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## ARTICLES

### **How a Drug Becomes “Ethnic”: Law, Commerce, and the Production of Racial Categories in Medicine**

**Jonathan Kahn, J.D., Ph.D.\***

#### INTRODUCTION

A drug called BiDil is poised to become the first pharmaceutical ever approved by the U.S. Food and Drug Administration (FDA) to treat heart failure specifically in African Americans—and only African Americans. On March 8, 2001, NitroMed, then a privately held biotech firm in Massachusetts, issued a press release triumphantly announcing the receipt of a letter from the FDA “describing the regulatory status and ultimate approvability of BiDil®,” pending the successful completion of a confirmatory trial of the drug in African Americans with heart failure.<sup>1</sup> Press reports have already touted this breakthrough as the first “ethnic” drug to treat heart failure.<sup>2</sup>

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\* Research Scholar, Center for Bioethics, University of Minnesota. I would like to thank Rene Bowser, Susan Craddock, Lennard Davis, Ray DeVries, Troy Duster, Carl Elliott, Stephen Epstein, Evelyn Hammonds, Jeff Kahn, Jay Kaufmann, Steve Miles, Michael Montoya, Jackson Mugerwa, John Robertson, Michael Root, John Song, and Karen-Sue Taussig for their helpful comments and suggestions.

1. Press Release, NitroMed, Inc., NitroMed Receives FDA Letter on BiDil® NDA, a Treatment for Heart Failure in Black Patients (Mar. 8, 2001), <http://www.nitromed.com/newsindex.html> (last visited Dec. 7, 2003).

2. See, e.g., Victoria Griffith, *FDA Paves the Way for First ‘Ethnic’ Drug*, FIN. TIMES, Mar. 8, 2001, at 13; *This Heart Drug Is Designed for African Americans*, BUS. WK., Mar. 26, 2001, at 71; Eliot Marshall, *Trial for “Ethnic” Therapy*, SCI. NOW, Mar. 26, 2001, at 2, at

NitroMed framed its announcement with a striking statistic: “[D]eath rates from heart failure are more than twice as high in black patients than in white patients.”<sup>3</sup> It heralded BiDil as presenting an opportunity to address “the disparity in outcomes for African American heart failure patients.”<sup>4</sup> NitroMed posited that the disparity might be due to “a pathophysiology found primarily in black patients that may involve nitric oxide (NO) insufficiency.”<sup>5</sup> A follow-up press release reiterated both the 2:1 statistic and the proposition that “observed racial disparities in mortality and therapeutic response rates in black heart failure patients may be due in part to ethnic differences in the underlying pathophysiology of heart failure.”<sup>6</sup>

Since NitroMed’s initial announcement, BiDil has emerged as a central player in ongoing debates over whether and how to use race and ethnicity as categories in biomedical research. It has also played a

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<http://sciencenow.sciencemag.org/cgi/content/full/2001/326/2> (last visited Dec. 17, 2003); Geraldine Sealey, *Race and the Heart: 1st Drug Developed for Black Heart Failure Patients*, ABCNEWS.COM (Mar. 21, 2003), at <http://abcnews.go.com/sections/living/DailyNews/bidil010321.html> (last visited Dec. 17, 2003).

I use terms for “ethnicity” and “race” interchangeably in this paper, primarily because that is how the main actors in the story use them. In scholarly literature on the subject, there is much discussion about the differences between “race” and “ethnicity.” Yet, even those who try to articulate more refined definitions of the two often end up defining each in terms of the other. For example, *Nature Genetics*, in a very well-meaning editorial requiring authors to explain how and why they use racial categories in science, provided as one of several definitions of race: “A distinct *ethnic* group characterized by traits that are transmitted through their offspring.” *Census, Race and Science*, 24 NATURE GENETICS 97 (2000) (emphasis added). It then provided as one of several definitions of ethnic groups: “A social group or category of the population that, in a larger society, is set apart and bound together by common ties of *race*, language, nationality or culture.” *Id.* (emphasis added). This confusion evidences a need to pay much greater attention to how and why these terms are used in various contexts and what purported meanings get attached to or elided by them. In this Article, I primarily use the term “race,” but I also employ the terms “ethnic” and “ethnicity.”

3. Press Release, NitroMed, Inc., *supra* note 1.

4. *Id.*

5. *Id.*

6. Press Release, NitroMed, Inc., NitroMed Initiates Confirmatory BiDil® Trial in African American Heart Failure Patients (Mar. 17, 2001), <http://www.nitromed.com/newsindex.html> (last visited Dec. 7, 2003). The 2:1 ratio was reiterated by the principal investigator of the African American Heart Failure Trial (A-HeFT). *Id.*



significant role at the forefront of broader political and legal discussions of the legitimacy of identifying and acting upon perceived biological or genetic differences among the races. This is hardly surprising, given NitroMed’s own emphasis on “ethnic differences in the underlying pathophysiology of heart failure.”<sup>7</sup> More surprising, however, is the lack of attention paid to just how BiDil became ethnic. Claims couched in scientific rhetoric and supported by the imprimatur of peer-reviewed journals are frequently afforded deference, and BiDil is no exception. Both the general news media and a number of science and medical journals have covered BiDil extensively without any substantial effort to investigate the claims made in press releases and medical reports.<sup>8</sup> The story they tell is of the path-breaking development of a new therapy for heart failure to help an underserved racial population.

However, when one investigates the origins and development of BiDil, a different and far more complex story emerges. At the most basic level, it turns out that BiDil became an ethnic drug through the interventions of law and commerce as much as through medical understanding of biological differences that correlate with racial groups. This part of the story has been masked both by well-meaning concerns about perceived health disparities and by an imprudent reliance on erroneous or incomplete statistical data.

This Article is first a retrospective analysis of how law, commerce, science, and medicine interacted to produce a distinctive understanding of BiDil as an ethnic drug, shaping which questions were asked at critical junctures in its development and orienting how they were pursued. Second, it is a prospective consideration of how the science and medicine thus produced may come to affect legal and commercial understandings of the significance of race in relation to biology. All of this unfolds against the backdrop of ongoing struggles over the legal, political, and biomedical status of race as a category for mobilizing resources and making claims in society.

Part I of this Article presents the context of current debates over the relation of racial to biological categories, particularly in the context of identifying and addressing health disparities. Part II presents the case for BiDil as made by its promoters. Their claims are built around assertions of differential rates of heart failure among blacks and whites, observed differences in average levels of nitric oxide in blacks and whites, and hypothesized underlying genetic differences between blacks and whites

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7. *Id.*

8. *See, e.g., infra* notes 17, 102 and accompany text.

that may account for such inter-race variation. These are the claims that framed NitroMed's approach to the FDA for approval of the race-based trial. Part III deconstructs the case for BiDil by going back to its origins in the late 1970s and early 1980s and exploring the story of how it became ethnic. BiDil was born in the early 1980s as a drug for everyone, with no ethnic marking. The primary forces driving the re-invention of BiDil as an ethnic drug, I argue, were legal and commercial, rather than biomedical. Part IV considers some of the implications of this story for the development of social policies to redress health disparities, and explores the broader legal and political ramifications it may hold for the status of racial groups in society. This last Part is animated by a concern that various interventions of the federal legal and regulatory apparatus in BiDil's journey toward ethnicity may be leading the federal government improperly to endorse the use of race as a biological category in classifying its citizenry. Finally Part V offers recommendations, including that the federal government must develop guidelines that will help its administrative agencies to distinguish the use of race as a socio-political category to redress historical inequities and social prejudice from the use of race as a purportedly biological category. These guidelines will be important for ensuring the appropriate development and marketing of new biomedical products and services.

### I. RACE, BIOLOGY, AND HEALTH DISPARITIES

The medical literature is replete with examples of health disparities that correlate with social categories of race.<sup>9</sup> The federal government has devoted considerable resources to identifying and redressing health disparities that correlate with race and/or socio-economic status. In 1985, the U.S. Department of Health and Human Services created an Office of Minority Health (OMH) "to improve and protect the health of racial and ethnic populations through the development of effective health policies and programs that will eliminate disparities in health."<sup>10</sup> OMH also monitors efforts to achieve the goals of *Healthy People 2010*, a federal

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9. See, e.g., U.S. DEP'T OF HEALTH & HUMAN SERVS., *HEALTHY PEOPLE 2010: UNDERSTANDING AND IMPROVING HEALTH* (2d ed. 2000), *available at* <http://www.healthypeople.gov/Document/tableofcontents.htm#under> (last visited Dec. 27, 2003). Such disparities involve not only prevalence of disease, but also quality of care. See, e.g., INST. OF MED., *UNEQUAL TREATMENT: CONFRONTING RACIAL AND ETHNIC DISPARITIES IN HEALTH CARE* (2002).

10. U.S. DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF MINORITY HEALTH, ABOUT OMH, *at* <http://www.omhrc.gov/OMH/sidebar/aboutOMH.htm> (last visited Dec. 19, 2003).

initiative that has a special focus on eliminating racial and ethnic disparities in health.<sup>11</sup>

The federal government has also played a primary role in driving the recent revolution in genomics through its multi-billion-dollar support of the Human Genome Project. One great hope of the project is to develop knowledge about gene structure and function that will “lead to revolutionary new ways to diagnose, treat, and someday prevent the thousands of disorders that affect us.”<sup>12</sup> The encounter between new genetic knowledge and efforts to identify and redress health disparities has generated heated debates over whether and how to use social categories of race in biomedical research.<sup>13</sup>

Since Richard Lewontin’s ground-breaking work on blood group polymorphisms in different groups and races in the 1970s,<sup>14</sup> scientists have understood that race will statistically explain only a small portion of genetic variations. As a recent editorial in *Nature Genetics* put it, “scientists have long been saying that at the genetic level there is more variation between two individuals in the same population than between populations and that there is no biological basis for ‘race.’”<sup>15</sup> Yet, current research bearing on the efficacy of BiDil casts heart failure in African Americans as a “different disease” that may have an underlying basis in genetic differences.<sup>16</sup> Popular accounts of the drug invariably mention the 2:1 mortality statistic and often echo the understanding that it reflects an underlying biological difference among the races.<sup>17</sup> Interestingly, press

11. See *id.*; U.S. Dep’t of Health & Human Servs., Healthy People 2010, at <http://www.healthypeople.gov/> (last visited Dec. 27, 2003).

12. U.S. DEP’T OF ENERGY, HUMAN GENOME PROGRAM, ABOUT THE HUMAN GENOME PROJECT, at <http://www.ornl.gov/hgmis/project/about.html> (last visited Dec. 7, 2003).

13. The literature on this topic is immense. For a good overview, see Sandra S. Lee et al., *The Meanings of ‘Race’ in the New Genomics: Implications for Health Disparities Research*, 1 YALE J. HEALTH POL’Y L. & ETHICS 33.

14. Richard C. Lewontin, *The Apportionment of Human Diversity*, 6 EVOLUTIONARY BIOLOGY 381 (1972).

15. *Genes, Drugs and Race*, 29 NATURE GENETICS 239, 239 (2001).

16. See Clyde W. Yancy, *The Role of Race in Heart Failure Therapy*, 4 CURRENT CARDIOLOGY REP. 218 (2002) [hereinafter Yancy, *Role of Race*]; see also Clyde W. Yancy, *Heart Failure in Blacks: Etiological and Epidemiological Differences*, 3 CURRENT CARDIOLOGY REP. 191 (2001); Clyde W. Yancy, Editorial, *Heart Failure in African Americans: A Cardiovascular Enigma*, 6 J. CARDIAC FAILURE 183 (2000) [hereinafter Yancy, *Cardiovascular Enigma*].

17. Major media outlets reporting on BiDil include the *New York Times*, *Wall Street Journal*, *Financial Times*, *Business Week*, the BBC and ABC News. See, e.g., Griffith, *supra* note 2; Sheryl Gay Stolberg, *Skin Deep: Shouldn’t a Pill Be Colorblind?*, N.Y. TIMES, May 13, 2001, at

accounts targeted primarily at African American audiences tend to share this view. For example, *Black Issues in Higher Education* approvingly quotes Dr. Clyde Yancy, a cardiologist from the University of Texas, Southwestern Medical Center in Dallas and a co-investigator in BiDil's confirmatory trial, who refers to the likelihood that there is a genetic basis for differential rates of heart failure between blacks and whites.<sup>18</sup> Similarly, the *Chicago Defender's* report on the "slight genetic differences" presumed to underlie such therapies as BiDil declares that "studies in this new century of astounding scientific advancement show that some diseases differ among races."<sup>19</sup>

On the one hand, the identification of health disparities with genetic variations may lead to the development of innovative new therapies of the

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4-1; Rachel Zimmerman, *Pair of Genes Is Said To Increase Risk of Heart Failure in Blacks*, WALL ST. J., Oct. 10, 2002, at D2; *This Heart Drug Is Designed for African Americans*, *supra* note 2; *Heart Drug Targets Black Patients*, BBC NEWS, Apr. 6, 2001, <http://news.bbc.co.uk/1/hi/health/1262093.stm> (last visited Nov. 5, 2003); Sealey, *supra* note 2. Many local and regional newspapers and television stations have also reported on the drug, as have numerous professional journals and newsletters. See, e.g., Editorial Board, *Trial for 'Ethnic' Drug*, 291 SCIENCE 2547 (2001); *First Clinical Heart Failure Study Exclusively for Blacks Conducted*, L.A. SENTINEL, Apr. 11, 2001, at A12; Ricki Lewis, *Race and the Clinic: Good Science?*, THE SCIENTIST, Feb. 18, 2002, at 16; Jessica Pasley, *Heart Study Examines Ethnicity Factors To Treat Disease*, THE REPORTER, March 15, 2002, <http://www.mc.vanderbilt.edu/reporter/?ID=1990> (last visited Jan. 5, 2004); Sharon Schmickle, *Under the Skin, We're All Alike - Except Medically*, Science Says, MINNEAPOLIS STAR-TRIBUNE, March 26, 2002, available at [http://health.csuohio.edu/healthculture/news/fulltext/st3\\_26\\_02.txt](http://health.csuohio.edu/healthculture/news/fulltext/st3_26_02.txt) (last visited Jan. 5, 2004); Press Release, University of Texas Southwestern Medical Center at Dallas, *Disparities in Black Americans' Responses to Heart-Failure Therapies May Signal 'Different Disease'* (May 13, 2002), [http://irweb.swmed.edu/newspub/newsdetl.asp?story\\_id=409](http://irweb.swmed.edu/newspub/newsdetl.asp?story_id=409) (last visited Jan. 5, 2004); *Clinical Trial To Look at Effectiveness of Heart Failure Medication in African-Americans*, Methodist Health Care System, at <http://www.methodisthealth.com/news/heart/april2001/index.htm> (Apr. 2001); *Congestive Heart Failure*, Heart-Help.net, at <http://www.heart-help.net/chfnew.html> (last visited Jan. 5, 2004); Victoria Stagg Elliott, *FDA May Approve New Heart Drug for Blacks*, Amednews.com, at <http://www.ama-assn.org/amednews/2001/03/26/hlsc0326.htm> (March 26, 2001).

18. *Noteworthy News: Heart Failure in Blacks May Signal 'Different Disease'*, BLACK ISSUES HIGHER EDUC., June 20, 2002, at 26, available at [http://www.findarticles.com/cf\\_dls/m0DXK/9\\_19/89077189/p1/article.jhtml](http://www.findarticles.com/cf_dls/m0DXK/9_19/89077189/p1/article.jhtml) (last visited Dec. 19, 2003).

19. *Slight Genetic Differences Justify Innovative Medical Treatment*, CHI. DEFENDER, May 1, 2001, at 9.

sort envisioned by the Human Genome Project and help to address significant health problems that disproportionately affect minority communities in the United States. On the other hand, linking genetic variation to racial groups may also contribute to what anthropologist Alan Goodman has noted as a “comeback” in “racialized notions of biology.”<sup>20</sup> Given our nation’s long and troubled history of mistreatment and oppression of racial groups based on (mis)understandings of biological difference—not least in the area of medical research<sup>21</sup>—such a “comeback” should give us pause. Additionally, as genetic explanations come to dominate discussions of health disparities, they could well lead to a reallocation of scarce resources away from addressing the larger social, economic, and political causes of such disparities. The appeal of taking a predominantly biomedical approach to addressing health disparities is undeniable—instead of fixing social inequality you simply fix molecules.

## II. THE CASE FOR BiDIL

Congestive heart failure<sup>22</sup> is a debilitating chronic disease that affects an estimated five million Americans, with approximately 400,000 to 700,000 new cases each year.<sup>23</sup> NitroMed currently estimates that there are approximately 750,000 African Americans who have been diagnosed with heart failure.<sup>24</sup> One recent estimate placed the direct health care costs of

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20. Alan H. Goodman, *Why Genes Don’t Count (for Racial Differences in Health)*, 90 AM. J. PUB. HEALTH, 1699, 1699 (2000).

21. See, e.g., TROY DUSTER, *BACKDOOR TO EUGENICS* (1990); JAMES H. JONES, *BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT – A TRAGEDY OF RACE AND MEDICINE* (1981); DANIEL J. KEVLES, *IN THE NAME OF EUGENICS* (1995).

22. The terms “congestive heart failure” (CHF) and “heart failure” (HF) are often used interchangeably, although technically the former is a subset of the latter. Nonetheless, CHF mortality comprises the vast majority of all HF mortality. BiDil is specified for the treatment of CHF.

23. Mardi Gomberg-Maitland et al., *Treatment of Congestive Heart Failure*, 161 ARCHIVES INTERNAL MED. 342 (2001). The data on prevalence are drawn from the National Health and Nutrition Examination Survey (NHANES III), which was taken between 1988 and 1993. See NAT’L HEART, LUNG & BLOOD INST., DATA FACT SHEET: CONGESTIVE HEART FAILURE IN THE UNITED STATES: A NEW EPIDEMIC, <http://www.nhlbi.nih.gov/health/public/heart/other/CHF.htm> (last visited Nov. 5, 2003).

24. NitroMed, Inc., SEC Filing, Form S-1/A, Registration No. 333-108104, at 2, (Oct. 2, 2003), <http://www.sec.gov/Archives/edgar/data/927829/000104746903032333/a2119126zs-1a.htm> (last visited Dec. 7, 2003).

treating heart failure at between twenty and forty billion dollars annually.<sup>25</sup> It is a complex condition and sometimes difficult to diagnose. Symptoms can include fatigue, weight gain, swollen legs or ankles, difficulty breathing, and a hacking cough, but in some cases the condition is asymptomatic. Unlike a heart attack, heart failure does not involve an immediate cessation of heart function but rather occurs when the heart functions improperly due to weakening by disease or defect. It is a progressive and ultimately fatal condition, with one in five persons dying within five years of onset.<sup>26</sup> Current guidelines specify that "most patients with heart failure should be routinely managed with a combination of four types of drugs: an angiotensin-converting enzyme (ACE) inhibitor, a beta-adrenergic blocker, a diuretic, and (usually) digitalis."<sup>27</sup> Adjunctive therapies, namely angiotensin II receptor blockers and spironolactone, have extended the therapeutic options within this scheme.<sup>28</sup>

BiDil belongs to none of these categories. It is a combination of two potent vasodilators—hydralazine and isosorbide dinitrate (H/I). By dilating blood vessels, vasodilators ease the strain put on the heart in pumping blood. BiDil is also believed to increase levels of nitric oxide in the blood, which is generally thought to be beneficial for many individuals suffering from heart failure.<sup>29</sup>

Advocates of BiDil point to the widely cited statistic (featured so prominently in NitroMed's press releases) that African Americans die from heart failure at a rate twice that of white Americans.<sup>30</sup> They connect current

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25. Milton Packer & Jay N. Cohn, *Consensus Recommendations for the Management of Chronic Heart Failure*, AM. J. CARDIOLOGY, Jan. 21, 1999, at 1A.

26. NAT'L HEART, LUNG & BLOOD INST., *supra* note 23.

27. See, e.g., AM. COLL. OF CARDIOLOGY & AM. HEART ASS'N, ACC/AHA GUIDELINES FOR THE EVALUATION AND MANAGEMENT OF CHRONIC HEART FAILURE IN THE ADULT (2001), available at <http://www.americanheart.org/presenter.jhtml?identifier=11841> (last visited Nov. 5, 2003); Packer & Cohn, *supra* note 25. Digitalis is the traditional prototype of a class of drugs known as cardiac glycosides.

28. See, e.g., AM. COLL. OF CARDIOLOGY & AM. HEART ASS'N., *supra* note 27; Packer & Cohn, *supra* note 25.

29. See Joseph A. Franciosa et al., *African-American Heart Failure Trial (A-HeFT): Rationale, Design, and Methodology*, 8 J. CARDIAC FAILURE 128, 129 (2002); see also NitroMed, BiDil® Backgrounder: Heart Failure, at <http://www.nitromed.com/bildil/DOCS/heartfailure.html> (last visited Dec. 31, 2003).

30. See, e.g., Franciosa et al., *supra* note 29 (involving numerous cardiologists); see also Press Release, NitroMed, Inc., NitroMed and Merck Form Strategic Collaboration (Jan. 7, 2003), <http://www.nitromed.com/newsindex.html> (last visited Jan. 4, 2004); Press Release, NitroMed, Inc., *supra* note 7; Press Release, NitroMed, Inc., *supra* note 1.

research indicating the importance of nitric oxide in preventing heart failure to other research suggesting that blacks seems to have lower levels of nitric oxide in their blood.<sup>31</sup> They argue that the unique combination of drugs in BiDil may be particularly efficacious in black patients because one of BiDil’s components, isosorbide dinitrate, is a nitric oxide “donor” and its other component, hydralazine, is an anti-oxidant which may enhance the efficacy of nitrates.<sup>32</sup>

NitroMed’s race-based trial—known as A-HeFT, the African American Heart Failure Trial—is currently underway. It was originally expected to be completed sometime late in 2003 but subsequent estimates by investigators suggest that enrollment will not be completed until sometime in 2004,<sup>33</sup> and recent statements by NitroMed contemplate that A-HeFT will not be completed until early 2005.<sup>34</sup>

A-HeFT cardiologist Clyde Yancy has argued that heart failure in blacks is a “different disease.”<sup>35</sup> Analyzing data published from the Studies of Left Ventricular Dysfunction (SOLVD) trials (examining racial differences in the natural history of left ventricular dysfunction), he asserted that socio-economic factors could not account for the difference in mortality rates between African Americans and white Americans.<sup>36</sup> According to Yancy, “all too frequently, there is an eagerness to impugn psychosocial factors, commonly known as socioeconomic status (SES), as the major explanation for any observed differences in cardiovascular disease seen in blacks.”<sup>37</sup> As evidence he pointed to a retrospective multivariate analysis of the SOLVD data controlled for educational level and “a history of financial distress.”<sup>38</sup> Even controlling for these socio-economic factors the data still show a higher mortality rate in blacks. Yancy concluded that this observation “seemingly supports the concept that physiologic explanations for disease expression might be present in this patient population.”<sup>39</sup> This led Yancy to hypothesize that there is ultimately a basic genetic difference in blacks that accounts for the “unique

31. See, e.g., Franciosa et al., *supra* note 29.

32. See *id.* at 129.

33. See Clyde W. Yancy, *Does Race Matter in Heart Failure?*, 146 AM. HEART J. 203, 205 (2003).

34. See, e.g., NitroMed, Inc., SEC Filing, *supra* note 24, at 11.

35. See, e.g., Yancy, *Role of Race*, *supra* note 16; Clyde W. Yancy, *Treatment of Heart Failure in African Americans: Clinical Update*, 12 ETHNICITY & DISEASE S19, S25 (2002).

36. Yancy, *Role of Race*, *supra* note 16, at 218.

37. *Id.*

38. *Id.*

39. *Id.*

epidemiology, worse prognosis, and potential variances in responses to pharmacological interventions in heart failure.”<sup>40</sup> The focus on locating differences at the molecular level is logically connected to the related search for a treatment that appears to work differentially well in blacks at this same level—hence BiDil. Further driving the case for BiDil are arguments made by some cardiologists that ACE inhibitors are less efficacious in black patients than in whites. Most prominent among these is a study published in 2001 in the *New England Journal of Medicine* that compared how blacks and whites responded to ACE inhibitor therapy.<sup>41</sup> While making no claims as to mortality rates, the study found ACE inhibitor therapy to be associated with a significant reduction in risk of hospitalization for white patients, but not for black patients.<sup>42</sup> The authors argued that “on the basis of available physiological, pharmacologic, and clinical data, it seems appropriate to consider current therapeutic recommendations [concerning ACE inhibitors] as applying to white patients but not necessarily to black patients.”<sup>43</sup>

Subsequent reporting on BiDil in major media—from the *Financial Times*<sup>44</sup> and *Business Week*<sup>45</sup> to ABC News<sup>46</sup> and the BBC<sup>47</sup>—has scrupulously noted the differential response to ACE therapy between blacks and whites. NitroMed’s own website refers to such research, noting that the package insert for the ACE inhibitor enalapril states that “black patients receiving ACE inhibitors have been reported to have a higher incidence of angioedema compared to non-blacks.”<sup>48</sup>

Dr. Jay Cohn, a cardiologist at the University of Minnesota and a co-

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40. *Id.* Yancy does provide a caveat that “race is an arbitrary social/political designation, and is pertinent as a crude marker of genetic variations only because of reproductive isolation within any given race.” *Id.* at 224. Yet this comes only after an extensive discussion of what he characterizes as “an emerging database of potentially important genetic variations that may explain” differences between black and white patients in heart failure. *Id.* at 224.

41. Derek V. Exner et al., *Lesser Response to Angiotensin-Converting-Enzyme Inhibitor Therapy in Black as Compared with White Patients with Left Ventricular Dysfunction*, 344 NEW ENG. J. MED. 1351 (2001).

42. *Id.* at 1355.

43. *Id.* at 1357.

44. Griffith, *supra* note 2.

45. *This Heart Drug is Designed for African Americans*, *supra* note 2, at 71.

46. Sealey, *supra* note 2.

47. *Heart Drug Targets Black Patients*, *supra* note 17.

48. NitroMed, BiDil® and the African American Heart Failure Trial (A-HeFT), at <http://www.nitromed.com/bildil/DOCS/background.html> (last visited Dec. 7, 2003).



author of the ACE inhibitor study, has followed up by arguing for a "unique strategy" for treatment of heart failure in African Americans.<sup>49</sup> Cohn contrasts results from previous heart failure trials indicating that blacks do not respond as well as whites to ACE inhibitors with results for BiDil<sup>50</sup>—he argues BiDil actually provides a greater benefit to blacks than to whites.<sup>51</sup>

The dual message is clear: ACE inhibitors do not work as well in blacks; BiDil works better in blacks. The case for BiDil can thus be roughly summarized as follows: 1) blacks die from heart failure at a rate twice that of whites; 2) given this great disparity it seems that there must be some underlying biological or genetic (as opposed to "merely" social or environmental) factor accounting for the difference; 3) supporting this hypothesis are studies that control for socioeconomic factors and still show racial differentials in outcome; 4) moreover, additional studies indicate that blacks do not respond as well as whites to certain front line heart failure therapies; 5) therefore, a response is called for that addresses this different biology; 6) enter BiDil, a pharmaceutical response to the statistical disparity that appears to have a differentially beneficial effect on blacks at the molecular level.<sup>52</sup>

### III. DECONSTRUCTING THE CASE FOR BiDIL

#### A. BiDil's Origins

How did we get to this point? If we go back to its origins, we find that BiDil did not begin as an ethnic drug. Rather it became ethnic over time and through a complex array of legal, commercial, and medical circumstances that transformed the drug's identity.<sup>53</sup>

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49. Jay N. Cohn, *Contemporary Treatment of Heart Failure: Is there Adequate Evidence to Support a Unique Strategy for African-Americans? Pro Position*, 4 CURRENT HYPERTENSIONS REP. 307, 307 (2002). Cohn co-authored the study by Exner et al., *supra* note 41.

50. Cohn, *supra* note 49. Cohn notes that previous heart failure trials also show that blacks do not respond as well as whites to angiotensin II receptor blockers and to at least one beta blocker. *Id.*

51. See Peter Carson et al., *Racial Differences in Response to Therapy for Heart Failure: Analysis of the Vasodilator-Heart Failure Trials*, 5 J. CARDIAC FAILURE 178 (1999); see also *infra* Part III.B.

52. This logic is made quite clear in NitroMed's own statement on BiDil. See NitroMed, *supra* note 48.

53. To paraphrase Shakespeare, some drugs may be born ethnic, some may achieve ethnicity, but BiDil had ethnicity thrust upon it. Cf. WILLIAM SHAKESPEARE, TWELFTH NIGHT,

Over the past twenty years a revolution has occurred in heart failure treatment with the development of a wide array of pharmaceutical interventions that improve both the quality of life and the longevity of people suffering from heart failure. One of the earliest breakthroughs came in the 1980s with the first Vasodilator Heart Failure Trial (V-HeFT I). This trial lasted from 1980 to 1985 and involved cardiologists from around the country working together with the U.S. Veterans Administration. It took patients who were already on a background regimen of digoxin and a diuretic and randomized them into three groups, one receiving a placebo, one receiving an alpha adrenergic blocker called prazosin, and one receiving a combination of hydralazine and isosorbide dinitrate (H/I)—the two drugs which comprise BiDil. The V-HeFT investigators found that prazosin proved no better than the placebo in reducing mortality. Their results indicated, however, that the H/I combination seemed to have a beneficial impact on mortality, though the difference was only of “borderline statistical significance.”<sup>54</sup>

The V-HeFT I trial was soon followed by V-HeFT II, which lasted from 1986 to 1991. This trial compared the efficacy of the H/I combination against the drug enalapril, an ACE inhibitor. It found an even more pronounced beneficial effect on mortality in the enalapril group, establishing ACE inhibitors as a front line therapy for heart failure.<sup>55</sup> ACE inhibitors, however, have not totally supplanted H/I because not everyone responds well to them and some cannot tolerate the side effects. One news report estimated that twenty to thirty percent of congestive heart failure patients do not respond favorably to standard therapies of “diuretics,

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act 2, sc. 5 (“Some are born great; Some achieve greatness; And some have greatness thrust upon ‘em.”).

54. Jay N. Cohn et al., *Effect of Vasodilator Therapy on Mortality in Chronic Congestive Heart Failure: Results of a Veterans Administration Cooperative Study*, 314 NEW ENG. J. MED. 1547, 1547 (1986).

At the time, it was believed that this beneficial impact was due to a distinctive hemodynamic effect produced by the H/I combination. However, since no other vasodilator regimen has had a similar effect, it is now believed that the combination may have a distinctive effect on levels of nitric oxide (NO) in the blood. NO is believed to help protect against damage to the heart that may result in heart failure. See, e.g., AM. COLL. OF CARDIOLOGY & AM. HEART ASS’N, *supra* note 27; Packer & Cohn, *supra* note 25; W. J. Paulus et al., *Nitric Oxide and Cardiac Contractility in Human Heart Failure: Time for Reappraisal*, 104 CIRCULATION 2260 (2001).

55. Jay N. Cohn et al., *A Comparison of Enalapril with Hydralazine-Isosorbide Dinitrate in the Treatment of Chronic Congestive Heart Failure*, 325 NEW ENG. J. MED. 303 (1991).

digitalis or ACE inhibitors . . . particularly ACE inhibitors."<sup>56</sup> Given current estimates that nearly five million Americans suffer from heart failure, that group potentially represents 1.5 million patients annually. Current guidelines still recommend considering the use of H/I for these patients.<sup>57</sup>

The V-HeFT investigators did not build the trials around ethnicity. They enrolled both black and white patients, and in the published reports of the trials' successes they did not break down the data by race. Rather, they presented H/I—BiDil's components—as generally efficacious in the population at large, without regard to race.<sup>58</sup> In 1987, one year after the results of V-HeFT I were published, Dr. Jay Cohn, one of the trials' principal investigating cardiologists, applied for a patent on a "method of reducing mortality associated with congestive heart failure using hydralazine and isosorbide dinitrate."<sup>59</sup> The U.S. Patent and Trademark Office issued the patent to Cohn in 1989.<sup>60</sup> Referring to V-HeFT I and II in the patent description, Cohn asserted that is had been "surprisingly and unexpectedly discovered that . . . a combination of hydralazine hydrochloride and isosorbide dinitrate has been [found] to substantially and significantly reduce the incidence of mortality in [congestive heart failure] patients."<sup>61</sup> Cohn's patent application did not mention race. He clearly conceived of this as a method to treat all people suffering from heart failure.

