ACE incentives, such as the physician, the hospital, or the patient.<sup>294</sup> By choosing the company, we deliver the incentive to the most powerful upstream player in the system, which then can deploy portions of that prize downstream, as they deem most effective.<sup>295</sup> A drug company receiving a \$100 million ACE incentive might find it cost effective to offer grants to hospitals with particular infection control problems, to the extent that such an effort helps the company continue to meet its

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292. Aaron S. Kesselheim & David M. Studdert, *Whistleblower-Initiated Enforcement Actions Against Health Care Fraud and Abuse in the United States, 1996-2005*, 149 ANNALS INTERNAL MEDICINE 342 (2008).

293. See Robert Pear, *U.S. Warns Drug Makers on Illegal Sales Practices*, N.Y. TIMES, Apr. 28, 2003, available at <http://query.nytimes.com/gst/fullpage.html?res=9D0CE2DB133DF93BA15757C0A9659C8B63>.

294. See, e.g., Saver, *supra* note 32 (focusing on the physician).

295. These payments may require exemptions from fraud and abuse laws and antitrust laws. See discussion *infra* Section IV.C.

ACE goals. Giving conservation incentives merely to doctors and hospitals, for example, pits them against the pharmaceutical marketing machine and fails to tap into the companies' vast market knowledge.<sup>296</sup> We suggest financial support (i.e., a billing code for infection control) to both providers and drug companies to support antibiotic conservation, promoting cooperation in the effort.

*D. Limited Waivers of Antitrust and Self-Dealing Laws*

Our final proposal addresses horizontal and vertical coordination problems in antibiotic markets. The biology of resistance does not respect the lines drawn by patents or antitrust law. Antibiotic resistance can cross multiple species and diminish the effectiveness of antibiotics both within classes and across classes. Resistance patterns are heterogeneous, which complicates conservation efforts.<sup>297</sup> Some private antibiotic conservation strategies would function better if manufacturers could cooperate horizontally in limiting the marketing, sale, and utilization of antibiotics with cross-resistance issues. For example, only two firms currently hold patents on commercially significant FDA-approved drugs in the fluoroquinolone class of antibiotics,<sup>298</sup> but resistance to these drugs can easily affect other drugs in this class.<sup>299</sup> The class itself should be understood as a form of commons, at least with respect to resistance. If the number of players was too large or transaction costs too high, perhaps regulation would be appropriate. The other option is private group coordination, which could be effective in this case given the relatively small number of sophisticated actors. If fluoroquinolones are to be managed for long-term public health, all of the relevant patent holders must work together to jointly manage the market. The patent owners (pharmaceutical companies) must work together to conserve antibiotics.

Competition law appears to forbid exactly this form of joint coordination among competitors. The pharmaceutical industry has received significant attention from competition authorities with regard to its patent and litigation settlement practices.<sup>300</sup> In this circumstance, however, economic models of drug

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296. ACE does not require the companies to disclose their private market information. The companies manage their actions as they see fit, in order to obtain the ACE incentives.

297. See *Vanishing Public Domain*, *supra* note 19, at 96-97.

298. Ortho-McNeil (levofloxacin and ofloxacin) and Bayer (ciprofloxacin and moxifloxacin). BMS withdrew gatifloxacin from the US market in April 2006 following publication of a negative article in the *New England Journal of Medicine* and Pfizer's US sales of alatrofloxacin ceased in 2003.

299. G. Thomas Ray et al., *Hospital-Level Rates of Fluoroquinolone Use and the Risk of Hospital-Acquired Infection with Ciprofloxacin-Nonsusceptible Pseudomonas Aeruginosa*, 41 CLINICAL INFECTIOUS DISEASE 441 (2005).

300. BUREAU OF COMPETITION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003:

resistance suggest “a mixed competition/monopoly regime can perform better than competition or monopoly alone.”<sup>301</sup> Likewise, hospitals and payors in a community might improve the public health by coordinating conservation activities on specific pathogens across all hospitals and payors, but might be reticent to do so given the possible sanction of antitrust laws. There are indications that authorities could be favorably disposed to such coordination. The U.S. Federal Trade Commission and Department of Justice have issued joint guidelines suggesting health care joint ventures that would otherwise be anticompetitive might be permitted in narrow circumstances.<sup>302</sup> Proper circumstances include clinical coordination to improve quality, which is the goal of antibiotic conservation.

Therefore, our third ACE proposal creates limited conservation-based antitrust waivers. We propose that the FDA identify particular bug-drug pairings for which cross-resistance is a problem. The IDSA has clearly identified pathogens of special concern in the United States because limited therapeutic options remain. These pairings might be an appropriate starting point. The FDA would be empowered to issue certificates, in consultation with the antitrust enforcement agencies that would permit limited joint coordination of conservation activities for the specified product markets. The concept we are proposing is akin to structure of the safe harbor exceptions to the Anti-Kickback statute, which lists a number of activities that are systematically excluded from federal prosecution.<sup>303</sup> In this case, the certificates would signal to private actors that joint coordination for antibiotic conservation was clearly encouraged, while limiting the potential for collusive mischief by specifying the qualifying drug-bug combinations. In this vein, we also support extending marketing exclusivity to the companies, again conditioned on meeting conservation targets. So long as firms are successfully managing the resource for long-term public health, they should be allowed to continue without the threat of generic entry in the antibiotic market. Generic entry adds another actor to the group that must coordinate activities, complicating efforts. If a company fails to meet the conservation goals, it might be appropriate to place the exclusive marketing rights into the hands of the government or another firm better poised to manage the resource.

Limited antitrust waivers will create a forum for possibly collusive discussions well beyond these particular antibiotics. Perhaps the meetings should

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SUMMARY OF AGREEMENTS FILED IN FY 2007 (2008), *available at* <http://www.ftc.gov/os/2008/05/mmaact.pdf>.

301. Mechoulam, *supra* note 171, at 4.

302. U.S. DEP'T OF JUSTICE AND FED. TRADE COMM'N, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE (1996), *available at* <http://www.justice.gov/atr/public/guidelines/0000.htm>.

303. 42 U.S.C. §§ 1320a-1327b(b)(3) (2006).

be public, to facilitate coordination amongst the downstream actors as well. In any event, the industry does not lack other opportunities for market discussions, and if collusion occurs in other drug markets it can hardly be blamed on the ACE program.

In addition to this horizontal coordination problem, drug companies will also want to incentivize their downstream stakeholders to cooperate in their antibiotic conservation efforts. As a result, we predict that drug companies will more readily support vertical antibiotic conservation efforts in hospitals and physician offices, because the success of these programs will most directly determine the extent of antibiotic resistance development—and continued revenue generation for the sponsor. Likewise, hospitals and independent long-term care facilities share patient populations that could benefit from a coordinated effort against resistance.<sup>304</sup> The self-dealing laws, including Stark II, prohibit many forms of financial relationship amongst referral sources.<sup>305</sup> It may be necessary to create specific safe harbors and exceptions to permit vertical coordination of antibiotic conservation efforts.

## V. IMPLEMENTATION ISSUES WITH ACE INCENTIVES

### *A. Designing Value-Based Reimbursement*

ACE incentives need not be uniform. A powerful new antibiotic should receive a greater reward; me-too antibiotics with minimal value and doubtful safety profiles should perhaps receive nothing at all, or even be penalized. ACE incentives should respond to the health impact of the drug. This will be a difficult task, with many technical obstacles and the ever-present threat of industry capture. Any pay-for-performance or value-based reimbursement system shares these risks. We address them only briefly here.

Building on the work of the IDSA task force, teams of infectious disease specialists, in consultation with government and international public health experts, should establish targets for ACE incentives that consist of microbes with emerging resistance to current therapy and/or substantial public health impact. Expert groups should then attempt to identify the size of the potential market and health impact for the needed antibiotic in each case by working with government officials, representatives from the pharmaceutical or biotech industries, and health economists. Factors related to the disease target, such as its morbidity, effectiveness of current treatment strategies, and rate of emerging resistance, can be used to identify the upper and lower bounds of the public health goals and

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304. See Outtersson, *supra* note 18.

305. Joan H. Krause, *A Conceptual Model of Health Care Fraud Enforcement*, 12 J.L. & POL'Y 55 (2003).

therefore the ACE incentive. Development-related factors, such as the ease of pharmacological research and rapidity of natural selection at the level of microbe, will affect the costs of development and pretrial testing.

The population health goals for any new agent should be flexible, taking into account the dynamics of the health care system as well as the characteristics of the target microbe. A new agent against VRE may find a much easier implementation strategy in acute care settings in developed countries, where VRE is most prevalent. Using this strategy will require additional investment in improved surveillance of antibiotic use and development of resistance. At timely intervals, the same infectious disease experts and public health officials who set the ACE incentive targets will judge the success of the product in treating the infectious disease for which it was approved.

Value-based reimbursement will also need to consider the structure of licensing agreements in the industry, which typically pay royalties based on sales during the patent term. ACE incentives should be considered sales for these purposes, at least as a default rule. For many antibiotics, the company marketing the product did not invent the molecule but acquired it through a license agreement from an inventor based at a university, non-profit research center (such as an academic medical center), or university-affiliated start-up biotechnology company. Some of the payments under ACE may not be included in the royalty calculations under some license agreements, which would be a windfall to the marketer and a loss to the original innovator. The companies will have to amend their licenses, or perhaps a default rule could be integrated into the structure of the ACE contract itself.

Finally, it should be noted that since the private value of antibiotics is such a small fraction of the social value, the amount of the value-based reimbursement system does not have to be finely tuned at first. As described above, the social value of antibiotics appears to be an order of magnitude higher than their private value. So long as clinically important conservation targets are set and the amount of ACE incentives are in the range of several billion dollars per year, we can expect that the resulting expenses will be well spent. The program may well be cost-effective within the health insurance sector alone, without even considering broader positive externalities.

### *B. The Strategic Antibiotic Reserve*

Limited periods of exclusivity, combined with value-based reimbursement, may not provide a reasonable potential market for some clinically important antibiotics. For example, a first-in-class antibiotic might need to be held in reserve for many years, and used only in the most urgent cases. We call this



concept the Strategic Antibiotic Reserve (SAR).<sup>306</sup> The clinical value of the SAR has already been demonstrated with the natural history of vancomycin, a drug that was inadvertently held in reserve for decades and is now a major antibiotic in helping manage MRSA and other extremely potent microbes.<sup>307</sup>

Holding a first-in-class antibiotic in reserve might be the right answer for public health, but it will be a financial disaster for the company, especially if the unit sales are quite small. It will be difficult for value-based reimbursement to deliver hundreds of millions of dollars in annual sales for several years of very sparing use. If the social value of holding a new class of antibiotic in the SAR is, to assume an example, \$200 million per year, it seems unwieldy to charge \$1 million each to two hundred patients (or to their insurers). Neither will longer periods of marketing exclusivity help much, since drugs in the SAR are by definition used only in extreme need and therefore the future projected sales revenue will be deeply discounted. The net present value of additional years of exclusivity after the patent term may be quite small.

For this reason, the ACE program includes supplemental cash prizes for placing important new antibiotics in the Strategic Antibiotic Reserve. These amounts must be quite substantial in order to properly align incentives, ranging towards a billion dollars per year for an important drug class. Current candidates might include daptomycin, a recent antibiotic with activity against MRSA. An expert advisory committee should make the designation of which antibiotics are worth reserving in this way. The financial arrangement with the company will be entirely voluntary, based on a contract with the government. The amount of the payment should be value-based as described above to promote both innovation and conservation. If a company tried to hold out with a critically important antibiotic, of course the government would retain the ability to use a compulsory license, with payment of just compensation for the taking.<sup>308</sup>

### *C. Other Considerations*

#### *1. Intellectual Property*

The ACE program does not replace the current patent-based exclusivity regime. Antibiotic patents are left in the hands of the companies. One exception to retaining patent rights might be the Strategic Antibiotic Reserve. For these drugs, an alternative model might be a voluntary government purchase of the

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306. See *Legal Ecology of Resistance*, *supra* note 19, at 624, 656-57, 677.

307. See *Legal Ecology of Resistance*, *supra* note 19, at 656.

308. See, e.g., JEROME H. REICHMANN WITH CATHERINE HASENZAH, NON-VOLUNTARY LICENSING OF PATENTED INVENTIONS (2003), available at [http://ictsd.org/downloads/2008/06/cs\\_reichman\\_hasenzahl.pdf](http://ictsd.org/downloads/2008/06/cs_reichman_hasenzahl.pdf).

patent for fair market value.<sup>309</sup> A patent buyout would eliminate the company's uncertainty as to the future value of the patent by setting a mutually agreed price. However, we see advantages to keeping the patent in the hands of the companies, even for a drug in the Strategic Antibiotic Reserve. A key goal of the ACE incentives is to co-opt the companies by giving them a continuing financial incentive to develop and sell antibiotics in line with public health needs. If a patent buyout severs that ongoing financial risk/reward to the company, then that incentive is lost. This is especially troublesome in the case where a company then markets follow-on drugs in the same functional resistance group, because the use of these drugs would reduce the strategic value of the previously-purchased antibiotic.

It should be noted that we are limiting this discussion to antibiotics. Generic access to cheap antibiotics is not entirely positive for public health, even on a merely static basis. Cheap (or free) antibiotics drive resistance and reinforce the overall low reimbursement levels in this drug class.<sup>310</sup> For other classes of antimicrobials, a different balance might be struck between patent law and generic access. Consider antiretrovirals (ARVs) used to treat AIDS. The reimbursed price for first-line treatment in the United States is very high, over \$10,000 per year, while the generic price in aid programs in sub-Saharan Africa is less than \$100.<sup>311</sup> This huge pricing differential was a keystone in ramping up treatment for millions of impoverished AIDS patients.<sup>312</sup> This model was triggered by unlicensed generics produced by Indian generic companies. For these ARVs, public health demanded quicker access to generics.

We have formulated the ACE program as voluntary, based in contract. New drug sponsors will have a choice of whether to enroll their patent-protected antibiotic in the ACE program. A voluntary system may be more palatable to pharmaceutical manufacturers because it is a less extreme step and gives them a veto. However, a voluntary arrangement is complicated by a number of logistical issues that might undermine the effectiveness of the ACE program. First, it would be difficult to incentivize adherence to ACE guidelines if a manufacturer were to refuse to participate and marketed their drug in a way that damaged other antibiotics through resistance. It might be necessary to control a rogue manufacturer through FDA restrictions on the sale and use of their product. Second, it would be complicated to manage the ACE system if it were to include

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309. See, e.g., Kevin Outterson & Aaron S. Kesselheim, *Market-Based Licensing for HPV Vaccines in Developing Countries*, 27 HEALTH AFF. 130, 134-35 (2008) (discussing a patent buyout for HPV vaccines).

310. See *supra* note 38 and accompanying text.

311. Outterson, *supra* note 154.

312. See Charles B. Holmes et al., *Use of Generic Antiretroviral Agents and Cost Savings in PEPFAR Treatment Programs*, 304 JAMA 313 (2010).

some new antibiotics but not others. For example, the system may experience administrative difficulties if it attempted to limit value-based reimbursement to only selected antibiotics. It might be difficult to specify causal relationships in cross-drug resistance within and between classes. Similarly, limited waivers of antitrust law may be more difficult to manage if the owners of some antibiotics in a particular class were outside the regulatory framework. Most of these problems will wane as more companies participate and also as we develop better understandings of the underlying biological relationships in resistance through public investment in basic research.

These issues may not be a realistic problem if the value-based reimbursement system was quite robust and generous. Hopefully, the companies will be eager to see increases in the reimbursement level for this class of drugs. Alternatively, the government also retains the power of eminent domain, with the condition of paying just compensation.<sup>313</sup> Governments also have monopoly power as a purchaser. This is effectively the current market situation in countries where government payors dominate the pharmaceutical market, including the European Union, Canada, and Australia.<sup>314</sup> Even in the United States, the role of government payors looms larger after the recent expansions in Medicare Part D and Medicaid.<sup>315</sup>

## 2. Access to Generic Antibiotics

Under ACE, prices to the patient will not change. From a health plan and social perspective, an expensive but effective antibiotic that meets a public health need is preferable to a low cost but ineffective one, particularly in a country with an adequate social insurance scheme for drugs. We recognize the significant impact of high drug prices in low- and middle-income countries, which calls for full exploitation of TRIPS flexibilities and differential pricing to equitably balance access needs.<sup>316</sup> It may not be necessary to affect the pricing in

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313. See Aaron S. Kesselheim & Jerry Avorn, *Biomedical Patents and the Public's Health: Is There a Role For Eminent Domain?*, 295 JAMA 434 (2006).

314. U.S. DEP'T OF COMMERCE, INT'L TRADE ADMIN., PHARMACEUTICAL PRICE CONTROLS IN OECD COUNTRIES: IMPLICATIONS FOR U.S. CONSUMERS, PRICING, RESEARCH AND DEVELOPMENT, AND INNOVATION 59, 77, 105 (2004), available at <http://www.ita.doc.gov/td/chemicals/drugpricingstudy.pdf>.

315. Kevin Outterson & Aaron Kesselheim, *How Medicare Could Get Better Prices on Prescription Drugs*, 28 HEALTH AFF. 832, w832-41 (2009).

316. Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y L. & ETHICS 193 (2005). The TRIPS Agreement is a global floor of minimum intellectual property rights. TRIPS flexibilities are non-mandatory legal tools available to WTO Members to enable each country to balance the twin goals of innovation and access to medicines. Differential pricing in this context is the willingness of

developing countries at all. The entire cost of the ACE program can and should be borne by high-income countries.

As to the developing countries, if an impact on global antimicrobial resistance is desired, then the ACE conditions should include both domestic and international targets. Of course, if the companies are being asked to manage a larger problem, their financial incentives must be increased appropriately. But this company mechanism benefits from not being directly dependant on the quality of governance in the developing world. The companies are adept at getting things done despite weak governance structures. They could put that knowledge to work against global antibiotic resistance.

### *3. Public Investment in Antibiotic Research*

Part of the ACE program involves enhanced investment in basic science funding that may lead to new antibiotic development. There have been numerous occasions where important drugs have emerged primarily as a result of public sector investment. For example, in the case of the anti-cancer drug paclitaxel, the NIH invested \$484 million to fund research that eventually allowed Bristol Myers-Squibb to secure FDA approval for this compound. Bristol Myers-Squibb marketed the drug as Taxol, earning \$9 billion in worldwide profits.<sup>317</sup> As a result, we anticipate that improved public funding of infectious disease and resistance research will ultimately develop useful end-products, or discoveries that lead directly to the development of new antibiotics. In cases where new antibiotics are developed in part from public funding, it may be appropriate to adjust the value-based reimbursement level to reward the end-product manufacturer at a level commensurate to the amount of investment it has made in the development of the product. If the drug was developed solely with private funds, then perhaps the value-based reimbursement should allow the company to capture the greater part of the social surplus from the drug. For drugs with significant public support, the proportion would be lower.<sup>318</sup> As a result, a larger

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drug companies to modify prices based on the ability of the purchaser to pay. Wealthy purchasers pay more; low-income populations pay much less.

317. U.S. GEN. ACCOUNTING OFFICE, TECHNOLOGY TRANSFER: NIH-PRIVATE SECTOR PARTNERSHIP IN THE DEVELOPMENT OF TAXOL (2003), *available at* <http://www.gao.gov/new.items/d03829.pdf>.

318. Notably, there is a risk that manufacturers would use public funds for their research and then refuse to participate in voluntary ACE contracts. In fact, many highly transformative drugs have been based on extensive public funding and then distributed via private markets at high cost to consumers. See Bhaven N. Sampat, *Academic Patents and Access to Medicines in Developing Countries*, 99 AM. J. PUB. HEALTH 9 (2009). However, if the ACE program sufficiently alters the reimbursement scheme for antibiotics to provide manufacturers with a competitive rate of return for new products that are properly managed, we predict that this problem will be minimized.

percentage of the health care savings brought by the antibiotic would inure back to the government to help account for its investment drug development. This feedback mechanism supports government investment in the next generation of innovative drugs.