Hydralazine and isosorbide dinitrate are generic drugs. Cohn and others later combined them into a single pill for easier administration. In 1992, a trademark application was filed for this new pill as BiDil®. The mark was formally registered in 1995 to Medco Research, Inc.,<sup>62</sup> a biotech

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56. *Boehringer Mannheim Pharmaceuticals Corporation to Market New Medco Heart Drug*, PR NEWswire, Nov. 9, 1993.

57. *See, e.g.*, AM. COLL. OF CARDIOLOGY & AM. HEART ASS'N, *supra* note 27; Packer & Cohn, *supra* note 25.

58. The reports were numerous, bearing on a variety of characteristics measured in the trials. It appears that none of these reports disaggregated the data by race until 1999 with the publication of Peter Carson et al., *supra* note 51.

59. U.S. Patent No. 4,868,179 (issued Sept. 19, 1989), <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=/netahtml/srchnum.htm&r=1&f=G&l=50&s1=4,868,179.WKU.&OS=PN/4,868,179&RS=PN/4,868,179> (last visited Dec. 13, 2003).

60. *Id.*

61. *Id.*

62. U.S. Trademark Registration No. 1896747 (registered May 30, 1995), <http://tess2.uspto.gov/bin/showfield?f=doc&state=an6u36.2.1> (last visited Dec. 13, 2003).

corporation in North Carolina's Research Triangle, which had earlier acquired the intellectual property rights to BiDil from Cohn. One report from 1997 estimated a potential market of up to sixty million dollars in annual sales for BiDil.<sup>63</sup>

By 1994, Medco had begun clinical testing of BiDil to establish its bioavailability and bioequivalence to the coadministration of the two H/I drugs separately—a critical precursor to approaching the Food and Drug Administration with a New Drug Application (NDA) to get approval for marketing BiDil.<sup>64</sup> By 1996, the completed study found BiDil to be bioequivalent, and Medco prepared to approach the FDA with its NDA. Jay Cohn noted at the time that “the BiDil® formulation represents a very convenient dosage form that, once approved [by the FDA], should lead to increased usage of this effective therapy.”<sup>65</sup> Later that year, Medco submitted an NDA to the FDA.<sup>66</sup> The following February, the Cardiovascular and Renal Drugs Advisory Committee of the FDA's Center for Drug Evaluation and Research held a meeting to consider Medco's BiDil application. Medco sent Cohn and three other representatives to the meeting to make the case for BiDil.

Cohn recommended approval of BiDil for congestive heart failure “on the basis of a survival benefit in V-HeFT I and trends for increased exercise tolerance and long-term ejection fraction in both trials.”<sup>67</sup> Ultimately, however, the Advisory Committee voted against approving BiDil.<sup>68</sup> The next day, Medco's stock plunged by twenty-five percent.<sup>69</sup>

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63. *Should've Asked for a Second Opinion (Medco Research Inc.'s Research on Drug BiDil Rejected by FDA)*, BUS. N.C., July 1997, at 14; see also *FDA Panel Rejects Medco's CHF Drug on Mortality Stats*, MED. INDUSTRY TODAY, Feb. 28, 1997 (noting an estimated total “cardiovascular market” at four billion dollars and a total market for BiDil at between twenty-five and sixty million dollars).

64. *Medco's New BiDil® Heart Failure Drug Formulation Begins Human Bioequivalence Testing*, PR NEWswire, Nov. 7, 1994.

65. *Medco Research Finds BiDil® Bioequivalent and Re-Acquires Rights from Boehringer-Mannheim Pharmaceuticals Plans to Submit NDA*, PR NEWswire, Apr. 2, 1996.

66. *Medco Research Files NDA for BiDil®*, PR NEWswire, July 3, 1996.

67. CTR. FOR DRUG EVALUATION & RESEARCH, CARDIOVASCULAR & RENAL DRUGS ADVISORY COMM., MINUTES FROM THE 80<sup>TH</sup> MEETING OF THE FOOD AND DRUG ADMIN. 2 (Feb. 27-28, 1997), [http://www.fda.gov/cder/foi/adcomm/97/cardac\\_022797\\_summin\\_agen\\_quest.pdf](http://www.fda.gov/cder/foi/adcomm/97/cardac_022797_summin_agen_quest.pdf) (last visited Oct. 11, 2003) [hereinafter MINUTES].

68. *Id.* at 3. Among other findings against BiDil, the Advisory Committee recommended unanimously that “there was no statistically significant effect on mortality for V-HeFT I.” *Id.* at 2.

69. *Medco Drug Hits FDA Wall*, TRIANGLE BUS. J., Feb. 27, 1997, available at

The Advisory Committee’s recommendation appeared to fly in the face of the extensive findings published in highly respected peer-reviewed journals that seemed to support Cohn’s confident patent application claim that the H/I combination “substantially and significantly reduced the incidence of mortality”<sup>70</sup> in congestive heart failure patients. Moreover, as Cohn emphasized before the committee, the American Heart Association, the American College of Cardiology, and the World Health Organization had all included H/I as a recommended therapy for patients who did not tolerate ACE inhibitors.<sup>71</sup>

Why was the extensive data from V-HeFT I and II inadequate? Cohn himself provided part of the answer, urging the committee to recall the age and the context of the study.

[K]eep in mind that this is a study designed 20 years ago. This was a VA cooperative study. This was not designed really as a regulatory study so that careful selection of criteria for endpoint were not as precise as one would see in a protocol designed today with the goal to come to this committee and ask for approval. So, one has to look at this a little differently than one might at a more recently organized mega-trial in which p values are clearly defined as the goals for the trial.<sup>72</sup>

The Advisory Committee agreed with Cohn as to the shortcomings of the dated study, but did not follow his suggestion that they look at its data “a little differently.” Instead, the committee followed the recommendations of their biostatisticians who found that “there were too many variables specified in the protocols as primary endpoints” for them to interpret the V-HeFT data “with any degree of certainty.”<sup>73</sup> Therefore, the Advisory Committee voted nine to three against recommending that BiDil be approved for use in congestive heart failure.<sup>74</sup> Following the FDA’s rejection, Medco got out of the BiDil business and let the intellectual

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<http://triangle.bizjournals.com/triangle/stories/1997/02/24/daily12.html> (last visited Dec. 18, 2003).

70. U.S. Patent No. 4,868,179, *supra* note 59.

71. CTR. FOR DRUG EVALUATION & RESEARCH, CARDIOVASCULAR & RENAL DRUGS ADVISORY COMM., TRANSCRIPT FROM THE 80<sup>TH</sup> MEETING OF THE FOOD AND DRUG ADMIN. 53 (Feb. 27, 1997), <http://www.fda.gov/ohrms/dockets/ac/97/transcript/3264t1.pdf> (last visited Aug. 5, 2002) [hereinafter TRANSCRIPT].

72. *Id.* at 61-62.

73. MINUTES, *supra* note 67, at 2.

74. *Id.* at 3. Once again, it is worth noting that the NDA and its rejection by the Advisory Committee were both grounded on an analysis of BiDil as a general drug applicable to all heart failure patients regardless of race or ethnicity.

property rights revert to Cohn.

### *B. BiDil's Ethnic Rebirth*

At this point, BiDil appeared to be dead in the water. However, in the transcript of the FDA meeting itself, there is a hint of BiDil's road to resurrection. Early on in his presentation before the Advisory Committee, Cohn noted:

The majority of the patients [in both V-Heft I and II] were Caucasian. That is, about seventy percent of them in both trials, but there was a fairly sizeable number of African Americans in the trial. We won't go into that, but we have much data comparing the Caucasian and African-American responses.<sup>75</sup>

The V-HeFT investigators had been tracking data by race from the outset. They had not, however, conceptualized BiDil as a racially specific therapy. To the contrary, Cohn chose quite deliberately not to "go into that" before the FDA.<sup>76</sup> It was only after the Advisory Committee recommended against approving BiDil for use in a general population that the V-HeFT investigators went back one more time to their data—data that Cohn himself reminded the Advisory Committee had been generated by a trial designed nearly twenty years earlier—and produced the first published studies analyzing the differential effects of H/I and enalapril by race.<sup>77</sup>

These race-based studies were completed in a broader context of rising

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75. TRANSCRIPT, *supra* note 71, at 20-21.

76. *Id.* at 21.

77. Of course, the investigators could have broken down the data into any one of a large number of other possible sub-groups: The V-HeFT I and II reports listed at least twenty-two baseline characteristics that could each have provided an alternative basis for retrospective analysis of efficacy, independent of race. See, e.g., Susan Ziesche et al., *Hydralazine and Isosorbide Dinitrate Combination Improves Exercise Tolerance in Heart Failure: Results from V-HeFT I and V-HeFT II*, 87 CIRCULATION VI-56 (Supp. 1993). In fact, a 1993 article by Cohn suggested a number of variables that might impact therapeutic responses but did not include race. He identified such issues as: "Do women respond the same as men? Do individuals with coronary disease respond differently than those with cardiomyopathy? Does ventricular geometry influence response to therapy? Are there biochemical or hormonal markers that will affect the response to specific intervention?" Jay N. Cohn, *The Vasodilator-Heart Failure Trials (V-HeFT): Mechanistic data from the VA Cooperative Studies*, 87 CIRCULATION VI-1, VI-2 (Supp. 1993). Each of Cohn's questions marked a potential sub-group for analysis, but interestingly, none of his questions concerned race.

political attention to the importance of addressing race and gender disparities in health policy and administration. In 1997, the federal government passed the Food and Drug Administration Modernization Act, which, among other things, required the Secretary of Health and Human Services "in consultation with the Director of the National Institutes of Health and the representatives of the drug manufacturing industry, [to] review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials."<sup>78</sup> That same year, President Clinton delivered a much publicized apology for the federal government's role in the notorious Tuskegee Syphilis Study, which exploited black men for decades in the name of medical research.<sup>79</sup> The BiDil investigators, then, were not the only ones closely considering race in medicine.

Against this backdrop, Cohn, together with Peter Carson, M.D., Susan Zeische, R.N., and Gary Johnson, M.S., published a paper in September 1999 titled *Racial Differences in Response to Therapy for Heart Failure: Analysis of the Vasodilator-Heart Failure Trials*.<sup>80</sup> The retrospective analysis of data from V-HeFT I and II compared a total of 395 black patients with 1024 white patients with similar baseline variables and characteristics (including age, history of coronary heart disease, hypertension, blood pressure, heart rate, etc.). It found that "the H-I combination appears to be particularly effective in prolonging survival in black patients and is as effective as enalapril in this subgroup. In contrast, enalapril shows its more favorable effect on survival, particularly in the white population."<sup>81</sup> Following a caveat about the limits of its data, the paper concluded that "the consistency of observations of a racial difference in response in V-HeFT I and V-HeFT II . . . lend credence to the suggestion that therapy for heart failure might appropriately be *racially tailored*."<sup>82</sup>

The paper argued that H/I (the BiDil drugs) appeared to work better in blacks than in whites.<sup>83</sup> More importantly, though not explicitly stated in the paper, the statistics on H/I's impact on black mortality might be sufficiently powerful to meet the FDA's threshold criteria for regulatory significance. That same month, NitroMed, a Boston-area biotech firm

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78. Food and Drug Administration Modernization Act of 1997, Pub. L. 105-115, § 115, 111 Stat. 2296, 2313.

79. President William J. Clinton, Remarks in Apology for Study Done in Tuskegee (May 16, 1997), at <http://www.cmh.pitt.edu/presremarks.html> (last visited Dec. 17, 2003).

80. Peter Carson et al., *supra* note 51.

81. *Id.* at 182.

82. *Id.* at 186 (emphasis added).

83. *Id.* at 183, 186.

specializing in the development and commercialization of nitric oxide enhanced medicines, announced it had acquired the NDA for BiDil and related intellectual property rights from Jay Cohn.<sup>84</sup> The announcement also disclosed NitroMed's plans to amend the NDA to seek an indication specifically for African American patients. Shortly thereafter, Jay Cohn and Peter Carson, the lead author of the article on racial differences in the V-HeFT data, applied for a patent on "methods for treating and preventing mortality associated with heart failure in an African American patient" with hydralazine and isosorbide dinitrate or mononitrate. They then assigned the patent rights to NitroMed.<sup>85</sup> Thus was BiDil reborn as an "ethnic" drug.

### *C. Statistical Mischief in Race-Based Mortality Rates*<sup>86</sup>

With its race-specific patent on file, the next step for NitroMed was to lay the groundwork to submit its amended NDA to the FDA. At this point the statistic that blacks die from heart failure at a rate twice that of whites began to play a significant role in the development of BiDil. Earlier that year, in February 1999, Peter Carson had co-authored a study by Dries et al. entitled *Racial Differences in the Outcome of Left Ventricular Dysfunction*—a prime indication of congestive heart failure.<sup>87</sup> Based on retrospective analysis of data from the SOLVD prevention and treatment trials, the article suggested that "there may be differences in the natural history of . . . left ventricular dysfunction between black and white patients."<sup>88</sup> Significantly, the study purported to control for socioeconomic factors by analyzing "[b]ase-line data on educational level and the percentage of participants reporting 'major financial distress' (yes vs. no)" during the

84. *NitroMed To Seek Heart Failure Indication for BiDil*, J. MED. INDUSTRY TODAY, Sept. 13, 1999, at 71; Press Release, NitroMed, Inc., NitroMed Acquires BiDil™ New Drug Application for Treatment of Congestive Heart Failure (Sept. 10, 1999), <http://www.nitromed.com/newsindex.html> (last visited Dec. 7, 2003).

85. U.S. Patent No. 6,465,463 (issued Oct. 15, 2002), <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=/netahtml/srchnum.htm&r=1&f=G&l=50&s1=6,465,463.WKU.&OS=PN/6,465,463&RS=PN/6,465,463> (last visited Dec. 13, 2003).

86. For a more complete analysis of this issue, see Jonathan Kahn, *Getting the Numbers Right: Statistical Mischief and Racial Profiling in Heart Failure Research*, 46 PERSP. BIOLOGY & MED. 473 (2003).

87. Daniel L. Dries et al., *Racial Differences in the Outcome of Left Ventricular Dysfunction*, 340 NEW ENG. J. MED. 609 (1999).

88. *Id.* at 616.



previous twelve months.<sup>89</sup> Framing the entire report was the assertion in the opening paragraph that “[t]he population-based mortality rate from congestive heart failure is 1.8 times as high for black men as for white men and 2.4 times as high for black women as for white women”—an overall black to white ratio of heart failure mortality of approximately 2:1.<sup>90</sup>

The logic behind the study is clear: There is a 2:1 disparity in mortality rates between blacks and whites; it seems unlikely that socioeconomic status (SES) alone can account for such a large difference; therefore, conduct retrospective analysis of heart failure data that purports to control for SES, and see if there is any remaining disparity that can be attributed to biology. The 2:1 statistic thus shapes which questions get asked and how they are pursued. However, although the logic is consistent there are two major problems with the study’s premise. First, the study’s conception of relevant socioeconomic influences on health is very thin. Second, the 2:1 statistic itself is not correct.

With regard to socioeconomic influences, the level of education and experience of financial distress certainly are relevant factors to consider in examining non-genetic environmental influences on the development and progression of heart failure. However, the implicit understanding that they are exhaustive of such relevant factors is puzzling, to say the least. As one letter in response to the article noted:

Obviously, it is impossible to control perfectly for the complex and somewhat nebulous concept of socioeconomic status in any study, and Dries et al. appropriately advise caution in the interpretation of their results. By focusing, however, on biological factors as the fallback explanation for their findings, the authors pay inadequate attention to the environmental, psychosocial, and economic factors that are just as likely, if not more likely, explanations of racial differences in health.<sup>91</sup>

Dr. Clyde Yancy, an advocate of identifying genetic factors underlying supposed racial disparities in heart failure mortality, has noted “a striking [sic] disproportionate incidence of hypertension as a plausible cause of heart failure.”<sup>92</sup> There is a vast array of medical and public health literature connecting racial differences in hypertension to social factors such as diet,

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89. *Id.* at 612.

90. *Id.* at 609.

91. Somnath Saha, *Letter to the Editor*, 341 NEW ENG. J. MED. 87 (1999) (citing N. Krieger et al., *Measuring Social Class in US Public Health Research: Concepts, Methodologies, and Guidelines*, 18 ANN. REV. PUB. HEALTH 341 (1997)).

92. Yancy, *Cardiovascular Enigma*, *supra* note 16, at 183.

environment, exercise, and stress.<sup>93</sup> Many of these social factors correlate strongly with social categories of race. For example, one study has shown that the stress of experiencing racism seems to elevate blood pressure.<sup>94</sup> The study by Dries et al. captures none of these variables.<sup>95</sup> Strangely, after noting the centrality of hypertension as a plausible cause of heart failure, Yancy goes on to cite the data from the Dries et al. study on socioeconomic factors as support for his hypothesis that heart failure is a “different disease” in African Americans with a genetic difference likely underlying the difference.<sup>96</sup> Yancy and Dries et al.’s thin conception of socioeconomic factors seems to indicate an underlying assumption that because hypertension is a biological condition, any disparities associated with its prevalence must similarly be biological.

As a source for the 2:1 mortality statistic, Dries et al. cited a 1987 editorial in the *American Heart Journal* written by Richard Gillum, M.D., from the Office of Analysis and Epidemiology Program at the National Center for Health Statistics. However, Gillum’s version of the statistic was outdated and differed in several important ways. First, Gillum’s statistic relies upon mortality rates from 1981—that is, eighteen years before the publication of Dries et al.’s article in 1999. By 1999, far more current data on mortality rates was readily available and indicated a substantial narrowing of the gap between blacks and whites between 1980 and 1995.<sup>97</sup>

93. See, e.g., William W. Dressler, *Lifestyle, Stress and Blood Pressure in a Southern Black Community*, 52 PSYCHOSOMATIC MED. 182 (1990); Michael J. Klag et al., *The Association of Skin Color with Blood Pressure in US Blacks with Low Socioeconomic Status*, 265 JAMA 599 (1991); D.R. Williams, *Black-White Differences in Blood Pressure: The Role of Social Factors*, 2 ETHNICITY & DISEASE 126 (1992).

94. Nancy Krieger & Stephen Sidney, *Racial Discrimination and Blood Pressure: The CARDIA Study of Young Black and White Adults*, 86 AM. J. PUB. HEALTH 1370 (1996); see also E. Harburg et al., *Socio-Ecological Stress, Suppressed Hostility, Skin Color, and Black-White Male Blood Pressure: Detroit*, 35 PSYCHOSOMATIC MED. 276 (1973); Williams, *supra* note 93.

95. As mentioned earlier, this study controlled only for education and a singular metric of financial history. See *supra* note 87, 89 and accompanying text.

96. Yancy, *Cardiovascular Enigma*, *supra* note 16.

97. Prior to the Dries et al. publication, the CDC’s *Morbidity and Mortality Weekly Report* (MMWR) noted that between 1980 and 1995 there was a steady narrowing in the gap between blacks and whites for mortality from heart failure. Indeed, looking at mortality rates for individuals age sixty-five and older (among whom approximately ninety-four percent of heart failure deaths occurred in 1994) the MMWR observed, “Because of greater declines in death rates for heart failure among black adults, from 1980 to 1995 the black:white ratio for men narrowed from 1.3:1 to 1.1:1 and for women from 1.4:1 to 1.1:1.” CTRS. FOR DISEASE CONTROL & PREVENTION, *Changes in Mortality from Heart Failure—United States, 1980-1995*, 47 MORBIDITY & MORTALITY WEEKLY REP. 633 (1998),

The failure of Dries et al. to find the more current data can only be described as reckless given both the controversial nature of claims connecting race with biology and the relative ease with which a knowledgeable researcher could obtain current data.

Second, Gillum specified that "for persons *aged 35 to 74 years*, the ratio of age adjusted rates for blacks and whites was 1.8 for men and 2.4 for women."<sup>98</sup> Dries et al.'s article failed to include Gillum's age specific qualification of the data. This is not a minor oversight. Rather it drastically alters both the meaning of the data presented and the overall framework within which the study is being presented. Gillum also noted that "the ratio of black-to-white rates [of mortality] was highest under age sixty-five, approaching 1 [i.e., 1:1] in persons seventy-five years of age and over."<sup>99</sup> Finally, by the numbers presented in Gillum's own table of statistics, the age group of thirty-five to seventy-four contained approximately sixty-nine percent of black heart failure mortality but only twenty-nine percent of white heart failure mortality.<sup>100</sup> Thus, seventy-one percent of whites who die from heart failure die after age seventy-four and are not captured in the age thirty-four to seventy-four statistic. By these statistics blacks may have *earlier* onset and *earlier* mortality from heart failure, but this is not the same thing as a *higher* mortality rate. In fact, the most current data available from the Centers for Disease Control and Prevention (CDC) and the National Center for Health Statistics place the age-adjusted ratio of black to white mortality from heart failure at something under 1.1:1 for 1999.<sup>101</sup>

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<http://www.cdc.gov/mmwr/preview/mmwrhtml/00054249.htm> (last visited Dec. 3, 2003). Moreover, the 1999 CDC Wonder data set provides an overall age-adjusted mortality rate ratio for blacks to whites of 1.08:1. See discussion *infra* note 101.

98. Richard F. Gillum, *Heart Failure in the United States, 1970-1985*, 113 AM. HEART J. 1043, 1043 (1986) (emphasis added).

99. *Id.*

100. *Id.* at 1044.

101. To obtain the current statistic, I went to the CDC Wonder mortality tables, typed in an information request for the most recent year available (1999) for the category of Heart Failure (ICD-10 I50.0) and asked for age-adjusted compressed mortality rates by race measured by the closest fiscal year standard population (FY2000). The results were an age-adjusted death rate for all blacks of 20.5 per million and all whites of 18.9 per million. Thus, the black to white ratio is approximately 1.08:1. The source of the Wonder Mortality Data Set is the CDC's Office of Analysis and Epidemiology at the National Center for Health Statistics. Seeking longer-term numbers, the compressed mortality from the years 1979 to 1998 using a FY2000 standard population leads to a ratio of roughly 1.14:1. If you use a FY1970 standard population the ratio rises to 1.27:1. This higher number over the longer term fits with data released in the CDC's *Morbidity and Mortality Weekly Report* (MMWR). See

Unfortunately, the 2:1 statistic has not been widely challenged, and it has since taken on a life of its own, appearing throughout both the popular media and in peer-reviewed medical and scientific journals.<sup>102</sup> Almost every reference to BiDil now appears in the company of the 2:1 statistic. Its wide circulation throughout discussions of race-based approaches to treating heart failure has been further aided by the federal government's own inept handling of statistics. For example, the website maintained by the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH), contains three different web pages that variously report the black to white mortality ratio from heart failure as 2:1,<sup>103</sup> 1.4:1,<sup>104</sup> and "slightly higher in blacks than in whites."<sup>105</sup>

A companion to the 2:1 statistic has been the assertion that ACE inhibitors work less well in black than in whites.<sup>106</sup> As noted above, Cohn and others made the assertion in an article published by the *New England Journal of Medicine* in May 2001<sup>107</sup>—a mere two months after NitroMed's announcement of the commencement of A-HeFT, the African American Heart Failure Trial. This assertion, when combined with findings that BiDil works better in blacks,<sup>108</sup> may be understood to imply that perhaps *all* African American heart failure patients should be taking BiDil—not merely those who cannot tolerate ACE inhibitors—a significant expansion of the potential market. Significantly, the entry for the ACE inhibitor

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discussion *supra* note 97.

102. See *supra* note 17 and accompanying text (discussing mention of the 2:1 statistic in popular media); see, e.g., Dries et al., *supra* note 87 (employing outdated mortality rate ratios); Yancy, *Cardiovascular Enigma*, *supra* note 16.

103. NAT'L HEART, LUNG, & BLOOD INST., FACTS ABOUT HEART FAILURE, <http://www.nhlbi.nih.gov/health/public/heart/other/hrtfail.htm> (last visited Dec. 18, 2003).

104. NAT'L HEART, LUNG, & BLOOD INST., *supra* note 23.

105. NAT'L HEART, LUNG, & BLOOD INST., MORBIDITY AND MORTALITY: 2002 CHARTBOOK ON CARDIOVASCULAR, LUNG, AND BLOOD DISEASES 39, *available at* [http://www.nhlbi.nih.gov/resources/docs/02\\_chtbk.pdf](http://www.nhlbi.nih.gov/resources/docs/02_chtbk.pdf) (last visited Dec. 7, 2003).

106. Cohn linked this assertion quite explicitly to the 2:1 statistic: "Because black people are twice as likely to suffer from heart failure and twice as likely to die from heart failure, the unique needs of this particular population must be addressed. . . . The results of the SOLVD trials provide statistically significant data on how disparate the outcomes for white and black patients truly are." Press Release, Univ. of Minn., Racial Disparity in Efficacy of Common Heart Failure Treatment (May 3, 2001), *at* <http://www.newswise.com/articles/2001/5/HEART.UMN.html> (last visited Nov. 7, 2003).

107. Exner et al., *supra* note 41.

108. *Id.*; see also Cohn, *supra* note 49.

Vasotec (enalapril) in the current edition of the *Physicians' Desk Reference* (PDR), in apparent—but not explicit—reference to the Exner et al. article, states in the section on “Indications and Usage” that “in controlled clinical trials ACE inhibitors have an effect on blood pressure that is less in black patients than in non-blacks.”<sup>109</sup>

Unlike the 2:1 statistic, the findings on ACE inhibitors have not gone unchallenged. Surprisingly, one of the strongest critiques has come from one of the co-authors of the original study, Dr. Daniel Dries. Dries published a paper in 2002 in which he took issue with the earlier *New England Journal of Medicine* piece and argued that “enalapril appears to be equally efficacious in black and white patients.”<sup>110</sup> Another article found the retrospective analysis of the SOLVD data was too weak to provide any conclusions regarding the lack of benefit ACE inhibitors offer black patients.<sup>111</sup> Yet another article argues that the data on ACE inhibitors are insufficient to support a “unique strategy” for treating African American heart failure patients.<sup>112</sup> Finally, a recent meta-analysis of major clinical trials found no evidence of racial differences in responses to ACE inhibitors.<sup>113</sup> Yet, the PDR retains the reference to racial difference.

Nonetheless, the combined retrospective analyses of the V-HeFT and SOLVD data, framed by the fallacious 2:1 mortality statistic, have propelled the emergence of BiDil as an apparent means to redress a health disparity in an underserved population. Hence it seems reasonable that by 2001, NitroMed had garnered the support of the Association of Black Cardiologists (ABC) and the Congressional Black Caucus in its bid for approval of the ethnically repositioned BiDil. NitroMed approached the FDA, and in March 2001 came the announcements that BiDil was expected to be approved by the FDA pending the successful completion of A-

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109. *Vasotec I.V. Injection*, in PHYSICIANS' DESK REFERENCE 2105 (2003), available at <http://www.biomed.lib.umn.edu/mdxcgi> (last visited Nov. 7, 2003).

110. Daniel L. Dries et al., *Efficacy of Angiotensin-Converting Enzyme Inhibition in Reducing Progression from Asymptomatic Left Ventricular Dysfunction to Symptomatic Heart Failure in Black and White Patients*, 40 J. AM. COLL. CARDIOLOGY 311, 311 (2002).

111. J.S. Kalus & J.M. Nappi, *Role of Race in Pharmacotherapy of Heart Failure*, 36 ANNALS PHARMACOTHERAPY 471, 471 (2002).

112. K.C. Ferdinand et al., *Contemporary Treatment of Heart Failure: Is There Adequate Evidence To Support a Unique Strategy for African-Americans? Con Position*, 4 CURRENT HYPERTENSIONS REP. 311 (2002).

113. Paul G. Shekelle et al., *Efficacy of Angiotensin-Converting Enzyme Inhibitors and Beta-Blockers in the Management of Left Ventricular Systolic Dysfunction According to Race, Gender, and Diabetic Status*, 41 J. AM. COLL. CARDIOLOGY 1529 (2003).

HeFT.<sup>114</sup> When NitroMed announced the initiation of A-HeFT at the annual meeting of the ABC, CEO Michael Loberg emphasized, "NitroMed looks forward to working closely with the ABC and other clinical thought leaders in the completion of this important trial."<sup>115</sup> Explaining the ABC's sponsorship of A-HeFT, B. Wayne Kong, CEO of the ABC, declared, "It is in the name of science that we participate."<sup>116</sup>

#### *D. Surrogate Markers and Surrogate Marketing*

The reinvention of BiDil as an ethnic drug enabled NitroMed to garner support beyond the ABC and the Congressional Black Caucus. On June 14, 2001, NitroMed announced the completion of a private financing round raising \$31.4 million from several venture capital firms to support the A-HeFT trials.<sup>117</sup> NitroMed's ability to raise such substantial funding in the aftermath of the "dot com" collapse in the stock market is testament to the business appeal of developing a drug at the forefront of biological niche marketing. Where drugs such as Viagra may target one sex or another, BiDil promises to lead the way in ethnic niche marketing of pharmaceuticals. On November 6, 2003, in the latest round of fundraising to support the development and marketing of BiDil, NitroMed went public. The initial public offering was managed by Deutsche Bank Securities and J.P. Morgan. NitroMed offered six million common shares at a target price of eleven dollars per share with a proposed market cap of \$305 million.<sup>118</sup> In the emerging field of pharmacogenomics, where drug

114. Press Release, NitroMed, Inc., *supra* note 1.

115. Press Release, NitroMed, Inc., *supra* note 7.

116. Stolberg, *supra* note 17. To further aid in recruiting patients for the trial, NitroMed has enlisted Feinstein Kean Healthcare, a subsidiary of Ogilvy PR Worldwide, one of the world's largest public relations firms. See Press Release, Humana, Inc., Humana and NitroMed Form Program to Expand Clinical Trial Access to Minorities (Aug. 8, 2002), <http://www.humana.com/corporatecomm/newsroom/releases/PR-News-20020808-150024-NR.html> (last visited Jan. 15, 2004).

117. Press Release, NitroMed, Inc., NitroMed Completes \$31.4 Million Private Financing (June 14, 2001), <http://www.nitromed.com/newsindex.html> (last visited Dec. 7, 2003).

118. See, e.g., NitroMed, Inc., SEC Filing, *supra* note 3; *NitroMed To Sell 6 Mln IPO Shares for \$11-\$13 Each*, REUTERS, Oct. 2, 2003, [http://biz.yahoo.com/rf/031002/health\\_nitromed\\_ipo\\_2.html](http://biz.yahoo.com/rf/031002/health_nitromed_ipo_2.html) (last visited Dec. 7, 2003); Press Release, NitroMed, Inc., NitroMed, Inc. Announces Its Initial Public Offering (Nov. 5, 2003), <http://www.nitromed.com/newsindex.html> (last visited Dec. 7, 2003); *Developer NitroMed Plans To Raise \$72 Million in IPO*, IPOHOME, Oct. 2, 2003, at <http://www.ipohome.com/marketwatch/iponews2.asp?article=3163> (last visited Dec. 7, 2003).

companies are hoping to tailor therapies ever more closely to the genetic profile of individuals or groups of consumers, identifying racial/ethnic correlations with disease is becoming big business. As one announcement for a 2004 conference on *Multicultural Pharmaceutical Marketing and PR* put it:

Major U.S. Drug [sic] manufacturers are making it a high priority area to cultivate relationships with ethnic consumers, physician groups, community networks and other key stakeholder groups to uncover new market growth. Disproportionately high incidence of diabetes, obesity, heart disease, cancer, HIV/AIDS, asthma and other health conditions among these segments require many strategic and tactical moves in pharmaceutical marketing and PR.<sup>119</sup>

To a significant degree, NitroMed’s development of BiDil can be viewed as one such strategic or tactical move.

In the context of pharmacogenomics the purportedly benign racialization of the BiDil becomes more problematic. In their analysis of potential impacts of the use of race in pharmacogenomics, Lee et al. observed:

Although the idea of individually tailored therapy is the goal, it appears likely that products will actually be targeted according to race. One can only speculate on the cultural impact of the commercialization of drugs for racialized populations and the decision by pharmaceutical companies to bring to market therapeutics created for a certain group of consumers.<sup>120</sup>

They concluded with the admonishment that “[c]areful policy guidelines on the marketing of medicines . . . to racially defined groups are needed.”<sup>121</sup> The cultural impact of BiDil is already becoming evident in the widespread coverage in the media lending support to the idea that race may be used as a biological category.

Ironically, many of the BiDil researchers are among the first to caution that they are merely using race as a surrogate marker to identify underlying genetic variation that accounts for the differential response to

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119. STRATEGIC RESEARCH INST., 5TH ANNUAL MULTICULTURAL PHARMACEUTICAL MARKETING & PR CONFERENCE, [http://www.srinstitute.com/ApplicationFiles/web/webFrame.cfm?web\\_id=205](http://www.srinstitute.com/ApplicationFiles/web/webFrame.cfm?web_id=205) (last visited Dec. 15, 2003).

120. Lee et al., *supra* note 13, at 57.

121. *Id.*

BiDil. Cohn himself has noted that “skin color is only a crude indication of underlying genetics differences.”<sup>122</sup> Similarly, the article he co-authored on racially differential responses to ACE inhibitor therapy cautions that “[i]t must be recognized that racial categorization is only a surrogate marker for genetic or other factors responsible for individual responses to therapy. Indeed, racial intermixing makes genetic distinctions problematic, and any identified differences will certainly not apply to all the members of each stratified group.”<sup>123</sup>

Yet, race remains a primary category around which these researchers organize their efforts. They present race as instrumental—a means to a larger end of more precisely tailored drug therapy, therapy that will be able to overlook race all together. Dr. Sally Satel, a psychiatrist and author of a *New York Times Sunday Magazine* article called *I Am a Racially Profiling Doctor*,<sup>124</sup> has characterized the work on BiDil this way:

The ultimate purpose of work like Cohn’s and other biological realists is to identify factors that may be genetic in origin. First, researchers hope that identifying particular genetic markers with certain ethnic groups will yield insight into the genetic basis of disease and reveal why certain conditions are more prevalent in some groups. Second, the ultimate goal is to understand differences between *individuals*, not between races or ethnic groups.<sup>125</sup>

Satel here lays out an idealized progression of medical research and, by implication, of marketing, toward truly individualized pharmacogenomic approaches to therapy that focus on genetic variation independent of racial categories. On the road to this ideal, however, Satel and others identify race as a useful category of medical analysis. For example, Cohn has explained that “[i]t seems to [him] absolutely ludicrous to suggest that this prominent characteristic [i.e., race] that we all recognize when we look at people should not be looked at.”<sup>126</sup>

Satel, Cohn and others who embrace such “racial profiling” in medicine move from social group to biological group to individual

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122. Griffith, *supra* note 4 (quoting Dr. Cohn).

123. Exner et al., *supra* note 42, at 1357.

124. Sally Satel, *I Am a Racially Profiling Doctor*, N.Y. TIMES MAG., May 5, 2002, at 56.

125. Sally Satel, *Medicine’s Race Problem*, 110 POL’Y REV. 49, 55 (2001), available at <http://www.policyreview.org/DEC01/satel.html> (last visited Dec. 17, 2003).

126. Jon Entine, *The Straw Man of Race*, 16 WORLD & I 294, available at [http://www.jonentine.com/reviews/straw\\_man\\_of\\_race.htm](http://www.jonentine.com/reviews/straw_man_of_race.htm) (last visited Dec. 27, 2002) (quoting Dr. Cohn).



genome. They begin with the assumption that it is useful and legitimate to use social categories of race as "crude markers" to get at biological groups of people who share a common genetic predisposition to a particular disease.<sup>127</sup> After a group is identified, the goal is to proceed to the level of the individual genome to explain disease. Once it is possible to scan individual genomes for genetic variations the need to refer to the biological group fades away. Without the biological group, the initial surrogate social group—in this case a racial group—is erased as irrelevant to understanding the disease. Here race is understood as epiphenomenal. True difference is cast at the material level of the molecule.

In his recent article *Does Race Matter in Heart Failure?*, Clyde Yancy captured this logical progression.<sup>128</sup> Answering his title's question in the affirmative, Yancy goes on to assert that

a group of patients do exist that appear to be at a particular risk for less good outcomes. Currently this group shares the same racial designation, a grouping that is overtly crude and completely arbitrary. What will hopefully emerge, however, are the exact clinical and *genetic descriptors of race* that will supercede something as nebulous as skin color and address the more compelling and appropriate physiological traits that put all persons at risk for heart failure.<sup>129</sup>

Yancy's use of the term "genetic descriptors of race" alongside his recognition of racial groupings as crude and arbitrary markers attests to how biomedical researchers may at once acknowledge concerns about the use of race as a biomedical category, while in practice affirming race as an objective genetic classification. Furthermore, his reduction of race to "skin color" evidences a strikingly simplistic conception of the term given social scientists' longstanding critique of it as unstable, historically contingent and generally hard to define in a concrete way.<sup>130</sup>

There are two additional problems with the model emerging from the work of Cohn, Satel, and Yancy et al. First, most diseases have powerful environmental and social components—many of which correlate with social categories of race. For example, a recent report from the Institute of Medicine found that racial and ethnic minorities tend to receive lower-quality health care than do whites, even when insurance status, income,

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127. See, e.g., Yancy, *supra* note 2, at 205.

128. *Id.*

129. *Id.* (emphasis added).

130. See e.g., MICHAEL OMI & HOWARD WINANT, RACIAL FORMATION IN THE UNITED STATES: FROM THE 1960S TO THE 1990S 54-55 (1994).

age, and severity of conditions are comparable.<sup>131</sup> An over-emphasis on the molecular basis of disease can undermine support for broad-based social policy approaches to redressing such health disparities. This need not be an either/or situation, but in a time of economic hardship, a genetically deterministic approach to disease could likely direct scarce resources away from more public health oriented social approaches to managing disease.

Second, the promise of fully individualized genomic medicine is decades away and in the "gap" between current practice and the full realization of pharmacogenomic medicine there is room for much potential harm. Consider that a widely available, affordable, and rapid technology for scanning individual genomes is years, perhaps decades off. In the meantime, researchers are working to correlate certain genetic variations with particular racial groups. When a drug such as BiDil gets produced, researchers understand that it works at the molecular level, affecting, for example, levels of nitric oxide in the blood. Nonetheless, a drug company cannot effectively market BiDil to the biological group of individuals who have a particular genetic polymorphism that may lead to lower levels of nitric oxide. Rather, NitroMed will market BiDil to the social group known as African Americans, because at this point we simply lack the resources or technology to scan every individual's genetic profile. Furthermore, although many individuals identifying with non-African American racial groups will have this variation, on average, a higher proportion of African Americans are hypothesized to have it. Hence, it is far easier to target African Americans than to identify a market of particular individuals who happen to respond well to BiDil because of their genetic makeup regardless of race. The corporation uses the fact of an identified biological difference to create a market based on a social group. Medical researchers may use race as a surrogate to get at biology in drug development, but corporations are using biology as a surrogate to get at race in drug marketing.

#### *E. The Role of Law in Race-ing BiDil*

The role of law as player in the emergence of BiDil as an ethnic drug began in 1980, more or less coincidentally with the initiation of V-HeFT I. That year, President Carter signed into law two pieces of legislation that would transform relations between industry and academic researchers.<sup>132</sup>

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131. INST. OF MED., *supra* note 13, at 1-2.

132. See, e.g., Sheldon Krimsky, *The Profit of Scientific Discovery and Its Normative Implications*, 75 CHICAGO-KENT L. REV. 15 (1999). Krimsky notes, "The new federal initiatives on technology transfer and academic-industry-government collaborations were responsible for

The first, the Stevenson-Wydler Technology Transfer Act,<sup>133</sup> encouraged interaction and cooperation among government laboratories, universities, big industries and small businesses. The second, the Bayh-Dole Patent and Trademark Laws Amendment,<sup>134</sup> allowed institutions conducting research with federal funds, such as universities, to retain the intellectual property rights to their discoveries. It is in this context that the research findings of V-HeFT, produced in cooperation with the U.S. Veterans Administration, could be commercialized through patent and trademark law. Thus Jay Cohn and Peter Carson were able to obtain intellectual property rights in BiDil-related patents and enter into deals with the likes of Medco and NitroMed to commercialize the discoveries made through the V-HeFT trials.

The first intervention of patent law in the development of BiDil, however, was negative and restrictive rather than productive. Following the successful completion of V-HeFT II in 1989, the next logical step would have been to conduct a trial that explored the combined effects of ACE inhibitors with H/I. Cohn himself pushed for such a trial and openly bemoaned the lack of corporate support to enable him and other cardiologists to go forward.<sup>135</sup> The key reason, as Cohn later noted, was because hydralazine and isosorbide dinitrate were both generic drugs. In the absence of intellectual property rights to the therapeutic compound, corporate support for further tests involving the components of BiDil would not be forthcoming.<sup>136</sup> Thus, years before BiDil was ever presented

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a marked rise in university patents. In 1980, American university patents represented one percent of all U.S. origin patents. By 1990, the figure rose to 2.4%. Within that decade, the number of applications for patents on NIH-sponsored inventions increased by nearly 300%." *Id.* at 22.

133. 15 U.S.C. § 3701 (1994). In particular, the Act encourages the transfer of technology developed in federal laboratories to the private sector for further development through Cooperative Research and Development Agreements. In some instances, this involves the transfer of legal rights, such as the assignment of patent title to a contractor or the licensing of a government-owned patent to a private firm. In other cases, the transfer endeavor involves the informal movement of information, knowledge, or skills through person-to-person interaction.

134. 35 U.S.C. §§ 200-212 (1994).

135. Jay N. Cohn, *Lessons from V-HeFT: Questions for V-HeFT II and the Future Therapy of Heart Failure*, 16 HERTZ 267, 270 (1991).

136. Reviewing the course of the V-HeFT trials, Cohn noted:

The natural evolution of V-HeFT would have mandated that the vasodilator regimen [to be combined with enalapril in V-HeFT III] would be the combination of the hydralazine and isosorbide dinitrate, which has been so effective in V-HeFT I and V-HeFT II. Unfortunately, the need for financial

to the FDA, the lack of relevant intellectual property value seemed likely to condemn hydralazine and isosorbide dinitrate to obscurity as treatments for heart failure. Not only did further trials of H/I in combination with other drugs seem unlikely, but there would be no money to push publicity and marketing of the H/I therapy as it was then understood.

Cohn revived the commercial prospects for BiDil in by patenting the method of combining hydralazine and isosorbide dinitrate to treat congestive heart failure,<sup>137</sup> and then by developing BiDil as a new drug—being a combination of H/I in single dose form. BiDil was a breakthrough of convenience: It made it easier to dispense and to use the H/I combination but was not itself a new therapy. With BiDil, a doctor only had to write one prescription and the patient only had to take a total of six pills (two pills three times a day) instead of sixteen (four pills four times a day).<sup>138</sup>

Yet, the measure of convenience to BiDil alone was insufficient to drive its development. A consultant to the FDA panel that ultimately rejected BiDil's NDA in 1997 noted that the two generic component drugs of BiDil are available for anyone to use for heart failure. The FDA's denial of the BiDil NDA would not change that. Rather, he observed that "the practical impact of the FDA not approving this combination today is that there won't be an economic incentive for the sponsor to get out and provide educational material for a lot of doctors to know how to use the drugs best."<sup>139</sup>

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support has made it necessary that the vasodilator be an agent with potential commercial interest. Thus, a calcium antagonist has been substituted in V-HeFT III for the hydralazine nitrate combination, and it will be felodipine – a calcium antagonist with considerable vasoselectivity.

Jay N. Cohn, *supra* note 78, at VI-2 to VI-3; *see also* Jay N. Cohn, Invited Editorial, *Treatment of Infarct Related Heart Failure: Vasodilators Other Than ACE Inhibitors*, 8 *CARDIOVASCULAR DRUGS & THERAPY* 119, 120 (1994) ("One of the problems with advocating non-ACE vasodilators in treatment of the post-infarct period relates to the inadequacy of the database on these drugs. Since hydralazine and isosorbide dinitrate are generic agents, there has been no effort on the part of a pharmaceutical company to mount large-scale trials or to develop an NDA for drug approval. In contrast, the ACE inhibitors have been heavily marketed and their use for infarct related heart failure appears to be growing rapidly.")

137. U.S. Patent No. 4,868,179, *supra* note 60.

138. Interview with Dr. Anne Taylor, Principle Investigator and Chairperson: A-HeFT, in Minneapolis, Minn. (Nov. 11, 2002). Of course, six pills a day is still considered a lot. Indeed, doctors generally do not expect to see a great improvement in patient compliance with a drug regimen until the dosage is down to two times per day. *Id.*

139. TRANSCRIPT, *supra* note 72, at 210.

The true breakthrough for BiDil, therefore, was not simply the combination of two generic drugs into one; it was the development of new intellectual property rights. With patent protection in hand, it would become advantageous for a drug company to develop and market BiDil aggressively to doctors and patients. For this reason, Medco acquired the rights to BiDil in the early 1990s and started investing time and money in conducting trials and developing marketing strategies in preparation for submitting its NDA to the FDA. Patent law, and to a lesser extent trademark law which allowed for added brand name value in the marking of BiDil®, thus provided a critical impetus toward the creation of BiDil. On the one hand, this comports well with the classic justification of patent law as providing a spur to invention. On the other hand it indicates how patent law may also distort a market, potentially obscuring less expensive generic alternatives that have the same therapeutic value.

However, Medco's efforts came to naught in February 1997, with the FDA Advisory Committee's rejection of its NDA for BiDil. Following the rejection, the value of the intellectual property rights plummeted along with Medco's stock; the rights reverted to Cohn, and Medco exited the story of BiDil's development.

The intervention of the federal regulatory system to deny the NDA marks the turning point on BiDil's journey toward ethnicity. The regulatory action taken by the Advisory Committee led the BiDil researchers to reconceptualize their drug along racial lines in order to get a “second bite” at the apple of FDA approval. By 1999, the value of the intellectual property rights to BiDil rebounded—not because of any changes to the underlying molecular structure or biological effects of BiDil as a drug, but because of the reanalysis of the old V-HeFT data along racial lines.

NitroMed acquired the intellectual property rights to BiDil in November 1999—a mere two months after the paper by Carson et al. identified purported racial differences in response to the H/I combination administered in V-HeFT I and II. In the hands of its new corporate handlers and their public relations consultants, BiDil soon was reborn as an ethnic drug. The subsequent spate of publicity attending the inauguration of A-HeFT demonstrated how the renewed value of the patent to BiDil provided an incentive for NitroMed to educate doctors and the public about the nature and value of this “new” drug for African Americans.

In the next logical extension of patent rights into the process of creating an ethnic drug, Cohn and Carson jointly filed for a new BiDil-related patent on September 8, 2000. With the title *Methods of treating and*

*preventing congestive heart failure with hydralazine compounds and isosorbide dinitrate or isosorbide mononitrate*, the 2000 patent appears much the same as Cohn's original 1989 patent.<sup>140</sup> Upon closer inspection, however, the abstract to the patent specifies that the "present invention provides methods for treating and preventing mortality associated with heart failure in an *African American* patient."<sup>141</sup>

The issuance of the new patent is commercially important because the original patent is set to expire in 2007. The new race-based patent will not expire until 2020. Significantly, in issuing the second patent, the United States Patent and Trademark Office (PTO) found that Cohn's first method-of-use patent for BiDil did not constitute "prior art" with respect to the new patent application. Rather, it found the application's race-specific method of treatment to be a "non-obvious" extension of the earlier concept and hence patentable.<sup>142</sup> A search of the U.S. PTO database for similar race-specific claims in a patent revealed this to be the only patent for such a race-specific drug treatment. Patent law is supposed to promote the invention of new and useful products. In the case of BiDil, patent law did not spur the invention of a new drug, but rather the recharacterization of an existing therapy for a particular segment of society—in short, the repackaging of the drug as ethnic.

With the issuance of the patent on October 15, 2002, race entered the world of patent law in a new and explicit way. The scope of patent protection is typically referred to in terms of "metes and bounds." The metaphors of physical property are quite deliberate. Cohn's and Carson's new patent racializes the "metes and bounds" of their intellectual property claims. As scholars such as Cheryl Harris<sup>143</sup> and Richard Thomson Ford<sup>144</sup> have noted, American law has a long tradition of characterizing property and physical spaces in racial terms—often to devastating effect. Whether in the most egregious and obvious form of race-based slavery or in subtler identifications of neighborhoods or even names<sup>145</sup> with race making it

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140. U.S. Patent No. 6,465,463 (issued Oct. 15, 2002), <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=/netahtml/srchnum.htm&r=1&f=G&l=50&s1=6,465,463.WKU.&OS=PN/6,465,463&RS=PN/6,465,463> (last visited Dec. 13, 2003).

141. *Id.* (emphasis added).

142. NitroMed, Inc., *supra* note 3, at 12.

143. Cheryl I. Harris, *Whiteness as Property*, 106 HARV. L. REV. 1707 (1993).

144. Richard Thomson Ford, *The Boundaries of Race: Political Geography in Legal Analysis*, 107 HARV. L. REV. 1841 (1994).

145. *See, e.g.*, Alan B. Krueger, *Sticks and Stones Can Break Bones, but the Wrong Name Can*

more difficult to obtain mortgages or jobs, the nature and value of property has long been profoundly influenced in and through its association with race.

Previous associations of race and property have generally involved a devaluing of associations with racial minorities. Certain more recent legal classifications of race, as in affirmative action, have the potential to offer challenges to exclusionary conceptions of racialized property rights.<sup>146</sup> The racialization of BiDil’s patent appears to be more in line with such assertedly “benign” uses of racial categories and has actually added value to the drug, hence the readiness of such groups as the Association of Black Cardiologists and the Congressional Black Caucus to support A-HeFT. In this regard, BiDil gains cultural capital by being characterized as a means to redress an important health disparity in a historically underserved population.

#### IV. LEGAL AND POLICY IMPLICATIONS OF RACE AS BIOLOGY IN THE WAKE OF BiDIL

There are dangers attending even purportedly benign uses of racial categories in the context of biomedicine that distinguish them from uses such as affirmative action. Specifically, in connecting race to biology, the advocates of BiDil run the risk of reviving long discredited notions of race as biology. This risk is less relevant to policies such as affirmative action that are often designed to redress specific past social or political inequities.<sup>147</sup> The role of the federal legal and regulatory system in producing BiDil as an ethnic drug is especially important because it lends the imprimatur of the state to the use of race as a biological category. Between the FDA’s letter commenting on the ultimate approvability of BiDil as a race-specific drug and the U.S. PTO’s recent issuance of the patent for using H/I in African American patients, powerful federal agencies have acknowledged the legitimacy of using race as a marker for biological difference. In this context, we see the federal government indirectly fueling the “comeback” in “racialized notions of biology” against which Alan Goodman cautioned.<sup>148</sup>

There are real health disparities in society that correlate with certain

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*Make a Job Hard to Find*, N.Y. TIMES, Dec. 12, 2002, at C2.

146. See, e.g., Harris, *supra* note 143, at 1768-91.

147. Cf. *City of Richmond v. J. A. Croson Co.*, 488 U.S. 469 (1989).

148. Alan H. Goodman, *Why Genes Don’t Count (for Racial Differences in Health)*, 90 AM. J. PUB. HEALTH 1669, 1699 (2000).

racial groups. As sociologist Troy Duster has noted, "We can and should refer to race when we consider it as part of a complex interaction of social forces and biological feedback loops."<sup>149</sup> Duster cautions, however, that "it is also a mistake to uncritically accept old racial classifications when we study medical treatments. The task is to determine how the social meaning of race can affect biological outcomes."<sup>150</sup> The story of BiDil is a story of the failure of a wide variety of actors—from medical researchers to federal regulators to drug company executives—to heed Duster's warning.

Some doctors and scientists are clearly concerned. One news report on BiDil quoted Craig Venter, who was CEO of Celera Genomics when it completed its rough draft of the human genome in 2001, as saying, "It is disturbing to see reputable scientists and physicians even categorizing things in terms of race. . . . There is no basis in the genetic code for race."<sup>151</sup> Dr. Charles Curry, a cardiologist at Howard University Hospital cautioned, "[I]f NitroMed starts bombarding blacks with ads, those patients and their doctors could ignore other potentially effective treatments. . . . Patients don't respond to medications in the same way, so marketing drugs by race can be misleading."<sup>152</sup> Mark Pfeffer of Harvard's Brigham and Women's Hospital expressed skepticism about A-HeFT's approach because it substituted skin color for genetic analysis.<sup>153</sup> Finally, Joseph Graves, an evolutionary biologist at Arizona State University, argued that "linking illness—or any other trait, like intelligence or athletic skill—to appearance is a fundamental scientific error."<sup>154</sup> He expressed the further concern that "scientists are often too quick to look for genetic explanations for disparities in health, when lifestyle may be the answer."<sup>155</sup>

Proponents of the race-based approach to BiDil try to define the individual by reference to a biological group (i.e., individuals who respond well to BiDil)—not a social group (i.e., African Americans). They assert that the biological group merely "correlates" with race. Hence, the proponents of BiDil acknowledge that they are using race merely as a

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149. Troy Duster, *Buried Alive: The Concept of Race in Science*, CHRON. HIGHER EDUC., Sept. 14, 2001, at B12.

150. *Id.*

151. Stolberg, *supra* note 21. Venter, however, here goes to the extreme of denying the significance of race altogether. The logic of his argument compels us to overlook the significance of health disparities such as varying rates of certain types of cancer or hypertension that do strongly correlate with certain *social* categories of race.

152. Sealey, *supra* note 4.

153. Editorial Board, *supra* note 21.

154. Stolberg, *supra* note 21 (quoting Dr. Graves).

155. *Id.*



surrogate marker to get at a distinctive underlying biology of response to heart failure therapy. Yancy, like Cohn, has argued that race "is pertinent [only] as a crude marker of genetic variation," and that "the only reason to have this discourse regarding racial differences in the natural history of cardiovascular disease is not to learn more about race per se, but rather to uncover new mechanisms of disease."<sup>156</sup>

However, in practice something different is happening. Hydralazine and isosorbide dinitrate do not address the social causes of heart failure, only the individualized biological ones. Such a therapy is administered based on understandings of biology. Cohn's and Carson's patent is not for a method of treatment that merely correlates with a social group—it specifies a chemical therapy for "African Americans." That is, it specifies African Americans as a biological group, and it has received the approval of the federal government for this classification. Now, NitroMed is similarly seeking regulatory approval for BiDil as a drug to treat African Americans, conflating social with biological categories. What sociologist Michael Omi observes with respect to the use of racial categories in the social sciences might well apply here: "[M]uch of sociological research, though firmly committed to a social as opposed to biological interpretation of race, nevertheless slips into a kind of objectivism about racial identity and racial meaning. . . . Although abstractly acknowledged to be a sociohistorical construct, race in practice is often treated as an objective fact."<sup>157</sup> The scholarly studies, press reports, and marketing copy for BiDil all contain brief caveats about race as a social category or as a crude marker for particular biological conditions. The caveats, however, are usually buried deep in the text, or else they are superceded by subsequent assertions or practices of treating race as, in effect, a genetic category (as with Yancy's hope to identify some "genetic descriptors of race"). The headlines always place in the foreground the identification of race with biology.

The drive to reduce disease to the level of the individual genome reflects a prototypically American emphasis on the autonomous, unencumbered individual as the primary subject of political and social concern.<sup>158</sup> This may appear to fly in the face of calls for "racial profiling" in medicine, but in fact there is an underlying and highly problematic logic at work here. In the context of the drive toward BiDil, those who

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156. Yancy, *Role of Race*, *supra* note 20, at 224.

157. Michael Omi, *Racial Identity and the State: The Dilemmas of Classification*, 15 LAW & INEQ. J. 7, 21 (1997).

158. See, e.g., Michael Sandel, *The Procedural Republic and the Unencumbered Self*, 12 POL. THEORY 81 (1984).

argue for racial profiling in medicine assert that it is permissible to use social categories of race as surrogates for biological characteristics that are understood to be “real” or “natural.” Conversely, social, economic, and political differences that correlate with social categories of race have been undervalued as important determinants of health. The implicit message here is that the purportedly biological differences identified by BiDil researchers deserve priority over the social differences identified by studies such as that conducted by the Institute of Medicine. Such prioritization promises to affect the allocation of scarce health care resources away from addressing the social bases of disease and toward what may be an excessive concentration on disease on the molecular level.

To the extent that such logic is extended into the realm of racial classifications in law it has some additional troubling implications. First, in a general way it may support certain efforts to undermine affirmative action. Affirmative action programs use race as a social classification to redress past and present social, economic, and political injustice. As race becomes re-imagined primarily in terms of biology (genetics in particular), such programs may increasingly come to be seen as based in “ephemeral” or insubstantial differences that are not the basis of legitimate classifications. In contrast, legal classifications based on so-called “real” differences based in biology may be put forth as sufficiently substantial to withstand heightened or strict scrutiny.

For example, it would be legal to discriminate against blind people when looking to hire a school bus driver. While the group “blind people” might be understood to constitute a “discrete and insular minority” that has historically experienced a measure of unjust discrimination, having sight would pass legal muster as a bona fide occupational qualification closely related to the compelling state interest of insuring the safety of both school children on the bus and pedestrians. The case for discrimination could become more complicated in the case of barring epileptics from being school bus drivers. Certainly, one would not want a school bus driver to have seizure while on the road. But whereas the probability that a blind person cannot see the road is one hundred percent, the probability that a person with epilepsy will have a seizure while driving is something far less than one hundred percent. Nonetheless, the probability of such a seizure is also far higher than it would be for someone who did not have epilepsy. As a result, even though anyone can potentially have a seizure while driving, the greater probability that a person with epilepsy would have a seizure would probably justify discrimination in this context as sufficiently narrowly tailored to serve the compelling interest of protecting the lives of school children. However,

what happens when we add to the equation the fact that many types of epilepsy can be effectively controlled through medication? For such cases the probability of seizure goes down even further—at what point does the probability cease to justify discrimination?

To the extent that the federal government marks race as a “natural” biological category it may open the door to new forms of race-based discrimination. Already, for example, employers are permitted under law to discriminate based on certain health conditions where such discrimination is mandated as a “business necessity,”<sup>159</sup> or in other situations where the health condition interferes with a “bona fide occupational qualification.”<sup>160</sup> Hence, the Supreme Court recently held it permissible under the Americans with Disabilities Act (ADA) for Chevron to refuse to hire Mario Echazabal to work in a refinery because his Hepatitis C would likely be aggravated by exposure to toxins at the refinery.<sup>161</sup> The ruling interpreted a section of the ADA that allowed employers to discriminate against workers whose condition posed a direct threat<sup>162</sup> to others in the workplace. At issue was whether the Act also covered conditions that only posed a direct threat to the workers themselves. The Court found that it did.<sup>163</sup> Thus, it legitimized Chevron’s discrimination against Echazabal on the basis of its assertion that his Hepatitis C would likely pose a direct threat to him in the distinctive

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159. *See, e.g.,* *Chevron v. Echazabal*, 537 U.S. 73, 80 (2002) (discussing, *inter alia*, § 12113(a) of the Americans with Disabilities Act, which allows employers to discriminate under a qualification standard shown to be job related and consistent with business necessity).

160. *See generally* Americans with Disabilities Act of 1990, Pub. L. No. 101-336, 104 Stat. 327 (1990) (codified at 42 U.S.C. §§ 12101-12213 (2000)). *See also, e.g.,* *Albertsons v. Kirkingburg*, 527 U.S. 555 (1999) (finding that an employer’s refusal to hire for a commercial interstate truck driving job an individual on the grounds that he did not possess binocular vision correctable to a specified degree as mandated under a federal regulation did not constitute a violation of the ADA because the legislative history of the subject regulation demonstrated the regulation was based on considerations of the general public’s safety); *Automobile Workers v. Johnson Controls, Inc.* 499 U.S. 187 (1990) (finding a policy barring all women of child-bearing age from jobs involving lead exposure as violative of Title VII of the Civil Rights Act because the policy did not involve the ability to perform the relevant jobs).

161. *Chevron*, 537 U.S. 73.

162. The ADA defines a “direct threat” as “a significant risk to the health and safety of others that cannot be eliminated by reasonable accommodation.” Americans with Disabilities Act of 1990, 42 U.S.C. § 12111 (2000).

163. *Chevron*, 537 U.S. at 86.

setting of a refinery. The ruling required an individualized medical assessment, yet it also recognized the legitimacy of discriminating against an individual based on a biological medical condition.<sup>164</sup> Justice Souter's opinion reflected a general understanding that a work-related biological condition may provide a legal basis for discrimination. There is cause for concern, however, when one considers the implications of applying the logic of Souter's opinion to a situation where racial categories have become biological. To the extent that legal institutions such as the U.S. PTO or the FDA come to mark certain biological conditions as "racial," race may become a surrogate not only for medical research but also for a wide array of legally sanctioned discrimination. Specifically, it deserves noting that while Echazabel was legally entitled to receive an individualized medical assessment of his health status—i.e., having Hepatitis C—the determination of whether that condition posed a direct threat to him under the ADA was still determined by reference to probabilistic correlations between that condition and certain expected health outcomes in the presence of certain potentially aggravating factors in the environment. As race becomes correlated with various biological conditions, it takes only one further step to correlate race with a health threat.

In the not too distant past we have clear examples of discrimination based on a particular genetic condition being justified by only the most tenuous of probabilistic links to potential harm. Sickle cell trait has been the basis for differential genetic screening of populations and the outright exclusion from certain forms of employment. Is coincidence that this sickle cell trait is among the most powerfully racially identified conditions in our culture? As sociologist Troy Duster notes, "In the United States, approximately one in twelve blacks are carriers [of the sickle cell trait]. Because of this, sickle cell is popularly thought to be a 'black person's disease,' and this image penetrates the consciousness of those who are even partially informed about these matters."<sup>165</sup> Sickle cell anemia is a condition that impairs a person's red blood cells from carrying oxygen. It can cause mild or severe pain in organs, joints or muscles, and in extreme cases even death. A "carrier" of the sickle cell "trait" has one copy of the sickle cell gene (in the language of biology, they are "heterozygous"); individuals with the actual disease have two copies of the gene, one from each parent (known as "homozygous"). People with the trait (i.e., one gene) but not the actual disease do not manifest any ill health effects.

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164. *Id.*

165. DUSTER, *supra* note 21, at 45.

Indeed it is thought that having one gene may enhance a carrier's resistance to malaria. While the prevalence of the sickle cell trait is higher in populations identified as African American than in populations identified as Caucasian American, the trait most emphatically is not exclusive to blacks or Africans. Rather, it is currently understood by the medical and scientific community as an artifact of populations descended from regions of the world with a high incidence of malaria such as West Africa. For example, the trait is also found among many Mediterranean populations, including especially Greeks and Sicilians, as well as certain Arab and Asian Indian populations, whereas it is rare in South African blacks.<sup>166</sup>

None of this mattered in the late 1960s when four black men died over an eleven month period while going through basic combat training at a U.S. Army camp at the relatively high altitude of 4,060 feet.<sup>167</sup> Autopsies revealed that all four had severe sickling of the red blood cells—although this could have been a consequence rather than a cause of their deaths. Nonetheless, a report of the deaths was published in the *New England Journal of Medicine* in 1970 and was followed up by a study conducted by the National Academy of Sciences (NAS). The NAS report found that the data were inadequate to support any specific conclusions but recommended that carriers of the sickle cell trait be excluded inter alia from copiloting an airplane. The U.S. Air Force Academy seized upon the NAS report to justify a new policy of excluding all blacks with the sickle cell trait. The policy continued until 1981 when a lawsuit finally prompted the Academy to end its policy.<sup>168</sup> Commercial air carriers adopted a similar policy that continued into the 1980s.<sup>169</sup> In this regard, it is instructive to reflect back upon the case of Echazabel. Just as the earlier Air Force Academy discrimination against blacks was done under the paternalistic guise of protecting them,<sup>170</sup> so too was the decision upholding Chevron's discrimination against Echazabel ultimately justified in the name of protecting him from danger. The ADA's concern for health risks or "direct

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166. See *id.*; JONATHAN MARKS, *HUMAN BIODIVERSITY: GENES, RACE, AND HISTORY* (1995). For a powerful history of the politics of sickle cell anemia in the United States, see KEITH WAILOO, *DYING IN THE CITY OF THE BLUES* (2001).