One objection is that this model might discourage private acceptance of public grant funding, since the large pharmaceutical companies would want to avoid the conditions described above. We think this is unlikely. Most recipients of NIH grant moneys are universities and other non-profit research groups. These groups depend on grant funding in a direct, immediate sense and will not oppose an explicit license term that modifies potential royalties to account for public support.

#### 4. Cross-Boundary Antibiotic Management Issues

The ACE program will need to account for the ability of microorganisms to spread resistance features across political and social boundaries. For example, overuse of antibiotics also occurs outside the realm of human medicine. Livestock farmers use antibiotics to increase production efficiency, which can enhance profitability and also lower food prices for consumers.<sup>319</sup> While antibiotics in livestock feed can help to promote animal growth, it has been linked to rising resistance rates in both animals and humans.<sup>320</sup> In 2008, the FDA issued an order banning the extra-label use of cephalosporin antibiotics in animal feed out of concern for rising resistance rates.<sup>321</sup> European authorities have moved more quickly to restrict animal uses of antibiotic classes that are important to human health.<sup>322</sup> These animal uses currently serve as a source of profits to antibiotic manufacturers. However, under the ACE program,

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319. Gay Y. Miller et al., *Productivity and Economic Impacts of Antibiotics Used for Growth Promotion in US Pork Production*, 35 J. AGRIC. & APPLIED ECON. 469 (2003).

320. Frank M. Aarestrup et al., *Glycopeptide Susceptibility Among Danish Enterococcus Faecium and Enterococcus Faecalis Isolates of Animal and Human Origin and PCR Identification of Genes Within the VanA Cluster*, 40 ANTIMICROBIAL AGENTS CHEMOTHERAPY 1938 (1996); Anthony E. van den Bogaard et al., *High Prevalence of Colonization with Vancomycin- and Pristinamycin-Resistant Enterococci in Healthy Humans and Pigs in the Netherlands: Is the Addition of Antibiotics to Animal Feeds To Blame?*, 40 J. ANTIMICROBIAL CHEMOTHERAPY 454 (1997); H. Gregg Claycamp & Barry H. Hooberman, *Risk Assessment of Streptogramin Resistance in Enterococcus Faecium Attributable to the Use of Streptogramins in Animals; Virginiamycin Risk Assessment* (2004) (draft for comment, available at <http://www.fda.gov/downloads/AnimalVeterinary/NewEvents/CVMUpdates/UCM054722/pdf>).

321. 73 Fed. Reg. 38,110 (Jul. 3, 2008).

322. Press Release, President of the Court of First Instance, *The President of the Court of First Instance Rules that Economic Interests Cannot Outweigh the Need To Protect Public Health* (June 30, 1999), available at <http://curia.europa.eu/en/actu/communiques/cp99/cp9948en.htm>.

manufacturers of new antibiotic agents will be better incentivized to take resistance emerging from cross-species uses into account when considering how to optimize use of their agents, which should make such additional regulations less necessary. Low-value uses in the animal sector will be replaced by higher-value uses in humans because the ACE incentives are conditioned on meeting public health goals.

Another important cross-boundary issue in the implementation of the ACE program involves whether a national-level response is the correct one. In a globalized world, perhaps all resistance issues are global. The medical evidence is more complex, as usual. To an unexpected degree, resistance issues can be local. In the Netherlands, extensive programs at the national level have maintained resistance at quite low levels.<sup>323</sup> In nearby France, Italy and Greece, utilization and resistance are much higher.<sup>324</sup> The Netherlands maintains this gradient across an open political barrier, which speaks to the power of national regulatory and cultural institutions to shape resistance patterns in the hospital and the community. So while we concede that many resistance issues might be global, we also insist that many national efforts such as this one are not in vain. A successful implementation of ACE in the United States could prompt similar efforts in the European Union and other valuable pharmaceutical markets. As the largest pharmaceutical market, the changes we propose to the United States will have significant spillover effects in the world, both in the types of new antibiotics that are developed and in the effectiveness and commitment to conservation globally. Since most pharmaceutical company profits are derived from U.S. sales, the ACE program will change the marketing of antibiotics globally. Inappropriate overuse in non-U.S. settings may contribute to resistance development, so pharmaceutical manufacturers will be incentivized by the ACE program to appropriately encourage conservation of their products elsewhere. Given the fact that large pharmaceutical manufacturers commonly use promotional activities to drive prescribing practices in non-U.S. markets,<sup>325</sup> we predict that their contributions can help stem antibiotic resistance arising from lower-income settings. If the value-based reimbursement is sufficiently generous, companies will manage the resources globally even in the absence of parallel efforts in other major markets.

The ACE program can also be adapted to global needs. As discussed above, the U.S. government's infectious disease advisers could keep global public health goals in mind when setting the conditions for ACE participation. Additional

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323. Wertheim et al., *supra* note 148.

324. H. Goossens, *Antibiotic Consumption and Link to Resistance*, 15 CLINICAL MICROBIOLOGY & INFECTION 12, 13 (2009).

325. JOEL LEXCHIN, *DECEPTION BY DESIGN: PHARMACEUTICAL PROMOTION IN THE THIRD WORLD* (1995).

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prizes could be contemplated for meeting global conservation targets. But these coordination tasks are complex, and the information on cross-resistance and the mobility of resistance may be difficult to interpret. We support the work of the traditional public health agencies of governments in this effort, but also suggest that the ACE program brings the companies on board as partners in these efforts. If the companies enjoy some informational advantages in these markets, their enthusiastic cooperation may be essential to continued global effectiveness of these drugs. ACE allows the companies to use this private information for public health, without requiring public disclosure.

## CONCLUSION

We share the concern that current incentives for antibiotic development are inadequate, but insist that new models are required before the market can properly evolve. Public health goals and the goals of the private actors—primarily pharmaceutical manufacturers—are woefully misaligned. Therefore, we promote value-based reimbursement that includes grants and prizes supporting both the production and conservation of antibiotics in an integrated program that accounts for dynamic effects and maximizes benefits to society. The ACE incentives, which are grounded less in property and more in contract, will address many of the problems that promote antibiotic resistance, especially the mismatch between the private value and social value of antibiotics. The incentives are focused on the private actors best positioned to coordinate private information and internalize both positive and negative externalities from antibiotic use. Most importantly, all payments are conditioned on continuing to meet conservation goals. Together, this package improves antibiotic markets for long term sustainability, a task that is urgently needed to avoid the disaster of a post-antibiotic era.





# **Adding Life to the Adolescent’s Years, Not Simply Years to the Adolescent’s Life: The Integration of the Individualized Care Planning & Coordination Model and a Statutory Fallback Provision**

**Kimberly Gordy\***

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## INTRODUCTION

Yesterday Tyler had friends over playing x-box and rock band. They were laughing, joking, and the biggest question on their minds was will tomorrow be a snow day. Today Tyler is surrounded by a team of nurses and doctors injecting 5 different toxic chemotherapy drugs directly into his heart . . . . By 5:00 the side effects had already begun. I am continually amazed at how smoothly Tyler makes the transition between these two worlds. It is a sign of great strength and maturity. He does a far better job than I do . . . . It is an amazing and humbling thing when your greatest life lesson is taught to you by your own teenage son.<sup>1</sup>

The above passage was written by the parent of seventeen-year-old Tyler Alfriend, a patient with stage IV Burkitt's Lymphoma and Leukemia. Tyler's ability to balance these opposing worlds exemplifies the dignity and maturity exhibited by so many teenage patients coping with critical illness. For these young adults, their teen years are not the jaunty bridge between childhood and adulthood, a time during which teens discover their world without regard for mature considerations. Instead, the reality of their illness often results in fulminant entry into adulthood. While coping with the realization that they may not reach their next birthday, these teens also assume the responsibility of assuaging the grief of their families. Although there is never a good time in one's life to face a life-threatening illness, experts have recognized that the adolescent years may be among the hardest.<sup>2</sup>

Many physicians admit that critically ill adolescent patients are in a relative "no man's land."<sup>3</sup> In many ways, adolescent patients are like pediatric patients, needing both emotional and physical support from their families. However, these patients are not children, and the maturity demonstrated by many teens warrants the medical decision-making autonomy given to adult patients. Take the case of Michael Miller, who at age sixteen was diagnosed with cancer so advanced that his treatment included fifty-one weeks of chemotherapy, radiation, and surgery.<sup>4</sup> In the wake of his diagnosis and his parent's admitted hopelessness, Michael's physician stated that Michael showed maturity when he "calmed his parents' fears and helped them focus on the task ahead."<sup>5</sup>

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1. Kyle Alfriend, *Round 5*, TYLER ALFRIEND—FIGHT TO WIN! A TEENAGERS VICTORY AGAINST BURKITT'S LYMPHOMA/LEUKEMIA (Mar. 10, 2008, 21:30 EST), <http://tyleralfriend.blogspot.com/2008/03/round-5.html>.

2. Cf. Roni Caryn Rabin, *In Cancer Fight, Teenagers Don't Fit In*, N.Y. TIMES, Mar. 16, 2010, at D1, available at <http://www.nytimes.com/2010/03/16/health/16canc.html> (discussing the difficulties facing teenage cancer patients).

3. See, e.g., *id.*; see also Rachel Hollis & Sue Morgan, *The Adolescent with Cancer at the Edge of No-Man's Land*, 2 LANCET ONCOLOGY 43, 43 (2001).

4. Elizabeth Jane Walker, *Roll Model: With Help from St. Jude, Michael Miller Transcends Obstacles in His Way*, PROMISE, Autumn 2009, at 6, available at <http://www.stjude.org/SJFile/Autumn09Prom.pdf>.

5. *Id.* at 8.

In a groundbreaking study conducted at St. Jude Children's Research Hospital, researchers produced data supporting what Michael Miller's physician already knew—that critically ill adolescents do have the ability to negotiate the complex medical decision-making process.”<sup>6</sup> The adolescent study's participants both understood the consequences of their decisions and were capable of participating in a decision process involving risks to themselves and to others.<sup>7</sup>

In spite of their evident developmental maturity, American adolescents lack the legal standing to apply these skills. As a result, the final months of their lives are often fraught with conflicts over decision-making autonomy, with the most severe conflicts necessitating judicial resolution. Although practitioners are aware of the “no man's land” that is adolescent critical illness, the available scholarship does not adequately address this significant bioethical conflict. As advances in medicine superannuate the current decision-making framework, this void in scholarship has never been more apparent. The current medical literature is limited by the assumption that a legal intervention is unnecessary so long as a trusting relationship between the doctor, patient, and family is maintained.<sup>8</sup> In reality, few physicians are equipped to manage a teen's end-of-life care, and the family often feels abandoned by the care team in the patient's final weeks.<sup>9</sup> Equally insufficient, the available law review literature focuses primarily on the public health rights of teens, such as a minor's right to seek an abortion. Unfortunately, the standards and arguments for these issues do not translate to a teen facing cancer or muscular dystrophy. Although a limited number of pieces offer an analysis of the common law mature minor doctrine,<sup>10</sup> these articles do not consider whether legal intervention is truly in the patient's best interest. Nor does the current literature offer a process designed to elucidate the adolescent patient's wishes without increasing conflicts arising from family disagreements, poor communication, and disjointed clinical care.<sup>11</sup> This Note overcomes these deficiencies by presenting a formalized process that integrates the expertise of the medical community with the resources of the legal system.

The proposed process is dependent upon a careful assessment of both the adolescent's personal wishes and the family's dynamics, followed by a negotiation process and the development of a comprehensive plan. This Note

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6. See Pamela S. Hinds et al., *End-of-Life Care Preferences of Pediatric Patients with Cancer*, 23 J. CLINICAL ONCOLOGY 9146, 9153 (2005).

7. *Id.* at 9146.

8. COMM. ON PALLIATIVE AND END-OF-LIFE CARE FOR CHILDREN AND THEIR FAMILIES, WHEN CHILDREN DIE: IMPROVING PALLIATIVE AND END-OF-LIFE CARE FOR CHILDREN AND THEIR FAMILIES 327 (Marilyn J. Field & Richard E. Behrman eds., 2003) [hereinafter WHEN CHILDREN DIE] (noting that promoting trust is a strategy for handling conflicts).

9. See *id.* at 328, 334.

10. See, e.g., Christophe Lemmens, *End-of-Life Decisions and Minors: Do Minors Have the Right To Refuse Life Preserving Medical Treatment? A Comparative Study*, 28 MED. & L. 479 (2009).

11. See *id.* at 293 (noting that cultural misunderstandings, poor communication, and deficient clinical care are avoidable conflicts).

recommends conducting an individualized assessment of each adolescent patient to ensure that he or she receives the appropriate level of autonomy needed to feel at peace with his or her condition, family, and care team.<sup>12</sup> By initiating communications long before the patient's imminent death, those conflicts which most often require judicial intervention will be identified by the medical team and family prior to the point of crisis. Legal intervention becomes the final option only if no other agreement can be reached.

This Note aims first to prove the benefits of individualized patient care, and second, to recommend a model to better implement this heightened level of patient-centered medicine. Part II argues that an adolescent's intrinsic assets are a more accurate tool for assessing a critically ill teen's maturity, and explains that critically ill minors are often better equipped to make well-conceived medical decisions than many healthy adults. Part III enumerates the limitations of a parent's decision-making capacity when faced with decisions about their critically ill child and the use of life-sustaining medical treatment (LSMT).<sup>13</sup> Part IV asserts that the current legal health care exceptions for minors are inappropriate when applied to critically ill adolescents. Finally, this Note advocates an individualized approach to adolescent medical decision making and recommends use of the Individualized Care Planning and Coordination Model (ICPC). The ICPC model, developed at St. Jude Children's Research Hospital, is a comprehensive yet compassionate tri-phase approach to advance care planning.<sup>14</sup> This Note both builds on the ICPC model and recommends that state legislatures adopt a statutory fallback provision to guide adolescent medical decision making.

## I. A PINCH OF THIS, A SPRINKLE OF THAT: WHAT ARE ADOLESCENTS MADE OF?

Because one must initially understand adolescent development before appreciating adolescent autonomy, this Part discusses how development relates to

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12. See generally Javier R. Kane & Joanne Hilden, *Tools To Aid Decision Making in the Care of Pediatric Patients with Cancer*, in AMERICAN SOCIETY OF CLINICAL ONCOLOGY EDUCATIONAL BOOK 188-89 (2007) (offering a thorough discussion of the importance of individualized care).

13. For the purposes of this Note, LSMT encompasses any treatment that could possibly delay a patient's imminent death in the foreseeable future. This includes well-known treatments such as ventilator support, cardio pulmonary resuscitation, antibiotics, artificial nutrition and hydration, and dialysis. This Note also discusses participation in a clinical trial, including the use of experimental chemotherapy for terminal cancer patients. Like LSMT, the treatment protocol in a Phase I clinical trial will not cure the patient. However, trial participation differs because such treatment may actually shorten the patient's lifespan. The purpose of a Phase I clinical trial is to evaluate a new drug or treatment course to determine the maximum tolerable dose, any toxicities, and the metabolism and elimination of the drug (pharmacokinetics). See Mason C. Bond & Sheila Pritchard, *Understanding Clinical Trials in Childhood Cancer*, 11 PEDIATRIC CHILD HEALTH 148, 148-49 (2006). Eligible participants have typically received, but not responded to the standard treatment protocol. The curative efficacy of the treatment is not evaluated at this stage. See *id.*

14. See Kane & Hilden, *supra* note 12, at 190. See St. Jude Children's Research Hospital, <http://www.stjude.org> (last visited Oct. 7, 2010), for general information on the hospital.

adolescent maturity. Applying proven theories of developmental psychology, the following Part redefines the manner in which an adolescent's maturity and decision-making ability should be evaluated. By eliminating the disadvantages of previous capacity assessments, the forthcoming discussion of the use of intrinsic assets to gauge maturity creates a more accurate assessment of a critically ill teen's maturity level. Next, these developmental assets are considered in the context of the critically ill minor, explaining why many critically ill minors are better equipped to make a well-conceived medical decision than are many healthy adults.

### *A. Redefining the Developmental Evaluation of Intrinsic Assets*

Society tends to measure an individual's development by the achievement of external milestones. For example, seventy-two percent of Americans surveyed consider the completion of school to be the milestone signifying the end of adolescence and the beginning of adulthood.<sup>15</sup> After graduation, Americans were more likely to rank full time employment and beginning a family to be milestones signifying maturity.<sup>16</sup> However, for the three thousand teens that die annually from chronic illnesses, these achievements are either impractical or impossible.<sup>17</sup> While these external milestones may signify adulthood, they are neither necessary nor sufficient for emotional and intellectual maturity. Rather, external milestones are a byproduct of an adolescent's intrinsic development—in other words, the ability to both reason as an adult and interact successfully with a peer group.

When evaluating maturity, a terminally ill teen's achievements should never be compared to those of their healthy peers. Teens should be assessed intrinsically to determine if they are functioning as successful young adults, albeit within the confines of their illness. The essential question is: but for the limitations of the illness, has the teen demonstrated the attainment of independence and appropriate social cognition necessary to prove an attainment of maturity?<sup>18</sup>

#### *1. Attainment of Independence: The Piaget Theory*

As adolescents progress through their teen years, developmentalists expect a

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15. Paul Arshagouni, "But I'm an Adult Now . . . Sort of": Adolescent Consent in Health Care Decision-Making and the Adolescent Brain, 9 J. HEALTH CARE L. & POL'Y 315, 317 (2006); Tom W. Smith, *Coming of Age in Twenty-First Century America: Public Attitudes Towards the Importance and Timing of Transitions to Adulthood*, 29 AGEING INT'L 136, 138 (2004).

16. See Smith, *supra* note 15, at 138-139.

17. David R. Freyer, *Care of the Dying Adolescent: Special Considerations*, 113 PEDIATRICS 381, 381 (2004).

18. *Id.* at 381-82 (noting that life-threatening illness alters the normal physical and psychological development of an otherwise normal adolescent).

gradual separation from the family unit. An emotionally healthy adolescent adopts a future-oriented view of the world, marked equally by a sense of individuality and a concern for others.<sup>19</sup> According to the Piagetian theory of development, this enhanced thought-process occurs because the teen has reached the formal operations stage, or the final stage of development.<sup>20</sup> Unlike younger children, teenagers have the capacity to think about the future, the abstract, and the hypothetical. Having this capacity signifies that they have reached the Piaget stage of formal operations."<sup>21</sup> As the ability to reason is a component of maturity, it is important to understand how the use of formal operations allows a teen, unlike a child, to consider many different alternatives at once. The following is an example of the difference in the reasoning ability of a child compared to that of an adolescent: A person is presented with five jars, each containing a colorless liquid. He or she is told that combining the liquids from three particular jars will produce a color, whereas using the liquid from either of the two remaining jars will not produce a color. A color can be produced, but he or she is not shown which combination produces this effect. Children at the concrete-operational stage typically try to solve this problem by combining liquids two at a time, but after combining all pairs, or possibly trying to mix all five liquids together, their search for the workable combination usually stops. An adolescent at the formal-operational stage, on the other hand, will explore all possible solutions, systematically testing all possible combinations of two and three liquids until a color is produced.<sup>22</sup> Just as adolescents can explore all possible solutions to make the color change, they are able to weigh all proposed treatment options and the consequences of selecting or rejecting the various choices presented by the physician. Having reached formal operations, the teen fosters an inner moral compass and utilizes deductive reasoning skills on a daily basis to make decisions.<sup>23</sup> Teens able to reason in this manner will have the ability to choose their path after a weighted evaluation. This new perspective allows the teen to foresee a life apart from his or her parents. Despite the egocentrism associated with this stage, this expression of autonomy is essential for establishing self-

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19. *Id.* at 382.

20. DOROTHY G. SINGER & TRACEY A. REVENSON, A PIAGET PRIMER: HOW A CHILD THINKS 26 (1996). The Piagetian theory of development has been applied by psychologists for decades and is a well-accepted measure of development. The four stages are (1) Sensory Motor, (2) Preoperational, (3) Operation, and (4) Formal. Although the Piagetian theories have been expanded and modernized over time, the core concepts remain in use by developmental psychologists. *Id.* at 20-26.