167. The following story is drawn largely from DUSTER, *supra* note 21, at 24-27; KEVLES, *supra* note 21, at 277-79; and Raymond R. Coletta, *Biotechnology and the Law: Biotechnology and the Creation of Ethics*, 32 MCGEORGE L. REV. 89, 97 (2000).

168. See DUSTER, *supra* note 21, at 25-26.

169. See *id.*; Coletta, *supra* note 167, at 97.

170. See Janet L. Dolgin, *Personhood, Discrimination, and the New Genetics*, 66 BROOK. L. REV. 755, 818 (2000).

threats"<sup>171</sup> introduces calculations of probabilistic correlation between biological condition and danger that draw upon claims put forth by biomedical researchers who assert correlations among race, genetics, and the risk of disease. This is not to say that these correlations are per se unreasonable, but it should alert us to be careful to prevent such correlations from becoming overly attenuated, especially when they are used in relation to race.

More recently, in the 1998 case of *Norman-Bloodsaw v. Lawrence Berkeley Laboratory*,<sup>172</sup> employees at Lawrence Berkeley Laboratory (LBL), a research institution jointly operated by the federal government and the University of California, brought suit when they discovered that LBL, without their knowledge or consent, had tested blood and urine from mandatory physical exams for syphilis, sickle cell trait, and pregnancy. The court ultimately found a cause of action to lie under Title VII of the Civil Rights Act of 1964 and under state and federal privacy claims.<sup>173</sup> The screening, for sickle cell in particular, was differentially administered based on race: Blacks were singled out for testing. While all the tests were offensive at a number of levels, of particular interest for our purposes is the fact that LBL, a major scientific research institution administered by one of the country's preeminent public universities, was, in practice, treating African Americans as a biological group to be screened for the sickle cell trait. LBL's practices demonstrated no appreciation either of the fact that sickle cell trait is not limited to African Americans or of the fact that merely having the trait does not predispose a carrier to any adverse health conditions. Rather, the social and cultural identification of sickle cell trait as "black" pervaded and warped the employment practices of a supposedly sophisticated scientific research institution as recently as the 1990s.

As more biological conditions become correlated with race, differential screening of individuals for those conditions and perhaps even outright group-based exclusions from employment, insurance or other benefits may result. The mistreatment of African Americans with sickle cell trait is instructive here. It should be understood not as anomalous but as paradigmatic of problems that may develop as genetic knowledge and technologies continue to advance.

In this regard, it is important to note that most efforts to address genetic discrimination focus on the production, circulation, and potential misuse of a particular individual's genetic information. Statutes covering

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171. Americans with Disabilities Act of 1990, 42 U.S.C. § 12111 (2000).

172. *Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260, 1261 (9th Cir. 1998).

173. *Id.* at 1264.

these problems tend to cover issues of privacy, information control, and the evaluation of individualized medical conditions.<sup>174</sup> Identifying certain biological conditions, especially genetic conditions, with racial groups presents challenges of a different order. Instead of implicating new forms of discrimination based on specific individualized genetic conditions—what Susan Wolf has terms “geneticism”<sup>175</sup>—the re-biologization of race promises to entangle existing groups that have historically been subject to various forms of discriminatory treatment, such as African Americans, with new biological categories that are being produced through advances in the new genetics. The U.S. Air Force Academy and LBL did not single out blacks for screening based on access to private individual genetic information, but rather because of the identification of the social group “African American” with the biological group “sickle cell carrier.”

As Lee et al. note, “Research utilizing race serves to ‘naturalize’ the boundaries dividing human populations, making it appear that the differences found reflect laws of nature. In fact, the use of race and ethnicity in biomedical research is problematic because it is caught in a tautology, both informed by, and reproducing, ‘racialized truths.’”<sup>176</sup> Such a dynamic portends the potential reinvigoration of legally sanctioned race-based discrimination by recasting particular aspects of race in terms of biological difference. Such discrimination is unlikely to appear in the familiar forms of the past. We should not expect to see direct segregation or exclusion of entire racial groups from rights and benefits based on their identification with genetic difference. Rather, subtler forms of differential treatment may arise based on tenuous correlations between genetic difference and racial groups; these correlations may lead to selective discrimination within those groups that is justified by reference to underlying “real” genetic distinctions. Harm may come not from deliberate animus toward a particular group, but from which questions get asked, by whom, and to what ends. Such harm occurred in the past when the U.S. Air Force Academy acted on incomplete information and inadequate studies to differentially screen and exclude blacks, and such harms may occur in the future. For example, from the conception of heart failure as a

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174. See, e.g., Nancy Kass, *The Implications of Genetic Testing for Health and Life Insurance*, in GENETIC SECRETS 299-316 (Mark Rothstein ed., 1997); Mark Rothstein, *The Law of Medical and Genetic Privacy in the Workplace*, in GENETIC SECRETS 281-298 (Mark Rothstein ed., 1997). See generally LORI ANDREWS ET AL., GENETICS: ETHICS LAW AND POLICY 592-734 (2002).

175. Susan Wolf, *Beyond Genetic Discrimination: Toward the Broader Harm of Geneticism*, 23 AM. J.L. & MED. 345, 350 (1995).

176. Lee et al., *supra* note 13, at 55 (citations omitted).

“different disease” in blacks there is the potential for misallocation of resources away from traditional population health measures directed at ameliorating health disparities and toward the development of race-specific drugs such as BiDil.

#### V. SOME PRELIMINARY RECOMMENDATIONS

In many respects, the story of BiDil is a cautionary tale about what Martha Minow has called the “dilemma of difference”: “[W]hen does treating people differently emphasize their differences and stigmatize or hinder them on that basis? And when does treating people the same become insensitive to their difference and likely to stigmatize or hinder them on *that* basis?”<sup>177</sup> In the case of biomedical research aimed at addressing race-based health disparities, however, this dilemma takes on a particular twist where treating people differently can both help and hinder them simultaneously. As noted above, treating sickle cell anemia as a “black” disease has led to serious instances of unjust discrimination. It has also, however, enabled the political mobilization of elements of the African American community to campaign for increased funding for sickle cell research and other related health programs which propelled the creation of the Office of Minority Health and the implementation of the *Healthy People 2000* and *2010* initiatives.<sup>178</sup>

Race is a social category but it has biological consequences. The two are not easily disentangled. Ignoring the relation between them can be as harmful as seeing them as essentially identical. The task becomes even harder when, as in the case of BiDil, the imperatives of commerce and of the federal regulatory system combine to influence understandings of the nature and status of race as a category in biomedical research. In the case of BiDil, we see that the power of the state, as manifested by regulatory agencies such as the PTO and the FDA, may be reinforcing and legitimizing ill-conceived understandings of racial difference as genetic. This has implications both for biomedical research and for broader social understandings of race.

To clarify our thinking, we must take to heart Duster’s admonition to use and understand racial categories as part of a “complex interaction of

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177. MARTHA MINOW, MAKING ALL THE DIFFERENCE: INCLUSION AND EXCLUSION IN AMERICAN LAW 20 (1990).

178. For example, current 2002 fiscal year CDC appropriations for “minority health” total \$747,472,000. CTRS. FOR DISEASE CONTROL & PREVENTION, MINORITY HEALTH FUNDING, at <http://www.cdc.gov/washington/funding/minorhea.htm> (last visited Dec. 15, 2003).



social forces and biological feedback loops.”<sup>179</sup> At a minimum, this should entail that any federal agency or institution conducting research with federal funds that reviews, approves, or itself uses race as a biological category or as a surrogate for a biological category be required to offer a clarification of their terms of analysis and a justification for using them in such a manner. In this regard, it is instructive to consider that the PTO already has provisions directing patent examiners to reject applications for design patents which disclose subject matter “which could be deemed offensive to any race, religion, sex, ethnic group, or nationality.”<sup>180</sup> The provisions also assert that “[t]here is a further basis for objection in that the inclusion of such proscribed language in a Federal Government publication would not be in the public interest.”<sup>181</sup> The PTO here seems to be acknowledging the significance of preventing the state from lending its imprimatur to improper uses of racial language. The basis is here laid for extending that concern from overtly offensive language to perhaps well-meaning but ill-conceived language that could promote a newly biologized understanding of racial difference.

Several prominent medical and scientific journals have recently adopted editorial policies that reflect a similar concern. The statement from the editors of *Nature Genetics* might well serve as a model for a regulatory admonition to such agencies as the FDA or the PTO when they are asked to review applications such as those submitted by the developers of BiDil:

The laudable objective to find means to improve the health conditions for all or for specific populations must not be compromised by the use of race or ethnicity as pseudo-biological variables. From now on *Nature Genetics* will therefore require that authors explain why they make use of particular ethnic groups or populations, and how classification was achieved. We will ask reviewers to consider these parameters when judging the merits of a manuscript – we hope that this will raise awareness and inspire more rigorous design of genetic and epidemiological studies.<sup>182</sup>

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179. Duster, *supra* note 149, at B12.

180. U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE, § 1504.01(e), [http://www.uspto.gov/web/offices/pac/mpep/documents/1500\\_1504\\_01\\_e.htm#sect1504.01e](http://www.uspto.gov/web/offices/pac/mpep/documents/1500_1504_01_e.htm#sect1504.01e) (last visited May 20, 2003).

181. *Id.* at § 608, [http://www.uspto.gov/web/offices/pac/mpep/documents/0600\\_608.htm#sec608](http://www.uspto.gov/web/offices/pac/mpep/documents/0600_608.htm#sec608).

182. *Census, Race and Science*, *supra* note 2, at 99.

If the FDA or the PTO had been following such guidelines, the story of BiDil would likely have unfolded quite differently. Requiring federal agencies to take a closer look at filings and applications that use race as a biological category could force applicants to provide more rigorous justification for their use of such terminology. Just as under equal protection jurisprudence, where strict scrutiny by the courts exposes invidious motives behind legal distinction based on suspect classifications,<sup>183</sup> so too a harder administrative look at race when used as a biological category might reveal instances of its improper use.

The objective here is not to forbid the use of race as a category in federal policy, law, or regulation. Rather, it is to begin to articulate an institutional mechanism of guidelines whereby relevant administrative actors would be required to distinguish between uses of race as a socio-political category from uses of race as a biological and/or explicitly genetic category. The former can be used to track and/or redress historical inequities and current social prejudices. The latter, perhaps as a consequence of seeking relevant regulatory approvals for patents, products, and/or services, involves federal recognition of the use of race as a biological category. Therefore, whenever an applicant uses race in relation to biology before an agent of the state a justification for the use should be required. This justification should involve, first, an assertion that it serves a compelling interest and, second, a showing that the application uses race as biology in a way that is narrowly tailored to serving that interest. The second prong is necessary to force a distinction between observed correlations between certain biomedical conditions and certain socially identified racial groups, and racially specific genetic causation purported to underlie such correlations. Here that would mean providing compelling scientific evidence to support an assertion of race-specific genetic difference underlying any observed correlations. To date, no such differences have been identified by biomedical science. In the case of BiDil the first criterion would probably be met. Providing an effective therapy for heart failure in African Americans would likely be a compelling interest, although the actual efficacy of BiDil in this regard is yet to be established. However, even if we assume that the first prong were met, the story of BiDil shows that this particular use of race in relation to biology was *not* narrowly tailored to serve that interest. Rather, given the history of BiDil and the peculiar nature of its distinctive transformation into an ethnic drug, it is evident that it was initially developed without reference to

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183. For the most recent Supreme Court pronouncement on this, see *Grutter v. Bollinger*, 123 S.Ct. 2325, 2337-38 (2003).

race and ultimately became racialized not because of clearly identified race-based biological differences but because of considerations of law and commerce.

In addition to these regulatory considerations of how and what the PTO and FDA should agree to sanction, there are myriad arenas where the identification of particular racial groups with specific genetic conditions could have possible legal ramifications. For example, racially correlated disease information raises issues of employment or insurance discrimination already touched upon in the story of sickle cell trait. In the realm of toxic torts, as gene-environment interactions become more fully understood, claims could be both organized and defended against by reference to racial categories.<sup>184</sup> It is also conceivable that a doctor might be sued for taking or failing to take race into account in making a diagnosis or prescribing treatment. How might this affect medical practice and the doctor patient relationship—especially as drugs increasingly are being marketed directly to consumers? In the case of BiDil, what is a doctor to make of the fact that, if approved, the FDA labeling specifies the drug for use only in African Americans, whereas guidelines from the American Heart Association specify the same H/I combination as a generally legitimate therapy for anyone who is intolerant of ACE inhibitors?<sup>185</sup>

Just how law and policy may become implicated in such diverse areas over time is impossible to foresee fully. What is foreseeable, however, is that as new genomics information becomes available, a range of actors will continue to seek correlations between racial and biological groups. Such correlations will not and should not be ignored. However, it is imperative that they not be invoked casually or without sufficient consideration of the complex relations between race and biology. Demanding a clear and full articulation of the basis and justification for developing and employing such correlations should be considered an essential starting point for confronting the challenges to come.

## CONCLUSION

In the end, the story of BiDil is much more than an individualized account of how a particular drug became focused on a single, ethnic segment of the population. The story is also part of a broader contest over

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184. See, e.g., Morris Foster & Richard Sharp, *Race, Ethnicity, and Genomics: Social Classifications as Proxies for Biological Heterogeneity*, 12 GENOME RES. 844 (2002).

185. See, e.g., AM. COLL. OF CARDIOLOGY & AM. HEART ASS'N, *supra* note 27.

classifications systems and context—which variables matter, as well as how and when. BiDil’s development has depended upon the strategic appropriation of the social category of race to justify patenting and regulatory approval of a drug that purports to act on a “true” biological basis of heart failure. In the story of BiDil, race plays the role of a valuable surrogate—i.e., it is presented as having no medical value in its own right but takes on significance to the extent that researchers can tie it to a “real” biological group through statistical correlations (hence the centrality of the statistic that blacks die from heart failure at a rate twice that of whites). The unrelenting urge to establish such race-based correlations has led to an egregious failure to interrogate what turns out to be an inaccurate statistic. Moreover, even as BiDil’s proponents acknowledge race to be merely a crude marker for biology, they have invoked race as biology to establish intellectual property rights, obtain regulatory approval, raise venture capital, and develop marketing campaigns. Regardless of the particular fate of BiDil as a drug to treat heart failure, its peculiar history on the road to the market presents a wide array of troubling and important issues concerning the future status of race as a category for constructing and understanding health disparities in American society.

## (How) Is Aging a Health Policy Problem?

Joseph White, Ph.D.\*

### INTRODUCTION

During the 1990s, the claim that an aging population constituted a long-term “crisis” became a policy cliché. This assertion became particularly popular among elite journalists and academics in the United States. For example, *Washington Post* columnist David Broder wrote of “the fiscal calamity that the retirement of the baby-boom generation poses for the early years of the next century.”<sup>1</sup> Former Director of the Congressional Budget Office (and current President of the Urban Institute) Robert Reischauer referred to “the demographic tsunami of the baby boom’s retirement.”<sup>2</sup> Moreover, the Congressional Budget Office and U.S. General Accounting Office began issuing reports projecting the date of economic doomsday caused by spiraling deficits that would be caused, in turn, by burgeoning pension and health care costs.<sup>3</sup> Because Medicare costs have grown far more quickly than Social Security obligations—though the latter will still remain larger than the former for many years—and because a significant portion of Medicaid spending also covers the elderly, much of this commentary has focused on health care costs in particular. Eminent health economist Victor Fuchs wrote that health care costs for the elderly “could plunge the nation into a severe economic and social crisis within two decades.”<sup>4</sup> Former Colorado Governor Richard D. Lamm wrote of “the

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1. David S. Broder, *The Party's Over: By 2000, the GOP or the Democrats Could Fade in Favor of a Third Party*, WASH. POST, Aug. 11, 1999, at C1.

2. Burt Solomon, *OK, Now What?*, 28 NAT'L J. 2394, 2394 (1996).

3. JOSEPH WHITE, *FALSE ALARM* 73-98 (2d ed. 2003).

4. Victor R. Fuchs, *Health Care for the Elderly: How Much? Who Will Pay?*, HEALTH AFF.,

moral imperative of limiting elderly health entitlements,” claiming that program costs would otherwise impoverish the young.<sup>5</sup>

Jeremiads about the challenges of aging in general, and of paying for the health care costs of the elderly in particular, have been especially loud in the United States, where they have dovetailed conveniently with an underlying ideological campaign to cut government programs.<sup>6</sup> However, these demographic trends and budgetary pressures exist in all countries, and so this concern is heard around the world. Indeed, it has become a common theme in the international policy community.<sup>7</sup> The World Bank, for example, has promoted this view of imminent crisis through its study *Averting the Old Age Crisis* and subsequent publications and conferences.<sup>8</sup> These worries regarding cost and inequity are based on plausible inferences. As people age, they tend to have higher medical expenses. Thus, if a larger portion of the population consists of older people, one might expect higher medical spending. In turn, pressure for higher spending poses issues of policy—how to pay, whether to pay—and ethics—the moral basis for providing or withholding benefits.

Yet, I will argue that, as a matter of both policy and ethics, policymakers and citizens need not worry about the implications of aging for medical costs. Aging of the population has some effect on health costs, but a much smaller effect than those factors that are both more susceptible to manipulation and pose less difficult ethical dilemmas. The aging of the population *does* pose economic and budgetary challenges, but the contribution of health care costs to this equation is relatively minor; policymakers would do better to focus on other concerns such as pension expenses and participation in the workforce. For these reasons, the health care costs of an aging population do not justify changes in health policy that would not otherwise be appropriate.

Nonetheless, aging poses a distinct health policy problem, which is only beginning to receive attention: The challenge will be less how to finance care than how to deliver it. The delivery challenge has two dimensions—how the health care system is organized and whether the

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Jan.-Feb. 1999, at 11, 11.

5. Richard D. Lamm, *The Moral Imperative of Limiting Elderly Health Entitlements*, in *POLICIES FOR AN AGING SOCIETY 199, 199* (Stuart H. Altman & David I. Shactman eds., 2002).

6. See generally WHITE, *supra* note 3.

7. See, e.g., ORG. FOR ECON. COOPERATION & DEV., *AGING IN OECD COUNTRIES* (Soc. Pol'y Stud. No. 20, 1996) [hereinafter *AGING IN OECD COUNTRIES*]; Peter Hicks, *The Impact of Aging on Public Policy*, *OECD OBSERVOR*, Dec.-Jan. 1996, at 19.

8. WORLD BANK, *AVERTING THE OLD AGE CRISIS* (1994).

necessary workers or caregivers will be available.

This Article begins by putting in perspective the effect of aging on health care spending. I compare aging to other factors and explain why America's peculiar health care finance system exaggerates our perception of the aging crisis. I challenge the notion that a growing population of the "old old," i.e., individuals age eighty-five and over, will be so expensive as to create severe ethical dilemmas. Next I look more closely at the distribution of costs and benefits between the elderly and other citizens. Specifically, I argue that increased longevity does not change the fairness of pay-as-you-go social insurance. Higher costs will call for tradeoffs, but there are good reasons to argue that health care for the elderly in particular should not be reduced. Rather, policymakers would do better to use caution today in all dimensions of budgetary policy to make choices easier in the future. They should also take steps to increase workforce participation, especially among the elderly.

Finally, I turn to what I see as the more significant effects of an aging population—the effects on demand for services, and the almost inevitable mismatch between the organization and supply of services on the one hand and geriatric care needs on the other. In this regard, long term care—which does not fit squarely into the categories of medical care, social service, or income protection—is of particular interest.

This Article is based on a review of the situation in the nations of the Organization for Economic Cooperation and Development (OECD) more generally. A comparative perspective reveals that discussion outside the United States is beginning to move beyond a simplistic focus on the "crisis" of future health care costs associated with an aging society. It is time for discussion within the United States to do the same.

## I. PUTTING THE HEALTH CARE SPENDING EFFECT OF AGING IN PERSPECTIVE

### *A. Aging Compared to Other Factors*

All other things being equal, an aging society should increase the share of gross domestic product (GDP) that is dedicated to medical services. The denominator reflects the number of workers, while the numerator depends on demand for medical services. The aging problem, as conventionally conceived, arises from the supposition that a larger share of the population will retire each year. Hence, the elderly population will rise more quickly than the supply of workers. As a result, if the population that demands medical services grows more quickly than the working population, spending on medical services can be expected to grow more

quickly than national production.

Yet all other things are never equal, and health care costs as a share of GDP depend on far more than demographic factors. Namely, health care costs depend on the extent to which new services are made available to citizens *of all ages*, on the extent to which those new services replace or supplement previous methods of care, and above all, on the prices paid for whichever services are provided. According to OECD statistics, the United States has the second smallest proportion of the population over age sixty-five among all rich democracies, yet by far the highest health care spending as a percent of GDP.<sup>9</sup> Why? As Gerard Anderson and colleagues argue, "It's the Prices, Stupid!"<sup>10</sup> We simply pay much more per service.

In some analyses, such non-demographic factors overwhelm any effect of population aging on spending. As Marmor and Oberlander have summarized, "[F]rom 1960 to 1990 there was no correlation across OECD nations between aging populations and growth in medical costs."<sup>11</sup> Using different techniques, Gruber and Wise reported that, from 1980 to 1991, there was a positive but not statistically significant relationship between the elderly share of the population and national health spending.<sup>12</sup> That relationship might imply, for example, that aging would cause health care spending in average OECD nations to rise by about 0.9% of GDP between 1990 and 2025.<sup>13</sup> However, that is distinctly smaller than the estimated

9. *Population 65 Years Old and Over - % of Total Population*, Org. for Econ. Cooperation & Dev., at <http://www.oecd.org/dataoecd/13/29/1935784.xls> (last visited Jan. 7, 2004) [hereinafter *Population 65 Years Old and Over*]; *Total Expenditure on Health - % GDP*, Org. for Econ. Cooperation & Dev., at <http://www.oecd.org/dataoecd/13/17/1935602.xls> (last visited Jan. 7, 2004) [hereinafter *Total Expenditures on Health*]. In the year 2000, 12.3% of Americans were 65 or over—tied with Australia and ahead of New Zealand at 11.7%. *Population 65 Years Old and Over*, *supra*. The United States spent 13% of GDP on health care; the nearest competitor was Switzerland at 10.7%. *Total Expenditure on Health*, *supra*.

10. Gerard F. Anderson et al., *It's the Prices, Stupid: Why the United States Is So Different from Other Countries*, HEALTH AFF., May-June 2003, at 89, 90.

11. Theodore R. Marmor & Jon Oberlander, *Rethinking Medicare Reform*, HEALTH AFF., Jan.-Feb. 1998, at 52, 55.

12. Jonathon Gruber & David Wise, *An International Perspective on Policies for an Aging Society*, in POLICIES FOR AN AGING SOCIETY, *supra* note 5, at 34, 57.

13. Gruber and Wise report a coefficient of 0.099, meaning that health spending as a percent of GDP would rise by 0.099 points for each one point increase in the elderly share of the total population. Gruber & Wise, *supra* note 12, at 55. The average percentage of population age sixty-five in OECD nations is projected to rise from 12.2% in 1990 to 21% in 2025. JEAN-MARC BURNIAUX ET AL., COPING WITH AGEING: A DYNAMIC APPROACH TO QUANTIFY THE IMPACT OF ALTERNATIVE POLICY OPTIONS ON FUTURE LABOUR SUPPLY IN OECD COUNTRIES



impact of other cost-increasing dynamics—which tend to be summarized as “technological progress.” A recent German study, for example, concluded that, due to aging, contribution rates to the sickness funds in Germany would have to rise from 13.6% of covered payroll to 16% by 2040.<sup>14</sup> “By comparison,” it added, “technological progress will more forcefully add the upward pressure producing a contribution rate of 23%.”<sup>15</sup>

*B. Medicare’s Deceptive Problem*

An aging United States population will raise Medicare costs proportionately more than those of any other nation’s national health care/insurance system. In all other rich democracies, when a person turns sixty-five the incremental cost to the national insurance fund, health service, or mandated insurance scheme is only the difference between that person’s medical costs at ages sixty-four and sixty-five. Because Medicare only covers the elderly and the disabled, when a person turns sixty-five the entire cost to Medicare is new.

However, it is a new cost only to the federal budget. When a person is added to the Medicare budget, costs to other payers, such as employers, fall; even the federal government may have an offsetting gain if it was previously granting a tax subsidy to an employer for providing private insurance.<sup>16</sup> If we were to consider society as a whole, or if the United States—like other wealthy democracies—guaranteed health care or insurance to anyone other than the elderly, the demographic effect would look smaller.

The aging population might be expected to raise Medicare spending

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71 (OECD Econ. Dep’t Working Paper No. 25, 2003). That increase in the aged population share, multiplied by the Gruber and Wise coefficient, yields slightly less than a 0.9% of GDP increase in health spending. Note, however, that Gruber and Wise’s estimate had a standard error of 0.069, so should be treated with caution. Gruber & Wise, *supra* note 12.

14. JURGEN VON HAGEN & ROLF R. STRAUCH, GERMAN PUBLIC FINANCES: RECENT EXPERIENCES AND FUTURE CHALLENGES 4 (Ctr. for Eur. Integration Stud. Working Paper No. B13, 2001).

15. *Id.*

16. The example of a person who is employed to age sixty-five, has health insurance through employment, and then retires and goes on Medicare is, of course, a simplification. Many people retire earlier, have some mix of coverage then from their former employer or other sources (e.g., a spouse’s employer), or never had insurance. However, in virtually all cases people who go on Medicare are giving up some other coverage, and the sponsor of the other coverage therefore is saving money.

by slightly more than two percent of GDP between 2000 and 2070.<sup>17</sup> But the Medicare Trustees projected that spending would rise by a total of 6.2% of GDP over the same seventy years.<sup>18</sup> In short, spending increases due to non-demographic factors are expected to be nearly double the level of increases resulting from demographic changes. These assumptions do indeed make Medicare seem unaffordable. Moreover, when applied to the health care system as a whole, these same assumptions yield presumably untenable results. If they are correct, American health care spending will rise to thirty-eight percent of GDP by 2075.<sup>19</sup> Clearly that would be a far more severe circumstance than the roughly two percent of GDP increase in Medicare costs attributed to demographic trends.

Thus, there is plenty of reason to worry about health care cost control.<sup>20</sup> Unfortunately, there is no credible evidence that changes in Medicare's entitlement, sometimes promoted as solutions to the cost problem, would do any good at all. The usual reform suggestion is that Medicare be turned from a defined benefit program, in which the federal government provides insurance for a standard set of benefits, into a "premium support" system, in which the federal government provides a contribution and individuals purchase insurance from a set of public and private options. However, the available data do not lend support to the idea that competition and privatization would save money.<sup>21</sup> For example,

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17. I do not have access to estimates of this precise effect. But, for example, the Congressional Budget Office estimated in 1998 that demographic factors alone would raise Medicare spending from 2.6% of GDP in 1995 to 4.4% in 2030, 4.5% in 2050 and 4.8% in 2070. CONG. BUDGET OFFICE, LONG-TERM BUDGETARY PRESSURES AND POLICY OPTIONS 49, 58 tbls. 4.2 & 4.5 (1998). It is important to note that spending net of enrollees' premiums would be a bit lower and the baseline for these 1998 estimates was significantly higher than actual spending in 2000. That is why I adjusted the figures as I did.

18. BD. OF TRS. OF THE SOC. SEC. & MEDICARE TRUST FUNDS, 2003 ANNUAL REPORT ON THE STATUS OF FEDERAL HOSPITAL INSURANCE TRUST AND SUPPLEMENTARY INSURANCE TRUST FUNDS 29 (2003), *available at* <http://www.cms.hhs.gov/publications/trusteesreport/2003/tabiia3.asp>.

19. HEALTH CARE FIN. ADMIN., TECHNICAL REVIEW PANEL ON THE MEDICARE TRS. REPORTS, REVIEW OF ASSUMPTIONS AND METHODS OF THE MEDICARE TRUSTEES' FINANCIAL PROJECTIONS 30 (2000), *available at* <http://www.cms.gov/publications/technicalpanelreport/report.pdf>.

20. I have argued elsewhere that policymakers could never adopt policies to promise some controlled level of spending more than a few years in the future. *See, e.g., WHITE, supra* note 3, at 110-13. Yet they should still control costs in the short run by any responsible methods they can find, following the best available information.

21. *See WHITE, supra* note 3, at 252; Marsha Gold, *Can Managed Care and Competition Control Medicare Costs?*, HEALTH AFF., Apr. 2, 2003 Web Supplement, at W3-176, *available at* <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.176v1.pdf>.

even after two successive years (1997 and 1998) in which traditional Medicare spending per enrollee *slightly shrank*, Medicare's costs per enrollee grew by only about twenty-five percent from 1999 through 2003, while private insurance premiums rose by about fifty-five percent.<sup>22</sup> Given Medicare's superior cost control performance, arguments that it must be reformed to look more like private insurance due to the coming demographic crisis are questionable at best. It would be more reasonable to infer that the rest of the system should be reformed to more closely resemble Medicare.

*C. The Mythical Ethical Challenge of the "Old Old"*

Within the general fear-mongering about health care costs for the elderly, one issue is treated as raising particularly severe ethical and financial issues: the growth in the population of "old old." The theory is that very old and frail people incur particularly high medical costs and that those costs are unproductive from a societal perspective since those people will die soon anyway.<sup>23</sup> Such financial concerns may be joined with bioethical concerns about the appropriateness of extending life for people with few prospects of surviving or worries about the need to allocate care in such a way that expensive care for the very old does not divert resources from care for younger persons.

Fortunately, as it turns out, neither end-of-life care nor aging within the elderly population makes much of an independent contribution to increases in total health care system costs. For example, within Medicare, spending at the end-of-life has remained a nearly constant share of total costs.<sup>24</sup> Population aging turns out to have cost-saving as well as cost-increasing implications.

Costs for an eighty-year-old person are, on average, much higher than

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22. I arrived at this figure by using data from BD. OF TRS. OF THE SOC. SEC. & MEDICARE TRUST FUNDS, 2003 ANNUAL REPORT ON THE STATUS OF FEDERAL HOSPITAL INSURANCE TRUST AND SUPPLEMENTARY INSURANCE TRUST FUNDS 29 tbl.IV.B1 (2003), *available at* <http://www.cms.hhs.gov/publications/trusteesreport/2003/tabivb1.asp>. See also Bradley C. Strunk et al., *Tracking Health Care Costs: Growth Accelerates Again in 2001*, HEALTH AFF., Sept. 25, 2002 Web Supplement, at 299, 306; Bradley C. Strunk et al., *Tracking Health Care Costs: Trends Stabilize but Remain High in 2002*, HEALTH AFF., Jan.-June Web Supplement, at 266, 272, *available at* <http://www.openminds.com/indres/Health%20Affairs%20June%202003.pdf>.

23. See PETER G. PETERSON, WILL AMERICA GROW UP BEFORE IT GROWS OLD? 26-27 (1996).

24. James Lubitz et al., *Longevity and Medicare Expenditures*, 332 NEW ENG. J. MED. 999 (1995).

for a sixty-five-year-old person.<sup>25</sup> The major reason is that an eighty-year-old is more likely to die, and mortal illness tends to be expensive. As life expectancies increase, there will be more eighty-year-old people, but each of them will also be less likely to die. Thus, the average cost of eighty-year-olds should go down as the number of eighty-year-olds goes up. Analyses have shown the two effects largely canceling each other out, not only in the United States's Medicare program, but in Switzerland<sup>26</sup> and across the OECD nations.<sup>27</sup>

Could the future have a different dynamic than the past? I have noted that longevity increases have been associated with lower spending at a given age because fewer people are dying at that age and dying is expensive. However, it is possible that future increases in life expectancy will be attributable to highly expensive medical interventions. In other words, there could be just as many eighty-year-olds having what would now turn out to be fatal illnesses in 2030 as there are today; their treatment could be as or more expensive in constant dollars; and more of the treatments could work. Then increased longevity would cause extra costs with no offsetting savings. That is possible, but entirely speculative. With equal logic, one could project that certain medical innovations (e.g., in cardiac care) will be relatively efficient; people will be "saved" more cheaply, and then die quietly of old age, also cheaply. Medicare data show that "the costs of medical treatment near death decrease with increasing age of death."<sup>28</sup> For the moment, it is reasonable to hypothesize that longevity increases in the future will have roughly the same profile as in the past.