21. *Id.* at 26. Cf. Marc H. Bornstein et al., *Human Behavior*, in *ENCYCLOPAEDIA BRITANNICA ONLINE*, <http://www.britannica.com/EBchecked/topic/275332/human-behaviour> (last visited Oct. 7, 2010) (explaining that Jean Piaget's fourth and final stage of formal operations is when an adolescent operates as an adult).

22. See Bornstein, *supra* note 21 ("[A]ccording to Piaget, children organize and adapt their experiences with objects into increasingly sophisticated cognitive models that enable them to deal with future situations in more effective ways.").

23. See SINGER & REVENSON, *supra* note 20, at 26.

confidence and integrity.<sup>24</sup>

## 2. Social Cognition and a Healthy Self-Image

The development of social cognition is concomitant with a healthy self-image.<sup>25</sup> This process takes place over the course of three sub-stages across the span of adolescence.<sup>26</sup> During early adolescence, ages ten to fourteen, the overall cognitive focus shifts one's attachment from parents to peers.<sup>27</sup> During middle adolescence, ages fifteen to seventeen, a teen's social development requires the consolidation of self-image and feelings of both achievement and power.<sup>28</sup> Middle adolescents also begin experimenting with ideas, friendships, and the way they present themselves to society.<sup>29</sup> This psychosocial process is referred to as role diffusion versus identity.<sup>30</sup> Role diffusion describes the process by which teens "try on" different personalities until they find their true self.<sup>31</sup> A physically healthy adolescent may experiment with styles and different peer groups in an effort to gain acceptance.<sup>32</sup> A teen's identity is composed of his or her self-concept, task behavior, and perceived peer acceptance.<sup>33</sup> Although this perception may or may not be accurate, projection is a common phenomenon during the adolescent period. Younger teens typically interpret the actions and attitudes of their peers as a reflection of their own self-worth and self-image.<sup>34</sup> During the period of late adolescence, teens enjoy a greater sense of security in who they are and in their relationships with others.<sup>35</sup> The teen fosters an "appreciation for meaningful relationships" and is acutely attuned to the dynamics within peer and family units.<sup>36</sup> This new appreciation gives them the

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24. See *id.* ("[I]n the formal operations stage, adolescents now ha[ve] the necessary 'mental tools' for living life.").

25. Cognition is defined as: "The mental activities such as thinking, reasoning, remembering, perceiving. The process by which the seemingly random information presented by the environmental and social stimuli around a person is organized into meaningful units for memory and ultimate action." *Id.* at 127-28.

26. Freyer, *supra* note 17, at 381.

27. *Id.*

28. *Id.*

29. See *id.* at 382 (noting that teens are able to consolidate these social processes because they have developed advanced abstract reasoning).

30. Cf. DONNA L. WONG, WONG & WHALEY'S CLINICAL MANUAL OF PEDIATRIC NURSING 271 (4th ed. 1996) (identifying the stage of adolescent patient development as one of identity versus role diffusion).

31. See Jennifer Wagaman, *Psychosocial Development of Adolescents: Two Stages of Development as Described by Erik Erikson*, SUITE101.COM, Dec. 11, 2008, [http://parentingteens.suite101.com/article.cfm/psychosocial\\_development\\_of\\_adolescents](http://parentingteens.suite101.com/article.cfm/psychosocial_development_of_adolescents).

32. *Id.*

33. *Id.* Task behavior refers to what activities people choose to become involved in. See *id.*

34. See *id.*

35. See Freyer, *supra* note 17, at 381-82.

36. *Id.* (explaining that late adolescence "is characterized by increase sense of comfort,



opportunity to become socially adept and independent.

*B. The Modern Day Secret Garden: The Critically Ill Adolescent's Opportunity to Attain Independence and Social Skills*

In *The Secret Garden*, "sickly" teen Colin Craven achieves normal emotional development after having had the opportunity to interact with peers and take on responsibility.<sup>37</sup> His "coming of age" depends upon his achieving normal social relationships and ending the isolation imposed on him by his caregivers. Like this classic character's, a critically ill teen's coming of age is not dependent upon his or her physical health, but is instead influenced by the strength and normalcy of his or her social relationships.<sup>38</sup> When critically ill teens are not exposed to the interactions necessary to facilitate this developmental growth, it is possible that these teens will reach developmental stages later than their peers.<sup>39</sup>

For the critically ill teen, the desire for independence constantly conflicts with the reality of needing constant care from family and medical professionals.<sup>40</sup> The prolonged hospital stays and frequent outpatient treatments can prevent a teen from attending school, participating in extracurricular activities, or forming romantic relationships.<sup>41</sup> Ultimately, overprotective parents and isolation from peers prevent teens from experiencing the necessary internal conflict of identity versus role diffusion.<sup>42</sup> These limitations support the belief that critically ill teens are less mature than their healthy counterparts.

Fortunately, psychosocial impairment does not have to be a side effect of critical illness. A recent study of teens receiving treatment for cancer in the first remission found that the patients were mostly well-adjusted when compared to their healthy peers.<sup>43</sup> Adolescent patients that receive age-appropriate social support are best enabled to follow as typical a developmental trajectory as

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awareness of others, and appreciation for meaningful relationships").

37. See generally Frances Hodgson Burnett, *THE SECRET GARDEN* (1998) (1911).

38. See Freyer, *supra* note 17, at 381-82, 386-87.

39. See Danai Papadatou & Judith M. Stillion, *Suffer the Children: An Examination of Psychosocial Issues in Children and Adolescents with Terminal Illness*, 46 AM. BEHAV. SCIENTIST 299, 299-315 (2002). ("Seriously ill children may find that either because of disease or treatment side effects . . . peers may begin to shun them . . . . [T]hey may not be able to take part in normal childhood activities . . . .").

40. Freyer, *supra* note 17, at 382.

41. See *id.*

42. See WONG, *supra* note 30, at 271 (mentioning the internal conflicts that accompany an adolescent patient struggling with identity versus role diffusion); Sarah J. Sinclair, *Involvement of Adolescents in Decision Making for Heart Transplants*, 34 AM. J. MATERNAL/CHILD NURSING 276, 278, 280 (2009) (noting the importance of positive peer influences and the need for open communication).

43. Freyer, *supra* note 17, at 382 (citing R.B. Noll et al., *Social, Emotional, and Behavioral Functioning of Children with Cancer*, 103 PEDIATRICS 71, 71-78 (1999)).

possible.<sup>44</sup>

Psychosocial support is often provided by in-hospital intervention programs, such as Child Life Services, or targeted experiences, including those provided by specialized camps for teens with chronic illnesses.<sup>45</sup> Child Life Services are available in most major pediatric centers. This service serves both inpatients and outpatients, and often directs the in-hospital school program and oversees the emotional transition from hospital to home.<sup>46</sup> All child life specialists have earned a minimum bachelor's degree and are trained to provide psychosocial support to pediatric and adolescent patients and their families. The child life specialist facilitates the learning process by which the teen becomes informed about the condition and prognosis, and customizes the information for the teen's level of development.<sup>47</sup> For example, older teens are encouraged to talk and learn about the illness through support groups and scientific literature.<sup>48</sup> The activities require the use of formal operations, and therefore challenge the teen both emotionally and intellectually.<sup>49</sup> To aid in the development of identity, the child life specialist will often require the patient to find a hobby, such as watercolor painting or learning a foreign language.<sup>50</sup> If the teen was previously involved in an activity, the care team would insist that the teen continue nurturing the established talent.<sup>51</sup>

It is imperative that hospitalized adolescents participate in both the adolescent life program and the in-hospital school program in order to develop normal social cognition.<sup>52</sup> These programs create opportunities for teens to form friendships with other patients, mirroring the peer interaction they would receive were they able to attend school. The child life team is also instrumental in helping patients preserve out-of-hospital friendships.<sup>53</sup> Because many teens are

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44. *Id.* at 386-87 (describing how social support and guidance can help adolescent patients experience meaningful events and relationships that may otherwise have been foreclosed to them).

45. Alyssa Quintero, *MDA Summer Camp*, QUEST, Mar./Apr. 2005, [http://www.mda.org/publications/Quest/q122golden\\_memories.html](http://www.mda.org/publications/Quest/q122golden_memories.html); Association of Hole in the Wall Camps, <http://www.holeinthewallcamps.org/Page.aspx?pid=332> (last visited Oct. 7, 2010).

46. See generally Child Life Council, the Child Life Profession, <http://www.childlife.org/The%20Child%20Life%20Profession> (last visited Oct. 7, 2010).

47. *Id.* ("All certified Child Life Specialists must complete a supervised 480-hour clinical internship, pass a national examination, and adhere to a minimum standard for continued professional development in order to maintain their certification.").

48. See *id.*

49. See SINGER & REVENSON, *supra* note 20, at 26-27, 127 (explaining formal operations).

50. Children's Hosp. & Research Ctr. Oakland, Child Life Services, [http://www.childrenshospitaloakland.org/child\\_life/life\\_overview.asp](http://www.childrenshospitaloakland.org/child_life/life_overview.asp) (last visited Nov. 2, 2010).

51. *Id.* See Christy Price Rabetoy, *The Benefits of a School Teacher vs. a Child Life Specialist Serving Pediatric Patients on Dialysis*, 35 NEPHROLOGY NURSING J. 399, 399-401 (2008).

52. See generally Child Life Council & Comm. on Hosp. Care, *Policy Statement: Child Life Services*, 118 PEDIATRICS 1757, 1757-61 (2006) (providing a thorough description of child and adolescent life services and advocating that these services should be considered an essential component of quality pediatric health care).

53. See Rabetoy, *supra* note 51, at 399-401.

apprehensive about peers visiting them in the hospital, the team provides "cool" activities, such as Wii games to help the adolescent bridge the gap between patient and peer.<sup>54</sup>

Camps designed for patients facing illness are especially important for developing age-appropriate maturity, as they facilitate the formation of their intrinsic developmental assets.<sup>55</sup> Participants experience the same activities that their healthy peers engage in during summer camp and have the opportunity to form meaningful relationships without the fear of peer rejection.<sup>56</sup> The most important component, however, is independence.<sup>57</sup> Teens are separated from their parents, accountable for their own enjoyment, and must independently perform as many daily tasks as physically possible.<sup>58</sup>

Each of the programs described above provides opportunities for increased self-awareness and reliance. The incorporation of problem solving and self-evaluation in these specialized activities forces ill teenagers to employ formal operations in the same manner that their healthy peers apply formal operations in school or extra-curricular activities.<sup>59</sup> While the physical development of a critically ill adolescent may be altered by illness, emotional maturity can be achieved with appropriate interventions.<sup>60</sup>

### *C. The Importance of a Workable Concept of Death*

As children move into adolescence, their beliefs about death evolve from perceiving it as temporary and reversible to understanding death to be universal, unalterable, and permanent.<sup>61</sup> A workable concept of death, an important developmental step, is perhaps the most important asset needed for mature medical decision making.<sup>62</sup> The realization and understanding of a workable concept of death is determined by an individual's personal encounters with

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54. See Georgetown Pediatrics, Child Life Program, <http://www.georgetownuniversityhospital.org/body.cfm?id=557459> (last visited Jan. 4, 2010); see generally Child Life Council & Comm. on Hosp. Care, *supra* note 52, at 1757-61; Beth Israel Medical Center's Child Life Program Receives Support From the Startlight Starbright Children's Foundation, [http://www.wehealny.org/pressroom/starlight\\_starbright\\_intern.pdf](http://www.wehealny.org/pressroom/starlight_starbright_intern.pdf) (last visited Nov. 2, 2010).

55. Alyssa Quintero, *MDA Summer Camp*, QUEST, Mar./Apr. 2005, [http://www.mda.org/publications/Quest/q122golden\\_memories.html](http://www.mda.org/publications/Quest/q122golden_memories.html) ("Camp is still so important because it gives the campers a sense of learning in terms of how to share and how to have patience. It's a great chance to learn about what life is really like.").

56. *Id.*

57. Association of Hole in the Wall Camps, <http://www.holeinthewallcamps.org/Page.aspx?pid=332> (last visited Nov. 7, 2009).

58. *Id.*

59. See generally Child Life Council & Comm. on Hosp. Care, *supra* note 52, at 1757-61 (describing the intellectual and social value of Child Life services).

60. Freyer, *supra* note 17, at 382 (noting that the physical changes associate with puberty are often absent or delayed as a result of treatment or disease).

61. *Id.*

62. *Id.*

death.<sup>63</sup> A healthy adolescent's experience with death is typically the demise of a grandparent or pet. Although this can be a profound loss, exposure to the dying process is often limited and thus death remains largely external in nature.<sup>64</sup>

Unlike their healthy peers, adolescents with a life-limiting illness will have developed an astute understanding of their own impending death as "the cumulative result of personal experiences with serious illness and medical treatment."<sup>65</sup> These teens have also experienced the death of friends, and thus fully understand the consequences of disease, treatment, and grief.<sup>66</sup> Death is understood not only in terms of its personal significance but also in the way it will affect their friends and family.<sup>67</sup>

## II. THE FAMILY UNIT: UNDERSTANDING AND ACCEPTING THE PROGNOSIS

Why would I want a tube in my throat? I saw other patients like that—I don't want that. I wouldn't be able to talk with my family or hold my Mom's hand. That is not living.

*15-year-old young woman with acute lymphoblastic leukemia*<sup>68</sup>

We were kind of really happy that they had chemotherapy, something else that we could try.

*15-year-old young woman with a solid tumor*<sup>69</sup>

We decided not to go with chemo because I don't want to be sick the rest of my days, and it's not like it is going to cure me, so I just said, 'we'll go home and take it from there.'

*15-year-old young woman with acute lymphoblastic leukemia*<sup>70</sup>

Pediatric palliative care is a uniquely challenging field and can be emotionally draining for the care team itself as well as the family.<sup>71</sup> The burden

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63. *Id.*

64. *Id.*

65. *Id.*

66. *See id.* (explaining that understanding death requires actual experiences with death, whereas many children are insulated from the dying process and only witness death in movies and video games).

67. *Id.* (highlighting the importance of a critically ill patient's understanding of death).

68. Hinds et al., *supra* note 6, at 9150.

69. *Id.*

70. *Id.*

71. Tammy I. Kang, David Munson & Jeffrey C. Klick, Preface, *Pediatric Palliative Care*, 54 PEDIATRIC CLINICS N. AM. xv, xv-xvi (2007). Palliative care is defined as "the active total care of patients whose disease is not responsive to curative treatment. Control of pain, of other symptoms, and of psychological, social, and spiritual problems is paramount. The goal of palliative care is achievement of the best quality of life for patients and their families." *Id.* at xv.

of facilitating medical decision making often falls on the pediatric palliative care team, and this team must be both sensitive to the patient's wishes and cognizant of the family dynamics in order to provide the patient with a positive "experience of life despite the sadness of an untimely death."<sup>72</sup> This Part explains the difficulties faced by the care team, parents, and the patient when there is no longer a realistic hope for a cure. Section A examines the reasons behind the parents' choice to continue treatment with a curative intent and the challenges providers face in effectively communicating prognosis. Section B explains why the patient's acceptance of prognosis is a gestalt entity, comprising both intuition and past medical experiences.

To ensure a thorough understanding of the prognosis, the palliative team has three responsibilities to a patient following a dying trajectory.<sup>73</sup> First, the patient and family must receive accurate and timely information on the diagnosis, prognosis, and treatment options.<sup>74</sup> Second, when the initial or subsequent treatments fail, the team must provide information about the burdens and benefits of the remaining treatment options and prognosis.<sup>75</sup> Third, when further life-prolonging interventions fail, the care team must then support the patient through the dying phase of the illness, as well as ensure that the family has support during and after the patient's death.<sup>76</sup>

When an adolescent has an illness that is life-limiting by nature or that has progressed beyond the possibility of a cure, the condition will take on one of two trajectories.<sup>77</sup> Understanding which trajectory the course of illness will take impacts the amount of preparation time the patient and family will have and underscores the importance of tailoring care to the specific course of illness.<sup>78</sup>

The first trajectory represents patients who have a fatal progressive condition, such as muscular dystrophy or cystic fibrosis.<sup>79</sup> These types of conditions are characterized by periods of slowly deteriorating health status, interrupted by potentially fatal medical crises.<sup>80</sup> The patient repeatedly survives until one crisis results in death.<sup>81</sup> Because treatments are successful until the one

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72. Freyer, *supra* note 17, at 387.

73. WHEN CHILDREN DIE, *supra* note 8, at 75. The article lists four possible trajectories; however, the *sudden, unexpected death trajectory* (e.g., car crash, SIDS) and the *death from lethal congenital anomaly* (e.g., condition leading to death immediately following birth) are beyond the scope of this Note.

74. *Id.*

75. *Id.*

76. *Id.*

77. *Id.* at 73-74.

78. *Id.* at 73.

79. *Id.* Approximately forty-five percent of the Cystic Fibrosis patient population is age eighteen or older. Cystic Fibrosis Foundation, About Cystic Fibrosis: Statistics, <http://www.cff.org/AboutCF> (last visited Oct. 7, 2010).

80. WHEN CHILDREN DIE, *supra* note 8, at 75.

81. *Id.*

time they are not, this rollercoaster trajectory may cause patients, parents, and even medical professionals to feel unprepared for the final failure of treatment.<sup>82</sup> However, early recognition that the patient has reached the final stage of his or her illness allows the goal of care to shift to maintaining physical and emotional comfort.<sup>83</sup> The turning point is often when life-sustaining medical treatment is more burdensome than beneficial.<sup>84</sup>

Duchenne Muscular Dystrophy (DMD), affecting males only, is one such disease that follows this dying trajectory. It occurs as a result of mutations in the dystrophin gene, and these mutations result in progressive muscle degeneration.<sup>85</sup> DMD, by its very nature, is an insidious disorder because patients with DMD typically do not demonstrate symptoms until ages two or three years old.<sup>86</sup> Most patients are diagnosed at five years old, typically after parents observe delayed developmental milestones or abnormal muscle function in the child.<sup>87</sup> As the young man enters his early teens, the muscles of the respiratory system begin to decline, leading to a need, first for non-invasive ventilation, and then for invasive ventilation via a tracheostomy as DMD progresses.<sup>88</sup> Young adults with DMD often suffer heart failure in their teens, and DMD is typically fatal during their teens or twenties.<sup>89</sup> Nevertheless, the fatal prognosis in no way means the young man should be treated as an invalid. For example:

[The young man] may not need a wheelchair until sometime between the ages of 10 and 12, and even then may not need it full time, but [parents] may want to prepare him for this eventuality ahead of time. If the child senses that a wheelchair is something the parents have long dreaded or that every therapy has been directed at “keeping him out of a wheelchair,” then the event almost has to seem like a defeat.<sup>90</sup>

The finality of this trajectory requires that families respectfully acknowledge that the disease will continue to progress despite the patient’s efforts to “fight.”<sup>91</sup> Because the progression of this disease is unavoidable, it is vital that families

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82. *Id.*

83. *Id.*

84. *Id.* at 76.

85. Katherine Bushby et al., *Diagnosis and Management of Duchenne Muscular Dystrophy, part 1: Diagnosis, and Pharmacological and Psychosocial Management*, 9 LANCET NEUROLOGY 77, 77 (2010).

86. Muscular Dystrophy Association, *Journey of Love: A Parent’s Guide to Duchenne Muscular Dystrophy*, ch. 2, <http://www.mda.org/publications/journey/2-2.html> (last visited Nov. 2, 2010) (noting that the first signs often appear innocuous, such as difficulty transferring from a seated position to a standing position).

87. Bushby, *supra* note 85, at 81.

88. Muscular Dystrophy Association, *supra* note 86, ch. 4, <http://www.mda.org/publications/journey/intro.html> (last visited Nov. 15, 2010).

89. *Id.* ch. 10.

90. *Id.* ch. 4.