If we extrapolate from experience to date, the organization and finance of health care will have far more effect on both the cost and quality of future medical care than will the effects of demographic change. From this perspective, population aging is, as Peter Zweifel and colleagues have suggested, a "red herring."<sup>29</sup>

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25. HOUSE COMM. ON WAYS & MEANS, 104TH CONG., 1996 GREEN BOOK: BACKGROUND MATERIAL AND DATA ON PROGRAMS WITHIN THE JURISDICTION OF THE COMMITTEE ON WAYS AND MEANS 246-47 tbls.3-50 (Comm. Print 1996).

26. Peter Zweifel et al., *Aging of Population and Health Care Expenditure: A Red Herring?*, 8 HEALTH ECON. 485 (1999).

27. See HOWARD OXLEY & MAITLAND MACFARLAN, HEALTH CARE REFORM: CONTROLLING SPENDING AND INCREASING EFFICIENCY (OECD Econ. Dep't Working Paper No. 149, 1994); see also AGING IN OECD COUNTRIES, *supra* note 7.

28. Lubitz et al., *supra* note 24, at 1001.

29. Zweifel et al., *supra* note 26.

## II. DISTRIBUTION BETWEEN THE ELDERLY AND OTHER CITIZENS

We have seen that demographic trends have a relatively small effect on health care costs, and in particular, the fear of increasing costs for the “old old” is not justified. Yet an important normative question remains: If there are more elderly compared to the number of workers, does that mean that publicly guaranteed benefits for the elderly should be reduced? In the standard formulation, “our children” will pay more for our health care when we retire than we did for “our parents’” health care, because we are expected to live longer than our parents. Is that fair?

### *A. Why Increasing Longevity Does Not Make Pay-as-You-Go Systems Unfair*

As the point is commonly argued in the case of pensions, the burden on “our children” or “our grandchildren” should be reduced by shifting from a system in which each generation pays for its predecessors through taxes to one in which the currently aging group pays for itself through some system of savings. In pension terms, it would be a shift from “pay-as-you-go” to “pre-funding.” Such an approach has been recommended for health care by one of the two current public trustees of the Medicare program, Thomas Saving.<sup>30</sup>

However, there is apparent inequity in changing from a pay-as-you-go system to a pre-funded arrangement: Some generation must pay twice, financing its elders in addition to pre-funding itself. Moreover, that inequity is unnecessary, since increasing life expectancies do not themselves alter the relative merits of pay-as-you-go funding.

In a pay-as-you-go system, the average person born in 2000 will pay more for retirement pension and health expenses than will the average person born in 1980 because the number of individuals who are retired during the life of a person who is born later will, other things equal, be increased due to the fact that more people will live to retirement and, once retired, they will live longer. That’s what increased life expectancy means. Yet the same logic applies to the individuals themselves: Increased life expectancy for a person born in 2000, compared to a person born in 1980, means the former would have to save more for herself alone because the ratio between her own years in retirement and years in work would be larger. Thus, either way, increasing longevity has the same effect. People born later have to set aside a larger share of their income while working,

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30. Phil Gramm et al., *Medicare Policy for Future Generations: Search for a Permanent Solution*, 338 NEW ENG. J. MED. 1307 (1998).

either through taxes to support those who have previously retired or savings to support themselves. The only legitimate question is how people can best guarantee themselves some security in old age, and greater longevity does not alter the relative security of tax-based redistribution as compared to individual savings.<sup>31</sup>

In practice, people contribute to social insurance systems, such as Social Security and Medicare, as part of a compulsory social contract, in which paying taxes to support others creates one's claim to benefits for one's self later. This contract has risks, but so do market investments. Each is a way to make claims upon the future; if there is an ethical difference it is in how they distribute risks.

The basic argument for social insurance approaches is that they spread risk in a more socially acceptable way than if the elderly relied entirely on family and market claims to benefits. Social insurance redistributes from high-earners to low-earners, from the relatively well to the sick, and from those with shorter lives to those who live longer. Compared to relying on personal investments, access to adequate living standards (including healthcare) while retired in a social insurance system depends much less on one's income while working, degree of luck with investments, and longevity after retirement. Reliance on intra-family transfers carries the same risks as personal investments, especially since individuals with low incomes tend to have children with low incomes, and so a parent's misfortune would be doubly visited upon his or her children.

### *B. Pressure on Other Programs or Incomes*

One might argue, however, that even a small increase in costs due to aging is "unaffordable" because the money could be better spent on other programs or better left in private pockets. In this view, health care costs for the elderly would be taken from education or aid to impoverished children, other public "investments in the future," national security, or private investments to develop the economy.

This argument has two components—one economic and one distributional. The common doomsday scenario claims that higher health

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31. The argument here does not apply to situations of unequal cohort size. There is more of an argument for having the baby boomers in some sense "pre-fund" their costs in retirement than for pre-funding simply due to increasing longevity. The boomers, however, can pre-fund their costs in more temporary and flexible ways, such as by creating budgetary conditions that decrease government debt obligations. Reducing debt service costs from 2020-2035, for instance, would free up revenues that could be used to cover some of the extra pension and health costs due to the size of the baby boom cohort.

care costs will devastate the economy. This argument assumes that government will incur these costs, but not raise taxes or reduce other spending to pay for them. Following that scenario, government deficits would rise steadily as borrowing yields higher interest costs and thus more borrowing. Eventually deficits would be so high that they would consume all possible sources of investment and so could be financed only by running down the nation's capital stock, destroying the economy.<sup>32</sup> Although this vision has been widely promoted, there is no reason to assume governments will let the budget situation become so dire. Governments respond to rising deficits by taking steps to control them, even if they do not do so as quickly or thoroughly as "deficit hawks" wish. Scenarios that presume governments will let deficits spiral irredeemably out of control are extremely speculative. Moreover, raising taxes to pay for this government spending may have little effect on the economy.<sup>33</sup>

The more serious issue is how the choices governments are likely to make to control deficits will affect citizens. From this perspective, what might be called the "affordability" of health care for the elderly is really a matter of preferences. The money could arguably be taken from other government programs that do not work as well, or, by taxes, from private consumption that one could consider to be of less social value. Whether health care for the elderly is less important than military spending, or than wealthier individuals buying more expensive automobiles, or than citizens' ability to consume liquor and tobacco, or than governments propping up declining industries, or than any other alternative consumption, are political and moral judgments that will be made differently by different people.

Only two things should be clear about such choices. First, health care spending for the elderly is not obviously less important than a whole range of alternative expenditures. Second, judgments about distributional tradeoffs concerning future consumption are best made by future consumers, according to their preferences, rather than by us. We certainly

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32. This doomsday scenario is at the heart of a series of forecasts done by the U.S. General Accounting Office beginning in 1992 and the U.S. Congressional Budget Office since 1997. *See, e.g.*, GEN. ACCOUNTING OFFICE, BUDGET ISSUES: ANALYSIS OF LONG-TERM FISCAL OUTLOOK (1997).

33. The evidence that raising taxes somewhat to pay for government spending as a share of GDP must have significant negative economic effects is quite weak. Available data are less than great, but for one simulation of effects, see KETIL HVIDING & MARCEL MÉRETTE, MACROECONOMIC EFFECTS OF PENSION REFORMS IN THE CONTEXT OF AGING POPULATIONS (OECD Study on the Pol'y Implications of Aging Working Paper No. 3, 1998). For a more extensive discussion and citation to U.S. analyses, see WHITE, *supra* note 3, at 73-98.

have no reason to assume that voters in, for example, 2020 will prefer to cut health care for the elderly—especially since voters in no rich democracy to date have made a similar choice.

Under what circumstances would reductions in health care targeted to the elderly be justified? It is surely reasonable to believe that health care, in principle, should be one of the highest priorities for social sharing. Pain, disability, and death are things most people would pay to avoid before they would purchase whatever else might be bought with, for example, the last twenty percent of an average retiree's income. Inequalities in access to relief of pain, or in access to life-saving treatment, may seem less acceptable than other inequalities.

Some commentators believe that social sharing to provide health care to eighty-year-olds is inherently less desirable than providing care to younger citizens. In Richard Lamm's words, "[w]e have created a Faustian bargain, according to which our aging bodies can and will divert resources that our children and grandchildren need for their own families and that public policy needs for other important social goods."<sup>34</sup> Yet Lamm's belief that a decent society would guarantee less health care to an eighty-year-old than to a forty-year-old does not appear, judging from existing social policies around the world, to be a common belief. In all rich democracies, access to medical care is more equalized than access to other goods, and there is no explicit discrimination against the old.<sup>35</sup> In the United States, the elderly are actually favored, being the only group guaranteed health insurance—perhaps because they are the group with the most obvious need. One reason for these policies may be that the distinction between the elderly and other people is ephemeral: Most individuals hope to be elderly some day. Another is human sympathy: Most people are likely to have elderly loved ones whose lives they value. And some objections may be moral: Defining some lives as more valuable than others simply due to age is incompatible with many ethical and religious traditions.

Policymakers can make future trade-offs easier by adopting more cautious policies in the present. They should be careful to control health care costs as much as possible. They should also avoid unnecessary military spending, cut taxes only if they can be sure not to create deficits that will cause higher interest costs, and avoid starting new programs of any sort

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34. Lamm, *supra* note 5, at 203.

35. See, e.g., NETHERLANDS: COMPLETE QUESTIONNAIRE INCLUDING BILATERAL FOLLOW-UP FOR THE 2000 REPORT ON PROGRESS (OECD Econ. Dep't Working Paper No. 1B, 1999) [hereinafter NETHERLANDS]; UNITED STATES REPLY TO OECD SURVEY (OECD Econ. Dep't Working Paper, 1999) [hereinafter U.S. REPLY].



which do not provide good value for money. By reducing interest costs in the future, such measures can make other programs more affordable. The Clinton Administration took this approach, building up a budget surplus through a mix of progressive tax increases, selectively reduced spending, and good fortune.<sup>36</sup> In this way, the United States was part of an international trend; most rich democracies were pursuing policies to reduce debt burdens and thus debt service. As the Economic Policy Committee of the European Community put it, it was important to realize “the contribution which budget discipline can make via a lower interest burden to meeting the costs of ageing populations, especially in high debt countries.”<sup>37</sup>

In short, while future trade-offs are an important consideration, there is little reason to assume that health care for the elderly per se should be the loser. Policy-makers would do best if they presently adopted cautious budget policies on all dimensions.

### III. THE OTHER SIDE OF THE EQUATION: THE ELDERLY AS WORKERS

In other countries, health care for the elderly and for workers are not really separate subjects; in essence, all are grouped in the same insurance pools. Health care arrangements then neither push nor pull people in or out of the work force. Cash income is another story: In most wealthy democracies, the sources of pensions for the elderly are very different from wages for workers. Hence, the choice to work or retire depends in part on governmental policies that set the terms for both contributing to and receiving pensions. There are obvious financial benefits from policy changes that, at the very least, stop discouraging individuals from working longer. Moreover, policies that discourage working with confiscatory effective tax rates seem unfair. By one calculation, the implicit tax on Dutch workers who work past the age when they could take retirement is 141%. In the United States, there is no such penalty.<sup>38</sup> In the future, reduced morbidity among the elderly should mean greater ability to work

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36. The end of the Cold War allowed a reduction in U.S. military spending totaling 1.5% of GDP. Legislation in 1990 and 1993, combined with a dose of good luck, raised revenues by 3.0% of GDP. In turn, debt service costs fell steadily. See CONG. BUDGET OFFICE, BUDGET AND ECONOMIC OUTLOOK: FISCAL YEARS 2002-2011 143, 147, 149 (2001). These policies would, if maintained, have paid for most of the projected increases in spending for Social Security and Medicare over the next 30 years. See WHITE, *supra* note 3.

37. EUROPEAN CMTY. ECON. POL’Y COMM., PROGRESS REPORT TO THE ECOFIN COUNCIL ON THE IMPACT OF AGEING POPULATIONS ON PUBLIC PENSIONS SYSTEMS 41 (2000).

38. Gruber & Wise, *supra* note 12, at 47.

at, for example, age sixty-seven. Changing job structures may mean that a larger share of jobs can be done by older persons, while the same emphasis on mental rather than physical abilities may require that individuals begin productive work at an older age. As a result of both more time spent in training while young and the greater ability to be productive while old, policies that encourage later retirement may be more equitable than current policies. On the other hand, the argument for raising ages of entitlement to pensions may be taken too far. Some work, such as driving delivery trucks or working in kitchens, is physically demanding, and therefore policies that alter pensions in order to encourage people to work longer should recognize that this makes more sense for some types of workers than for others. But this difference can be recognized in part by basing entitlement to pensions on years in the work force as much as age: Workers whose jobs involve physical labor are likely to have spent less time being educated, and so to have entered the work force sooner than those workers whose jobs allow them to maintain productivity later in life. On the whole, the most reasonable response to the fact that population aging under current law would produce a shrinking labor force is to adjust pension laws and other policies so as to encourage greater labor force participation. By raising revenues, this in turn would make health care costs for the elderly more affordable.

To summarize, there is little ethical or financial reason to focus on reducing health care spending on the elderly. Policies to increase workforce participation, so long as they are not punitive, are a much better idea. Both conclusions are supported by recent analyses from the OECD and European Community (EC). For example, the OECD's "seven principles to guide the reforms needed to address demographic pressures" only call for "a greater focus on cost-effectiveness in health care," rather than any direct reduction in the entitlement to care.<sup>39</sup> Those principles include reducing incentives for early retirement, diversifying the mix of pension sources, and improving labor market opportunities for older workers.<sup>40</sup> The first questions in the OECD's review of national policies to address the challenges of an aging society focus on "[r]etirement [i]ncentives and [l]abour [s]upply."<sup>41</sup> The European Community's work

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39. ORG. FOR ECON. COOPERATION & DEV., POLICY REPORT: MAINTAINING PROSPERITY IN AN AGEING SOCIETY 1, 2 (1998).

40. *Id.* at 2.

41. NETHERLANDS, *supra* note 35; U.S. REPLY, *supra* note 35; GERMANY: QUESTIONNAIRE 2000 ORIGINAL REPORT (OECD Econ. Dep't Working Paper, Jan. 27, 2000), *available at* <http://www.oecd.org/dataoecd/22/55/2425505.pdf> (last visited Dec. 23, 2003).

has also highlighted the importance of labor supply issues.<sup>42</sup> Policies to increase labor supply could include further encouragement of childbearing and of women entering the work force (though these may seem to be contradictory goals). A September 2003 review in the *OECD Observer* recommended a “radical policy package” that “would include the following steps: eliminate early retirement schemes; make old-age pension schemes actuarially neutral so that pensions fully reflect time spent in work; raise standard retirement ages; increase childcare subsidies; eliminate tax discrimination against female participation; and enhance the role of part-time work.”<sup>43</sup> Apparently denying health care specifically to the elderly was viewed as more than “radical,” because it was not been suggested.

No one should imagine that policies to increase the workforce are easy to implement. Employers prefer not to hire older workers, other things being equal.<sup>44</sup> Additionally, factors such as the rate of female participation in the labor force depend on more than pensions.<sup>45</sup> Yet, it is instructive that the trend among analysts and policymakers in other wealthy democracies is to emphasize workforce and pension responses to the challenges of an aging society and to view health care as a different question—one that should be treated on its own merits for all citizens.

#### IV. MATCHING SERVICES TO NEED FOR AN AGING POPULATION

While the impact of an aging population on the cost of health care is likely to be less significant than many have predicted, its implications for the organization of our health care system will surely be enormous. The elderly consume both more and different health care services than younger persons, and our health care system will need to adjust both its supply and its structure to provide these services.

##### *A. Appropriateness of Care for the Elderly*

Generally speaking, aged bodies do not work quite the same way as

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42. See EUROPEAN CMTY. ECON. POL’Y COMM., *supra* note 37.

43. Jean Phillipe Cotis, *Population Ageing: Facing the Challenge*, OECD OBSERVER, Sept. 26, 2003, available at [http://www.oecdobserver.org/news/fullstory.php/aid/39/Population\\_growth:\\_facing\\_the\\_challenge.html](http://www.oecdobserver.org/news/fullstory.php/aid/39/Population_growth:_facing_the_challenge.html) (last visited Dec. 23, 2003).

44. ORG. FOR ECON. COOPERATION & DEV., WORK FORCE AGEING: CONSEQUENCES AND POLICY RESPONSES (OECD Working Paper No. AWP4.1, 1998).

45. See EUROPEAN CMTY. ECON. POL’Y COMM., *supra* note 37, at 41.

those of young people. Not only are they particularly prone to such diseases as osteoporosis and Alzheimer's,<sup>46</sup> but clinical indicators may have different implications for the old as compared to the young. For example, lower blood pressure appears to be a sign of good health in young people, but bad health in very old people.<sup>47</sup> In addition, *low* cholesterol is associated with mortality in older persons, though that may not be evidence against prescribing statins.<sup>48</sup> Metabolic processes in older people can also differ from those in younger persons; thus the elderly are both more prone to anorexia and more prone to hypotension after eating.<sup>49</sup> There are also cases in which they appear to metabolize drugs differently than do the young.<sup>50</sup> For all these reasons, studies done on other populations may not accurately predict the performance of treatments among the elderly.

The elderly may also interact with medical professionals differently. Age creates comprehension and communication problems; at the same time, relationships with physicians and their offices can take on a social role—the medical office as a place to go—which fits poorly with the cost control needs of medical payers. Moreover, the elderly are more likely to suffer from chronic illnesses and multiple conditions, which require more complex coordination of care than is the norm for younger patients. America's "medical care ad-hoc-racy" is not very good at such coordination.<sup>51</sup>

### *B. Supply of Caregivers for the Elderly*

Thus, there is good reason to believe that care for some of the elderly can require a different skill set, both for individuals and for institutions, than is needed to care for most other patients.<sup>52</sup> The need for training and

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46. John E. Morley, *Editorial: Hot Topics in Geriatrics*, 58 J. GERONTOLOGY, SERIES A, MED. SCI. 30, 30-31 (2003).

47. Tamara B. Harris, *Commentary: Aging Well and Aging Poorly: Primary and Secondary Low Blood Pressure*, 58 J. GERONTOLOGY, SERIES A, MED. SCI. 662, 662 (2003).

48. Morley, *supra* note 46, at 30.

49. John E. Morley, *Editorial: Drugs, Aging, and the Future*, 57 J. GERONTOLOGY, SERIES A, MED. SCI. 2, 6 (2002).

50. Eric C. Petrie et al., *Increased Plasma Norepinephrine Response to Yohimbine in Elderly Men*, 58 J. GERONTOLOGY, SERIES A, MED. SCI. M155, M155 (2003).

51. David M. Lawrence, *My Mother and the Medical Care Ad-Hoc-Racy*, HEALTH AFF., Mar.-Apr. 2003, at 238.

52. See Christine Tassone Kovner et al., *Who Cares for Older Adults?*, HEALTH AFF., Sept.-Oct. 2002, at 78.

research in geriatric medicine is already high and will grow dramatically. Yet the extent of such a focus varies significantly across countries and is particularly low in the United States. Greg O'Neill and Patricia P. Barry report that "only three of the nation's 145 medical schools have a full-time department of geriatrics that requires a mandatory rotation in geriatrics for students and residents, and less than 3% of all medical students take even one course in geriatrics. In contrast, every medical school in Great Britain and 19 of Japan's 88 medical schools have such a department."<sup>53</sup> Only twenty-three percent of American nursing programs have a required course in geriatrics.<sup>54</sup> Yet, while the need for training in geriatric care has been obvious for years, there has been hardly any response within American academic medicine. The government could try to encourage changes in medical and nursing school curricula, but governments generally have great difficulty shaping behavior within medical institutions or medical supply more generally. In any event, there is a very long way to go, and it is highly unlikely that training will catch up to need before many decades have passed.<sup>55</sup>

While the medical needs of the elderly pose significant workforce challenges, these are exacerbated by the need for an expanded supply of the broad set of quasi-medical and non-medical services grouped under the title "long-term care." As Joshua Wiener explains, "[L]ong-term care services are largely provided by unskilled paraprofessionals, who are overwhelmingly women and disproportionately represented by racial minorities and ethnic groups. Low wages and benefits, hard working conditions, heavy workloads and a job that has been stigmatized by society make worker recruitment and retention difficult."<sup>56</sup> Helping people to dress, eat, urinate, and defecate simply is not an attractive career. Dealing with individuals in various stages of dementia is trying. Perhaps these jobs could be made more attractive with large dollops of money, but difficulties like lack of respect, dead-end jobs, the cultural gap, and the physical and mental stress of the work are not easily addressed with money.<sup>57</sup> People who do this kind of work with compassion often have some inner calling or

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53. Greg O'Neill & Patricia P. Barry, *Training Physicians in Geriatric Care: Responding to Critical Need*, PUB. POL'Y & AGING REP., Winter 2003, at 17, 17.

54. Mathy Mezey & Christine Tassone Kovner, *Nursing's Geriatric Workforce Caring for Older Adults*, PUB. POL'Y & AGING REP., Winter 2003, at 22.

55. See O'Neill and Barry, *supra* note 53.

56. Joshua M. Wiener, *Country Portrait: United States of America*, in FOUR COUNTRY CONFERENCE, AGING AND HEALTH POLICY 87 (2001).

57. See Susan C. Eaton, *Frontline Caregivers in Nursing Facilities: Can Policy Help in Recruitment and Retention Crisis?*, PUB. POL'Y & AGING REP., Winter 2003, at 8.

strength, which is hard to produce with any kind of policy. And, even that inner light may burn out quickly for many careproviders: Scandals in nursing homes surely reflect the greed of some for-profit proprietors, but may also show the difficulty of finding workers and supporting them in a culture of caring for the elderly.

As society ages, we should expect those challenges to worsen, for there will be greater need, and fewer workers to meet the need. Increasing the number of workers by encouraging people in their late sixties to work is unlikely to be the answer to filling the physically demanding jobs of caring for the elderly—lifting and clothing individuals in their eighties, for example. If future workers on average will be better-educated, that may make it easier for them to work longer at white-collar jobs, but is unlikely to make them more willing to work in jobs providing personal services to individuals who need help with daily living. Moreover, some of the same trends that increase women's labor force participation (and so increase the total workforce), such as the breakdown of barriers to more and more types of jobs, may further reduce interest in joining the nursing and other caring workforces.

In the end, then, where will the caregivers be found? Some nations are coming to rely more on immigrant nurses, and this policy may be worth considering and encouraging. However, this may not be so easy to arrange. If giving care is not likely to be an attractive career; perhaps it can be made preliminary to, or a condition for embarking, on a career. Systems of national service, or of student aid conditional upon prior service, might provide some of the necessary labor.<sup>58</sup> Yet that too poses challenges, ranging from how to create those programs to how to ensure that the work is done well.

### *C. Who Should Pay for Long-Term Care?*

Long-term care is a mix of professional services, nonprofessional caregiving, and the expenses of daily life. A nursing home provides shelter and food that, conceptually, are not medical benefits at all. Nor are they really "risks" in the same sense as medical expenses: Many people will not get very sick in a given year, while everyone must live and eat somewhere. The fact that many services are not professional helps explain why they have historically been separate from medical benefits—excluded from the insurance programs and left for the state, provincial, or local governments

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58. I say conditional upon prior service because I do not trust any system's ability to enforce requirements for service after individuals have already received their benefit.

to provide.<sup>59</sup> Canada has no long-term care guarantee comparable to its Medicare,<sup>60</sup> and indeed “no national standard” for such care.<sup>61</sup> Germany and Japan have only instituted such programs very recently.<sup>62</sup> The Netherlands is exceptional in having had fairly universal—though not satisfactory to all—arrangements for quite a while.<sup>63</sup> In spite of this history and related budget concerns, the policy trend is modest movement toward expansion of long-term care benefits. Japan and Germany’s creation of long-term care programs in the 1990s is especially remarkable in light of Japan’s economic stagnation and the high costs of German reunification. It seems likely that one reason for these expansions is that long-term care services, being associated with evident disability, cannot be accused of creating disincentives to work. In Japan’s case especially, long-term care benefits might even make it easier for women to participate in the workforce, as daughters or daughters-in-law are freed from having to stay home with aged parents. So, unlike pensions, the international concern about improving labor-market participation does not militate against expansion of long-term care benefits.

One could still raise questions regarding who should be responsible for long-term care. Should people save for themselves or through social insurance, and should programs be pay-as-you-go or pre-funded? In practice, as opposed to academic speculation, private-market solutions to the need for long-term care do not seem to be a major policy trend.<sup>64</sup> Pre-funding of long-term care is less practical than the pre-funding of pensions, and could be crowded out by saving for pensions. Pre-funding requires that costs be predictable, but long-term care benefits are much less predictable than pension needs because future patterns of disability are uncertain.<sup>65</sup> If policymakers seek to create publicly-managed funds of

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59. Mark Merlis, *Caring for the Frail Elderly: An International Review*, HEALTH AFF., May-June 2000, at 142.

60. Raisa Deber, *Country Portrait: Canada*, in FOUR COUNTRY CONFERENCE, *supra* note 56, at 57.

61. Merlis, *supra* note 59, at 142.

62. John C. Campbell & Naoki Ikegami, *Long-Term Care Insurance Comes to Japan*, HEALTH AFF., May-June 2000, at 26; Alison E. Cuellar & Joshua Wiener, *Can Social Insurance for Long-Term Care Work?: The Experience of Germany*, HEALTH AFF., May-June 2000, at 8.

63. Paul Schnabel, *Country Portrait: The Netherlands*, in FOUR COUNTRY CONFERENCE, *supra* note 56, at 79.

64. The standard private-market approach would be voluntary long-term care insurance. The difficulty is it would be almost impossible to get people to voluntarily buy this insurance at the prices at which it would be offered.

65. STEPHANE JACOBZONE ET AL., LONG TERM CARE SERVICES TO OLDER PEOPLE, A

private assets to help pay for future pension costs (as has been proposed in the United States and other countries), there will be fears of the government managing too large a pension fund.<sup>66</sup> Given those fears of letting governments manage too much money, they are not likely to be allowed to set up further investment funds for long-term care.

Long-term care also poses, in a particularly acute form, an issue that is common to all social insurance: Who is really being protected by the programs? Pensions, for example, protect not only the elderly, but their children, who might otherwise have to pay to support parents. Medicare's popularity also must be related to the fact that, if workers' parents and grandparents were not guaranteed medical insurance, the workers would be more likely to get stuck with huge and unpredictable medical bills. Yet, long-term care would protect children not only from a financial but also a physical burden—the chance that middle-aged or even older women, in particular, might have to assist aged parents with activities of daily living. Germany offers a cash benefit, in lieu of a service benefit, in part on the assumption that many children would choose to care for their parents, but would want to replace some of the income that they otherwise would earn in the market. Family caregivers are even given time off and pension credits.<sup>67</sup> Long-term care choices therefore involve uniquely complex relationships among the family, the market, and the state.

Demand for long-term care of various sorts will increase. Yet, as noted above, long-term care's finance and delivery tend to be separated from core health programs. In the Netherlands it is part of the "exceptional medical expenses" system, wholly public and separate from the health insurance funds. In the United States, most long-term care is not part of the universal entitlement of Medicare, but instead public support is confined to Medicaid, a means-tested entitlement, and some programs for veterans. This would not appear problematic if the set of caregivers and institutions were entirely separate from the mainline health system. Yet they are not, and separate financing pools can cause managers to concentrate on cost-shifting (hospitals to nursing homes and back; states to federal government and back) more than care-giving.

On balance, the complexities of long-term care in particular do not challenge the above conclusion—that health care costs for the elderly *per se* should not be viewed as an economic burden that must be fixed. First,

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PERSPECTIVE ON FUTURE NEEDS (OECD Working Paper No. AWP 4.2 Eng., 1998).

66. WHITE, *supra* note 3, at 161-67.

67. Cuellar & Wiener, *supra* note 62, at 17.



coverage in many countries is partial at best.<sup>68</sup> Second, some coverage might even have helpful labor market effects. Third, any projections of future costs involve great uncertainties due to unpredictable morbidity. As with health care more generally, the trend in other countries is more toward guaranteeing coverage than toward taking it away.

### CONCLUSION

This Article has reviewed the health policy implications of an aging society. As stated at the outset, claims that a growing proportion of elderly persons in the population require reductions in social guarantees of access to health care are a common part of analytic and policy discourse. Yet, I have argued, this discussion tends to overstate some challenges and understate others.

For a number of reasons, I have contended that the challenge of health care costs posed by population aging is exaggerated. First, the contribution of population aging to total medical costs is small compared to other trends. Second, in America, separate budgeting of Medicare costs makes increases in spending on the elderly seem more significant than they should from a broader societal perspective. Third, claims that higher government spending on health care is inherently harmful to the economy deserve great skepticism—there may be mild negative effects but, so long as governments actually pay for the costs, there should be little long-term harm. Fourth, the claim that a growing proportion of the “old old” especially threatens higher costs is not supported by existing data. What might be termed bioethical concerns caused by aging populations can also be overstated. Arguments posing a conflict between “the young” and “the old” are suspect because normal young people generally wish to become old eventually, so benefits for the elderly are also benefits for themselves. Notions that the old should receive less medical care so as to leave more resources for the young do not fit well with ethical or religious traditions that value human life *per se*. Moreover, the border between “young” and “old” is not so easily defined: If by “old” we mean people over age sixty-five, then many of those individuals can be very productive members of society. If the concern is actually that people who are so old as to be mostly dependent should give way to the young, then that concern must not only overcome the basic ethical objection to valuing some lives more than others, but the fact that the “old old” do not represent a major factor in increasing health care costs.

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68. Merlis, *supra* note 59, at 141-44.

It is true that in any situation where the share of the population that is working declines and the share that is retired increases, there is a resource-distribution conundrum. Retirees always live on the production of current workers; social arrangements differ only in how they claim that production—through investment income, intra-family transfers, or communal sharing (government or other) arrangements. Thus, an increasing proportion of retirees means either that retirees get less (if their share of workers' production is stable) or workers keep less (if workers' contribution to retirees increases with the larger proportion of retirees). This distributional concern applies not only to consumption of health care but, more directly, to pension finance. As this Article has argued, however, reduction of health care for the elderly seems one of the least desirable responses to this challenge. Skepticism about reducing health care for the elderly appears to have become the norm, as referenced above, in analyses by the Organization for Economic Cooperation and by the European Community. Those analyses and this Article argue that the most appropriate response is to increase the supply of workers, particularly by having policies to encourage later retirement.

In short, an aging society poses an array of challenges, but health finance is neither a major factor nor the proper lens through which to perceive the most important financial and ethical dilemmas. In fact, the health policy problem that appears to be most directly related to aging is the anticipated health care and caregiving labor shortage. The general concern about how economies will function with the low proportion of workers that are currently projected is especially relevant to how the health sector, which employs large numbers of low-skilled workers in relatively undesirable jobs, will function when there is an even greater need for those workers.

It is not clear that any government will be able to do much to address these labor supply problems. However, a range of policies—from encouraging immigration to providing training to subsidizing such work as national service—may be relevant and appropriate. Policymakers would do well to spend more time thinking about labor issues—and less about how to define insurance benefits or pay for health care thirty years from now.

## ***Pharmaceutical Research and Manufacturers of America v. Walsh: The Supreme Court Allows the States To Proceed with Expanding Access to Drugs***

**Timothy Stoltzfus Jost, J.D.\***

### INTRODUCTION

On May 19, 2003, the Supreme Court in *Pharmaceutical Research and Manufacturers of America v. Walsh* affirmed a court of appeals decision allowing for the implementation of the Maine Act to Establish Fairer Pricing for Prescription Drugs.<sup>1</sup> The Maine program attempted to leverage the considerable market power of the Medicaid program to force drug companies to offer the state a discount on pharmaceuticals. The state in turn would pass the savings on to its uninsured residents. Manufacturers that refused to negotiate a discount with the state would face the prospect of their products being available to Maine Medicaid recipients only with prior authorization, resulting in a considerable loss of market share for these manufacturers.<sup>2</sup>

The *Walsh* case permits states to use the market power they wield through their Medicaid programs to make prescription drugs more affordable to their residents, albeit subject to some constraints. The Court decisively rejected a broad constitutional challenge to the Maine program based on the prohibition against state interference with interstate commerce.<sup>3</sup> Had this challenge succeeded, it would have put at risk a wide range of state pharmaceutical programs. The badly splintered Court left unclear, however, the precise conditions under which states may use their Medicaid market power to benefit residents not covered by Medicaid. The Court established only that the Pharmaceutical Research and Manufacturers of America (PhRMA), the trade association that brought

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1. *Pharm. Research & Mfrs. of Am. v. Walsh*, 123 S.Ct. 1855 (2003).