91. *See id.*

understand the ultimate prognosis.<sup>92</sup>

The second trajectory outlines the patient with a potentially curable disease, such as cancer, who initially responds to treatment but eventually dies of the disease or its further treatment.<sup>93</sup> Typically, the patient responds positively to aggressive and possibly life-threatening treatment and may receive a favorable prognosis.<sup>94</sup> However, in the event of a relapse, the patient must then decide if he or she wishes to continue treatment with a curative intent.<sup>95</sup>

Patients receiving stem cell transplantation (SCT) often follow the second dying trajectory.<sup>96</sup> Although the overall cure rate of childhood cancer is 70%, the survival rate for patients needing pediatric SCT is much lower.<sup>97</sup> Patients receiving this treatment modality experience a significant decrease in their quality of life, and families often struggle with the uncertain prognosis.<sup>98</sup> For example, patients with acute myeloid leukemia (AML), have a 40% to 60% five-year survival rate.<sup>99</sup> However, after a relapse, the survival rate is reduced to 25%.<sup>100</sup> As previously noted, patients on the second trajectory often die of the treatment itself.<sup>101</sup>

Morbidity during the immediate transplantation period is significant, with patients experiencing mucositis, pain, veno-occlusive disease, and respiratory complications. These children are also more likely to die of treatment-related complications than are those who die secondary to a malignancy but without transplantation as part of their treatment. Furthermore, patients, family members, and their clinicians experience significant physical, emotional, and spiritual distress.<sup>102</sup>

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92. *Id.* (illustrating that families should avoid imposing expectations on the child that will result in his feeling like a "failure").

93. *WHEN CHILDREN DIE*, *supra* note 8, at 75.

94. *Id.*

95. *See id.*

96. *See* Justin N. Baker et al., *A Process To Facilitate Decision Making in Pediatric Stem Cell Transplantation: The Individualized Care Planning and Coordination Model*, 13 *BIOLOGY BLOOD & MARROW TRANSPLANTATION* 245, 245 (2007) [hereinafter ICPC I]; *see also* *WHEN CHILDREN DIE*, *supra* note 8.

97. *WHEN CHILDREN DIE*, *supra* note 8, at 75; ICPC I, *supra* note 96, at 245.

98. ICPC I, *supra* note 96, at 245-46.

99. *Id.* at 245-46 (describing survival rates for patients receiving allogenic stem cell transplants). This is from a sibling or parent; an unrelated donor may also be used. *See* National Cancer Institute, Bone Marrow Transplantation and Peripheral Blood Stem Cell Transplantation, <http://www.cancer.gov/cancertopics/factsheet/Therapy/bone-marrow-transplant> (last visited Nov. 9, 2009).

100. ICPC I, *supra* note 96, at 246 (illustrating the poor survival rate associated with relapse in patients initially treated with allogenic transplantation).

101. *Id.* (noting that these patients are more likely to die of treatment-related complications than are those who die secondary to a malignancy but without transplant).

102. *Id.*

The above information and clinical examples illustrate the importance of prognostication in medical decision making. Unrealistic prognostic expectations may lead families to ask for medically inappropriate interventions that create “inescapable suffering” and offer no curative benefit.<sup>103</sup> These unrealistic expectations are the primary source of contention between the adolescent patient, the parents, and the care team.<sup>104</sup>

### *A. Impaired Parental Decision-Making Capacity*

Parents are often the most reluctant to accept a child’s fatal prognosis.<sup>105</sup> Despite the fact that earlier parental recognition of this prognosis is associated with a greater treatment emphasis on reducing patient suffering, most families remain hopeful that their child will be the one to “beat the odds.” There is a considerable delay in recognizing that their child has no realistic chance for a cure.<sup>106</sup> The realization that a child will not survive comes to each parent differently, and is referred to as the “parent-defined end-of-life care period.”<sup>107</sup> In the majority of cases, the physician documented that the patient entered the end-of-life care period three months before the parent-defined end-of-life care period.<sup>108</sup> For example, in a recent study surveying the parents of children who died from cancer, the first recognition that the child had no realistic chance for survival occurred, on average, 106 days prior to death.<sup>109</sup> In contrast, the physician first documented that the patient had begun a dying trajectory 206 days prior to death.<sup>110</sup>

The majority of patients in this study had previously undergone the standard treatment for their cancer. At the time of the study, 74% of patients were enrolled in a research protocol.<sup>111</sup> Although most parents remembered the care team discussing the fact that their child had no realistic chance for cure, less than half of these parents reported understanding that their child’s condition was terminal through this discussion.<sup>112</sup> As a result of this research, palliative care teams must now be aware that a formal discussion is not an effective means of communication for more than half of these families.<sup>113</sup>

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103. *Id.*

104. *See id.* at 246-50.

105. Joanne Wolfe et al., *Understanding of Prognosis Among Parents of Children Who Died of Cancer: Impact on Treatment Goals and Integration of Palliative Care*, 284 JAMA 2469, 2469 (2000).

106. *Id.*

107. *Id.* at 2470, 2472.

108. *Id.* at 2473.

109. *Id.* at 2471.

110. *Id.*

111. *Id.*

112. *Id.* at 2472. Ninety percent of parents felt that it was appropriate to discuss this topic, but only sixty-two percent of parents were uncomfortable with the manner in which it was discussed.

113. *Id.* Thirty percent of parents reported that this understanding came from a perceived



This two-part study first documented the parents' primary goal of treatment during the parent-defined end-of-life period. After the child's death, parents were asked what the goal should have been to ascertain if these preferences had changed. Twenty-eight percent of participating parents reported that their primary goal of pursuing cancer-directed therapy had been to cure cancer. However, after their child's death, only 13% of parents still believed that the primary goal of cancer-directed therapy should be to cure. On the other hand, during the end-of-life period, only 13% of parents chose cancer-directed treatment primarily for the purpose of lessening suffering. Yet after their child's death, 34% of parents stated that this should be the primary reason for choosing to continue care. Finally, 15% of parents said that they based their final treatment decisions on extending the life of their child without hope of a cure. Only 6% felt, after their child's death, that this should be the primary goal.<sup>114</sup>

The study then compared the physician's purpose for treatment decisions during the patient's final month of life with the parent's purpose for treatment decisions. Of the patients who continued to receive cancer-directed therapy during this period, 42% of physicians reported that the purpose of the cancer-directed treatment was to reduce suffering.<sup>115</sup> Yet, only 19% of parents stated that reducing suffering was the primary goal of the treatment.<sup>116</sup> More than half of the parents surveyed reported that the overarching goal of therapy was to extend life during this period, while simultaneously reporting that the purpose of symptom management was to lessen suffering.<sup>117</sup> In contrast, 79% of bereaved parents responded that the primary goal of any treatment during the end-of-life period should be to lessen suffering.<sup>118</sup>

Alternatively, the study demonstrated that when both the physician and the parent can come to a consensus about the prognosis at a minimum of fifty days prior to death, parents are more satisfied with the quality of palliative care.<sup>119</sup> Thirty-seven percent of parents who met this criterion felt very prepared for the symptoms their child experienced during the last month of life.<sup>120</sup> Additionally, 50% of the interviewed physicians described the patient's death as very peaceful.<sup>121</sup> These statistics may not seem persuasive at first glance. However, when the consensus was reached with less than fifty days remaining, only twenty percent of parents felt prepared and only twenty-six percent of physicians stated

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change in their child's appearance or behavior. Nine percent reported that this understanding came from a feeling or dream. *Id.*

114. *Id.*

115. *Id.*

116. *Id.*

117. *Id.*

118. *Id.*

119. *Id.* at 2473.

120. *Id.*

121. *Id.*

the death was peaceful.<sup>122</sup>

Overall, these data suggest that the end-of-life decisions made by parents, although they may assuage parental grief, do not help to ease the child's suffering. These statistics may also provide evidence that parental denial is the root of most end-of-life conflicts.

*B. A Gestalt Entity: Understanding Prognosis Through Intuition and Experience*

Few researchers have formally investigated the end-of-life preferences of terminally ill adolescents.<sup>123</sup> Focusing instead on the preferences of parents and clinicians, the patient's viewpoint went unheard in previous population-centered research. Fortunately, the past five years have produced research employing new methodologies, each carefully designed to elucidate this information scientifically yet sensitively.<sup>124</sup> While the number of studies may be limited, the conclusions provide invaluable insight into the heart of this unique population. In one such study, a seventeen-year-old young man remarked:

We've been through the main steps . . . if it was going to work, probably it already would have worked. Stuff like the radiation, the chemo stuff, and then the experimental chemo, and we have been through several chemos and stuff, so I figured if it was going to slow it down or stop it, you know, it would have done it by now. And, if it hadn't done it by now, it's just going to grow, so I may as well be at home having fun.<sup>125</sup>

In contrast to the delay in recognition by many parents, this comment reflects the realism many terminally ill adolescents have concerning their own prognosis.<sup>126</sup> Perhaps unique to pediatrics, these patients will often accurately describe their prognosis even if their parents attempt to withhold the information.<sup>127</sup> When compared to clinically similar adults, pediatric patients are

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122. *Id.* In a similar study, a physician stated, "She would have an easier death than if we had done a lot of manipulation with machines," when asked what influenced recommendations to parents. Hinds et al., *supra* note 6, at 9152 (showing a general physician preference for less invasive end-of-life care treatments).

123. Hinds et al., *supra* note 6, at 9146.

124. *See, e.g., id.* This study interviewed multiple adolescents, their parents, and their physicians regarding end-of-life care decisions.

125. *Id.* at 9150.

126. Compare Wolfe et al., *supra* note 105, at 2469 (arguing that considerable delay exists in parental recognition that children have no realistic chance for cure), with Hinds et al., *supra* note 6, at 9153 ("Patients [aged 10-20] in this study were able to accurately identify their treatment options and understood that their death would be one of the outcomes of their decision.").

127. *See* Leslie S. Kersun & Eyal Shemesh, *Depression and Anxiety in Children at the End of Life*, 54 PEDIATRIC CLINICS N. AM. 691, 694 (2007) (noting that dying pediatric patients know significantly more about their disease than is expected when one considers the information provided to them).

more aware of the significance of their illness and are more perceptive to the emotional isolation from their families.<sup>128</sup>

Even when terminally ill pediatric patients are not included in discussions regarding prognosis, they systematically learn about their disease through its predictable stages, resulting in an accurate assessment of their prognosis.<sup>129</sup> The first stage is the recognition that the disease is serious, and is closely followed by the second stage, the realization that medication and treatment are necessary.<sup>130</sup> The patient also learns the taboos of sickness and death, discovering this is not a welcome topic of discussion.<sup>131</sup> The third stage marks an understanding of the purposes and implications of special procedures, such as the possibility of death from chemotherapy.<sup>132</sup> The fourth stage is that of recognition and acceptance, whereby patients recognize that their condition may be permanent, and comprehend that relapses often result in death.<sup>133</sup> The fifth and final stage brings about the realization that there are a finite number of treatments available and that a cure is likely not possible.<sup>134</sup> A child's progression through these stages occurs irrespective of age or intelligence.<sup>135</sup> Rather, the stages are determined and defined by the patient's life experiences.<sup>136</sup> There is substantial evidence suggesting that an adolescent patient will consider these experiences when making a decision regarding LSMT, and that a patient will also evaluate the potential outcomes and the impact of this decision on others, including "loved ones, staff, and future patients unknown to them."<sup>137</sup>

Research demonstrating the value of individual experiences unhinges the strongest arguments against adolescent medical decision making.<sup>138</sup> Critics argue that a minor's medical decisions are based on a limited world view, are not "part of a well-conceived life plan," and do not account for future consequences.<sup>139</sup> As suggested by one psychiatrist, the reason for abridging autonomy is the "recognition that although he may be [competent, the limitations of his experience have] distorted his capacity for sound judgment."<sup>140</sup> Lainie Ross, in her article, *Health Care Decisionmaking by Children: Is It in Their Best*

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128. *Id.*

129. *Id.*

130. WONG, *supra* note 30, at 295.

131. *Id.*

132. *Id.*

133. *See id.*; *see also* Kersun & Shemesh, *supra* note 127, at 694.

134. *See* WONG, *supra* note 30, at 295.

135. Kersun & Shemesh, *supra* note 127, at 694 (noting the surprising fact that a four-year-old child "may understand more about a disease and prognosis" than a much older child).

136. *Id.*

137. Hinds et al., *supra* note 6, at 9152-53.

138. *See id.* (discussing the value of each patient's experiences and preferences).

139. Lainie Friedman Ross, *Health Care Decisionmaking by Children: Is It in Their Best Interest?*, 27 HASTINGS CENTER REP. 41, 42 (1997).

140. *Id.* at 43 (quoting psychiatrist Willard Gaylin).

*Interest?*, furthers this argument by stating that decision-making authority sacrifices long-term autonomy in the name of present-day instant gratification.<sup>141</sup> Her theory asserts that intermediate autonomy must be sacrificed in order for a minor to eventually gain the life and decision-making experience required to develop long-term autonomy.<sup>142</sup> However, these arguments are inappropriate when applied to the adolescent on a dying trajectory. Critics of adolescent autonomy, such as Ross, appear ignorant of the fact that a terminally ill minor does not have the opportunity to consolidate a lifetime of experiential learning with long-term autonomy.<sup>143</sup> A terminally ill teen's decision to forego a second or third round of experimental chemotherapy is very different from that of the teen refusing to seek treatment for anorexia because she cannot conceptualize the harm she is doing to her body.<sup>144</sup> The adolescent patient has the proven ability to understand the prognosis after consolidating his or her experiences and can therefore consider the outcomes of a decision in the short term (e.g., side effects of an experimental drug), the immediate term (e.g., extending the dying trajectory), and the longer term (e.g., dying).<sup>145</sup> The decisions made during the end-of-life stage are the final decisions afforded adolescent patients, and teens will therefore employ "a lifetime's worth of experience" when making their final choices.

### III. THE LEGAL AND MEDICAL FRAMEWORKS FOR ADOLESCENT DECISION MAKING

"[T]he experience, perspective, and power of children' [should] be taken most seriously," wrote Dr. William G. Bartholome in the first publication of the Informed Consent, Parental Permission, and Assent Statement by the American Academy of Pediatrics (AAP) Committee on Bioethics.<sup>146</sup> Yet nearly twenty years later the significance of the experiences and perspectives of many adolescents is still being questioned in the realm of medical decision making.<sup>147</sup> Unfortunately, this has resulted in inconsistent case outcomes and irreparable harm to the vulnerable family unit during a time of medical crises.<sup>148</sup> This Part outlines the current legal rights and medical perceptions of minors. Section A

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141. *Id.* at 42-44.

142. *Id.* at 42.

143. Freyer, *supra* note 17, at 383 (criticizing Ross's theory).

144. Ross, *supra* note 139, at 45. Ross's example of "child liberation" run wild is that of a fourteen-year-old diabetic who refuses insulin because her boyfriend's religious beliefs forbid the use of medical care. *Id.* This Note proposes that this is an ineffective example because is not a reflection of a decision by a mature minor.

145. Hinds et al., *supra* note 6, at 9152.

146. Comm. on Bioethics, *Informed Consent, Parental Permission, and Assent in Pediatric Practice*, 95 PEDIATRICS 314, 314 (1995) [hereinafter AAP].

147. Derry Ridgway, *Court-Mediated Disputes Between Physicians and Families Over the Medical Care of Children*, 158 ARCHIVES PEDIATRICS & ADOLESCENT MED. 891, 896 (2004).

148. *Id.*

discusses the reasonableness of emancipation and the misapplication of *Roper v. Simmons*<sup>149</sup> to adolescent medical decision making. This section also explains the deficiencies of the mature minor doctrine. Section B outlines the American Academy of Pediatrics' recommendations with respect to adolescent assent, dissent, and consent to treatment with a curative intent.

There are ongoing, yet separate, discussions of this issue within the medical and legal communities.<sup>150</sup> The medical community is largely in favor of adolescent medical decision making.<sup>151</sup> For example, a policy statement issued by the American Academy of Pediatrics states that fourteen is the age at which pediatric patients should be permitted to exercise appropriate control over their care.<sup>152</sup> However, the legal community is more conservative, advocating for parental authority in decision making.<sup>153</sup> Few courts are willing to even address this issue, and when they do, the family is scrutinized under the media's microscope.<sup>154</sup>

### *A. The Legal Restrictions – From the Impractical to the Unpredictable*

#### *1. Status-Based Exceptions*

United States federal law has not created a bright-line "age of majority." In its place, each state has created its own laws, often predicated on the political climate, to determine when a teen gains the legal rights of an adult.<sup>155</sup> *Parens patriae*, the proactive philosophy that government ought to protect the welfare of minors,<sup>156</sup> has been invoked by state legislatures to justify governing many rights, such as the legal age for driving, voting, enlisting in the armed services, and the consumption of alcohol.<sup>157</sup> The legislature also sets the age at which parental consent is no longer needed for medical and mental health treatment.<sup>158</sup> In the majority of states, a patient must be eighteen in order to consent to

149. *Roper v. Simmons*, 543 U.S. 551 (2005).

150. See Ridgway, *supra* note 147, at 896 (noting the legal community's focus on case precedent and court assessments); see also AAP, *supra* note 146, at 317 (regarding the adolescent's opinion as the determinative decision-making factor).

151. AAP, *supra* note 146, at 317.

152. See *id.*

153. See Jennifer L. Rosato, *Let's Get Real: Quilting a Principled Approach to Adolescent Empowerment in Health Care Decision-Making*, 51 DEPAUL L. REV. 769, 772 (2002).

154. WHEN CHILDREN DIE, *supra* note 8, at 293.

155. See Norman M. Goldfarb, *Age of Consent for Clinical Research*, 4 J. CLINICAL RES. BEST PRACTICES 1, 1 (2008), [http://www.firstclinical.com/journal/2008/0806\\_Consent\\_Age.pdf](http://www.firstclinical.com/journal/2008/0806_Consent_Age.pdf). *Parens patriae* is a fluid philosophy that can fluctuate with the policy expectations of the day. See Rhonda Gay Hartman, *Coming of Age: Devising Legislation for Adolescent Medical Decision-Making*, 28 AM. J. L. & MED. 409, 411-12 (2002).

156. See Hartman, *supra* note 155, at 411. The degree of this protection varies by political leanings and social demands.

157. See Goldfarb, *supra* note 155, at 2.

158. See Hartman, *supra* note 155, at 419-21.

treatment; however, some states have adopted statutory exceptions based on the adolescent's legal status, including emancipation, personal status, and clinical status.<sup>159</sup>

*(a) Emancipation*

In certain states, a minor may become legally emancipated, or receive the same rights as an adult, before reaching the age of majority.<sup>160</sup> While this may seem to be a possible avenue for securing the right to make medical decisions, a terminally ill minor will almost never qualify for legal emancipation. The typical emancipation process requires that the teen prove that he or she is legally married or living physically apart and financially independent from a parent or guardian.<sup>161</sup> For instance, in Colorado, a minor must prove independence in matters of care, custody, and earnings.<sup>162</sup> In other states, the need for medical care expressly voids emancipation.<sup>163</sup> All told, any showing of financial instability or living dependence on the part of the teen voids the emancipation.<sup>164</sup> This provision is certainly problematic for the critically ill minor because even if it were possible for the teen to be financially independent, emancipation prohibits a parent from being a caretaker for the teen. Appreciably, when a teen is on a dying trajectory, it is not in the best interest of the teen to rely solely on the hospital or private nursing care as his or her end-of-life support system. For these reasons, emancipation is not a realistic avenue for terminally ill minors to achieve autonomy.

*(b) Personal & Clinical Status Exceptions*

Certain states permit a teen to consent to treatment based on his or her

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159. *Id.* at 419-20.

160. The following states do not have an emancipation statute: Arizona, Arkansas, Delaware, Georgia, Idaho, Indiana, Iowa, Kentucky, Minnesota, Mississippi, Missouri, Nebraska, New Jersey, New York, North Dakota, Ohio, South Carolina, Tennessee, Wisconsin. Neither do certain counties in Pennsylvania. Juvenile Law Center, Emancipation in the United States, <http://jlc.org.c25.sitepreviewer.com/index.php/factsheets/emancipationus> (last visited Nov. 10, 2010). While emancipation typically grants the minor the same rights as an adult, a state may still place restrictions on certain freedoms. *See* NEV. REV. STAT. § 129.130 (2009) (prohibiting an emancipated minor from consuming alcohol until age twenty-one).