2. 123 S.Ct. at 1863-64.

3. 123 S.Ct. at 1870-71.

the case, had not yet proven that the Maine program violated the Medicaid statute by imposing a state requirement lacking a "Medicaid purpose."<sup>4</sup> The Court also suggested that states might do well to consult the Department of Health and Human Services (HHS) before proceeding with Medicaid-related drug programs.<sup>5</sup>

This Article begins by examining the scope and seriousness of the pharmaceutical access problem in America. It proceeds to describe briefly the range of programs that state governments currently employ or are considering to address this problem. Next, it discusses the opportunities states have to leverage their Medicaid market power to expand drug access among non-recipients of Medicaid. It then examines the Court's decision in *Walsh* and how it affects these programs. The Article concludes by considering additional possibilities the *Walsh* decision opens up for states to expand access to drugs.

### I. THE PROBLEM: MANY AMERICANS CANNOT AFFORD DRUGS

The problem addressed by the Maine program is a familiar one: The cost of pharmaceuticals has risen dramatically in the recent past. Expenditures for retail prescription drugs increased 16.4% in 2000 and another 15.7% in 2001, and are expected to increase at double-digit rates through the rest of this decade.<sup>6</sup> While drugs still represent a relatively small fraction of national health care expenditures (a little over 10%), the burden of drug costs falls disproportionately on a small number of individuals, most notably those with chronic diseases.<sup>7</sup> The median per capita drug expenditure for elderly persons in 1998 was \$895, but for the highest-spending one percent it was \$6,597.<sup>8</sup> The high cost of drugs often results in the inability of individuals to obtain needed medications. A recent eight-state study of Medicare beneficiaries found that 25% of uninsured beneficiaries failed to fill at least one prescription during 2001 due to cost, 27% skipped doses to make their medications last longer, and

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4. 123 S.Ct. at 1867-70.

5. 123 S.Ct. at 1870.

6. Stephen Heffler et al., *Health Spending Projections for 2001-2001: The Latest Outlook*, 21 HEALTH AFF. 207, 209 (2002); Katherine Levit et al., *Trends in U.S. Health Care Spending, 2001*, 22 HEALTH AFF. 154, 156 (2003).

7. John A. Poisal & Lauren Murray, *Growing Differences Between Medicare Beneficiaries with and Without Drug Coverage*, 29 HEALTH AFF. 74, 80 (2001).

8. Uwe Reinhardt, *Perspectives on the Pharmaceutical Industry*, 20 HEALTH AFF. 136, 140 (2001).

20% spent less on other basic needs to afford prescription drugs.<sup>9</sup> Though the prevalence of insurance coverage for drugs is much greater than it was two decades ago, it is still lower than coverage for other health care goods and services. In fact, some seventy million Americans have no insurance for prescription drugs.<sup>10</sup>

Most importantly, Medicare does not yet cover most outpatient drugs, and thus many senior citizens and disabled persons otherwise covered for health care costs lack drug coverage.<sup>11</sup> Although Congress recently adopted a Medicare prescription drug benefit, the program still leaves significant gaps in drug coverage for Medicare beneficiaries.<sup>12</sup> The legislation imposes a \$250 deductible and—once that is met—a 25% coinsurance obligation.<sup>13</sup> Moreover, a gap in coverage—commonly referred to as the “doughnut hole”—exists once total spending exceeds \$2,250.<sup>14</sup> Beyond this threshold, the beneficiary receives no further coverage until her total out-of-pocket spending reaches \$3,600 (referred to as the “stop-loss” level), after which the legislation covers 95% of drug costs.<sup>15</sup> Under the legislation, low-income beneficiaries (i.e., those under 150% of the poverty level) will face lower cost-sharing and will receive coverage in the “doughnut hole,” but only if they pass an asset test.<sup>16</sup> Furthermore, the new benefit will not take effect until 2006, leaving Medicare beneficiaries responsible for high drug costs for another two years, though perhaps assisted somewhat by pharmacy discount cards.<sup>17</sup> Expanding drug coverage to persons other than Medicare beneficiaries is not even on the congressional policy agenda.

9. Dana Gelb Safran et al., *Prescription Drugs and Seniors: How Well are the States Closing the Gap?*, HEALTH AFF. W253, W265 (Web Exclusive, July 31, 2002), available at [http://www.healthaffairs.org/WebExclusives/Safran\\_Web\\_Excl\\_073102.htm](http://www.healthaffairs.org/WebExclusives/Safran_Web_Excl_073102.htm) (last visited Dec. 2003).

10. CTR. FOR POL’Y ALTERNATIVES, PLAYING FAIR, STATE ACTION TO LOWER PRESCRIPTION DRUG PRICES (2000), available at <http://www.stateaction.org/cpa/publications/pub.cfm?ID=112> (last visited Dec. 2003).

11. See KAISER FAMILY FOUND., MEDICARE AND PRESCRIPTION DRUGS FACT SHEET, available at <http://www.kff.org/medicare/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14186> (last visited Dec. 30, 2003).

12. Pub. L. 108-173, tit. I (2003).

13. Pub. L. 108-173 §§ 1860D-2(b)(1) & (2).

14. Pub. L. 108-173 § 1860D-2(b)(3).

15. Pub. L. 108-173 § 1860D-2(b)(4).

16. Pub. L. 108-173 § 1860D-14.

17. Pub. L. 108-173 § 1860D-31.

## II. THE PROPOSED SOLUTION: STATE PROGRAMS TO MAKE DRUGS MORE AFFORDABLE

For the immediate future, therefore, it appears that progress in expanding public programs to help cover drug costs is most likely to come at the state level.<sup>18</sup> The states have in fact been actively trying to address this problem, devising a diverse set of approaches that vary in the populations they serve, the extent of assistance they offer, and the mechanisms they employ to reach their access goals.

The most straightforward solution is simply to provide drug coverage for those most in need, either directly or through subsidized insurance plans. As of November 2003, thirty-five states had adopted laws to create pharmaceutical assistance programs, and twenty-nine such plans were operational.<sup>19</sup> All of these programs cover senior citizens, many cover disabled persons, and a few cover the uninsured generally.<sup>20</sup> Most impose income eligibility limits, which vary from 88% (in Florida) to 500% (in Massachusetts) of the federal poverty level.<sup>21</sup> However, the greatest disadvantage of these programs is that they must be paid for by the states, virtually all of which are under a constitutional obligation to balance their budget every year, and most of which are facing very tight budgets during the current economic downturn. Some states have financed these programs with tobacco settlement funds. However, funding remains tight, and it is unlikely that these direct state drug programs will expand in the immediate future. Most of the programs are still small (only five had more than 100,000 members in 2003).<sup>22</sup> Furthermore, even in states with well-established programs, many eligible persons do not participate because of low program awareness, complex and burdensome eligibility requirements and procedures, and limited benefits.<sup>23</sup>

Some states have also used their Medicaid programs to make drugs more available to the poor and uninsured, a strategy that allows them to

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18. The Medicare prescription drug legislation also contemplates the continued existence of state pharmaceutical assistance programs to assist Medicare beneficiaries with premium or cost-sharing obligations imposed by the new drug benefit legislation. See Pub. L. 108-173, § 1860D-23.

19. NAT'L CONF. OF STATE LEGISLATURES, STATE PHARMACEUTICAL ASSISTANCE PROGRAMS (2003), <http://www.ncsl.org/programs/health/drugaid.htm> (last visited Dec. 2003).

20. *Id.*

21. *Id.* In 2003, the federal poverty level was \$8,980 for an individual. 68 Fed. Reg. 6456 (2003).

22. *Id.*

23. Safran et al., *supra* note 9.

take advantage of federal funds to help pay for the cost of the program. Although outpatient prescription drugs are an optional service under federal Medicaid law, all state Medicaid programs do in fact cover prescription drugs.<sup>24</sup> There are several ways in which states can use Medicaid to expand drug coverage. First, several states have simply expanded eligibility for their Medicaid programs, thus giving poor residents the full benefit of Medicaid coverage, including prescription drug coverage.<sup>25</sup> The federal Medicaid law offers states a broad menu of opportunities for Medicaid eligibility expansions beyond the minimum required federal coverage, including covering, for example, seniors and disabled persons with incomes up to the poverty level, working disabled persons up to 250% of the poverty level, or pregnant women and infants up to 185% of the poverty level.<sup>26</sup> Expanding Medicaid to cover all of the populations permitted optional coverage under federal law (or even the broader populations permitted coverage under federal Medicaid waiver provisions) can help to address the fact that drug coverage is unaffordable for many low-income persons. However, this option is very costly to states. Although the federal government funds approximately one half to four fifths of Medicaid costs,<sup>27</sup> the remainder must be paid for by the state, and when the state Medicaid program is expanded, the state must cover this cost for all mandatory services (including hospital and nursing home care), not just for drugs.<sup>28</sup>

Therefore, several states have applied for and received federal Medicaid waivers to provide drug benefits to an expanded population, usually senior citizens and disabled persons with incomes under 200% of the poverty level.<sup>29</sup> Drug-only Medicaid coverage is not an alternative

24. THE HENRY J. KAISER FAM. FOUND., KAISER COMM'N ON MEDICAID & THE UNINSURED, MEDICAID AND PRESCRIPTION DRUGS (2002),

<http://www.kff.org/content/2002/20020213/1609-02.pdf> (last visited Dec. 2003).

25. See FAMILIES USA, EXPANDING MEDICAID: STATE OPTIONS, COULD YOUR STATE DO MORE TO EXPAND MEDICAID FOR SENIORS AND ADULTS WITH DISABILITIES? (2002),

<http://www.familiesusa.org/media/pdf/ExpandingMedicaid.pdf> (last visited Dec. 2002).

26. 42 U.S.C. § 1306a(a)(10)(A)(ii)(IX), (X), (XIII) (2000).

27. NAT'L HEALTH LAW PROGRAM, AN ADVOCATES GUIDE TO THE MEDICAID PROGRAM 2.4 (2001).

28. 42 U.S.C. §§ 1396a(1)(10)(B), 1396d(a) (2000).

29. As of May 2003, this included Illinois, Wisconsin, South Carolina, Florida, Indiana, and Maryland. These Medicaid expansions to cover optional populations offer only drug benefits. NAT'L CONF. OF STATE LEGISLATURES, STATES AND "PHARMACY PLUS" MEDICAID WAIVER OPTIONS (2003), <http://www.ncsl.org/programs/health/pharmplus.htm> (last visited Dec. 2003).

explicitly permitted by the Medicaid statute, but HHS has indicated its willingness to offer such waivers.<sup>30</sup> The federal Court of Appeals for the District of Columbia, however, held that such programs are permissible only if they involve a state contribution to the funding of the program, which could make this approach also costly to states.<sup>31</sup>

### III. THE WALSH ALTERNATIVE: USE MEDICAID MARKET POWER TO EXPAND ACCESS

Many states, reluctant to expand state-funded programs when their funds are scarce, have explored strategies that expand drug access by forcing down the prices charged by drug manufacturers. States justify this practice in a number of ways. Drug manufacturers garner famously high profit margins. During 2002, the top ten U.S. drug companies averaged profits as a percent of revenue of 17%, nearly five and half times the profits of the median Fortune 500 company.<sup>32</sup> These profits represented more than half the total net profits of all Fortune 500 companies combined.<sup>33</sup> Even if one considers return on assets, which might be a more accurate representation of their true profits, these top ten drug manufacturers earned 14.1% for 2002 when the Fortune 500 median return on assets was just 2.3%.<sup>34</sup> Because drug manufacturers are granted effective monopolies on new drugs both through patent protection and through statutory market exclusivity periods,<sup>35</sup> they are able to charge prices far above competitive levels. Once generics are finally introduced, the amounts consumers pay for drugs fall rapidly, with generics usually costing less than half as much as multiple-source brand name drugs.<sup>36</sup> However, until

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30. See CTR. FOR MEDICARE & MEDICAID SERV., PHARMACY PLUS SECTION 1115 WAIVER RESEARCH AND DEMONSTRATION PROJECTS, TECHNICAL GUIDANCE AND FACT SHEET, <http://cms.hhs.gov/medicaid/1115/RXFACTSHEET41202.pdf> (last visited Dec. 2002).

31. *Pharm. Research & Mfrs. of Am. v. Thompson*, 251 F.3d 219 (D.C. Cir. 2001). In the challenged program, Vermont has attempted to use the drug rebate as the state matching funds, and thus contributed none of its own money.

32. PUB. CITIZEN CONG. WATCH 2003, 2002 DRUG INDUSTRY PROFITS: HEFTY PHARMACEUTICAL COMPANY MARGINS DWARF OTHER INDUSTRIES 1 (2003), [http://www.citizen.org/documents/Pharma\\_Report.pdf](http://www.citizen.org/documents/Pharma_Report.pdf) (last visited Dec. 2003).

33. *Id.*

34. *Id.*

35. Market exclusivity periods block FDA marketing approval for some generic substitutes even after patents expire or for products or uses that are not patentable. David G. Adams et al., 2 FUNDAMENTALS OF LAW AND REGULATION, 180-84 (1997).

36. CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS



generics become available, the market does little to discipline prices.

Manufacturers justify their high returns by arguing that they are necessary to finance research and development. There is some truth in this: Drug research is very expensive and risky; the drug development process is protracted and often unsuccessful. Drug company research and development costs tend to track profits, and countries that have placed strict limits on drug prices have seen drug research lag.<sup>37</sup> Even so, the argument has been oversold. Drug companies currently spend far less on the research and development of new products than they do on administration and on the advertising and marketing of their existing products—including expensive but highly successful direct-to-consumer advertising of prescription drugs.<sup>38</sup> Moreover, more than one third of medical and health research and development in the United States is funded by the American taxpayer.<sup>39</sup> Pharmaceutical companies also gain from generous tax benefits, which heavily subsidize their research efforts.<sup>40</sup> Arguably then, it is only fair that the public, including those who cannot otherwise afford high-priced drugs, realize some of the benefits of its investment. States can thus reasonably claim that it is fair to compel drug companies to give up some of their profits to make drugs more available to those who cannot afford them.

Perhaps more to the point, states that attempt to limit the amount that the uninsured (or elderly, or poor) have to pay for drug products are simply trying to get for their constituents the same deal that drug manufacturers already offer in the private sector to high volume purchasers. Drug manufacturers face high front-end fixed costs (including research and development costs), but comparatively low variable costs, and

AFFECTED PRICE AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 27-32 (1998).

37. See Patricia M. Danzon, *Making Sense of Drug Prices*, 23 REGULATION 56 (2000); F.M. Scherer, *The Link Between Gross Profitability and Pharmaceutical R&D Spending*, 20 HEALTH AFF. 216 (2001).

38. See FAMILIES USA, PROFITING FROM PAIN: WHERE PRESCRIPTION DRUG DOLLARS GO (2002), <http://www.familiesusa.org/site/DocServer/PPreport.pdf?docID=249> (last visited Dec. 2003).

39. MICHAEL E. GLUCK, THE HENRY J. KAISER FAM. FOUND., FEDERAL POLICIES AFFECTING THE COST AND AVAILABILITY OF NEW PHARMACEUTICALS 40 (2002), <http://www.kff.org/rxdrugs/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14078> (last visited Dec. 2003). The National Institute of Health (NIH) funded, in part, the development of fifty-two of the seventy-seven cancer drugs approved by the FDA by 1996, and the NIH and FDA contributed to the development of forty-five of the fifty top-selling drugs approved by the FDA between 1992 and 1997. *Id.* at 20.

40. *Id.* at 23-25.

thus are ideally situated to engage in price discrimination.<sup>41</sup> They charge much less to high-volume purchasers in a position to refuse to purchase their product (e.g., managed care organizations or hospitals) than they do to low-volume purchasers (e.g., retail pharmacies or individual consumers paying out-of-pocket).<sup>42</sup> The drug industry's own advertising has claimed that private insurance companies pay 30% to 39% less for drugs than do the uninsured.<sup>43</sup> States would do their needy residents a great service if they could simply procure for them the same deal that the drug companies already offer to many other private purchasers.

The most obvious strategy for accomplishing this would be for states to use the approach already taken to drug pricing under the Medicaid program—mandating price discounts. Under the Omnibus Budget Reconciliation Act (OBRA) of 1990, drug manufacturers must, in most instances, provide state Medicaid programs with rebates for drugs sold to Medicaid beneficiaries.<sup>44</sup> The rebate equals the difference between the drug manufacturer's average wholesale price and the best price it offers to other buyers (other than the federal government), or at least 15.1%—essentially providing states the price discrimination benefit enjoyed by other large purchasers.<sup>45</sup> The federal government collects pricing information from drug manufacturers and uses it to determine the size of the rebate states can demand for particular drugs.<sup>46</sup>

The 1990 OBRA legislation also provided an important benefit for the drug manufacturers: It prohibited the states from excluding from a state drug formulary any of the products produced by a manufacturer that agreed to a rebate program.<sup>47</sup> Prior to the adoption of this legislation, several states had begun to exclude certain high cost drugs from their formularies. Since Medicaid is responsible for over 17% of drug expenditures,<sup>48</sup> exclusion from a Medicaid formulary posed a real threat to drug companies.

Though states are generally prohibited from excluding the drugs of

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41. In this respect, they are like airlines or hotels.

42. ROY LEVY, FED. TRADE COMM'N, *THE PHARMACEUTICAL INDUSTRY: A DISCUSSION OF COMPETITIVE AND ANTITRUST CHALLENGES IN AN ENVIRONMENT OF CHANGE* 73-95 (1999).

43. See CTR. FOR POL'Y ALTERNATIVES, *supra* note 10, at 8.

44. Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143 (codified as amended at 42 U.S.C. § 1396r-8).

45. 42 U.S.C. § 1396r-8(c) (2000).

46. *Id.*

47. David Chavkin, *Medicaid and Viagra: Restoring Potency to an Old Program?*, 11 HEALTH MATRIX 190, 203 (2001).

48. Katherine Levit et al., *supra* note 6, at 158 (2003).

cooperating manufacturers from formularies, they are allowed to impose prior authorization requirements on some drugs subject to certain conditions.<sup>49</sup> Medicaid prior authorization programs must respond to an authorization request by telephone within twenty-four hours, and must also provide for the dispensing of a seventy-two-hour supply of drugs while awaiting authorization.<sup>50</sup> Nevertheless, requiring prior authorization for a drug frequently has the effect of denying patients access to it, often because they do not learn of the requirement until a pharmacy refuses to fill a prescription for which the physician did not obtain a prior authorization.<sup>51</sup> As a result, it has the effect of reducing the drug's sales.

Maine's program, at issue in *Walsh*, attempted to use this lever—the threat of requiring prior authorization—to make discounts available to all residents of the state who lacked insurance coverage for drugs, regardless of income.<sup>52</sup> The statute creating the program directed Maine's Commissioner of the Department of Health Services to enter into "voluntary" agreements with drug manufacturers to extend to the general population rebates on their drugs and to use his or her "best efforts" to secure rebates equal to those extended to the state under the Medicaid program.<sup>53</sup> These rebates were to be passed back to pharmacies that sell drugs to eligible Maine residents at discounts reflecting the rebates. Drug manufacturers who refused to extend voluntary rebates were to be sanctioned by having their identities released to the public and their products covered under the Medicaid program only on a "prior

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49. 42 U.S.C. § 1396r-8(d) (2000).

50. 42 U.S.C. § 1396r-8(d)(5) (2000).

51. See Brief of Amicus Curiae Legal Services Organizations Representing Medicaid Beneficiaries at 4-13, *Pharm. Research & Mfrs. of Am. v. Walsh*, 123 S.Ct. 1855 (2003) [hereinafter "Amicus Brief"].

52. ME. REV. STAT. ANN. tit. 22, §§ 2681(2)(F), (5) (West 2003). After the Supreme Court's decision, Maine enacted a more limited program, Maine Rx Plus, covering only persons whose income is below 350% of the poverty level, or who have drug costs exceeding 5% of household income or medical costs exceeding 15% of household income. See *Maine Governor Signs New State Prescription Drug Discount Program into Law*, KAISER DAILY POL'Y REPORT, June 26, 2003, [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=3&DR\\_ID=18501](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=18501) (last visited Dec. 2003). The Maine Rx Plus program was finally implemented on January 17, 2004. See KAISER FAMILY FOUND., MAINE PRESCRIPTION DRUG DISCOUNT PROGRAM TO TAKE EFFECT SATURDAY (2004), [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?DR\\_ID=21708](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=21708).

53. ME. REV. STAT. ANN. tit. 22, § 2681(3), (4) (West 2003).

authorization” basis.<sup>54</sup> Although the state argued that the prior authorization program would be operated so as to assure that Medicaid recipients had access to needed medications, it also acknowledged that the program might in some instances block recipients from receiving their doctors’ first choice of drug. In fact, other states that have implemented prior-authorization programs have seen dramatic reductions in use of pharmaceutical products placed on prior-authorization status.<sup>55</sup>

#### IV. THE SUPREME COURT’S RESPONSE: *PhRMA v. WALSH*

In the case that culminated in *PhRMA v. Walsh*, the trade association that represents most of the brand name drug manufacturers in the United States challenged the Maine program, arguing that the statute creating the program violated the United States Constitution in two respects. First, PhRMA contended that the statute violated the Supremacy Clause, which recognizes the preeminence of federal over state law, because the statute imposed a prior authorization requirement on drug coverage under the state Medicaid program—thus inflicting a significant burden on Medicaid recipients—for reasons unrelated to the purposes of the federal Medicaid statute.<sup>56</sup> In this argument, PhRMA was supported by amicus briefs filed by the United States Solicitor General and by organizations representing Medicaid recipients, which noted that Medicaid beneficiaries have indeed suffered in states with prior authorization programs.<sup>57</sup>

PhRMA also argued that the Maine program was unconstitutional because it violated the so-called dormant Commerce Clause. The dormant or negative Commerce Clause is a court-created doctrine implied by—rather than explicitly found in—the Constitution. Article one, section eight, clause three of the Constitution gives the federal government the authority to regulate commerce “among the several States.” In a series of cases, the Supreme Court has stated that this federal authority to regulate interstate commerce implies a prohibition against the states’ doing so.<sup>58</sup>

The dormant Commerce clause has generated a number of complex strands of doctrinal development over the years. Most successful dormant Commerce Clause cases, however, involve laws through which a state has

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54. ME. REV. STAT. ANN. tit. 22, § 2681(7) (West 2003).

55. See Amicus Brief, *supra* note 51.

56. 123 S.Ct. at 1867.

57. *PhARMA v. Concannon*, Brief for the United States as Amicus Curiae Supporting Reversal, 2002 WL 31156279; *PhARMA v. Concannon*; Amicus Brief, *supra* note 51.

58. See, e.g., *Okla. Tax Comm’n v. Jefferson Lines, Inc.*, 514 U.S. 175 (1995); *Healy v. Beer Inst.*, 491 U.S. 324 (1989).

attempted to favor its own businesses at the expense of other states<sup>59</sup> or to regulate transactions that take place inside other states.<sup>60</sup> Where a state simply attempts to regulate transactions within its own borders (including regulating prices), the Clause has not been held to apply; and where a state attempts to further its own legitimate, non-protectionist interests through laws that incidentally impose burdens on interstate commerce, the laws are usually upheld under a balancing test.<sup>61</sup>

PhRMA argued that the Maine statute violated the dormant Commerce Clause because it 1) set prices for drugs sold by manufacturers and thus regulated transactions between manufacturers and wholesalers, which in most instances took place outside of Maine, and 2) favored Maine consumers at the expense of drug manufacturers located in other states.<sup>62</sup>

The federal district court accepted both of PhRMA's constitutional arguments, holding that the Maine drug program was inconsistent with both the federal Medicaid law and the dormant Commerce Clause.<sup>63</sup> The First Circuit Court of Appeals, however, reversed the district court judgment, holding that the program in fact promoted the purposes of the Medicaid program by making drugs available to low-income people and thus helping them to stay off of Medicaid.<sup>64</sup> It further held that the program did not violate the dormant Commerce Clause because it promoted an important state purpose while minimally burdening commerce and because it only governed transactions wholly within Maine.<sup>65</sup>

The Supreme Court upheld the court of appeals' decision rejecting the district court's preliminary injunction.<sup>66</sup> However, the Court was deeply divided in its reasoning, producing no single majority opinion. Justice Stevens announced the judgment of the Court in an opinion joined in its entirety by only two other Justices, Souter and Ginsburg.<sup>67</sup> Justice Breyer concurred in most of Justice Stevens' opinion, and in the judgment of the Court.<sup>68</sup> Justices Thomas and Scalia wrote their own opinions, agreeing

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59. *See* *Or. Waste Sys., Inc. v. Dep't of Env'tl. Quality*, 511 U.S. 93 (1994).

60. *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970).

61. *Id.*

62. 123 S.Ct. at 1870.

63. 123 S.Ct. 1865.

64. *Pharm. Research & Mfrs. Of Am. V. Concannon*, 249 F.3d 66, 74-79 (1st Cir. 2001).

65. 249 F.3d at 79-84.

66. *Pharm. Research & Mfrs. of Am. v. Walsh.*, 123 S.Ct. 1855 (2003).

67. *Id.* at 1860.

68. *Id.* at 1871. Justice Breyer wrote separately to opine that the district court should have been instructed to seek the view of the Secretary of Health and Human Services as to

with the result of the Court, but disagreeing with the reasoning of Justice Stevens' plurality opinion.<sup>69</sup> Finally, Justices O'Connor, Rehnquist, and Kennedy dissented from part of the Court's judgment.<sup>70</sup>

All of the Justices agreed on one thing: The dormant Commerce Clause does not prohibit Maine's program.<sup>71</sup> The Maine statute neither attempted to regulate prices of out-of-state transactions nor favored Maine manufacturers to the disadvantage of out-of-state competitors; thus, it did not fall within earlier decisions finding state legislation to violate the dormant Commerce Clause.<sup>72</sup>

On the Medicaid issue, however, the Court was divided. Six Justices agreed that the lower court should not have entered a preliminary injunction blocking the Maine program, but they offered four different opinions supporting this result. Justice Stevens, writing for himself and Justices Ginsburg and Souter, opined that the district court erred in holding that the Maine program served no Medicaid purpose.<sup>73</sup> Stevens agreed with the court of appeals that the program would provide services to some "medically needy" persons and also that Medicaid expenditures might be reduced because of early provision of drugs to "borderline" persons whose conditions might otherwise worsen, making them eventually a burden on the Medicaid program.<sup>74</sup> Stevens further argued that the prior authorization program itself might encourage the use of more cost-effective drugs, thus saving Medicaid money.<sup>75</sup> He also noted that the each state has considerable discretion in administering its Medicaid program, and that PhRMA would have had to have shown that the Maine program had a more severe impact on the access of Medicaid recipients to drugs to overcome Maine's exercise of its discretion in this instance.<sup>76</sup> Stevens concluded that further proceedings would be necessary to resolve these issues, noting that the results might very well depend on actions that HHS might take as a result of the Maine scheme.<sup>77</sup>

Justices Breyer, Scalia, and Thomas each wrote separately, joining in the result, but not the reasoning, of the Court. Both Scalia and Thomas

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the permissibility of Maine's program.

69. *Id.* at 1873 (Scalia, J., concurring), 1874 (Thomas, J., concurring).

70. *Id.* at 1878.

71. *Id.* at 1870-71.

72. *Id.*

73. *Id.* at 1867-68.

74. *Id.*

75. *Id.* at 1868.

76. *Id.* at 1868-69.

77. *Id.* at 1869-70.

have little use for the dormant Commerce Clause, and gave short shift to that argument.<sup>78</sup> Both would also have thrown out the Medicaid case altogether, with Scalia taking the position that only HHS has the power to enforce the Medicaid statute through terminating state funding,<sup>79</sup> and Thomas arguing that there was no conflict between the Maine program and the Medicaid statute because the statute allows prior authorization programs without regard to the state's motive for adopting them. Thomas further pointed out that HHS, not the courts, is responsible for policing state compliance with Medicaid requirements.<sup>80</sup> Ultimately, both Thomas and Scalia saw the matter as primarily the concern of HHS, and did not believe that PhRMA's challenge was properly before the Court.

Justice Breyer, in his opinion, suggested that the appropriate course for the lower court on remand would be to stay the proceedings under the doctrine of primary jurisdiction, and to ask HHS for its views on the permissibility of the Maine plan.<sup>81</sup> Thus, Justice Breyer also believed that HHS should rule on the Maine plan.

Finally, Justices O'Connor, Rehnquist, and Kennedy dissented on the Medicaid issue, arguing that the Maine statute was preempted by the federal Medicaid law because it imposed a prior authorization requirement on Medicaid recipient for purposes unrelated to the Medicaid program.<sup>82</sup> The dissenters contended that there was no factual basis for the plurality's conclusion that the program furthered purposes related to the Medicaid

78. *Id.* at 1873-74 (Scalia, J., concurring), 1879 (Thomas, J., concurring).

79. *Id.* at 1874.

80. *Id.* at 1874-78. The fact that none of the other Justices joined Scalia and Thomas in their argument that courts have no role in overseeing the Medicaid program would seem to sound a death knell for the arguments raised by the district court in *Westside Mothers v. Haveman*, 133 F. Supp. 2d 549 (E.D. Mich. 2001). The lower court in that case held that the federal courts have no jurisdiction over the states in Medicaid cases under 42 U.S.C. § 1983, and that the Eleventh Amendment bars the courts from providing relief against states that violate Medicaid requirements. The district court was reversed on appeal, *Westside Mothers v. Haveman*, 289 F.3d 852 (6th Cir. 2002), and its position has been rejected by other courts. *See, e.g., Antrican v. Odom*, 290 F.3d 178 (4th Cir. 2002). Seven Justices in the *Walsh* case seem to have no problem with the Court permitting direct challenges to state administration of their Medicaid programs, though several suggest that it might be better if the Department of Health and Human Services take a first look at challenges to Medicaid programs, perhaps foreshadowing a future exhaustion requirement. *See Timothy S. Jost, The Tenuous Nature of the Medicaid Entitlement*, 22 HEALTH AFF. 145 (2003).

81. *Pharm. Research & Mfrs. of Am. v. Walsh*, 123 S.Ct. at 1872-73.

82. *Id.* at 1878-82.

program.<sup>83</sup>

Three conclusions emerge from the multiple opinions when read together. First, the entire Court agreed that state attempts to leverage the Medicaid program to force discounts from drug companies do not violate the dormant Commerce Clause. Second, seven justices—all but Thomas and Scalia—agreed that a state should only be allowed to use the Medicaid program to obtain discounts for non-Medicaid recipients if it can show a “Medicaid purpose” for such a program, which some would explicitly tie to the statutory requirement that services be provided in a manner consistent with “the best interests of [Medicaid] recipients.”<sup>84</sup> Finally, six justices—all but the dissenters—agreed that the opinion of HHS regarding the permissibility of a state drug program that uses the state’s Medicaid purchasing power is important; and at least three—Thomas, Scalia, and Breyer—would regard it as well nigh decisive.

#### V. THE RAMIFICATIONS OF *WALSH* FOR STATE DRUG PROGRAMS

The most immediate result of *Walsh* is that it clears the way for states to move forward with adopting and implementing programs to expand access to drugs for the elderly and uninsured using their Medicaid market power. The drug manufacturers have been largely successful in blocking such programs through three years of litigation, but—with the ground rules for such programs now established by the Supreme Court—states can proceed.