161. *See, e.g.*, ALA. CODE § 26-13-1 (LexisNexis 2010) (granting relief from disabilities when parents are absent, insane, or dead); ALASKA STAT. § 09.55.590 (2009); ARIZ. REV. STAT. ANN. § 12-2451 (2009); CONN. GEN. STAT. § 46b-150 (2009); FLA. STAT. § 743.015 (2009); HAW. REV. STAT. § 577-25 (2009); 750 ILL. COMP. STAT. 750/30-7 (LexisNexis 2010); KAN. STAT. ANN. § 38-108 (2009); ME. REV. STAT. ANN. tit. 15, § 3506-A (2009); MD. CODE ANN., [Emancipation] § 3-826.1 (LexisNexis 2009); MONT. CODE ANN. § 41-1-501 (2009).

162. COLO. REV. STAT. § 19-1-103 (2005).

163. FLA. STAT. § 743.015 (2009) (stating that emancipation requires an explanation of how the needs of the minor with respect to medical care will be met).

164. *See supra* note 161.

having special legal status, such as being legally married. Like emancipation, these exceptions also vary by state and generally reflect the political climate. For instance, in Texas, a teen can consent to medical treatment if he or she is in the military or married because this is automatically emancipating.<sup>165</sup> The logic behind both the marriage- and military-status exceptions is similar: both create a responsibility between a minor and a third party, which obviates the parent-child relationship.<sup>166</sup>

Interestingly, some states permit a minor to consent to medical treatment if the minor has become a parent. Depending on the state, a minor-parent's ability to consent to health care is defined in one of three ways: (1) a minor can consent to the care of her child, but cannot consent to her own care unless it is pregnancy related;<sup>167</sup> (2) a minor can consent to the health care of her custodial child and for herself; or (3) a minor can consent to her own health care if she has given birth previously.<sup>168</sup> The third provision is the broadest, as it is not necessary that the minor have custody of the child.

The above pregnancy-related state laws assume that minors who become pregnant are, by default, more mature and capable of making complex decisions than those who choose to avoid teen pregnancy. However, research shows that teen motherhood actually restricts social and personal growth, the two tenets of mature decision making.<sup>169</sup> In contrast, the responsibility and emotional toll of a terminal illness is proven to instill in the adolescent patient the ability to evaluate options, weigh consequences, and then make a complex, multi-variable decision.<sup>170</sup> While it seems incongruous that bright-line provisions exist for teens that give birth, these consent provisions demonstrate the inability of the legislature to consider the intrinsic assets which more accurately signify maturity.

## 2. *The Supreme Court as an Adolescent Psychologist*

The judiciary does not often involve itself in adolescent development and psychology. However, in 2005, the Court directly addressed adolescent maturity and decision-making ability. In *Roper v. Simmons*, the United States Supreme Court invalidated the juvenile death penalty on the grounds that it violated the Eighth Amendment's ban on cruel and unusual punishment.<sup>171</sup> The Court's assessment of juvenile culpability eliminated the "case-by-case," or totality of

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165. TEX. FAM. CODE ANN. §§ 32.003, 101.003 (Vernon 2008).

166. Goldfarb, *supra* note 155, at 1.

167. FLA. STAT. § 743.065 (2009).

168. MINN. STAT. § 144.342 (2009).

169. See KATHLEEN STASSEN BERGER, *THE DEVELOPING PERSON THROUGH CHILDHOOD AND ADOLESCENCE* 447 (2003).

170. *Id.*; see also Hinds et al., *supra* note 6, at 9152-53.

171. 543 U.S. 551 (2005). This reaffirmed its prior holding that "[c]apital punishment must be limited to those offenders . . . whose extreme culpability makes them 'the most deserving of execution.'" *Id.* at 568 (quoting *Atkins v. Virginia*, 536 U.S. 304, 319 (2002)).

circumstances analysis, which had been the cornerstone of previous judicial evaluations of capacity. “In capital cases, the Constitution demands that the punishment be tailored to both the nature of the crime itself and to the defendant’s personal responsibility and moral guilt.”<sup>172</sup> Prior to *Roper*, this required an inquiry into the “degree of harm inflicted on the victim, as well as to the degree of the defendant’s blameworthiness.”<sup>173</sup>

Invalidating the longstanding situational analysis, the *Roper* Court opined that juvenile culpability is automatically mitigated by the three inflexible realities of adolescent maturity: (1) adolescents are impulsive due to an underdeveloped sense of responsibility;<sup>174</sup> (2) adolescents are susceptible to negative influences and peer pressure, in part because of their limited “control . . . over their . . . environment”;<sup>175</sup> and (3) adolescents have incomplete character formation.<sup>176</sup> In essence, the majority held that all teenagers react and respond to situations identically. Although multiple developmentalists have adduced evidence that an adolescent’s experiences weigh more heavily on maturity than age alone, the Court’s majority concocted a bright-line rule that maturity transforms the moment a teen reaches his or her eighteenth birthday.<sup>177</sup> When applied, a seventeen-year-old high school senior, regardless of past criminal behavior, malice, or intent, is legally of diminished mental capacity and lesser culpability; by comparison, his eighteen-year-old codefendant is deemed to be more mature, and therefore more culpable for the crime, despite any mitigating factors, such as coercion by the seventeen-year-old peer to commit the crime.<sup>178</sup> The defendant in *Roper*, for example, stated that he believed he could “get away with it” because he had not yet turned eighteen.<sup>179</sup> This indicates that the defendant did consider the perceived risk of punishment.<sup>180</sup> It is therefore not implausible to

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172. *Id.* at 589; see also *Tison v. Arizona*, 481 U.S. 137, 149 (1987); *Eddings v. Oklahoma*, 455 U.S. 104, 111-112, (1982); *Enmund v. Florida*, 458 U.S. 782, 801 (1982).

173. *Roper*, 543 U.S. at 590 (citing *Enmund v. Florida*, 458 U.S. 782, 815 (1982)).

174. *Id.* at 569 (quoting *Johnson v. Texas*, 509 U.S. 350, 367 (1993)).

175. *Id.*

176. *Id.* at 572-73. These characteristics were argued in the amicus brief filed by the American Medical Association, the American Psychiatric Association, the American Society for Adolescent Psychiatry, and others. It is important to note that the argument indicated that the mental capacity is further diminished in juvenile offenders. Brief of the Am. Med. Ass’n et al. as Amici Curiae Supporting Respondent at 10-16, *Roper v. Simmons*, 543 U.S. 551 (2005) (No. 03-633). For a more comprehensive discussion, see Arshagouni, *supra* note 15, at 340-42.

177. *Roper*, 543 U.S. at 598 (O’Connor, J., dissenting) (noting that the Court’s decision is “premised on three perceived differences between ‘adults,’ who have already reached their 18th birthdays, and ‘juveniles,’ who have not”). See Freyer, *supra* note 17, at 382 (advocating that an adolescent’s experiences are a key facet of developmental growth).

178. *Roper*, 543 U.S. at 600-01 (O’Connor, J., dissenting). Justice O’Connor noted that the fact that juveniles are *generally* less culpable for misconduct than adults does not necessarily mean that an especially depraved seventeen year old cannot be *sufficiently* culpable to merit the death penalty. *Id.*

179. *Id.*

180. *Id.* at 601.



conclude that a manipulative seventeen-year-old could be substantially more culpable than his or her eighteen-year-old codefendant, yet may still receive a lesser sentence on account of his or her age.

Balancing this distinction against the Court's ruling in *Atkins v. Virginia*, which held that the mentally retarded cannot be sentenced to capital punishment, *Roper* indicates that a minor defendant is of comparable capacity.<sup>181</sup> In *Atkins*, the Court opined:

Because of their impairments . . . [such persons] by definition . . . have diminished capacities to understand and process information, to communicate, to abstract from mistakes and learn from experience, to engage in logical reasoning to control impulses, and to understand the reactions of others.<sup>182</sup>

This reasoning is strikingly similar to the three-factor justification in *Roper*. As noted by Justice O'Connor in her dissent, this similar line of logic falsely equates adolescent maturity with the "major lifelong impairments suffered by the mentally retarded."<sup>183</sup> *Roper*'s notation that the adolescent population engages in impulsive, impetuous, and ill-considered behavior is categorically flawed because it negates the adolescent who does demonstrate mature formal operations and social cognition.<sup>184</sup> This possibility alone warrants individualized scrutiny of each teen's development, and not a general assumption that teens have an underdeveloped sense of responsibility, an increased susceptibility to peer pressure, and an incomplete personal character.<sup>185</sup>

For these reasons, the cavil framework of *Roper* is not a persuasive argument against adolescent medical decision making. First, it is well established that terminally ill adolescents do not have an underdeveloped sense of responsibility.<sup>186</sup> On the contrary, one important study showed that terminally ill teens are often more altruistic than their healthy counterparts.<sup>187</sup> This phenomenon, referred to as the *maturational effect of a life-ending illness on an adolescent*, is often manifested through a teen's conscious choice to participate in a Phase I clinical trial because it may benefit others, even if it might cause personal harm.<sup>188</sup> For example, a nineteen-year-old with a solid tumor made the following remarks about experimental chemotherapy:

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181. *Atkins v. Virginia*, 536 U.S. 304 (2002).

182. *Id.* at 318.

183. *Roper*, 543 U.S. at 602 (O'Connor, J., dissenting).

184. *See id.* at 618.

185. *Id.* at 572-73. These characteristics were argued in the amicus brief filed by the American Medical Association, the American Psychiatric Association, the American Society for Adolescent Psychiatry (and others). It is important to note that the argument indicated that the mental capacity is further diminished in juvenile offenders. *See* Brief of the Am. Med. Ass'n et al. as Amici Curiae Supporting Respondent, *supra* note 176, at 10-16.

186. Hinds et al., *supra* note 6, at 9153.

187. *See id.*

188. *See id.*

If I don't take it, my family would support me, but they don't want me to quit. Grandpa said he would worry himself to death if I don't try it. My boyfriend wants me to take it for him. I don't want to do it but for my family.<sup>189</sup>

The Court's second assertion, that the limited control over a teen's environment results in an undue influence of peer pressure, is also inapplicable to terminally ill teens.<sup>190</sup> Although critically ill teens are extensively limited by their condition, the decision to continue or discontinue treatment is the most personal way of exercising control over their intimate, physical environment.<sup>191</sup> When making a decision regarding treatment, the teen is often subjected to intense peer pressure from loved ones to continue fighting.<sup>192</sup> A willingness to openly discuss and advocate for one's personal beliefs exhibits strength, rather than a susceptibility to peer pressure.<sup>193</sup> Finally, the argument that incomplete character formation prevents a terminally ill teen from making a mature medical decision is an insensitive and inapt assertion. Adolescents on a dying trajectory have complete character formation, in the sense that they are who they are right now, and there is no opportunity for future change. This should be respectfully considered by those questioning an adolescent's capacity for end-of-life decisions.

### 3. *The Mature Minor Doctrine*

The mature minor doctrine is currently recognized in a limited number of states.<sup>194</sup> This doctrine permits an adolescent to make a medical decision free from parental consent if the teen can satisfy criteria both specified and evaluated by the judiciary. The widely adopted criteria are set forth as follows:

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189. *Id.* at 9150.

190. *Roper*, 543 U.S. at 569.

191. *Cf.* Maureen Carroll, *Transgender Youth, Adolescent Decisionmaking, and Roper v. Simmons*, 56 UCLA L. REV. 725, 746 (2009) (arguing that denying transgender adolescents' requests for hormones diminishes their control "over the most personal and fundamental component of their physical environment: their own bodies").

192. Hinds et al., *supra* note 6, at 9150 (noting that many patients felt that family members would want them to continue treatment).

193. *Cf.* Carroll, *supra* note 191, at 746 (noting that when transgendered teens who are "routinely misrecognized by others" take steps to "facilitate intra-and inter-subjective recognition of a core (gendered) self," their actions reflect a strong sense of that core self, not a weak response to peer pressure").

194. Certain states have adopted some form of the mature minor doctrine. These include: Arkansas, Idaho, Illinois, Kansas, Mississippi, Nevada, New Mexico, New York, Ohio, Tennessee, and West Virginia. *See* ARK. CODE ANN. § 9-27-362 (2009); IDAHO CODE ANN. § 39-3801 (2009); MISS. CODE ANN. § 41-41-3(3) (2009); NEV. REV. STAT. § 129.030(2) (LexisNexis 2009); N.M. STAT. § 24-7A-6.21 (2009); *In re E.G.*, 549 N.E.2d 322 (Ill. 1989) (holding that a bright-line consent restriction of eighteen is improper if it restricts the constitutional rights of mature minors); *Younts v. St. Francis Hosp. & Sch. of Nursing, Inc.*, 469 P.2d 330 (Kan. 1970); *Lacey v. Laird*, 139 N.E.2d 25 (Ohio 1956); *Cardwell v. Bechtol*, 724 S.W.2d 739 (Tenn. 1987); *Belcher v. Charleston Area Med. Ctr.*, 422 S.E.2d 827 (W. Va. 1992).

Whether a minor has the capacity to consent to medical treatment depends upon the age, ability, experience, education, training, and degree of maturity or judgment obtained by the minor, as well as upon the conduct and demeanor of the minor at the time of the incident involved. Moreover, the totality of the circumstances, the nature of the treatment and its risks or probable consequences, and the minor's ability to appreciate the risks and consequences are to be considered.<sup>195</sup>

The seminal mature minor case, *Belcher v. Charleston Area Medical Center*, advocated for both the integrity of the decision-making process and the autonomy of the adolescent whose life was at issue.<sup>196</sup> The *Belcher* court held that when a physician is treating a "mature minor," the minor has both the right to consent to a procedure and to elect to withhold a treatment.<sup>197</sup> In *Belcher*, the parents of muscular dystrophy patient Larry Belcher, aged seventeen years and eight months, brought a wrongful death action alleging medical malpractice against the medical center where Larry died.<sup>198</sup> After a common cold exacerbated the effects of his disease, Larry was admitted to the pediatric intensive care unit, where he was intubated for respiratory support.<sup>199</sup> Larry's parents told the physician that they did not want Larry reintubated or resuscitated unless Larry himself requested it, and the physician had his parents sign a progress note indicating that Larry was not to be reintubated in the event of respiratory failure.<sup>200</sup> The physician then formalized the note into a "Do Not Resuscitate" order, and although Larry could communicate and was not cognitively impaired, he did not involve Larry in the decision.<sup>201</sup> Larry went into respiratory arrest the following day, and was neither reintubated nor resuscitated.<sup>202</sup> His parents contended, and the court agreed, that Larry should have been consulted prior to the issuance of the "do not resuscitate" order. Thus, the court's holding recognized the "mature minor" exception.<sup>203</sup>

Although *Belcher* is not the only mature minor case, and this doctrine varies by court, *Belcher* uniquely captured the underlying policy of the doctrine. The court turned a medical assumption into irreducible dicta:

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195. *Cardwell*, 724 S.W.2d at 748. This standard was reaffirmed in the decisive mature minor case of *Belcher*, 422 S.E.2d at 827.

196. *Belcher*, 422 S.E.2d 827 (W. Va. 1992); see also Hartman, *supra* note 157.

197. *Belcher*, 422 S.E.2d at 836-38 (recognizing a mature minor exception to the common law parental consent rule). The court rejected the argument that this applies only to the consent to treatment as opposed to assent, or, affirmatively seeking treatment instead of allowing treatment to be administered or withheld. *Id.*

198. *Id.* at 830.

199. *Id.*

200. *Id.*

201. *Id.*

202. *Id.*

203. *Id.* at 830-31.

It is difficult to imagine that a young person who is under the age of majority, yet, who has undergone medical treatment for a permanent or recurring illness over the course of a longer period of time, may not be capable of taking part in decisions concerning that treatment.<sup>204</sup>

In other words, the weight of this reasoning provides a legal foundation for the argument that experience, rather than age, is a more reliable indicator of an adolescent's ability to make medical decisions. Unfortunately, while the mature minor doctrine is an important policy shift toward adolescent autonomy, there are several flaws that prevent this from being a workable solution for a terminally ill minor.

*(a) The Limitations of the Mature Minor Doctrine*

The mature minor doctrine is an imperfect process for determining whether an adolescent is mature. First, not every state conducts the capacity assessment in the same manner, creating a politicized conflict between state courts.<sup>205</sup> For example, a West Virginia physician can treat a minor free from liability for failure to obtain parental consent if he or she used his or her best medical judgment to assess the minor's maturity.<sup>206</sup> The physician is protected because the *Belcher* court concluded that the decision whether to allow a minor to make medical decisions should be made by the patient's physician.<sup>207</sup> However, if that same patient were to appear before an Illinois state court, the trial judge, and not the physician, would determine whether or not the adolescent is mature enough to make independent medical decisions.<sup>208</sup> Regrettably, neither approach is a best practice for quality patient care. Under a physician-determinative standard, a physician will be placed in the judicial and media spotlight, and he or she will likely be second-guessed during the process.<sup>209</sup> Additionally, because the physician's professional obligation is to the patient and not the parent, the promise of immunity places a significant professional burden on the treating physician.<sup>210</sup> On the other hand, the judicial-determinative standard may produce

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204 *Id.* at 827.

205. Melinda T. Derish & Kathleen Vanden Heuvel, *Mature Minors Should Have the Right To Refuse Life-Sustaining Medical Treatment*, 28 J.L. MED. & ETHICS 109 (2000) (explaining that cases do not systematically resolve this social issue because states come to different conclusions as to who should determine a minor's capacity).

206. *Belcher*, 422 S.E.2d at 837-38.

207. *Id.*

208. *In re E.G.*, 549 N.E.2d 322, 327 (Ill. 1989) (seventeen-year-old leukemia patient refused a blood transfusion based on religious beliefs).

209. Derish & Heuvel, *supra* note 205, at 116 (discussing the weaknesses of the mature minor doctrine).

210. *Id.* See also *WHEN CHILDREN DIE*, *supra* note 8, at 304 (explaining that the physician's primary obligation is to the patient).

a result biased on the state's adoption of the *parens patriae* philosophy.<sup>211</sup> This is especially problematic for the minor because a minor will not have the right to legal representation during the process unless emancipated, which is highly unlikely, or if a physician suspects abuse.<sup>212</sup> Equally concerning is the fact that judges and juries lack experience in weighing the medical information presented by experts.<sup>213</sup> This may lead to a decision based on a misunderstanding of facts or one unduly influenced by the heartbreak of allowing a child to pass away.

The second problem with the doctrine's capacity assessment is its use of irrelevant factors to measure maturity.<sup>214</sup> Ideally, when applying the doctrine a court should first assess a minor's competence and then determine whether any strong countervailing interests justify circumscribing the minor's autonomy.<sup>215</sup> However, most courts focus on a myriad of external, unrelated factors because they are ill-equipped to properly assess a teen's development.<sup>216</sup> For example, in *Younts v. Saint Francis Hospital & School Of Nursing, Inc.*, the court weighed the semi-conscious state of the mother, the father's unavailability, and the mother's likely consent to the minor's surgery more heavily than the overall maturity of the minor.<sup>217</sup> Even the seemingly well-balanced *Belcher* factors, when scrutinized, favor external milestones. For instance, this analysis requires a court to consider the ability and level of education separately from the minor's degree of maturity. As emphasized previously, judging a terminally ill minor by extrinsic assets penalizes the minor for the physical limitations of his or her illness.<sup>218</sup> Also in error, the court evaluates age rather than maturity, although studies have proven that a terminally ill teen is often more mature than an older, healthy peer.<sup>219</sup>

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211. Cf. Derish & Heuvel, *supra* note 205, at 117.

212. *Id.* at 116 (noting that the present medical-legal system does not afford a terminally ill minor access to an attorney or the court unless she wishes to be emancipated or is abused/neglected).

213. WHEN CHILDREN DIE, *supra* note 8, at 317.

214. Jennifer L. Rosato, *The Ultimate Test of Autonomy: Should Minors Have a Right To Make Decisions Regarding Life-Sustaining Treatment*, 49 RUTGERS L. REV. 1, 22 (1996) (disfavoring the courts' use of a broad-reaching factor analysis).

215. See *id.* (questioning whether courts actually apply a mature minor doctrine when making a decision regarding adolescent autonomy).