Although the majority of the Justices in *Walsh* agreed that it was important that HHS review state plans to use the Medicaid program to secure drug rebates for their residents, this may not be an insurmountable barrier to the implementation of these plans. In fact, the Center for Medicare and Medicaid Services (CMS), a federal agency within HHS, has indicated its willingness to approve the use of Medicaid preauthorization programs to force drug companies to offer rebates for the benefit of non-Medicaid populations.<sup>85</sup> CMS approval of two such programs in Michigan covering low-income elderly persons and poor pregnant adolescents has already been upheld in a lower federal court decision that Justice Thomas described in his opinion as providing a “careful analysis” of the issue.<sup>86</sup>

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83. *Id.* at 1880-81.

84. 42 U.S.C. § 1396a(a) (19) (2000).

85. Letter from Dennis G. Smith, Director for Medicaid and State Operations, Centers for Medicare & Medicaid Services, to State Medicaid Directors (Sept. 18, 2002), on file with author and available at <http://www.cms.gov/states/letters/smd91802.pdf>.

86. *Pharm. Research & Mfrs. of Am. v. Thompson*, 259 F.Supp.2d 39 (D.D.C. 2003). *See Pharm. Research & Mfrs. of Am. v. Walsh*, 123 S.Ct. at 1877, n.5 (Thomas, J., concurring).



CMS based its approval of the Michigan program on its findings that the program was likely to save the Medicaid program money by keeping people whose income is marginally above Medicaid limits off of Medicaid, and that the Michigan prior authorization programs offered adequate protections for Medicaid recipients who needed a drug subject to prior authorization for a particular therapeutic reason.<sup>87</sup> HHS objected to the Maine program in its Supreme Court amicus brief primarily because Maine did not impose any income limits.<sup>88</sup> As this feature has now been changed,<sup>89</sup> HHS might well approve the plan.

In the end, of course, rebates at the 15% level, such as those available under Medicaid, may not be sufficient to make drugs available to many poor Americans. Because of this, the refusal of the Court to apply the dormant Commerce Clause in *Walsh* may be even more important in expanding the ways in which states can bring down drug prices for their residents. As long as state programs only regulate in-state transactions, and are not used to discriminate against out-of-state and in favor of in-state merchants or industries, states have considerable scope to bargain with pharmaceutical companies for lower drug prices.

A number of states are adopting aggressive strategies to bring down drug prices, perhaps even below the price levels enjoyed by the Medicaid program. Some, for example, are engaged in bulk drug purchasing of drugs at a state or regional level to force down drug prices for state employees and for Medicaid recipients, and could potentially expand this strategy to make drugs more affordable for uninsured residents.<sup>90</sup> Several states are also considering purchasing drugs from Canada, where prices are regulated, to make drugs more affordable for state employees<sup>91</sup>—

87. *Pharm. Research & Mfrs. of Am. v. Thompson*, 259 F. Supp. 2d at 74-75.

88. See Brief for the United States as Amicus Curiae Supporting Reversal at 21-22, *Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66 (1st Cir. 2001) (No. 01-188). As noted above, subsequent to *Thompson*, Maine amended its statute to impose limits on financial eligibility. See *Maine Governor Signs State New Prescription Drug Discount Program into Law*, *supra* note 52.

89. See *Maine Governor Signs New State Prescription Drug Discount Program into Law*, *supra* note 52.

90. See NAT'L CONF. OF STATE LEGISLATURES, PHARMACEUTICAL BULK PURCHASING: MULTI-STATE AND INTER-AGENCY PLANS (2003) <http://www.ncsl.org/programs/health/bulkrx.htm> (last visited Dec. 2003).

91. See THE HENRY J. KAISER FAM. FOUND., MINNESOTA TO EXPLORE BUYING PRESCRIPTION DRUGS FROM CANADA (2003), [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=3&DR\\_ID=20033](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=20033) (last visited Dec. 2003).

another strategy that could potentially be expanded to cover the beneficiaries of state programs. Some states are even considering state maximum drug price controls.<sup>92</sup> Certainly, the *Walsh* dormant Commerce Clause ruling removes one important drug industry argument in opposing state drug price regulation programs.

#### CONCLUSION

In the absence of decisive federal action to make drugs available to Medicare recipients and the uninsured, a number of states are moving forward with state programs to expand drug availability. These programs have faced vigorous challenges from the drug industry. *PhRMA v. Walsh* gives the green light to one important strategy for making drugs more affordable—using state Medicaid market power to force down prices. Perhaps even more importantly, however, *Walsh*'s Commerce Clause ruling opens the door to even more aggressive state actions to control drug costs. The case, therefore, marks an important milestone in efforts to make the benefits of modern pharmaceuticals available to all Americans, and not just to those fortunate enough to be insured.

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92. See NAT'L CONF. OF STATE LEGISLATURES, 2002 PRESCRIPTION DRUG DISCOUNT, BULK PURCHASING, AND PRICE-RELATED LEGISLATION (2003), <http://www.ncsl.org/programs/health/drugdisc02.htm> (last visited Dec. 2003).

## NOTE

### New Diagnoses and the ADA: A Case Study of Fibromyalgia and Multiple Chemical Sensitivity

Ruby Afram\*

#### INTRODUCTION

From its inception in 1990, the Americans with Disabilities Act (ADA) has been a groundbreaking piece of civil rights legislation: a highly flexible, individually responsive law that intended to bring “some 43,000,000” disabled Americans into society’s mainstream.<sup>1</sup> To ensure the envisioned access and opportunity, the ADA sought to replicate for people with disabilities the type of protections that the Civil Rights Act of 1964 provided to women and minorities.<sup>2</sup> It barred discrimination on the basis of disability in employment<sup>3</sup> and required that all public entities<sup>4</sup> and public accommodations provided by private entities<sup>5</sup> be accessible to the disabled population. The law was controversial, however, because it differed in an important way from traditional civil rights legislation.<sup>6</sup> The civil rights movement had articulated a fundamental imperative: “[D]iscrimination according to characteristics irrelevant to job

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1. Americans with Disabilities Act of 1990, Pub. L. No. 101-336, 104 Stat. 327 (1990) (codified at 42 U.S.C. §§ 12101-12213 (2000)). For the reference to “some 43,000,000,” see *id.* § 12101.

2. JOSEPH P. SHAPIRO, NO PITY: PEOPLE WITH DISABILITIES FORGING A NEW CIVIL RIGHTS MOVEMENT 105 (1993).

3. 42 U.S.C. § 12112 (2000).

4. *Id.* § 12132.

5. *Id.* § 12182. For definitions of covered entities, see *id.* § 12181 (2000).

6. SHAPIRO, *supra* note 2, at 115.

performance and the denial of access to public accommodations and public services was . . . against the law.”<sup>7</sup> When that imperative played out in the course of everyday life it resulted in businesses opening their doors and their organizations to a wider swath of society. Generally, however, it did not require them to change the way they did business, just whom they included—in economic terms, a relatively inexpensive adjustment. In comparison, the ADA was invasive legislation; it imposed affirmative duties on companies to adjust the way they did business in order to accommodate the special needs of their employees and clients.<sup>8</sup> Even though the law limited the burden on employers by requiring that they make modifications for employees and clients only when the adjustments were easy to achieve and of reasonable expense, the ADA imposed new costs on all entities required to comply with its mandates.<sup>9</sup>

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7. NAT’L COUNCIL ON DISABILITY, EQUALITY OF OPPORTUNITY THE MAKING OF THE AMERICANS WITH DISABILITIES ACT (1997), <http://www.ncd.gov/newsroom/publications/pdf/equality.pdf>.

8. SHAPIRO, *supra* note 2, at 115.

9. *Id.* Title I of the ADA covers employment: “The term ‘employer’ means a person engaged in an industry affecting commerce who has 15 or more employees for each working day in each of 20 or more calendar weeks in the current or preceding calendar year, and any agent of such person . . .” 42 U.S.C. § 12111(5)(A) (2000). Title II of the ADA covers public services provided by a public entity: “(1) Public entity. The term ‘public entity’ means—(A) any State or local government; (B) any department, agency, special purpose district, or other instrumentality of a State or States or local government; and (C) the National Railroad Passenger Corporation, and any commuter authority . . .” 42 U.S.C. § 12131(1) (2000).

Title III of the ADA covers public accommodations provided by private entities:

(7) Public accommodation. The following private entities are considered public accommodations for purposes of this title [42 USCS §§ 12181 et seq.], if the operations of such entities affect commerce—

- (A) an inn, hotel, motel, or other place of lodging . . . ;
- (B) a restaurant, bar, or other establishment serving food or drink;
- (C) a motion picture house, theater, concert hall, stadium, or other place of exhibition or entertainment;
- (D) an auditorium, convention center, lecture hall, or other place of public gathering;
- (E) a bakery, grocery store, clothing store, hardware store, shopping center, or other sales or rental establishment;
- (F) a laundromat, dry-cleaner, bank, barber shop, beauty shop, travel service, shoe repair service, funeral parlor, gas station, office of an accountant or lawyer, pharmacy, insurance office, professional office of a health care provider, hospital, or other service establishment;
- (G) a terminal, depot, or other station used for specified public transportation;
- (H) a museum, library, gallery, or other place of public display or collection;
- (I) a park, zoo, amusement park, or other place of recreation;

The affirmative duties that differentiate the ADA from other civil rights legislation have, in the years since its passage, made it the target of a backlash.<sup>10</sup> Different groups have sought to cabin the ADA's impact, and one major limitation has come from the courts. In two important ADA cases, *Sutton v. United Airlines*<sup>11</sup> and *Toyota v. Williams*,<sup>12</sup> the United States Supreme Court latched onto the figure "43,000,000" as a way to justify a restrictive interpretation of the law's provisions, making the figure an effective ceiling on the number of disabled Americans protected by the law. The history of the ADA, however, makes it clear that "43,000,000" was never intended to be a ceiling; it was intended to convey the enormity of the problem that the ADA addressed.<sup>13</sup> Congress clearly foresaw that the

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(J) a nursery, elementary, secondary, undergraduate, or postgraduate private school, or other place of education;

(K) a day care center, senior citizen center, homeless shelter, food bank, adoption agency, or other social service center establishment; and

(L) a gymnasium, health spa, bowling alley, golf course, or other place of exercise or recreation.

42 U.S.C. § 12181(7) (2000).

10. See, e.g., Matthew Diller, *Judicial Backlash, the ADA, and the Civil Rights Model*, 21 BERKELEY J. EMP. & LAB. L. 19, 20-23 (2000) (discussing ADA advocates' "horror" at how case law under the ADA has developed and seeking to explain these "negative" outcomes); Chai R. Feldblum, *Definition of Disability Under Federal Anti-Discrimination Law: What Happened? Why? And What Can We Do About It?*, 21 BERKELEY J. EMP. & LAB. L. 91 (2000) (reviewing the limitations that courts have imposed on the ADA by using its definitional language to set high and complex barriers to litigation); Cary Lacheen, *Achy Breaky Pelvis, Lumber Lung and Juggler's Despair: The Portrayal of the Americans with Disabilities Act on Television and Radio*, 21 BERKELEY J. EMP. & LAB. L. 223, 233 (2000) (discussing the negative portrayal of the ADA in popular culture media).

11. *Sutton v. United Airlines, Inc.*, 527 U.S. 471 (1999) (stating that Congress did not intend to provide coverage in the ADA for persons whose conditions could be alleviated by corrective measures such that their impairment did not substantially limit a major life activity). Justice O'Connor's majority opinion limited ADA suits to those whose *corrected* condition still "substantially limited a major life activity." *Id.* at 482.

12. *Toyota Motor Mfg., Ky., Inc. v. Williams*, 534 U.S. 184, 198 (2002) (holding "that to be substantially limited in performing manual tasks [under the ADA], an individual must have an impairment that prevents or severely restricts the individual from doing activities that are of central importance to most people's daily lives" and that "[t]he impairment's impact must also be permanent or long-term"). Justice O'Connor, again writing for the majority, stated: "If Congress intended everyone with a physical impairment that precluded the performance of some isolated, unimportant, or particularly difficult manual task to qualify as disabled, the number of disabled Americans would surely have been much higher." *Id.* at 197.

13. See Steny H. Hoyer, *Not Exactly What We Intended*, *Justice O'Connor*, WASH. POST,

aging of the Baby Boomers would result in an increased number of Americans being protected by the law in the years following its passage.<sup>14</sup> A desire to make the law highly flexible and inclusive informed the Act's legislative history. Congress chose expansive language and a broad definition of disability.<sup>15</sup> Professor Kevin Smith has written, "Given the wide variety of physical and mental conditions which can adversely affect an individual's ability to perform a major life activity . . . Congress neither defined what constitutes a physical or mental impairment nor listed the universe of possible impairments."<sup>16</sup>

This built-in flexibility initially allowed two possible avenues of growth for the ADA, distinct from the growth in the elderly population. The first was a flexible and generous interpretation of the law's provisions that might have provided protection under the ADA to more than the forty-three million Americans estimated by Congress. The Supreme Court clearly rejected this possibility in both *Toyota* and *Sutton*, binding itself instead to an inflexible and restrictive understanding of the law. The

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January 20, 2002, at B1 (discussing the ADA after *Toyota*). Congressman Hoyer wrote:

When we wrote the ADA, we estimated that 43 million people would be covered. That seemed like a lot and we thought that showed we intended the law to be broad rather than narrow. Until the ADA passed, the average guy thought of a disability as something that meant you couldn't walk or see or hear. Our broader estimate helped build support for the legislation.

Now, however, O'Connor has cited that figure to say that carpal tunnel and other conditions might push the national total of people protected under the ADA far beyond 43 million and that Congress did not intend that. "If Congress intended everyone with a physical impairment that precluded the performance of some isolated, unimportant, or particularly difficult manual task to qualify as disabled, the number of disabled Americans would surely have been much higher," she wrote. But the number we used wasn't designed to limit the effect of our legislation, but to show its breadth.

*Id.*

14. The Congressional "findings and purposes" noted that "some 43,000,000 Americans have one or more physical or mental disabilities, and this number is increasing as the population as a whole is growing older." 42 U.S.C. § 12101 (2000).

15. See Feldblum, *supra* note 10, at 125-34 (discussing the legislative history of the adoption of the definition of disability in the ADA).

16. Kevin H. Smith, *Disabilities, Law Schools, and Law Students: A Proactive and Holistic Approach*, 32 Akron L. Rev. 1 (1999). Smith quotes the Equal Employment Opportunity Commission (EEOC) regulations for the ADA, 29 C.F.R. pt. 1630, app. § 1630 (1998): "[T]he ADA . . . [does] not attempt a 'laundry list' of impairments that are 'disabilities.' The determination of whether an individual has a disability is not necessarily based on the name or diagnosis of the impairment the person has, but rather on the effect of that impairment on the life of the individual." *Id.* at 42 n.118.

second possibility—the development and recognition of new illnesses and new diagnoses covered by the ADA—existed outside of the framework of the law; because the ADA did not include an exhaustive list of qualified conditions, it also did not attempt to identify a process by which new disabilities might be recognized under the law.

Given the structure of the law, recognition of new conditions need not be problematic for the ADA. The law offers highly-individualized protection, and citizens seeking that protection do not have to prove that they have a particular condition.<sup>17</sup> Instead, in order for a plaintiff to sue, courts have required that she first show that she is a person with a disability, as defined by the ADA. The status of a plaintiff claiming a current disability depends on three key factors: She must (1) have an impairment that (2) “substantially limits” her in (3) a “major life activity.” Agencies responsible for enforcing various titles of the ADA have issued regulations attempting to clarify the meaning of these phrases. Like the language of the statute, the regulations are broadly inclusive of the conditions covered. The Equal Employment Opportunity Commission is responsible for issuing the regulations interpreting Title I, and it uses sweeping language to define a physical or mental impairment as “any physiological disorder, or condition, cosmetic disfigurement, or anatomical loss . . . or . . . any mental or psychological disorder.”<sup>18</sup> The Department of Justice regulations for Titles II and III of the ADA closely

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17. This differs from the two disability benefits programs run by the Social Security Administration—the Supplemental Security Income Program (SSI) and the Federal Old-Age, Survivors, and Disability Insurance Program (OASDI)—for which there is a list of covered conditions, as well as an alternate process for demonstrating that a condition that is not listed is similar in nature to those on the list. 20 C.F.R. § 404, subpt. P, app. 1 (2003). The basic requirement for either program is that in order to receive benefits, the claimant must be legally disabled under a five-step claim and benefit determination process. Aimee E. Bierman, Note, *The Medico-Legal Enigma of Fibromyalgia: Social-Security Disability Determinations and Subjective Complaints of Pain*, 44 WAYNE L. REV. 259, 267-69 (1998).

18. The regulation states:

(h) Physical or mental impairment means:

(1) Any physiological disorder, or condition, cosmetic disfigurement, or anatomical loss affecting one or more of the following body systems: neurological, musculoskeletal, special sense organs, respiratory (including speech organs), cardiovascular, reproductive, digestive, genito-urinary, hemic and lymphatic, skin, and endocrine; or  
 (2) Any mental or psychological disorder, such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities.

29 C.F.R. § 1630.2(h) (2003).

track this language.<sup>19</sup> Presumably, a person with a new condition that met these requirements, though it was not known or recognized at the time of the ADA's passage, would be entitled to protection under the law.

Obtaining coverage under the ADA, however, has proven no mean feat, even for plaintiffs with traditionally recognized conditions.<sup>20</sup> Phrases that seem straightforward have generated a large body of complex case law. Definitional challenges involving the requirements or meaning of each key phrase are often put forth by defendants and adopted by the courts. These challenges have restricted access to the ADA's protections,<sup>21</sup>

19. The regulation states:

(1) (i) The phrase physical or mental impairment means—

(A) Any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more of the following body systems:

Neurological, musculoskeletal, special sense organs, respiratory (including speech organs), cardiovascular, reproductive, digestive, genitourinary, hemic and lymphatic, skin, and endocrine;

(B) Any mental or psychological disorder such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities.

(ii) The phrase physical or mental impairment includes, but is not limited to, such contagious and noncontagious diseases and conditions as orthopedic, visual, speech and hearing impairments, cerebral palsy, epilepsy, muscular dystrophy, multiple sclerosis, cancer, heart disease, diabetes, mental retardation, emotional illness, specific learning disabilities, HIV disease (whether symptomatic or asymptomatic), tuberculosis, drug addiction, and alcoholism.

(iii) The phrase physical or mental impairment does not include homosexuality or bisexuality.

28 C.F.R. § 35.104(1) (2003).

20. See, e.g., Susan M. Gibson, *The Americans with Disabilities Act Protects Individuals with a History of Cancer from Employment Discrimination: Myth or Reality*, 16 HOFSTRA LAB. & EMP. L.J. 167 (1998); Barbara Hoffman, *Between a Disability and a Hard Place: The Cancer Survivors' Catch-22 of Proving Disability Status Under the Americans with Disabilities Act*, 59 MD. L. REV. 352 (2000).

21. See *Toyota Motor Mfg., Ky., Inc. v. Williams*, 534 U.S. 184 (2002) (holding "that to be substantially limited in performing manual tasks [under the ADA], an individual must have an impairment that prevents or severely restricts the individual from doing activities that are of central importance to most people's daily lives" and that "[t]he impairment's impact must also be permanent or long-term"); *Albertson's, Inc. v. Kirkingburg*, 527 U.S. 555, 565 (1999) (noting that "mitigating measures must be taken into account in judging whether an individual possesses a disability"); *Sutton v. United Air Lines, Inc.*, 527 U.S. 471 (1999) (holding that a "disability" under the ADA has to be determined with regard to the corrective measures that are available); *Bragdon v. Abbott*, 524 U.S. 624 (1998) (holding that HIV is a disability under the ADA). The language "qualified individual with a disability" was first interpreted by the Supreme Court in a case arising under section 504 of the Rehabilitation Act of 1973. *Southeastern Cmty. Coll. v. Davis*, 442 U.S. 397 (1979). The language relating "qualified individual" to "essential functions" of the job in the Title I



creating high barriers to success for plaintiffs.<sup>22</sup> Suits by plaintiffs with new conditions have been especially tricky; defendants have attempted to enhance the pattern of definitional restriction by attacking ADA claims made by plaintiffs with recently discovered illnesses. Plaintiffs bringing claims under novel or fresh diagnoses have been greeted by charges from defendants that their claims are based on invalid or unrecognized medical conditions.

As the number of people with known conditions has grown in the years since the passage of the ADA so, too, has the number of recognized disabling conditions.<sup>23</sup> No formal barrier keeps the law from expanding to cover new disabling conditions as they are discovered. The important question, then, is how new diagnoses have actually been treated in ADA litigation in the years since the law's passage. Focusing on ADA Title I litigation, this Note studies the treatment of two "new" diagnoses that have actually been challenged by defendants in ADA lawsuits: fibromyalgia and multiple chemical sensitivity (MCS).<sup>24</sup> Both diagnoses were initially highly controversial, but have gained wider acceptance within the medical community in the thirteen years since the passage of the ADA. Nonetheless, neither is without its skeptics. There are parallels between the two illnesses: both lack a known etiology; both occur much more frequently in women than in men; and, unlike most "established" conditions, neither has a generally accepted, "objective" medical test that allow for its diagnosis. Yet ADA suits centered on the two diagnoses have met somewhat different fates in the federal courts. Neither has received a

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definitions appeared in *School Board of Nassau County v. Arline*, 480 U.S. 273 (1987).

22. See Feldblum, *supra* note 10, at 139. Feldblum reports that:

[T]he editors of the National Disability Law Reporter . . . found that, in 110 ADA cases in 1995 and 1996, the question had been raised as to whether the plaintiff met the statutory definition of disability under the ADA. . . . [I]n only *six* of those cases had the judges definitively found the plaintiffs met the statutory definition.

*Id.* at 139.

23. See, e.g., Jane E. Brody, *The Road to Wellness, Paved With 1,900 Pages*, N.Y. TIMES, June 3, 2003, at F7 (discussing the addition of new conditions in the newest edition of Merck Manual and stating "[t]he new version adds 35 chapters and 400 pages. . . . Under 'Diseases of Unknown Cause,' conditions like chronic fatigue syndrome and multiple chemical sensitivity syndrome are described dispassionately along with honest assessments of treatments that have or have not worked"); *Six Years Later* . . ., WASH. POST, May 20, 2003, at F02 (discussing changes to the Merck Manual of Medical Information, including the inclusion of new conditions like "Gulf War syndrome, multiple chemical sensitivity, chronic fatigue syndrome, [and] sick building syndrome").

24. MCS is also known as "multiple chemical sensitivities."

warm welcome, but while courts have generally accepted a diagnosis of fibromyalgia, MCS has had been subjected to significant exclusion—most importantly through the use of the *Daubert* standard for expert testimony and evidence, established by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*<sup>25</sup> Because ADA litigation is often so fact-specific, every piece of information about an employee's condition may be vital to the outcome of the case. Defendants have exploited this by using *Daubert*, originally established in the field of mass tort litigation, to effectively exclude expert testimony about MCS. Without such testimony, some plaintiffs lack evidence crucial to proving components of their discrimination claim. As a result, new conditions such as MCS are left out in the cold.

In attempting to understand why the two illnesses have met with different receptions, and what it means for the inclusion of new diagnoses under the ADA, Part I of this Note provides an overview and history of fibromyalgia; Part II does the same for multiple chemical sensitivity. Parts I and II are designed to give a sense of the complex debates that have surrounded the emergence of the two diagnoses and to provide a basic medical framework for the Note's later legal analysis. Part III surveys the case law that has developed around the two illnesses, analyzing significant trends and comparing results under the two illnesses with general statistics

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25. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). In fact, a significant body of literature has developed concerning the ADA and MCS. Several other commentators have previously observed, as I do in this Note, that the use of the *Daubert* standard to exclude expert testimony makes it exceedingly difficult for individuals suffering from MCS to bring successful ADA claims. See, e.g., Peter David Blanck & Heidi M. Berven, *Evidence of Disability After Daubert*, 5 PSYCH. PUB. POL. & L. 16 (1999) ("The few federal courts that have applied the *Daubert* formulation to expert testimony relating to MCS have found clinical ecology evidence inadmissible . . ."); Andrew K. Kelley, *Sensitivity Training: Multiple Chemical Sensitivity and the ADA*, 25 B.C. ENVTL. AFF. L. REV. 485, 496 (1998) (noting that "courts have refused to allow expert testimony regarding MCS because it lacks scientific reliability, thereby failing to meet the standards for expert opinion testimony established by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*" and that "MCS sufferers who have brought [ADA] claims have had very limited success"); Amy B. Spagnole, *The MCS Controversy: Admissibility of Expert Testimony Regarding Multiple Chemical Sensitivity Syndrome Under the Daubert Regime*, 4 SUFFOLK J. TRIAL & APP. ADV. 219, 234 (1999) ("In applying the *Daubert* standard to MCS litigation, every federal court, which has ruled on the issue of admissibility of expert testimony regarding MCS, has found the proffered testimony inadmissible."). This Note differs from these earlier studies by comparing the relative successes of MCS and fibromyalgia sufferers under the ADA and by offering a new resolution to this problem. See *infra* Part IV.

on lawsuits brought under Title I of the ADA. Part IV attempts to explain why the two illnesses have fared differently in the courts, focusing on the role of the *Daubert* standard and its possible implications for the fate of new diagnoses in ADA litigation. Part V argues that using *Daubert* to bar plaintiffs' claims is entirely inappropriate in the civil rights context and that it frustrates the ADA's inclusive intent. However, because of current trends in the law, it may be necessary for the courts to reconcile the seemingly contradictory directives of the *Daubert* exclusion and its progeny case law with the ADA's inclusiveness. Drawing on current case law, this Note then suggests a resolution that will allow the ADA to expand and encompass citizens whose conditions were unknown or widely unaccepted at the time of the law's passage.

### I. FIBROMYALGIA—AN OVERVIEW

Fibromyalgia is a common musculoskeletal syndrome characterized by generalized pain, irregular sleep patterns, fatigue, and a wide range of secondary symptoms.<sup>26</sup> A diagnosis of fibromyalgia requires pain in at least eleven of eighteen specific sites on the body. Pain caused by the condition can be severe or limited; it may be continual or occur in flares, with periods of remission. The condition affects between three and six million Americans,<sup>27</sup> and occurs most commonly in women between the ages of twenty and fifty.<sup>28</sup> Women are ten times more likely than men to be diagnosed with fibromyalgia. There is no single treatment that works well for all patients, or even for a large majority,<sup>29</sup> and the cause of the illness remains unknown. Questions about fibromyalgia's existence as a clinical entity have dominated its history and continue to appear in modern

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26. Daniel H. Reiffenberger & Loren H. Amundson, *Fibromyalgia Syndrome: A Review*, 53 AM. FAM. PHYSICIAN 1698 (1996). Fibromyalgia has been defined as causing "widespread and chronic musculoskeletal aching or stiffness associated with soft tissue tenderness at multiple, characteristic sites." *Id.* at 1698 (quoting Muhammad B. Yunus, *Fibromyalgia Syndrome: New Research on an Old Malady*, 298 BRIT. MED. J. 474 (1989)).

27. Robert W. Bradford & Henry W. Allen, *Recent Progress in Clinical Applications and Research in Fibromyalgia: Part I*, TOWNSEND LETTER FOR DOCTORS & PATIENTS, Nov. 1, 2001, at 28 [hereinafter Bradford & Allen, *Part I*].

28. Linda C. Higgins, *Proposed Fibromyalgia Guide May Help Doctors Pin Down a Puzzler*, MED. WORLD NEWS, June 12, 1989, at 10.

29. See Robert W. Bradford & Henry W. Allen, *Recent Progress in Clinical Applications and Research in Fibromyalgia: Part III*, TOWNSEND LETTER FOR DOCTORS & PATIENTS, Jan. 1, 2002, at 74 [hereinafter Bradford & Allen, *Part III*].

coverage of the condition.<sup>30</sup>

Fibromyalgia is not a new condition. There are anecdotes of similar illnesses that date back to the seventeenth century.<sup>31</sup> For generations, however, physicians thought that the disabling illness was, quite literally, all in the patient's head. For most of its known history, those who studied the condition believed its genesis to be psychosomatic.<sup>32</sup> The terms fibrositis and fibromyositis became popular when it was believed that inflammation in the connective tissues between muscles and bone was responsible for the pain the condition caused.<sup>33</sup> The term "fibromyalgia" did not exist until 1976.<sup>34</sup>

Early efforts to understand the illness focused on identifying and describing any standard symptoms or indicators of the disease. The onset of fibromyalgia brought with it few physiological changes that could be detected with standard medical tests.<sup>35</sup> The illness's high level of correlation with depression reinforced physicians' assumptions that they were dealing with a psychosomatic illness. Later studies showed that "the majority of people with fibromyalgia do not experience abnormal levels of depression or anxiety."<sup>36</sup>

The idea that fibromyalgia existed entirely within the patient's head, however, continued to haunt the medical community, the popular press, and those unfortunate enough to suffer from the debilitating illness. In the early 1980s, research on fibromyalgia was still limited;<sup>37</sup> by the late-1980s, however, it had experienced significant growth. In 1988, a small study released by a group of Pennsylvania physicians showed that patients with fibromyalgia demonstrated abnormal muscle metabolism function dissimilar to that of a control group. According to Dr. Robert Gatter, Chief of Rheumatology at Abington Memorial Hospital, it was "the first

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30. See *infra* notes 40-62 and accompanying text.

31. Daniel J. Clauw, *Fibromyalgia: More Than Just a Musculoskeletal Disease*, 52 AM. FAM. PHYSICIAN 843 (1995) [hereinafter Clauw, *Musculoskeletal*].

32. Charles D. Bankhead, *Fibromyalgia May Really Be in the Muscle, Not in the Mind*, MED. WORLD NEWS, Sept. 12, 1988, at 34.

33. See Mirinda J. Kossoff, "I Hurt All Over" (Chronic Pain Condition Fibromyalgia), PSYCH. TODAY, May 1999, at 42, 42.

34. See Clauw, *Musculoskeletal supra* note 31, at 843.

35. Linda Klein, *Fibromyalgia Syndrome: Shedding Light on the "Mystery Disease"*, ARTHRITIS TODAY, May 1989, at 50.

36. Melissa James, *Fibromyalgia Research: Growing by Leaps and Bounds*, ARTHRITIS TODAY, May 1989, at 54, 54.

37. *Id.* at 54.

semblance of something measurable that's abnormal in these patients."<sup>38</sup> Other contemporary studies linked fibromyalgia to "[a]bnormal levels of neurotransmitters" and mild alterations in the operation of the immune system.<sup>39</sup>

Despite these initial findings, and estimates that twenty percent of all rheumatology referrals were for fibromyalgia, the diagnosis still met with a high level of skepticism.<sup>40</sup> Patients applying for disability benefits were often rejected because, despite debilitating muscle tenderness, they lacked any sort of objective evidence of their condition.<sup>41</sup> In an attempt to remedy this problem and to standardize diagnoses of fibromyalgia, in 1989 the Multi-Center Fibromyalgia Criteria Study released the first version of the modern diagnostic criteria for fibromyalgia, requiring "[t]enderness in at least 11 of 18 specified sites on the body, accompanied by widespread pain."<sup>42</sup> Such symptoms differentiated the condition from other regional

38. Bankhead, *supra* note 32, at 34. Bankhead writes, "Using phosphorus magnetic resonance spectroscopy, Pennsylvania physicians found that nine fibromyalgia patients had one or more metabolic abnormalities, which were not seen in 22 controls, according to a report at the American Rheumatism Association meeting." *Id.* Bankhead also notes that the previous year Don Goldenberg and associates at Boston University released a similar study in the *Journal of the American Medical Association* in which they looked at biopsies of trapezius muscles in control and affected patients. *Id.*

39. James, *supra* note 36, at 54.

40. Bankhead, *supra* note 32, at 34 (quoting Dr. Tom Bohr of Stanford Medical Center as stating "It's not simply contemporary medical prejudices that keep many physicians from using the diagnosis of fibromyalgia. There simply never has been good evidence for it as a syndrome distinct from affective disorders.").

41. *Id.*

42. Higgins, *supra* note 28, at 10. Higgins further wrote:

Investigators at 16 university and private-practice arthritis or pain clinics evaluated a total of 293 patients with fibromyalgia and 265 control patients matched for age and sex. The control patients had common regional pain disorders that could be easily confused with fibromyalgia – possible inflammatory arthritis, mild osteoarthritis, shoulder pain syndromes, and neck and back pain syndromes.