216. See *id.*; see also WHEN CHILDREN DIE, *supra* note 8, at 317 (explaining that both judges and juries have difficulty basing decisions on technical, medical information).

217. *Younts v. St. Francis Hosp. & Sch. of Nursing, Inc.*, 469 P.2d 330, 338 (Kan. 1970). The use of factors unrelated to maturity has been in place for as long as the doctrine as existed. The *Belcher* court cites to the *Bakker v. Welsh* decision, where the court considered whether adult relatives accompanied the minor to the physician, that the minor was near the age of majority, and that the minor's father impliedly consented to treatment. *Belcher*, 422 S.E.2d at 836 (citing *Bakker v. Welsh*, 108 N.W. 94 (Mich. 1906)).

218. See generally Part II.

219. *Id.*

*(b) When Parents Oppose the Minor's Right To Refuse Treatment*

Even in states where the mature minor doctrine permits a teen to consent to treatment, courts weigh heavily against the minor's right to refuse treatment if there is any opposition from parents, guardians, adult siblings, and other relatives.<sup>220</sup> While the doctrine may overcome the legal presumption that a minor is incompetent, it fails to prevail over the assumption that parents will act in the best interest of their child.<sup>221</sup> Courts often afford the assumption of "parent knows best" the weight of a legal presumption.<sup>222</sup> However, when parents are faced with the imminent death of a child, their judgment is often clouded by unspeakable grief and loss of control.<sup>223</sup> For example, when asked about end-of-life decisions, the mother of a fourteen-year-old end-stage cancer patient remarked, "I am . . . prolonging the inevitable until a cure comes along . . . . I want her to be healed. I keep telling her to hold on . . . ."<sup>224</sup>

This profound sense of powerlessness is often exacerbated by exhaustion and the atmosphere in the Pediatric Intensive Care Unit.<sup>225</sup> In some instances, other relatives or advisors may pressure parents to continue LSMT, despite the adolescent's wishes.<sup>226</sup> Finally, parents may choose a Phase I clinical trial to prolong their child's life or to make their teen's life seem more meaningful, because the loss feels so senseless otherwise.<sup>227</sup> The following two statements were made by the parents of end-stage cancer patients:

What my daughter goes through would be very important to another child. It's not just to save her but children in the near future that could possibly come down with this particular type of cancer...

*Mother of a 17-year-old girl with a solid tumor*<sup>228</sup>

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220. See, e.g., *In re E.G.*, 549 N.E.2d 322, 328 (Ill. S.Ct.1989); *In re Swan*, 569 A.2d 1202 (Me. 1990); *In re Rosebush*, 491 N.W.2d 633 (Mich. App. 1992); *Belcher*, 422 S.E.2d at 827 (W. Va. 1992).

221. See Derish & Heuvel, *supra* note 205, at 117 (noting the almost automatic assumption that, as long as physicians provide adequate information, parents will always make the best decisions about medical care).

222. *Id.*

223. *Id.*

224. Hinds et al., *supra* note 6, at 9151.

225. See Annette R. Pejic, *Verbal Abuse: A Problem for Pediatric Nurses*, 31 PEDIATRIC NURSING 271 (2005) (noting that this type of stress is proven to reduce a parent's ability to control emotional outbursts). These emotions also affect a parent's judgment and self-control. For example, there is a positive correlation between the severity or unpredictability of the child's condition and the parent's likelihood of verbally abusing a nurse or allied health professional. *Id.*

226. Cf. Derish & Heuvel, *supra* note 205, at 117 (describing tensions between adolescents who wish to refuse LSMT and parents who disagree).

227. Hinds et al., *supra* note 6, at 9151 (quoting a parent's reasoning for choosing trial).

228. *Id.*

Hopefully and in someway, we will be able to get through all this and go on with our life, but if it does not work out, we'll want someone else to benefit.

*Mother of a 17-year-old girl with a brain tumor*<sup>229</sup>

While most parents try to make the best possible decision regarding end-of-life treatment, the reality is that the decision to postpone a patient's imminent and inevitable death can greatly increase suffering. When interviewed, an eighteen-year-old cancer patient described his reasons for discontinuing treatment, even though there was a chance it would prolong his life:

I want to die. I just want to get it over with . . . it feels like I'm being tortured, not tortured, not forced, they are not purposely doing this, but they might as well just chain me up to the wall and put needles in my arms.<sup>230</sup>

Supporting this theory is a 2008 study analyzing the feelings of bereaved parents toward end-of-life treatment options. The children of the participating parents had undergone a median of three different treatment regimens, including chemotherapy, radiation, and stem cell transplantation.<sup>231</sup> The study first interviewed parents during the tenure of their child's illness. Researchers asked the parents to report their goals of cancer-directed therapy, first upon diagnosis and then upon realizing that their child's cancer was terminal.<sup>232</sup> The participants were then contacted one year or more after their child's death and asked to respond to a clinical vignette. The vignette assessed parents' willingness to recommend chemotherapy to another family whose child had no realistic chance for cure.<sup>233</sup> The study concluded that, even if they had chosen experimental treatment for their own child, the majority of bereaved parents would not recommend experimental treatment for incurable cancer to other similarly situated families.<sup>234</sup> Although most parents chose additional treatment with the goal of curing their child's cancer, the extent of patient suffering was higher than both parents and researchers anticipated.<sup>235</sup> The parents who felt their child had

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229. *Id.*

230. *Id.* at 9150.

231. Jennifer W. Mack et al., *Parents' Views of Cancer-Directed Therapy for Children With No Realistic Chance for Cure*, 26 J. CLINICAL ONCOLOGY 4759, 4760 (2008). The patients in this study "died with progressive cancer, not as a result of treatment complications." *Id.* at 4761. Patients who received treatment for incurable cancer were comparable to those who did *not* receive such therapy with respect to parent race, site of care, duration of disease, and duration of the end-of-life period. *Id.* Interestingly, parents whose children received treatment for incurable cancer in the end-of-life "period tended to have higher educational attainment and income" than the parents whose children did not receive such therapy. *Id.* They also "used . . . a greater number of different cancer regimens" and they chose "to discontinue therapy [significantly] closer to the time of death." *Id.*

232. *Id.*

233. *Id.*

234. *Id.*

235. *Id.* at 4762-63.

suffered without benefit reported they would not recommend this course of treatment to the hypothetical family presented in the vignette.<sup>236</sup>

Although inconsistent with the current legal framework, pediatric and adolescent psychologists also recommend that the competency and motivations of the parents be assessed if they object to a minor's refusal of LSMT.<sup>237</sup> If the patient expresses a difference of opinion, a parent or guardian's grief should not overly influence the final medical judgment.<sup>238</sup> The mature minor doctrine will not truly be effective until minors are afforded an adult's right to consider another person's preference for continuing LSMT—*without* being bound by that preference.<sup>239</sup>

*(c) An Ill-Equipped Judiciary*

Another significant problem with the mature minor provision is the costly, disruptive, and unpredictable litigation process that it engenders.<sup>240</sup> The side effects of litigation can be very emotionally injurious.<sup>241</sup> The judicial process subjects the patient to the global media and frequently creates hostility within the family and care team.<sup>242</sup> In several reported legal disputes, a change in the patient's medical status renders the court-authorized interventions inappropriate; nevertheless, the family's integrity has already been compromised by the relentless media attention paid to court-mediated pediatric disputes.<sup>243</sup> In the rare case that the judicial intervention does reach a resolution, the historical record suggests that judges are more than willing to override a mature minor patient's preferences.<sup>244</sup> In a survey of fifty judicial interventions, courts acknowledged the pediatric patients' preferences in only ten of the disputes.<sup>245</sup> The survey also showed a judicial disregard for the physicians' recommendations when the disputes concerned life-threatening or disabling conditions.<sup>246</sup> Although many of the courts purported to apply the mature minor doctrine, the most frequently cited reason for the decision to override the patient's choice was an interest in

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236. *Id.* at 4761-63.

237. Telephone Interview with Donna J. Follansbee, Ph.D., Research Consultant at The Barbara Davis Center for Childhood Diabetes (Nov. 10, 2009) [hereinafter Follansbee Interview].

238. *Id.* (adding that the motives of a parent's refusal of LSMT must also be reviewed, as this can occur out of exhaustion or depression).

239. See Derish & Heuvel, *supra* note 205, at 117.

240. WHEN CHILDREN DIE, *supra* note 8, at 318.

241. See Ridgway, *supra* note 147, at 896.

242. *Id.*

243. *Id.* at 896.

244. *Id.* at 896.

245. *Id.* at 891. "Courts acknowledged the pediatric patients' views in only 10 of the disputes (9 of the 19 cases involving adolescents and 1 of the 31 cases involving children younger than 12 years)." *Id.*

246. *Id.* at 891.



protecting children's health.<sup>247</sup> One can fairly question whether this justification is a reasonable interest or a mere political cloak, because preserving health is not an issue if the patient is on a dying trajectory.

Further complicating the issue is the lack of reliable case precedent.<sup>248</sup> Most rulings made in response to physicians seeking judicial intervention to enforce treatment for minors against the wishes of the parents do not result in court-published opinions.<sup>249</sup> The limited number of published opinions that address physician-parent disputes do not adequately address the ethical, legal, and medical issues of the case.<sup>250</sup> Nevertheless, because so few cases exist, these cases establish the legal precedent that shapes subsequent rulings across the United States. When faced with a dispute, state courts often cite other state courts, thereby creating a de facto national jurisdiction for court-mediated pediatric disputes.<sup>251</sup>

Litigation proceedings also place the patient's care team under the professional microscope.<sup>252</sup> Often the result of zealous reporting, this professional scrutiny affects the physician's relationships with both colleagues and other patients. Unlike other technical cases, where outside expert testimony is heard during proceedings, the medical testimony in mature minor cases is usually limited to that of the treating physician's.<sup>253</sup> Because a trial judge and jury lack medical proficiency, the majority of mature minor case summaries are scientifically incomplete when published.<sup>254</sup> Unfortunately, the resultant public record includes inaccuracies, which are often falsely attributed to the treating physician.<sup>255</sup> This inevitable problem places a tremendous professional burden on those physicians forced to seek a judicial intervention in order to fulfill their ethical obligation to their patients.

#### *B. What the Pediatric Team Knows: The Medical Community's Recommendation*

The medical community has recently placed an enhanced focus on patient and family-centered care. Unlike the legalistic approach to medical decision making, the pediatric guidelines mandate the adolescent's involvement, as well as an effort by clinicians to see care through the adolescent's eyes.<sup>256</sup> Although parents may have the legal right to make decisions, pediatric clinicians have an ethical obligation to afford the adolescent an opportunity to discuss his or her

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247. See *id.*; see also Derish & Heuvel, *supra* note 205, at 117.

248. See Ridgway, *supra* note 147.

249. *Id.* at 891.

250. *Id.* at 895-96.

251. *Id.* at 896.

252. *Id.* at 896.

253. *Id.* at 895.

254. *Id.*

255. *Id.* at 895-96.

256. *Id.*

preferences and concerns regarding care.<sup>257</sup> This model imparts upon medical professionals the ethical duties of fidelity and professional integrity.<sup>258</sup> Fidelity, the responsibility of health care professionals to place the interests of their patients first, is at the heart of the patient-centered care model.

The American Academy of Pediatrics (AAP) has adopted a bright-line approach to pediatric patient-centered care.<sup>259</sup> The AAP policy states that pediatric patients should always be included in the decision-making process, and remarks that “indeed, some patients have specific legal entitlements to either consent or to refuse medical intervention.”<sup>260</sup> The AAP further states that physicians should obtain the informed consent of an adolescent patient in the majority of circumstances.<sup>261</sup> However, under the current legal framework, pediatric patients have very little opportunity to provide informed consent to medical treatment.<sup>262</sup> In light of these limitations, the AAP has outlined specific guidelines for obtaining the *assent* of a pediatric patient.<sup>263</sup> These guidelines are directed at pediatric patients of all ages, and are to be modified according to age and development:

1. Helping the patient achieve a developmentally appropriate awareness of the nature of his or her condition.
2. Telling the patient what he or she can expect with tests and treatments.
3. Making a clinical assessment of the patient’s understanding of the situation and the factors influencing how he or she is responding (including whether

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257. *Id.* at 896.

258. WHEN CHILDREN DIE, *supra* note 8, at 303-04. Professional integrity refers to the requirement that physicians act for the benefit of all patients. *Id.* The obligation is typically discussed in reference to the allocation of medical resources. *Id.* at 305. Although relevant, it is beyond the narrow scope of this Note.

259. AAP, *supra* note 146, at 314.

260. *Id.* The AAP states that there must be “persuasive reasons” to do otherwise. *Id.*

261. *Id.* at 314-15. The AAP lists the following components as necessary in order to obtain informed consent:

1. Provision of information: Patients should have explanations, in understandable language, of the nature of the ailment or condition; the nature of proposed diagnostic steps and/or treatment(s) and the probability of their success; the existence and nature of the risks involved; and the existence, potential benefits, and risks of recommended alternative treatments (including the choice of no treatment).
2. Assessment of the patient’s understanding of the above information.
3. Assessment, if only tacit, of the capacity of the patient or surrogate to make the necessary decision(s).
4. Assurance, insofar as is possible, that the patient has the freedom to choose among the medical alternatives without coercion or manipulation.

*Id.* at 315.

262. *Id.* at 315-16.

263. *Id.*

there is inappropriate pressure to accept testing or therapy).

4. Soliciting an expression of the patient's willingness to accept the proposed care. *Regarding this final point, we note that no one should solicit a patient's views without intending to weigh them seriously. In situations in which the patient will have to receive medical care despite his or her objection, the patient should be told that fact and should not be deceived.*<sup>264</sup>

The AAP has also vehemently argued that a pediatric patient, especially an adolescent, has the full authority to refuse assent.<sup>265</sup> The refusal of assent, also referred to as dissent, should carry considerable weight in the context of participation in clinical research, and clinicians should avoid coercion in treatment whenever possible.<sup>266</sup> According to the AAP, an adolescent's dissent is ethically, if not legally, binding.<sup>267</sup>

In order to successfully integrate the AAP's recommendations, the patient/care team relationship must be based on trust.<sup>268</sup> When the patient is critically ill, maintaining this balance is considerably more difficult because physicians must address palliative care without eroding hope.<sup>269</sup> The patient and family will benefit most from end-of-life care discussions if the physician is skilled in facilitating this conversation.<sup>270</sup> However, most physicians feel unprepared and uncomfortable having any type of end-of-life discussion. According to one survey, only two percent of pediatric oncologists report a rotation on a palliative care service, and thus the most common palliative experiences are of a "trial and error" nature.<sup>271</sup> One survey suggested that some fourth-year medical students are asked by their attending or resident physician to "handle" dying patients because their attending or resident physician is uncomfortable working with these patients, and is seizing the opportunity to displace the responsibility.<sup>272</sup> One such "student reported that he felt that his inept and unguided effort to discuss a patient's preferences for resuscitation 'doomed' the patient to terrible, prolonged death."<sup>273</sup> However, as this behavior is cyclical, the student will likely pass on these cases to other unprepared students when he is finally a resident. This unstructured and unguided approach to palliative care education places patients, families, and care teams at risk for conflicts that are otherwise preventable.<sup>274</sup>

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264. *Id.* (emphasis added).

265. *Id.* at 316.

266. *Id.*

267. *Id.* at 317.

268. Kane & Hilden, *supra* note 12, at 188-89.

269. See Wolfe et al., *supra* note 105, at 2474.

270. Cf. Kane & Hilden, *supra* note 12, at 189.

271. WHEN CHILDREN DIE, *supra* note 8, at 329.

272. Cf. *id.* at 334.

273. Cf. *id.*

274. See *id.* at 329.

The broader legal and medical communities need to recognize what pediatric palliative care specialists already know: the integration of palliative care into the pediatric medicine curriculum will reduce suffering in children who pass away, improve the quality of life for children who survive, and reduce the number of conflicts that end in a courtroom.<sup>275</sup> The Committee on Palliative and End-of-Life Care for Children and Their Families advocates that pediatric residency programs require more extensive preparation in palliative care for those pediatric specialists who care for children with life-threatening medical conditions.<sup>276</sup> The number of pediatric palliative care fellowships should also increase, as this would bring palliative care into the mainstream, removing the discomfort and fear from the field.<sup>277</sup> Moreover, continuing education programs focused on palliative care are a simple way to provide both introductory and advanced education for all pediatric professionals, including nurses and allied health professionals.<sup>278</sup> These strategies will permit a smoother incorporation of palliative care into the patient's care plan, thereby reducing preventable conflicts and the need for judicial intervention.

#### IV. IN THE TRENCHES: THE ICPC/STATUTORY COMBINATION MODEL AT WORK

The subsequent sections outline an individualized, proactive approach to improve the adolescent medical decision-making process. Because a custom-tailored care plan defines true patient-centered care, this Note recommends a two-part solution incorporating the goals of the patient, their family, and their care team.<sup>279</sup> First, pediatric treatment centers should adopt the Individualized Care Planning and Coordination model, and implement this protocol upon diagnosis of a serious illness. Second, this Note advocates for legislative involvement, encouraging state legislatures to enact a fallback statutory provision modeled after Section 24-7A-6.1 of the New Mexico Uniform Health-Care Decisions Act.

##### *A. The Individualized Care Planning & Coordination Model*

The primary purpose of the Individualized Care Planning and Coordination (ICPC) model is to establish a coordinated multi-disciplinary decision-making process.<sup>280</sup> This ICPC model is a three-step progression during which the care team first assesses the patient's understanding of the prognosis, as well as the

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275. *Id.* at 349.

276. *Id.*

277. *Id.*

278. *Id.*

279. See ICPC I, *supra* note 96, at 247 (noting that quality treatment requires a full spectrum of care, including an understanding of the child's personal illness experience and the family's perceptions).

280. *Id.*

family's comprehension of the illness trajectory.<sup>281</sup> During Phase I, the Relationship phase, the team elucidates the patient's personal treatment goals, as well as their family's treatment goals.<sup>282</sup> This comprehensive needs assessment is then used during the second phase, which consists of a multi-disciplinary negotiation of the best possible treatment plan.<sup>283</sup> The individualized care plan is designed to balance medical and personal goals, maintain family integrity, and foster a trusting relationship among family and care team.<sup>284</sup> The coordinated care plan is implemented in the third and final phase. This includes an immediate action plan and crucial follow-up assessments to ensure that the plan is meeting the patient's needs.<sup>285</sup>

The ICPC model functions best when implemented at diagnosis, as it creates a strong, trust-based foundation of care.<sup>286</sup> The model is then reinitiated if the patient's clinical status worsens, warranting a different course of treatment. For example, the care team reinitiates the first step if the patient's cancer relapses or the muscular dystrophy patient becomes wheelchair or ventilator dependent.<sup>287</sup> This fluidity is one of the many advantages of this model. It enables the care team to prepare the family for loss, thereby lowering the risk of psychological disturbance during the end-of-life and bereavement periods.<sup>288</sup> In other words, the patient and family may hope for the best, while preparing for the worst.<sup>289</sup> The following sections detail the progression of one ICPC cycle.

### *1. Phase I: Relationship*

During the first phase, the goal is to facilitate an open dialogue between the care team and the patient/family.<sup>290</sup> This is a three-way conversation, as the care team must understand the personal realities of both the patient and the family and share the necessary information for decision making.<sup>291</sup> The team then prepares a comprehensive needs assessment based on the acquired information for use in the second phase.<sup>292</sup>

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281. *Id.* at 246-47.

282. *Id.* at 248.

283. *Id.* at 249-50.

284. *Id.* at 252.

285. *Id.* at 251.

286. *Id.* at 248-49.

287. *Id.*

288. Justin N. Baker et al., *Integration of Palliative Care Practices into the Ongoing Care of Children with Cancer: Individualized Care Planning and Coordination*, 55 PEDIATRIC CLINICS N. AM. 223, 240 (2008) [hereinafter ICPC II].

289. *Id.*

290. ICPC I, *supra* note 96, at 248.

291. *Id.*

292. *Id.* at 249.

*(a) Empathy for the Illness Experience*

St. Jude Children's Research Hospital physicians recently commented that the ability to listen with an empathetic presence is the most powerful tool in the clinician's arsenal.<sup>293</sup> Because this directly affects patient and parent outcomes, this is arguably the most important practice for mitigating avoidable conflicts. In order to engage in effective communication and subsequently generate the needs assessment, the clinician must appreciate the illness experience from both the patient's perspective and from the perspective of the family.<sup>294</sup> When talking with the patient or family, experts recommend that the clinician be comfortable with silence and create a safe, nonjudgmental atmosphere.<sup>295</sup> Because the adolescent has distinct experiences from those of the parents, this process opens an independent discussion about each party's fears, perceptions, beliefs, preferences, and values.<sup>296</sup> From this, the team can anticipate and understand the patient's and the family's coping strategies, and in so doing, prevent a crisis from becoming a conflict.<sup>297</sup>

*(b) Candid Conversations*

In order to generate a needs assessment, the clinician has the responsibility of sharing relevant information with the patient and the family.<sup>298</sup> As discussed above, the sharing of negative or disappointing news can reduce the quality of the doctor/patient relationship if handled improperly.<sup>299</sup> The ICPC model alleviates this problem by taking an individualized, yet structured approach. In line with the International Pediatric Oncology Society, the model incorporates a protocol for physicians to facilitate this discussion by including the use of exploratory questions, empathetic statements, and validating responses.<sup>300</sup>

During this process, it is critical that the physician identify the main decision-maker within the family unit.<sup>301</sup> This step will help avoid a judicial intervention for two reasons. First, unlike the judge, the clinician is in the best position to evaluate whether the primary decision maker has the capacity to make

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293. *Id.* at 248.

294. *Id.* at 248.

295. *Id.*

296. *Id.*

297. *See id.* at 252.

298. *Id.* at 248.

299. *Id.*

300. *Id.* at 248-49. The following lists different responses recommended by clinicians to facilitate open conversation:

"I want to listen to you tell me more about that."

"What are you hoping for now?"

"We were all hoping for a better result."

301. *Id.* at 252.

medical decisions.<sup>302</sup> While courts rely on the general legal definition of competent when assessing a parent's decision-making capacity, the clinician has the opportunity to assess the parent's ability to put aside grief in order to make a decision that is in the best interest of the patient.<sup>303</sup> For example, legally competent, educated, and medically savvy parents may still lack the emotional capacity or clear judgment needed during their child's end-of-life period.<sup>304</sup> Other factors, including language barriers, place of residence (i.e., whether hometown is in a rural area with difficult hospital accessibility), or religion may influence the way in which a family makes decisions.<sup>305</sup> In many families, demographic factors influence (1) which family member is the decision-maker and (2) how that person makes medical choices.<sup>306</sup> Once the clinician has identified a particular family's decisive issues, a compromise is more likely to be obtained during conflict resolution.

Second, the clinician must determine what the patient's rights are relative to the rights of the family.<sup>307</sup> If the patient is at all capable of participating in decision making, the physician should elucidate his/her preferences for treatment and quality of life.<sup>308</sup> Even if the parent states that the teen is the primary decision-maker, the clinician must be aware of any undue family pressure placed on the teen to make a specific decision, as this indicates the parent remains the true decision-making force in the family.<sup>309</sup> An understanding of family dynamics ensures that the patient's rights and preferences are being respected to the greatest extent possible in both ethics and the law.<sup>310</sup>

### *(c) The Needs Assessment Formula*

The ICPC needs assessment is the most accurate way to assess a minor's decision-making capacity. Unlike other methods, such as the mature minor doctrine, this assessment details a patient's needs according to the domains of his or her personal illness experience.<sup>311</sup> The needs assessment incorporates the relational aspects of care with the patient's physical, social, psychological,

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302. ICPC II, *supra* note 288, at 232.

303. See Follansbee Interview, *supra* note 237.

304. Derish & Heuvel, *supra* note 205, at 117. As evidenced in the previous section, parents often select a treatment plan for their child in order to prolong the inevitable; however, when interviewed after their child's death, they would not recommend the same decision to another family. See Mack, *supra* note 231, at 4761 (stating that parents frequently stated in retrospect that the goal of cancer treatment should be to lessen suffering).

305. ICPC II, *supra* note 302, at 232.

306. *Id.*

307. *Id.*

308. *Id.*

309. See ICPC I, *supra* note 96, at 249 (discussing an adolescent's concern for family when making decisions).

310. *Id.*

311. *Id.* at 248.

cultural, and educational needs. While this may seem like an overwhelming task, the method is successful because the comprehensive needs assessment incorporates feedback from an interdisciplinary team of specialists, including, but not limited to, the medical, psychological, and social services.

The use of a comprehensive assessment negates the fear that the emotional volatility of adolescence might lead a teen to want to discontinue LSMT, equating this withdrawal with adolescent suicide.<sup>312</sup> One of the more potent arguments against adolescent medical decision-making stems from the stereotypical adolescent tendency to have mood swings, feed off the dramatic, and experience exaggerated emotions.<sup>313</sup> However, as the needs assessment incorporates a multidisciplinary approach, every treating service, including psychology/psychiatry, coordinates efforts via shared documentation and frequent meetings.<sup>314</sup> Under the ICPC protocol, the interdisciplinary team members include, but are not limited to, the primary physician (oncologist, orthopedist, etc.) and the psychology, child life service, and the palliative care services.<sup>315</sup>

The ICPC approach differs from the typical system. In a non-ICPC setting, services meet independently to discuss the patient's needs in relation to their specific service. For example, a tumor board will only examine the patient's cancerous tumors, but will not address the side effects or symptoms the patient may be experiencing. The problem with this method is the resultant lack of communication between the services.<sup>316</sup> For example, a recent study found that pediatric oncology care team members often underestimate adolescent psychosocial symptoms, and as a result, the appropriate psychology consultation is not sought.<sup>317</sup>

By contrast, the ICPC model mandates coordination between services. During the interdisciplinary team meetings, the team reassesses the patient's clinical condition, relational care needs, and changes in treatment goals, always

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312. See Kersun & Shemesh, *supra* note 127, at 700 (addressing concerns that the withdrawal of LSMT is type of teen suicide or pediatric physician assisted suicide); see also Jennifer L. Rosato, *The Ultimate Test of Autonomy: Should Minors Have a Right To Make Decisions Regarding Life-Sustaining Treatment*, 49 RUTGERS L. REV. 1, 72 (1996) (differentiating and assuaging the fear that this is the equivalent of teen suicide).

313. Allyn R. Hines & Sharon E. Paulson, *Parents' and Teachers' Perceptions of Adolescent Storm and Stress*, 41 ADOLESCENCE 597, 597-98 (2006) (discussing the public perception that adolescents are emotionally unstable, moody, and troubled). The authors reference G. Stanley Hall's 1904 characterization of the adolescent period as one of "sturm und drang" or "storm and stress." *Id.* at 597-98. One may wonder whether J.K. Rowling had this in mind when she depicted the Durmstrang Quidditch star, Victor Krum, as moody and surly. See J.K. ROWLING, HARRY POTTER AND THE GOBLET OF FIRE (2000).

314. ICPC II, *supra* note 288, at 232.

315. *Id.* at 239.

316. *Id.*

317. Kersun & Shemesh, *supra* note 127, at 695.



modifying the needs assessment when necessary.<sup>318</sup> It makes possible the immediate identification of a depressive disorder or generalized anxiety disorder, and ensures that a true disorder will be distinguished from the expected level of anxiety and sadness resulting from illness.<sup>319</sup> For example, unlike the symptoms of depression in a medically healthy person, “symptoms of anhedonia (lack of interest in pleasurable activities) are considered to be more specific to the diagnosis of depression in the medically ill patients and are less influenced by medical status.”<sup>320</sup> Likewise, suicidal ideation in adolescent patients may indicate inadequate pain management, not a genuine desire to end one’s life.<sup>321</sup> Therefore, the care team must have an understanding of the course of the patient’s illness and his or her normal coping mechanisms, in addition to knowledge of the unique symptoms of a depressive disorder in medically ill patients.<sup>322</sup> Because specialists on the ICPC interdisciplinary team share this information on a regular basis, the care team can immediately respond if the patient shows signs of an impending crisis. While critics of adolescent end-of-life decision making show concern that autonomy will result in suicide, the ICPC process ensures that suicidal ideation will not mask itself as an emotionally healthy request to discontinue care.<sup>323</sup> Treatment decisions are always made after addressing the psychosocial needs of the patient and their family.<sup>324</sup>

## 2. Phase 2: Negotiation

The negotiation phase can begin once the team has created the needs assessment. This next step combines prognosticating and discussing goals of care and specific treatment options” available for the patient.<sup>325</sup> This phase includes a mutual discussion between the patient, family, and care team about the patient’s trajectory, medical goals, and life goals.<sup>326</sup> The overriding objective is to reach a

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318. ICPC II, *supra* note 288, at 234.

319. See Kersun & Shemesh, *supra* note 127, at 691-92 (explaining the importance of communication and specialized training in distinguishing the two constructs of symptomatic depression and anxiety versus a disorder).

320. *Id.* at 695.

321. *Id.* at 700. See generally NELSON TEXTBOOK OF PEDIATRICS ch. 40 (18th ed. 2007).

322. See Kersun & Shemesh, *supra* note 127, at 691-92. Comparable to the mainstream external factors for maturity, standardized symptoms of anxiety and depression do not provide an accurate indication in a terminally ill pediatric patient. *Id.*

323. *Id.* at 700 (noting that requests for euthanasia are short-lived if handled in an empathetic manner and the team addresses the following: depression, loneliness, and physical symptoms). After addressing these concerns allows the care team to distinguish between a request for suicide or a request to discontinue LSMT.

324. See ICPC II, *supra* note 288, at 238-39 (stating that psychosocial and spiritual needs are consistently identified as very important to patients and their families, and psychological concerns are frequently under addressed but should be managed as aggressively as physical symptoms).

325. ICPC I, *supra* note 96, at 249.

326. *Id.* at 250-51.

consensus regarding care that matches the patient's medical reality and personal values system.<sup>327</sup> The ICPC model is unique in its incorporation of case scenarios as a demonstrative tool.<sup>328</sup> Contrasting potential clinical care scenarios aids the patient and family in assessing the possible treatment options and potential outcomes.<sup>329</sup> The ICPC model lessens the potential for conflict because supportive care alternatives are always presented alongside the scenario in which treatment with a curative intent is withdrawn.<sup>330</sup> Research has shown that families are more receptive to a discussion of end-of-life care when there is a clear understanding that the goal is to lessen suffering.<sup>331</sup> Parents are less likely to fear discontinuation of LSMT if they are confident that supportive care is immediately available to help their teen reach any remaining personal goals.<sup>332</sup>

Because the negotiation phase necessitates difficult conversations about a patient's possible relapse or death, it is during this phase that the team will likely encounter any discordant steps in the process.<sup>333</sup> "Conflicts may even be productive or beneficial in some situations, for example, when parents may pursue an issue in disagreement rather than capitulating to a course of action and later regretting their silence."<sup>334</sup> Conflict can also benefit the patient's care team, as "overly confident or assertive clinicians may become more sensitive to parental concerns and values."<sup>335</sup> However, the most severe conflicts are destructive rather than productive, and almost always center on treatment decisions.<sup>336</sup> These situations commonly begin with a parent's unrealistic expectations regarding prognosis or a patient's wish to move toward comfort care before the parents are ready to discontinue treatment with curative intent.<sup>337</sup>

When the needs assessment indicates that the discordance is likely to become an insoluble conflict, the ethics committee should be consulted in an effort to reach a resolution.<sup>338</sup> The ethics committee's role within the ICPC is that of moderator.<sup>339</sup> An effective committee is comparable to a confidential forum used to facilitate communication, conflict resolution, and support of

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327. *Id.* at 253.

328. *See id.*

329. *Id.* at 250-51.

330. *Id.* at 251.

331. *Id.*

332. *Id.*

333. *Id.* at 249.

334. WHEN CHILDREN DIE, *supra* note 8, at 308.

335. *Id.* at 308.

336. *Id.* at 308.

337. *Cf.* ICPC I, *supra* note 96, at 249-51 (discussing the challenges of moving from curative treatment to comfort care). The shift for patients and families is gradual and uneven. Parents may need reassurance that they have an appropriate grasp of their child's condition. *Id.* at 251.

338. *Id.* at 249; *see also* ICPC II, *supra* note 302, at 231.

339. *Id.*

relationships.<sup>340</sup> Its purpose is not to make treatment recommendations, and the family should be reassured of this fact.<sup>341</sup> When the ethics committee is “sprung” on a family, parents quickly become skeptical and hostile toward the hospital as an institution.<sup>342</sup> For instance, one parent remarked,

I think in particular of two times when we made a particular request and were told that the ethics committee would be called. I’m now on the ethics committee at Children’s Hospital here and . . . [I advocate there] that ethics committees not be viewed like the legal system. That’s not helpful or open to families but one other thing to be really frightened about.<sup>343</sup>

Instead, the committee should be presented as a constructive and compassionate resource for families and the medical team.<sup>344</sup> As part of the ICPC care coordination, families should be told of the ethics committee’s existence when they initially learn about the amenities of the treating pediatric care center.<sup>345</sup> Introducing the committee during the negotiation phase mitigates the fear-based reaction that occurs when the committee is called to review a patient’s case without warning. The committee should be considered part of the care team, as a consultation may alter the care plan during the final phase of the ICPC model.

### *3. Phase 3: The Individualized Care Coordination Plan Process*

After arriving at a consensus approach to care through negotiation, the care team, patient, and family can generate a comprehensive care plan.<sup>346</sup> “The ICPC process guides the development of a care plan that takes into account their needs, values, and perceptions, as well as the medical care” appropriate for the patient’s illness.<sup>347</sup> The following is an outline of the domains and the detail required to document the plan for compliance with the model.

- **Disease Management:** This domain must be carefully documented, as it includes the care plan for disease directed medical treatment, including further use of chemotherapy, radiotherapy, and surgery.<sup>348</sup> This domain also directly addresses end-of-life disease management. For example, the patient may document whether they want to continue invasive diagnostic procedures, even including something as basic as a blood draw for

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<sup>340.</sup> *Id.*

<sup>341.</sup> *Id.*

<sup>342.</sup> WHEN CHILDREN DIE, *supra* note 8, at 293.

<sup>343.</sup> *Id.*

<sup>344.</sup> *Id.*

<sup>345.</sup> See ICPC II, *supra* note 288, at 231 (explaining that the ethics committee promotes care coordination and is an integral partner with the palliative care service).

<sup>346.</sup> See ICPC I, *supra* note 96, at 251.

<sup>347.</sup> *Id.*

<sup>348.</sup> *Id.* at 253.

analysis.<sup>349</sup> The care team will also document the patient's specific preferences for LSMT, including ventilator support, antibiotics, kidney dialysis, transfusions, and artificial hydration and nutrition.<sup>350</sup> The ICPC documentation is a proactive strategy to mitigate the atmosphere of crisis and panic that drives many decisions about life-sustaining interventions.<sup>351</sup>

- **Physical Aspects of Care:** The domain involves non-diseased-directed physical treatment. The focus is on symptom management and rehabilitation.<sup>352</sup> The interdisciplinary team members include pain management specialists and physical and occupational therapists. This Note advocates that the team should also include a reproductive endocrinologist because future fertility is a significant concern for newly diagnosed cancer patients.<sup>353</sup> Clinicians used to overlook the fertility implications in pediatric cancer patients.<sup>354</sup> Fortunately, as pediatric cancer survivor rates increase, fertility preservation is becoming an integral part of adolescent cancer treatment.<sup>355</sup> Accordingly, the ICPC

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349. *Id.* at 251.

350. *Id.*; see also WHEN CHILDREN DIE, *supra* note 8, at 298-99 (describing the most common forms of LSMT).

351. See WHEN CHILDREN DIE, *supra* note 8, at 298-99 (noting that LSMT decisions are often made in haste and panic, and this type of decision making leaves all those involved deeply distressed).

352. See ICPC I, *supra* note 96, at 253.

353. See Matthew J. Loscalzo & Karen L. Clark, *The Psychosocial Context of Cancer-Related Infertility*, in ONCOFERTILITY: FERTILITY PRESERVATION FOR CANCER SURVIVORS 180, 182-83 (Teresa K. Woodruff & Karrie Ann Snyder eds., 2007) (recognizing the importance of fertility to many cancer patients, and how psychosocial screening can alert physicians to patients' fertility preservation desires); Stephanie J. Lee et al., *American Society of Clinical Oncology Recommendations on Fertility Preservation in Cancer Patients*, 24 J. CLINICAL ONCOLOGY 2917, 2921 (2006) (noting a vast majority of cancer patients treated during their reproductive years are interested in discussing fertility preservation options). Many cancer treatments are toxic to the reproductive organs, and cancer survivors sometimes feel "incomplete" if they become infertile. Gregory Dolin et al., *Medical Hope, Legal Pitfalls: Potential Legal Issues in the Emerging Field of Oncofertility*, 49 SANTA CLARA L. REV. 673, 674 (2009).

354. Cf. Carrie Nieman et al., *Fertility Preservation and Adolescent Cancer Patients: Lessons from Adult Survivors of Childhood Cancer and Their Parents*, in ONCOFERTILITY: FERTILITY PRESERVATION FOR CANCER SURVIVORS, *supra* note 353, at 201, 208 (recounting how some cancer survivors did not remember talking to their physicians about fertility concerns).

355. Cf. Dolin et al., *supra* note 353, at 674. ("Whereas in the past fertility was not even part of the discussion when deciding on the proper treatment, now it is a top concern of many newly diagnosed cancer patients."). The University of Texas MD Anderson Cancer Center offers sexuality and fertility counseling, as well as sperm banking, as part of its Adolescent and Young Adult Program. MD Anderson Adolescent & Young Adult (AYA) Program, <http://www.mdanderson.org/patient-and-cancer-information/care-centers-and-clinics/childrens-cancer-hospital/support-programs/aya-program.html> (last visited Oct. 7, 2010). The Texas Children's Hospital Cancer Center specifically notes that psychosocial challenges of treating teenaged patients include issues of intimacy and fertility. Texas Children's Hospital, <http://www.texaschildrens.org/Parents/TipsArticles/ArticleDisplay.aspx?aid=983> (last visited Oct.

care plan should include the patient's fertility preservation decision. Just as parents are not permitted, without good cause and court approval, to forcibly sterilize their children, it has been argued that when a parent chooses not to consent to fertility preservation, the adolescent is deprived of his or her right to procreate.<sup>356</sup> Although policy, history and precedent indicate that a minor should have full autonomy regarding fertility preservation, there is no specific case law or legislation on this issue.<sup>357</sup> This makes the ICPC the optimal forum to address these issues, as the ethics committee and hospital risk management are automatically a part of the coordinated interdisciplinary team and can be consulted should a conflict arise.<sup>358</sup>

- **Psychological Aspects of Care:** This section of the care plan documents the patient or family's need for emotional support.<sup>359</sup> This includes the previously discussed anxiety and depressive disorders, but also incorporates grief and bereavement counseling.<sup>360</sup>
- **Spiritual Aspects of Care:** Based on the information learned during the Relationship phase, the care team will be aware of the patient's and family's spiritual beliefs. The team will document any religious

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7, 2010). Semen cryopreservation is available for post-pubescent male patients. Ovarian tissue cryopreservation, where cortical tissue strips are obtained and re-implanted at the time of remission, may be an option for females depending on the type of cancer. *In vitro* follicle maturation is in the experimental phase. Cf. Evelyn E. Telfer et al., *A Two-Step Serum-Free Culture System Supports Development of Human Oocytes from Primordial Follicles in the Presence of Activin*, 23 HUM. REPRODUCTION 1151, 1155 (2008) (reporting success of growing human follicles from cortical strips); Min Xu et al., *Tissue-Engineered Follicles Produce Live, Fertile Offspring*, 12 TISSUE ENGINEERING 2739, 2739-40 (2006) (mentioning ovarian tissue cryopreservation as one option for preserving fertility).

356. Dolin et al., *supra* note 353, at 698-704 (citing Kathleen M. Boozang, *CAM for Kids*, 1 Hous. J. Health L. & Pol'y 109, 123 (2001) ("[A] court order is typically obtained before an incompetent minor is sterilized . . . .")); cf. *Michigan Protection & Advocacy Serv. v. Kirkendall*, 841 F. Supp. 796, 801 (E.D. Mich. 1993) ("[S]terilization is defined by the legislature as an extraordinary measure which is to be decided by a court and undertaken only pursuant to court order."); *In re Truesdell*, 304 S.E.2d 793, 806 (N.C. Ct. App. 1983) (recognizing that procreation is a fundamental right and delineating standards the state must meet to compel sterilization).

357. See Dolin et al., *supra* note 353, at 707-12; see also Christine Muckle, Comment, *Giving a Voice to Intersex Individuals through Hospital Ethics Committees*, 2006 WIS. L. REV. 987, 1000-01 (2006) (noting that in sterilization cases, courts do not show parents "the same level of deference they would normally receive").

358. The issue of what to do with stored gametes/genetic material is beyond the scope of this issue. Case law suggests that courts will look to "wishes expressed by the deceased donor during the course of his life." Dolin et al., *supra* note 353, at 710; see also *id.* at 704 (citing *Hecht v. Superior Court*, 20 Cal. Rptr. 2d 275 (Ct. App. 1993)); *Estate of Kievernagel*, 166 Cal. App. 4th 1024 (Ct. App. 2008); cf. *Kurchner v. State Farm Fire & Cas. Co.*, 858 So. 2d 1220, 1221 (Fla. Dist. Ct. App. 2003) (relying on *Hecht* to conclude that frozen sperm is to be treated like personal property).

359. ICPC I, *supra* note 96, at 253.

360. *Id.*

preferences, chaplain or clergy requests, and the family's general definitions of hope, meaning, and faith.<sup>361</sup>

- **Social Aspects of Care:** The social services department and the child life department are actively involved in this domain. The plan should document sibling and parent support, the patient's goals concerning self-care and privacy, and any financial support issues the family is facing.<sup>362</sup>
- **Cultural Aspects of Care:** The family's cultural preferences and customs, learned during the Relationship phase, should be documented in the plan.<sup>363</sup> The team should encourage continued participation in cultural practices or holidays to preserve an atmosphere of normalcy.
- **Care of the Imminently Dying:** When a patient is near the end-of-life period, the plan will document symptoms, coping, anticipatory guidelines, communication, grief, and funeral arrangements.<sup>364</sup> The documentation will also include the child life team's role in end of the life care. The child life team will help families discuss the impending death with siblings, extended family, and friends.<sup>365</sup> Child life specialists also help make mementos of the child, including handprints after the child dies.<sup>366</sup> The care team at St. Jude Children's Research Hospital recommends that members attend the funeral, and that the team maintain contact with the family for thirteen months after the child's death.<sup>367</sup>
- **Ethical and Legal Aspects of Care:** Every ethics consultation and risk management involvement must be documented.<sup>368</sup> The plan will also document the withholding or withdrawing of treatment with curative intent.<sup>369</sup>
- **Educational Aspects of Care:** The plan should document when the family is presented with information on anticipatory guidelines, home health, hospice, and the dying process.<sup>370</sup> Their comprehension level should also be documented.
- **Relational Aspects of Care:** The care team should first document if the patient and family are effectively communicating emotions and grief

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361. *See id.*

362. *See id.*

363. *See id.*

364. *See id.*

365. Anne E. Kazak et al., *Evidence-Based Assessment, Intervention and Psychosocial Care in Pediatric Oncology: A Blueprint for Comprehensive Services Across Treatment*, 32 J. PEDIATRIC PSYCHOL. 1099, 1104 (2007).

366. *Id.*

367. *See* ICPC II, *supra* note 288, at 229.

368. ICPC I, *supra* note 96, at 253.

369. *See id.*

370. *See id.*

together.<sup>371</sup> If this is not occurring, the team can provide guided therapeutic sessions to ensure opportunities for expression of love, gratitude, forgiveness, and farewell.<sup>372</sup>

- **Structure of Care:** Lastly, the team should document the utilization of pediatric center resources, care coordination plans, and discharge planning.<sup>373</sup> An essential purpose of the ICPC plan is to “integrate quality palliative care into the mainstream of medical treatment of all children suffering from chronic, life-threatening, and life-limiting illnesses, regardless of the curative intent of therapy.”<sup>374</sup> As part of the ICPC model’s care coordination, the palliative service works with the family throughout the course of illness, not just during the end-of-life period.<sup>375</sup> As a result, the family and patient will experience continuity in care during the times of crisis, such as a relapse or during the final weeks of life.<sup>376</sup> Without the ICPC approach, families and patients often report feelings of abandonment during the end-of-life period, and this complicates the grief process after the patient’s death.<sup>377</sup> Under the ICPC care coordination practice, the family will have an established relationship with the palliative service when curative efforts are finally replaced by comfort measures.<sup>378</sup> Discussions with various providers will not have to be repeated as a result of poor physician communication. The patient and family will receive information from a consistent, trusted team.<sup>379</sup>

This Note recommends one additional domain designed specifically for adolescents: The Adolescent Advanced Directive or what Weiner et al. calls *How I Wish to Be Remembered*.<sup>380</sup> An advanced care planning document is important for any terminally ill patient, and there is particular need for a document designed specifically for adolescents. Based on a study conducted by physicians and researchers at the National Institutes of Health’s Pediatric Oncology and Mental Health branches, this Note recommends that adolescent patients be provided with an advance directive pre-tailored to document the specific planning concerns of adolescents. Although over 90% of the young adults surveyed by the researchers

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371. *See id.*

372. *See id.*

373. *See id.*

374. ICPC II, *supra* note 288, at 224-29 (explaining that the ethics committee promotes care coordination and is an integral partner with the palliative care service).

375. *Id.* at 234-35.

376. *Id.* at 228.

377. *Id.* at 238-39.

378. *Id.*

379. *Id.* at 239.

380. *See generally* Lori Wiener et al., *How I Wish To Be Remembered: The Use of an Advance Care Planning Document in Adolescent and Young Adult Populations*, 11 J. PALLIATIVE MED. 1309 (2008) (discussing an adolescent’s need to share personal, emotional, and spiritual wishes).

stated that the use of a directive “could be helpful” to them, the study found that the adolescents who participated in the study were dissatisfied with the advance directive most commonly used with adult patients.<sup>381</sup> Participants cited both a lack of open-ended questions and a disproportionate focus on concerns that were of a low priority to the young adult population.<sup>382</sup> Respondents did not consider, for instance, concerns about assisted living, hospice, and medical record release to be a particularly important use of the document.<sup>383</sup> Other feedback included complaints about inaccessible language.<sup>384</sup> For example, participants disliked the phrase “health care agent,” citing it to be unclear and impersonal.<sup>385</sup> The term “chosen responsible adult” was determined the best alternative among study participants.<sup>386</sup> Additionally, the respondents wanted an open-ended section that would detail who and what they wanted around them at the end-of-life, including friends, personal items, and music.<sup>387</sup> This type of structured yet flexible document will provide an excellent addition to the ICPC’s patient-centered approach when working with terminally ill adolescents.

The ICPC Model is the best preventative measure a pediatric medical center can adopt in an effort to avert conflicts amongst patients, their families, and the health care team. However, should an end-of-life conflict prove irresolvable, this Note advocates that state legislatures enact a statutory fallback provision. The following section recommends the type of legislative language best suited to resolve an adolescent end-of-life conflict.

### *B. A Proposed Statutory Solution: Use of New Mexico’s Statute*

Section 24-7A-6.1 of the New Mexico Uniform Health-Care Decisions Act is an ideal forced exit to a conflict because of its specificity and consideration of the overall illness experience. The Act reads as follows:

A. Except as otherwise provided by law, a parent or guardian of an unemancipated minor may make that minor’s health-care decisions.

B. A parent or guardian of an unemancipated minor shall have the authority to withhold or withdraw life-sustaining treatment for the unemancipated minor, subject to the provisions of this section and the standards for surrogate decision-making for adults provided for in the Uniform Health-Care Decisions Act.<sup>388</sup>

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381. *Id.* at 1311-12.

382. *Id.* at 1312-13.

383. *Id.*

384. *Id.*

385. *Id.*

386. *Id.*

387. *Id.* at 1313.

388. The Act reads as follows:



C. Subject to the provisions of Subsection B of this section, *if an unemancipated minor has capacity sufficient to understand the nature of that unemancipated minor's medical condition, the risks and benefits of treatment and the contemplated decision to withhold or withdraw life-sustaining treatment, that unemancipated minor shall have the authority to withhold or withdraw life-sustaining treatment.*

D. For purposes of Subsection C of this section, *a determination of the mental and emotional capacity of an unemancipated minor shall be determined by two qualified health-care professionals, one of whom shall be the unemancipated minor's primary physician and the other of whom shall be a physician that works with unemancipated minors of the minor's age in the ordinary course of that physician's health-care practice.* If the unemancipated minor lacks capacity due to mental illness or developmental disability, one of the qualified health-care professionals shall be a person whose training and expertise aid in the assessment of functional impairment.

E. If the unemancipated minor's primary physician has reason to believe that a parent or guardian of an unemancipated minor, including a non-custodial parent, has not been informed of a decision to withhold or withdraw life-sustaining treatment, the primary physician shall make reasonable efforts to determine if the uninformed parent or guardian has maintained substantial and continuous contact with the unemancipated minor and, if so, shall make reasonable efforts to notify that parent or guardian before implementing a

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A. The Uniform Health-Care Decisions Act does not affect the right of an individual to make health-care decisions while having capacity to do so.

B. An individual is presumed to have capacity to make a health-care decision, to give or revoke an advance health-care directive and to designate a surrogate.

C. Unless otherwise specified in a written advance health-care directive, a determination that an individual lacks or has recovered capacity or that another condition exists that affects an individual instruction or the authority of an agent shall be made by two qualified health-care professionals, one of whom shall be the primary physician. If the lack of capacity is determined to exist because of mental illness or developmental disability, one of the qualified health-care professionals shall be a person whose training and expertise aid in the assessment of functional impairment.

D. An individual shall not be determined to lack capacity solely on the basis that the individual chooses not to accept the treatment recommended by a health-care provider.

E. An individual, at any time, may challenge a determination that the individual lacks capacity by a signed writing or by personally informing a health-care provider of the challenge. A health-care provider who is informed by the individual of a challenge shall promptly communicate the fact of the challenge to the supervising health-care provider and to any health-care institution at which the individual is receiving care. Such a challenge shall prevail unless otherwise ordered by the court in a proceeding brought pursuant to the provisions of [N.M. STAT. ANN. § 24-7A-14 (West 2009)].

N.M. STAT. ANN. § 24-7A-11 (West 2009).

decision.<sup>389</sup>

This is the best language for several reasons. First, an established rule is significantly easier to apply than a common law doctrine when the issue involves important “public policy and societal concerns.”<sup>390</sup> Second, the New Mexico statute is preferable because it does not automatically require judicial intervention. As evidenced by the similarly controversial realm of adolescent abortion, many courts are reluctant to hear cases that are politically and ethically charged, and therefore may handle the cases improperly or reject the case altogether.<sup>391</sup> In a recent survey of Texas courts’ preparedness to handle the judicial bypass proceeding available to adolescent’s seeking abortion, fewer than half met the statutory criteria.<sup>392</sup> These courts did not acknowledge that their office was responsible for handling the judicial bypass procedure, nor did they disclose that a minor could have an attorney appointed for her.<sup>393</sup> Some county clerks stated that their court refused to handle anything regarding abortions.<sup>394</sup> When asked, more than two judges refused to appoint the minor an attorney, which is her right under the Texas Family Code.<sup>395</sup> Several other judges are on record as saying that they personally do not believe in abortion and will not grant a waiver for a minor.<sup>396</sup>

Although the volume of adolescent medical autonomy case law is nominal when compared to abortion-related bypass procedures, this practiced avoidance is

389. N.M. STAT. ANN. § 24-7A-6.1 (West 2009) (emphasis added).

390. *In re Rosebush*, 491 N.W.2d 633 (Mich. Ct. App. 1992) (Sawyer, J., dissenting); *see also In re Long Island Jewish Med. Ctr.*, 557 N.Y.S.2d 239, 243 (N.Y. Sup. Ct. 1990) (praising a “mature minor” doctrine); *Commonwealth v. Nixon*, 761 A.2d 1151, 1155 (Pa. 2000) (applying public policy considerations).

391. *See* Helena Silverstein & Leanne Speitel, “*Honey, I Have No Idea*”: Court Readiness To Handle Petitions To Waive Parental Consent for Abortion, 88 IOWA L. REV. 75 (2002).

392. *Id.* at 75-85.

393. Melissa Jacobs, *Are Courts Prepared To Handle Judicial Bypass Proceedings?*, 32 HUM. RTS. J. SEC. INDIVIDUAL RTS. & RESPONSIBILITIES 4, 5 (2005). The Texas Family Code requires a court to appoint an attorney *ad litem* for a minor if she has not retained one herself; the hearing and ruling must take place by 5:00 P.M. of the second business day following the application or the waiver will be deemed granted; the court must grant the minor’s request if it finds by a preponderance of the evidence that a “minor is mature and sufficiently well informed” to make the abortion decision independently, or that notification would not be in her best interest, or that notification “may lead to physical, sexual, or emotional abuse of the minor;” lastly, the court must protect the minor’s anonymity. TEX. FAM. CODE ANN. § 33.003(i)(k) (Vernon 2010).

394. *Id.* at 5.

395. *Id.* The following information was also reported: two courts stated that a guardian *ad litem* would be appointed for the fetus; one stated that the petition would not be granted unless the mother’s health was in imminent danger (although the statute creates a separate exception for emergencies); one court erroneously stated that the father of the baby had to be notified and given twenty days to respond; and multiple courts believed that minors had to prove indigence to qualify for a court-appointed attorney, even though the statute does not require a showing of financial need. *Id.*

396. *Id.*

nevertheless documented in published opinions. In one case, the court refused to acknowledge the mature minor doctrine, instead deferring the task of “taking a hard look at the mature minor doctrine for either statutory or decisional law” to the state legislature.<sup>397</sup>

The cogency and clarity of the statutory language of the New Mexico law should be the model for other state legislatures. The New Mexico statute, unique in its specificity, provides a roadmap for physicians, medical centers, and families. The statute first sets forth a rule stating that an unemancipated minor shall have the authority to withhold or withdraw life-sustaining treatment if he or she has sufficient capacity to understand the illness, the risks and benefits of treatment, and the likely consequences of the decision.<sup>398</sup> A provision of this nature is not exclusive to the law of New Mexico; other states, including Arkansas, have provisions with similar language.<sup>399</sup> However, the New Mexico legislature’s direction on how to determine said capacity is what makes this statute truly accessible to patients, families, and care teams in times of crisis.<sup>400</sup> The statute provides that emotional capacity be determined by two physicians, one of whom is the primary physician.<sup>401</sup> Because this statute is recommended as a fallback provision to the ICPC model, the treating physician will have the benefit of thoroughly understanding a patient’s maturity and comprehension of prognosis and consequences. The physician will also be aware of the decisive factors of the choice to withdraw or withhold LSMT. A determination of mental and emotional capacity must also be made by a second physician that works with similarly situated minors in the ordinary course of his practice. This incorporates necessary checks and balances that ensure the treating physician is not overburdened with this responsibility.<sup>402</sup>

Combining the ICPC Model and the statutory fallback provision is a reliable and responsible solution to the problem of adolescent patient autonomy. It affords critically ill adolescents the autonomy many of them desire and deserve. Perhaps most importantly, the combination preserves the family integrity, enhances the patient’s quality of life, and empowers patients to choose how they wish to be remembered.

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397. *In re Long Island Jewish Med. Ctr.*, 557 N.Y.S.2d 239, 243 (N.Y. Sup. Ct. 1990) (granting the relief requested because it found that the patient was not a mature minor under the circumstances, although there was much merit to the mature minor doctrine itself). The court recommended that the NY Legislature or the appellate courts take a “hard look at the mature minor doctrine and make it either statutory or decisional law.” *Id.*

398. *See* N.M. STAT. ANN. § 24-7A-6.1 (West 2009).

399. *See, e.g.*, ARK. CODE ANN. § 20-9-602(7) (West 2009) (stating that any unemancipated minor of sufficient intelligence to understand and appreciate the consequences of the proposed surgical or medical treatment or procedures may make medical decisions for himself or herself).

400. *See id.* The extremely broad Arkansas statute gives no guidance on how to determine “sufficient intelligence to understand and appreciate the consequences of the proposed surgical or medical treatment or procedures.”

401. N.M. STAT. ANN. § 24-7A-6.1 (West 2009).

402. *Id.*

## CONCLUSION

To cure sometimes, to relieve often, to comfort always – this is our work.<sup>403</sup>

- *Motto of the Palliative Care Team at St. Jude Children's Research Hospital.*

Originally developed for patients undergoing stem cell transplantation, the ICPC is ideal for patients with any illness associated with significant suffering, a high incidence of morbidity and mortality, and the need to make frequent difficult decisions in an ethical manner.<sup>404</sup> The integration of the ICPC Model with the statutory fallback provision will support teens through the no man's land of adolescent critical illness. It ensures that the adolescent patient's relationship with his or her family does not become collateral damage of the overall illness experience.

Tyler Alfriend and Michael Miller are not the exception; they are the rule. As previously noted, the family dynamic is changed when a teen is diagnosed with a critical illness, as the teen often assumes the role of emotional caregiver to his or her parents.<sup>405</sup> Establishing an integrated approach to care first requires an acknowledgement that the current assumptions regarding adolescent maturation are outdated and inaccurate. Each critically ill adolescent responds differently to illness, and the ICPC model allows the care team to see beyond the patient's age and assess maturity on an individual basis. In the case of Michael Miller, his oncologist admitted worrying that he would begin skateboarding as soon as he would leave the hospital.<sup>406</sup> Despite this concern, his care team looked beyond his love of ollies and kickflips, recognizing and respecting his maturity and positive attitude. "Michael was a joy to take care of," his physician commented. "He was well aware of everything he was missing at home . . . but he went through everything with a smile."<sup>407</sup> Understanding the personality of each patient builds a stronger physician-patient relationship, and allows the patient and family to rise above emotional set-backs.

As illustrated above, patient-tailored care will ease the heartbreak of illness, reduce conflict, and ensure that the family feels as though the patient had the best possible life and death. This Note demonstrates how legal and medical professionals can work together to establish a fluid, individualized approach to adolescent medical autonomy. The analysis proves the efficacy of the model in diverse clinical settings and that, when implemented, it will improve the lives of all pediatric patients facing life-threatening conditions and challenges. The three phases of the model are a comprehensive yet compassionate approach to advance care planning. The Relationship phase builds a center of trust between the

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403. ICPC II, *supra* note 288, at 223.

404. *Cf.* ICPC I, *supra* note 96, at 246-47.

405. *Id.* ICPC I, *supra* note 96, at 246.

406. Roll Model, *supra* note 4.

407. Roll Model, *supra* note 4.

patient, family, and physician. Each party has the responsibility to share relevant information with each other and to ensure that the patient's care team can generate a comprehensive needs assessment. The Negotiation phase allows both the patient and the parents an opportunity to voice their concerns regarding the care plan. During this phase, the team can bring in any specialist, including an ethicist, to assist in resolving any discordant step in the process. Finally, the plan's implementation ensures that the totality of the patient's needs is met by his or her care team. Through these processes, the care team will identify disagreements before they occur and attempt to mitigate and resolve any conflicts. Should a problem persist, the statutory component of the combination model permits the physician to fulfill his ethical obligations to the adolescent patient without the fear of a public judicial intervention.

Eliminating the "no man's land" of adolescent critical illness requires reducing emotional harm and bridging the gap between childhood and adulthood. This Note argues that the implementation of the ICPC protocol will enhance the adolescent patient's quality of life, reduce overall family stress, and offer an alternative to courtroom adjudication. Because the benefits of the ICPC model are so extensive, the ICPC structure should be implemented at any pediatric care center that strives to provide patient-centered care.