After experts diagnosed patients' conditions by their usual standards, specially trained investigators who had no knowledge of the diagnoses interviewed the patients. Their evaluations included more than 300 variables. They also performed tender point examinations at 30 sites and dolorimetry at nine sites.

. . . The most useful measures turned out to be a minimum of 11 out of a possible 18 tender points, as well as skeletal pain in at least three regions: left-and right-sided plus upper or lower quadrant. About 70% of the controls and 98% of the fibromyalgia patients had widespread pain.

pain disorders with which its symptoms often overlapped; patients with conditions other than fibromyalgia had significantly fewer tender points and experienced much lower levels of pain when those points were palpated.<sup>43</sup> Using this system, doctors were able to differentiate patients suffering from fibromyalgia from patients afflicted by other pain-related conditions, like arthritis, at a rate of almost ninety percent.<sup>44</sup>

The presence of discrete, sensitive areas (pressure points) on the body—often unknown to a patient until palpated by their doctor—was not a new finding. It was already considered to be the best way to diagnose fibromyalgia. The Multi-Center Fibromyalgia Criteria Study, however, was the first time investigators had agreed on the exact number and location of tender points and the accompanying symptoms; every North American physician who had contributed significantly to fibromyalgia research received an invitation to participate. Previously, physicians used different ratios to diagnose fibromyalgia, varying from four out of forty tender points up to twelve of fourteen points. The study results, presented that same year to the American College of Rheumatology (“ACR”),<sup>45</sup> supported the use of the eighteen-point-system for diagnosing fibromyalgia. The ACR’s acceptance of the system gave new legitimacy to what had been viewed previously as a “waste basket” diagnosis<sup>46</sup>—one that was offered when every other possibility had been discarded. Vigorous debate about the condition continued.<sup>47</sup>

One major concern of the medical community was—and continues to be—lack of objective physical evidence of the condition.<sup>48</sup>

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Higgins, *supra* note 28, at 11.

43. *Id.* at 10.

44. Peter Jaret, *18 Points of Pain: Closing in on Barely Noticeable Tender Spots May Illuminate the Mystery of Fibromyalgia*, HEALTH, July/Aug. 1990, at 62, 64.

45. Higgins, *supra* note 28, at 10.

46. For recognition of the fact that some may consider fibromyalgia to be a “‘waste-basket’ diagnosis,” see Paul Davidson, *Fibromyalgia: A Painful and Treatable Illness*, at <http://www.sfms.org/sfm/sfm202b.htm>.

47. Jaret, *supra* note 44, at 62, 64.

48. Daniel Clauw, an expert on the illness, notes that it is not clear why fibromyalgia has been singled out for this treatment:

Unfortunately, not all health care professionals . . . want to diagnose and manage fibromyalgia. However approximately 40 percent of patients seen in the primary care setting have symptoms with no identifiable cause, and most practitioners are comfortable making and managing other symptom-based diagnoses such as migraine and tension headache, irritable bowel syndrome and dysmenorrhea.

Daniel J. Clauw, *Treating Fibromyalgia: Science vs. Art*, 62 AM. FAM. PHYSICIAN 1492 (2000)

Mary Dunkin has noted, “Unlike inflammatory forms of arthritis, which can be verified through blood tests, and degenerative arthritis, which can be confirmed by X-rays, fibromyalgia produces no obvious [or consistent biological indicator] signs.”<sup>49</sup> Patients have been linked to a variety of abnormalities.<sup>50</sup> To date, fibromyalgia is an illness of no known etiology; in other words, it has no determinable cause. There are theories, but nothing certain.<sup>51</sup> The current definition of fibromyalgia groups patients by the symptoms they manifest; a diagnosis in this form does not preclude the possibility that different patients with the same symptoms are actually suffering from distinct conditions.<sup>52</sup> Patients diagnosed with fibromyalgia have responded to a wide range of treatments, and within the studies of the individual treatments, patients have had a wide range of responses; everything from antidepressants to acupuncture has provided various degrees of relief.<sup>53</sup> This may in part explain why, though fibromyalgia has become a widely recognized, studied, and diagnosed condition over the past decade, the search for its cause and its cure(s) continues to frustrate the medical community.

The uncertainty about fibromyalgia in the medical community has carried over into the coverage of the illness in the popular press. The early coverage of the condition gave it labels like “the mystery disease.” The stories often reported on the skepticism of the medical community.<sup>54</sup> One article referred to it as “the Rodney Dangerfield of diseases,” noting that despite the high number of people it affected, fibromyalgia typically “gets

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[hereinafter Clauw, *Science vs. Art*].

49. Mary Anne Dunkin, *Fibromyalgia: Out of the Closet*, ARTHRITIS TODAY, Sept. 1993, at 24.

50. These include abnormalities in neuroendocrine performance, central neuropeptide levels, and functional brain activity. Bradford & Allen, *Part I*, *supra* note 27. For a brief, but comprehensive overview of current studies about the causes and manifestations of fibromyalgia, see *id.*; and Bradford & Allen, *Part III*, *supra* note 29.

51. “The very existence of fibromyalgia as a distinct clinical entity has been questioned, partly because . . . [of] the absence of a clearly defined mechanism by which to define the disease.” Bradford & Allen, *Part I*, *supra* note 27, at 28. Put in slightly different terms: there is neither a recognizable, measurable cause *nor* an effect that consistently occurs with the condition.

52. See Clauw, *Science vs. Art*, *supra* note 48, at 1492 (discussing ways in which fibromyalgia may be related to similar conditions or overlap with them and considering what can be gained in treatment by recognizing the connection between certain conditions).

53. Allen and Bradford, *Part III*, *supra* note 29.

54. See, e.g., Klein, *supra* note 35; Elizabeth Pennisi, ‘Mystery Pain’ May Defy Diagnosis, But It’s All Too Real, *Researchers Find*, CHI. TRIB., Apr. 7, 1985, at C2.

no respect.”<sup>55</sup> As more information about fibromyalgia became widely available, the press shifted its emphasis from the mysterious nature of the disease to the realities of living with it,<sup>56</sup> but the stories still emphasized how hard the illness was to diagnose and treat.<sup>57</sup> One article pointed out that the severity of the illness could cause sufferers to make substantial life changes, including “quitting work, changing jobs or working part time.”<sup>58</sup> Articles detailed the chronic and severe pain the condition can cause, and how severely it can limit day-to-day activity, focusing on the stories of individual women to illustrate the point.<sup>59</sup> As the condition gained acceptance as a medical diagnosis with widespread impact, coverage about it included articles conveying everyday methods of coping with fibromyalgia to the general public.<sup>60</sup> Reports extended from television and print coverage to Internet sites, with fibromyalgia support groups forming all across the country.<sup>61</sup> As with work in the medical community, however, even the more recent popular coverage about fibromyalgia reflects some level of continuing skepticism about the condition—especially about its cause.<sup>62</sup>

## II. MULTIPLE CHEMICAL SENSITIVITY—AN OVERVIEW

Multiple chemical sensitivity is another condition that has received increased exposure in the medical community and popular press during the years since the passage of the ADA.<sup>63</sup> Like fibromyalgia, it is a

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55. Rob Bogin, *Puzzling Illness a Pain to Diagnose*, ROCKY MOUNTAIN NEWS, Dec. 17, 1995, at 72A.

56. See, e.g., Ann Hardie, *When Life Becomes One Big Pain: Fibromyalgia Can Be Physical, Mental Drain*, ATLANTA J. & CONST., Aug. 23, 1994, at B6.

57. See, e.g., Karen Garloch, *Woman Finds Support for Baffling Disease – on Internet*, DALLAS MORNING NEWS, Dec. 21, 1997, at 18A; Karen Miller Medzon, *Test Makes Painful Discovery – Debilitating Fibromyalgia Hard to Detect*, BOSTON HERALD, June 27, 1999 at 41; Leslie Sowers, *Where Don't You Hurt?; Fibromyalgia Remains a Mystery Ailment, but the Pain Is No Less Real*, HOUSTON CHRON., Oct. 21, 1996, at 1.

58. Hardie, *supra* note 56, at 6.

59. See, e.g., Joanne Kabak, *Awareness of Fibromyalgia Needs to Be Much Improved*, NEWSDAY, Sept. 14, 1999, at C04.

60. See, e.g., Linda Buch, *Strength Training May Ease Fibromyalgia*, THE DENVER POST, Feb. 16, 2003, at L-05.

61. Jerome Groopman, *Hurting All Over: With So Many People in So Much Pain, How Could Fibromyalgia Not Be a Disease?*, THE NEW YORKER, Nov. 13, 2000, at 78.

62. See, e.g., Jane E. Brody, *Real Illness, Real Answers*, N.Y. TIMES, Aug. 1, 2000, at F8. (noting “‘is it a real disease?’ is the most frequently asked question about fibromyalgia”).

63. One article from 1993 notes, “Unless you’ve been on a desert island, you have



“syndrome of symptoms,”<sup>64</sup> and its cause is unknown. Women comprise eighty-five to ninety percent of MCS patients; symptoms most commonly develop between the ages of thirty and fifty.<sup>65</sup> No standard test explains what triggers the symptoms of MCS, but symptoms commonly begin following “a single heavy exposure to a substance, with recurrences triggered by lower levels of the same substance or seemingly innocent or related substances, such as odors or fragrances.”<sup>66</sup> Frequently cited triggers of the condition are “pesticides, solvents, paints and lacquers, and formaldehyde, but can include virtually anything from anaesthetics to exhaust fumes.”<sup>67</sup> One thing on which the medical community agrees is that “MCS is not a standard allergic reaction, as it does not involve immunoglobulin and the release of histamine and other chemicals associated with allergies.”<sup>68</sup>

The modern history of MCS<sup>69</sup> began in the 1950s with Theron Randolph, a Chicago physician. In 1962, Randolph released a book

probably heard of [MCS].” Howard M. Sandler, *Multiple Chemical Sensitivity: Myth or Reality?*, OCCUPATIONAL HAZARDS, Apr. 1993, at 53. Mike Monroe, a character on the television show *Northern Exposure*, supposedly suffered from MCS, “forc[ing] him to live in a geodesic dome, where he wears white gloves, and breathes filtered air.” Charlotte Sutton, *Is This Illness Symptomatic of the Times?*, ST. PETERSBURG TIMES, Feb. 6, 1993, at 1A.

64. Thomas L. Kurt, *Multiple Chemical Sensitivities – A Syndrome of Pseudotoxicity Manifest As Exposure Perceived Symptoms*, JOURNAL OF TOXICOLOGY: CLINICAL TOXICOLOGY, Mar. 1995, at 101.

65. Michael K. Magill & Anthony Suruda, *Multiple Chemical Sensitivity Syndrome*, 58 AM. FAM. PHYSICIAN 721 (1998).

66. Kurt, *supra* note 64, at 101; *see also* Tim Chapman, *Suffering From a Sensitive Issue*, 15 CHEMISTRY & INDUSTRY 592, 592 (1998) (quoting a 1995 European Commission report describing MCS as “sensitivity which begins as specific hypersensitivity to a single agent, or class of substances, but which may evolve into non-specific hyper-responsiveness” and noting that “[s]ymptoms do not disappear when the agent is removed, and sensitivities may also spread to other substances”). This differed from an American report released a few years later. *See infra* text accompanying note 95.

67. Chapman, *supra* note 66, at 592.

68. *Id.* In his relatively early article on the topic, Howard Sandler argued that the theory of MCS “goes against one of the tenants of immunology, that if a substance acts as an allergen, a specific antigen-antibody (‘lock and key’) relationship develops. The body will only recognize the precise antigen or one with the same chemical ‘key’ within its structure.” Sandler, *supra* note 63, at 53.

69. Kurt, *supra* note 64, at 101 (“At the turn of the century, a similar syndrome was called neurasthenia, exemplified by Marcel Proust, who was so intolerant of perfumes and other odors that he lived and wrote as a recluse in his cork-lined Paris apartment.”).

entitled *Human Ecology and Susceptibility to the Chemical Environment*,<sup>70</sup> articulating his theory that “individuals could be adversely affected by extremely low-level chemical exposures in their environment.”<sup>71</sup> At first greeted with extreme skepticism, Randolph’s theory later developed a following that included Dallas thoracic surgeon William Rea. In the mid-1970s Rea set up a clinic to treat patients with MCS.<sup>72</sup> Two common theories provided the groundwork for studies in MCS. The first was that the symptoms of MCS arise from an initial “overwhelming assault on the immune system” by multiple chemical stimuli, causing “crossover reactions” in response to other chemicals.<sup>73</sup> The second was that the condition is caused by a high-level exposure to a single chemical, so that afterwards, even at very low levels of exposure, the patient’s reaction to environmental factors is significant.<sup>74</sup> After sensitization, even minor exposures to a substance can produce symptoms, and patients may become sensitive to low doses of substances other than the initiating chemical.<sup>75</sup> Magill and Suruda have noted that, “[p]atients with MCS syndrome can have severe symptoms that interfere with daily life and work.”<sup>76</sup> Symptoms for MCS, though widely varied, typically manifest themselves in three ways: in the central nervous system, in “respiratory and mucosal irritation,” or in gastrointestinal pain.<sup>77</sup>

From the 1960s through the 1980s, MCS specialists used the title “clinical ecologists” to describe themselves; in the mid-1980s the title became “environmental medicine specialists.”<sup>78</sup> This change in name did not alter the fact there was no agreed-upon method for diagnosing MCS.<sup>79</sup> Indeed, “The lack of widely accepted, standardized, clinical and

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70. John Bower, *Are You Chemically Sensitive?*, EAST WEST, Mar. 1991, at 22. Randolph released a later book in 1982, *An Alternative Approach to Allergies*, that contained detailed descriptions of case histories and treatments. *Id.*

71. Sandler, *supra* note 63, at 53.

72. Kurt, *supra* note 64, at 101.

73. *Id.*

74. Sandler, *supra* note 63, at 53.

75. *See id.* at 53.

76. Magill & Suruda, *supra* note 65, at 721.

77. *Id.*

78. Kurt, *supra* note 64, at 101.

79. Gail E. McKeown-Eyssen et al., *Multiple Chemical Sensitivity: Discriminant Validity of Case Definitions*, 56 ARCHIVES ENVTL. HEALTH 406, 406 (2001) (“The variety of symptoms reported, the lack of consistency in physical findings or laboratory test results—together with the variability of substances that reportedly provoke symptoms—make it difficult for investigators to formulate a case definition of MCS.”).

epidemiologic criteria for [MCS] syndrome has led to confusion about the identification of the condition and slowed pertinent research.”<sup>80</sup> As with fibromyalgia, the syndrome suffered a credibility defect because it had been linked to various psychological conditions, including anxiety disorders and agoraphobia,<sup>81</sup> leading some to dismiss it as “a haven for quacks and neurotics.”<sup>82</sup> This perception was exacerbated by the fact that in an attempt to avoid symptoms, “[p]atients often significantly alter their behavior in an attempt to avoid presumed precipitants of symptoms. They may have withdrawn from activities, friends and family in an attempt to eliminate chemical exposures.”<sup>83</sup> In 1989, eighty-nine top clinicians and researchers of MCS, despite having diverse views of the condition, developed consensus criteria for the definition of MCS. The five criteria “defin[ed] MCS as [1] a chronic condition [2] with symptoms that recur reproducibly [3] in response to low levels of exposure [4] to multiple unrelated chemicals and [5] improve or resolve when incitants are removed.”<sup>84</sup>

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80. D.J. Kutsogiannis & Ann L. Davidoff, *A Multiple Center Study of Multiple Chemical Sensitivity Syndrome*, ARCHIVES ENVTL. HEALTH, May 2001, at 196.

81. Thomas Kurt has noted, “Case series studies performed by investigators evaluating MCS patients have consistently shown neuropsychiatric problems that have included depression, somatization disorders, anxiety/panic disorder often with agoraphobia, history of recent major changes in life events, history of physical or sexual abuse and history or [sic] addictive disorders.” Kurt, *supra* note 64, at 102.

82. Chapman, *supra* note 66, at 592. *But see* Magill & Suruda, *supra* note 65, at 721 (“[I]t is unclear if a causal relationship or merely an association exists between MCS and psychiatric problems.”).

83. *Id.* at 723. Magill and Suruda report:

In one study of 35 patients with occupationally related MCS . . . 97 percent of the patients had stopped activities outside the home, 91 percent had limited their travel, 89 percent had limited their contact with friends and 77 percent had left a job. Many changed home routines: 97 percent had stopped using cleaning compounds . . . 94 percent stopped using fragrances, 91 percent changed their diet and 86 percent changed the type of clothing they wore.

*Id.* (internal citation omitted). For one example of an individual who took the life changes to an extreme, see Karen Abbott, *Is It Medical or Mental? Sufferers of Multiple Chemical Sensitivities Puzzle Doctors*, ROCKY MOUNTAIN NEWS, February 24, 1994, at 2A (relating the story of Nancy Ward, who lives in “Supercan,” a silver trailer outfitted in only natural materials to prevent chemical exposure). Nancy Ward is not the only MCS sufferer who has isolated herself in an attempt to prevent chemical exposure. Herman Staudenmayer, a psychologist who treats MCS sufferers, has noted, “[I]ndividuals with MCS] will isolate themselves, either in their homes, or they live in the mountains, they live in the desert, they live in porcelain-lined trailers and, in the most extreme cases, in some kind of bubble environment.” *Id.*

84. *Multiple Chemical Sensitivity: A 1999 Consensus*, 54 ARCHIVES ENVTL. HEALTH 147, 147

Another problem arose from the actual research done by clinical ecologists. Patients are tested for MCS by undergoing exposure to a variety of substances; patients then report any symptoms to their physician. These tests were condemned by organizations like the American Medical Association because they were “rarely blind” and were “wholly . . . subjective.”<sup>85</sup> In one of the few double-blind studies, when twenty MCS patients were subjected to doses of either clean air or chemicals, none of the patients could accurately determine if they had been exposed to the chemicals.<sup>86</sup>

Study of the condition got a major boost around the same time from an unexpected source—the returning Gulf War veterans. Before Desert Storm the vast majority of patients with MCS were women, and the condition was often linked to hysteria, but by 1993, several thousand Gulf War veterans—generally previously-healthy males—reported mysterious ailments that may be linked to exposure to biological and chemical warfare agents, as well as petrochemicals from Kuwaiti oil fires.<sup>87</sup> Many believed they had MCS. In 1994, in a radical position change, the American Medical Association acknowledged that MCS was not solely a psychological disorder, but maintained that further research was required before MCS could be defined as a clinical entity; several federal agencies, including the U.S. Department of Environmental Protection and the U.S. Consumer Product Safety Administration, concurred.<sup>88</sup> The U.S. Department of Veterans Affairs (VA), hoping to avoid a debacle similar to the one over the use of Agent Orange in Vietnam, agreed to study the illness. Congress appropriated five million dollars over ten years for studies by the National Academy of Sciences.<sup>89</sup> Still, a comprehensive approach was lacking,<sup>90</sup> and by 1998, the studies were still not complete. One study that involved more

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(1999) [hereinafter *A 1999 Consensus*].

85. Chapman, *supra* note 66, at 592.

86. *Id.*

87. See Usha Lee McFarling, *Military Launches Assault on Mysterious Gulf War Ailments*, THE BOSTON GLOBE, Mar. 14, 1994, at 25.

88. Thomas D. Williams, *Studies of Gulf War Vets' Illnesses Continue*, THE HARTFORD COURANT, Oct. 31, 1998, at A7.

89. John Ritter, *Ailing Gulf Vets Ask Why/ Unexplained Illnesses Stump the VA*, USA TODAY, Nov. 11, 1993, at 1A [hereinafter Ritter, *Unexplained Illness*]. Veterans still had long waits for exams—many for months—and few were sent to special referral centers; the detoxification unit for MCS was still waiting for more funding in December of 1993. John Ritter, *Ailing Veterans vs. the VA/ "No Budget" for Gulf War Treatments*, USA TODAY, Dec. 14, 1993, at 2A [hereinafter Ritter, *No Budget*].

90. Ritter, *No Budget*, *supra* note 89, at 2A.

than 20,000 servicemen—split between those who served in the war and those who did not—indicated that 14.5 percent of Gulf War veterans reported signs of severe MCS, while only 4.5 percent of those who did not serve abroad had symptoms consistent with MCS.<sup>91</sup>

Despite the sluggishness of the military's response, MCS began to have an impact in other areas. Though it had no clear clinical definition, many believed that MCS was emerging as a major medical problem, and some doctors began to accept that patients were experiencing real physical symptoms, even if there was no clear diagnosis for their problem.<sup>92</sup> Between fifteen and thirty percent of the U.S. population may suffer from MCS; five percent may have the particularly severe reactions that make MCS disabling.<sup>93</sup> Several federal agencies, including the U.S. Department of Social Security<sup>94</sup> and the U.S. Department of Housing and Urban Development (HUD), identify MCS as a disabling medical condition.<sup>95</sup>

In 1999, a decade after the first consensus criteria were released, a group of clinicians released a sixth criterion: that the symptoms occur in multiple organ systems. The six criteria were commonly included in MCS studies, but the consensus report emphasized that standardized use in clinical settings was “still lacking, long overdue, and greatly needed.”<sup>96</sup> Research by state and federal agencies has shown that while MCS is a commonly diagnosed chronic disorder in civilians, it is more common still among American Gulf War Veterans.<sup>97</sup> Nonetheless, the condition remains *highly* controversial, in part because of the lack of standardization that

91. Williams, *supra* note 88. Another survey of approximately 1,100 Gulf War veterans, undertaken in 1995 and released in 1999, was based on responses to questionnaires, and it showed similar results. Slightly over thirteen percent of respondents qualified for a diagnosis of MCS, and there were no appreciable effects of gender, race, duty status (active or reserve) or rank, though MCS was slightly more prevalent in women and African Americans. Howard M. Kipen et al., *Prevalence of Chronic Fatigue and Chemical Sensitivities in Gulf Registry Veterans*, 54 ARCHIVES ENVTL. HEALTH 313 (1999).

92. Valerie Ulene, *A Sensitive Question*, L.A. TIMES, May 5, 2003, at 4.

93. Molly Ivins, *Allergies: The Rodney Dangerfield of Disease*, BUFFALO NEWS, Sept. 25, 1998, at 3d.

94. Chapman, *supra* note 66, at 592.

95. Michelle Malkin, *The Patients are Victimized When Bullies Corrupt Science*, SEATTLE TIMES, Apr. 29, 1997, at B4. HUD recognized in 1989 that people with MCS were disabled and qualified for assistance under the Affordable Housing Act. Julie Appleby, *Environment Built to Be Bare: In Marin County, A HUD-Backed Haven Is Designed for the Chemically Sensitive*, WASH. POST, Mar. 2, 1995, at T08.

96. *A 1999 Consensus*, *supra* note 84, at 147.

97. *See id.*

infects diagnoses.<sup>98</sup> Currently, there are at least four major suggested etiologies for MCS: physical,<sup>99</sup> stress, misdiagnosis,<sup>100</sup> and illness belief.<sup>101</sup>

Much about MCS remains unknown and undefined, and unlike fibromyalgia, the development of MCS as a diagnosis has met with resistance from industry, as well as the medical community. Manufacturers of everything from fragrances to chemical pesticides have billions of dollars at stake; some doctors suggest that industry public relations efforts are the only reason MCS research has moved so slowly and remained so controversial.<sup>102</sup> If this is the case, the anti-MCS movement has certainly

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98. *Id.*

99. Three basic mechanisms fall under the physical etiology: allergy, direct toxic effects, and neurobiologic sensitization. The allergy theory holds that chemical exposures “cause the development of allergies to low levels of many chemicals, not just the initiating one;” the toxicological effects theory proposes that low dose exposure instead acts as poison; the neurobiologic sensitization theory states that an “affected person develops increasing neurologic sensitivity to adverse effects of chemicals.” Each of these theories has problems: careful studies comparing patients with MCS and control patients have found no difference in immunological testing; objective evidence is lacking for the second proposal; and the third pattern has been documented only in animals, not in humans, and not at the low doses reported to cause MCS. Magill and Suruda, *supra* note 65, at 721.

100. A stress etiology has been suggested as an alternative theory of causation because “about one-half the patients with MCS in various studies meet the criteria for depressive or anxiety disorders.” Many have diagnosed sleep disorders, or meet the criteria for them. However, as with fibromyalgia, there are difficulties in developing studies that can effectively separate actual causation from mere incidence. Patients with MCS have higher rates of sleep-disorders, depression and anxiety than the general public, but it is unclear whether the conditions cause MCS, are caused by it, are simply associated with it, or whether perhaps both MCS and the psychiatric conditions result from a common underlying neurobiological mechanism. The complexity of these interactions is one reason that the third suggested etiology, misdiagnosis, is often put forward in discussion of MCS. As under fibromyalgia, there is the suggestion that MCS sufferers may all be suffering from the same condition that is not MCS—for example, MCS overlaps heavily with chronic fatigue syndrome—or they may be suffering from several different conditions that present similar symptoms. *Id.* at 721.

101. The final etiology, illness belief, is a variant of the “it’s all in your head” school of thought. This theory holds that regardless of the syndrome’s physiological, toxic, or psychiatric origins, there is a culture of belief that attaches to MCS and defines its mechanisms and manifestations in a patient’s mind. This belief is a result of a patient’s interaction with the array of support groups, clinicians, hotlines, lawyers, journalists, media, and websites that discuss and support MCS. *Id.* at 721.

102. Ann McCampbell, *Multiple Chemical Sensitivities Under Siege*, TOWNSEND LETTER FOR DOCTORS & PATIENTS, Jan. 1, 2001, at 20. McCampbell is the head of the MCS Task Force of New Mexico. She blasts the chemical industry, providing in-depth explanations of the ways

been effective: Even in the most recent material, highly contentious debate about the condition continues.<sup>103</sup>

### III. FIBROMYALGIA, MCS, AND THE ADA

The results for fibromyalgia and MCS in the ADA litigation are tied to the fate of ADA litigation as whole. Ruth Colker's 1999 comprehensive study of ADA employment litigation refutes the popular perception that the ADA has been a "windfall for plaintiffs."<sup>104</sup> Colker's study found that the results for plaintiffs in ADA cases are far worse than in other, similar areas of civil rights law: "[O]nly prisoner rights cases fare as poorly."<sup>105</sup> Defendants prevailed in over ninety-three percent of ADA employment discrimination cases; on appeals by plaintiffs, courts decided eighty-four percent of the cases in the defendant's favor.<sup>106</sup> Colker found that almost forty percent of ADA cases were decided through summary judgment;<sup>107</sup> she argues that courts are too willing in ADA cases to take cases from the jury and that they set too high a standard of evidence for defeating defendants' motions for summary judgment.<sup>108</sup>

The results in fibromyalgia and MCS litigation not only support Colker's findings, but paint an even bleaker picture for ADA plaintiffs. The following findings are based on a complete search of ADA litigation on Westlaw and on the Eighth Circuit website for all cases involving the ADA and either "MCS," "fibromyalgia," "fibrositis," or "fibromyositis," with the hope of creating as complete a picture as possible of how courts have

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industry has fought the MCS diagnosis. She reports that, like the tobacco industry, the chemical industry often uses "non-profit front groups with pleasant sounding names, neutral-appearing third party spokespeople, and science-for-hire studies to try to convince others of the safety of their products." *Id.*

103. For descriptions of the current status of the debate see, for example, Joan Axelrod-Contrada, *Your Health: Are Fragrances Making Some People Sick?*, BOSTON GLOBE, July 8, 2003, at C3 ("Although some doctors believe that MCS is a legitimate illness, others maintain that patients really have an undiagnosed allergy or a psychosomatic ailment. The American Medical Association's Council on Scientific Affairs does not recognize MCS as a clinical condition."); and Ulene, *supra* note 92 ("Is multiple chemical sensitivity—extreme reactions to common compounds—a disorder, as some doctors think, or just fiction, as others say?").

104. Ruth Colker, *The Americans with Disabilities Act: A Windfall for Defendants*, 34 HARV. C.R.-C.L. L. REV. 99, 101, 103 (1999) (reviewing every appellate decision and many of the district court cases decided since the ADA became effective in 1992).

105. *Id.* at 100.

106. *Id.*

107. *Id.* at 126.

108. *Id.* at 160.

handled the two emerging diagnoses.<sup>109</sup> Colker notes that several sources of bias exist in her study, and those same methodological problems exist here. Particularly troubling is the high rate of unavailable opinions at both the trial court and appellate levels. Looking solely at published opinions may skew the data if published opinions overstate plaintiff success rates. In traditional employment litigation, for example, data indicate that plaintiffs are four times more successful in published opinions, as compared to unpublished ones.<sup>110</sup> If a court grants summary judgment, it is more likely to provide a written opinion than if it grants a motion to dismiss or enters a directed verdict; thus, as Colker notes, a focus on published opinions may downplay advantages enjoyed by defendants at the summary dismissal stage while “overstating the prevalence of summary judgment decisions for defendants.”<sup>111</sup> The “problem of unpublished opinions” extends to the appellate level as well.<sup>112</sup> To weed out cases in which the nature of fibromyalgia or MCS, interacting with the ADA, did not play a decisive role in the court’s decision, cases in which MCS or fibromyalgia were one among many illnesses/conditions listed (with no substantive discussion of any of the illnesses), and cases that were decided on procedural grounds unrelated to the stated ADA claim were excluded. That left forty fibromyalgia cases and eighteen MCS cases. The earliest cases for both conditions came in 1995.<sup>113</sup> Because thirty-seven of the thirty-nine fibromyalgia cases and seventeen of the eighteen MCS cases were employment cases, the analysis below focuses on Title I employment

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109. The following “terms and conditions” searches were used: “fibromyalgia and ADA”; “fibrositis and ADA”; “fibromyositis and ADA”; “(MCS or “multiple chemical sensitivity!”) and ADA.”

110. Colker, *supra* note 104, at 104.

111. *Id.*

112. Colker writes:

Since 1972, the Judicial Conference of the United States has taken the position that United States Courts of Appeals should publish opinions only where a decision has obvious precedential value . . . . [E]ach court of appeals has been allowed to create its own rules on publication, so the circuits lack a uniform policy on publishing opinions.

*Id.* The opinions of the Third, Fifth, and Eleventh Circuits are not available through any electronic source. Westlaw selectively publishes the opinions of the Sixth, Ninth, Tenth and D.C. Circuits; the Sixth and Tenth sometimes send their opinions to Lexis as well. The Eighth Circuit runs its own Internet site, and the Second has a searchable database for all unpublished opinions. *Id.* at 104 & n.30. Colker states that only about forty-two percent of all appellate affirmances are available to the public. Colker, *supra* note 104, at 105.

113. Whillock v. Delta Airlines, Inc., 926 F. Supp. 1555 (N.D. Ga. 1995) (MCS); Taylor v. Albertson’s, Inc., 886 F. Supp. 819 (W.D. Okl. 1995) (fibromyalgia).



litigation.<sup>114</sup>

### A. *The Fibromyalgia Cases*

Among the fibromyalgia cases, motions for summary judgment by the defendant on ADA claims were granted or affirmed in thirty-three of the thirty-seven cases (almost ninety percent); a motion to dismiss for failure to state a claim was granted in another case. In only four cases did plaintiffs survive motions to dismiss or motions for summary judgment, and in none of those cases is there a later record of the plaintiff prevailing at trial. It is possible that the cases were settled favorably for the plaintiff out of court, or are still in litigation, but based on published opinions, fibromyalgia suits under the ADA appear to be an almost total failure. While these results are similar to those for other disabilities claimed under the ADA, analysis does suggest a greater focus on the nature of the disease (i.e., fibromyalgia) in those cases. Questions about the severity of the illness arise in the opinions,<sup>115</sup> as do questions about the occasionally intermittent nature of its symptoms.<sup>116</sup> Interestingly, even in the early cases, no court rejects evidence about fibromyalgia as an illness, and several explicitly accept fibromyalgia as a diagnosis, or state that it qualifies as an impairment under the ADA<sup>117</sup>

114. Almost all of the cases were Title I suits against private employers, though two of the MCS cases and one of the fibromyalgia cases were Title II suits brought against public entities.

115. *Mincey v. Dow Chemical Co.*, 217 F. Supp. 2d 737, 740 (M.D. La. 2002) (noting testimony by employee's physician that "he did not consider fibromyalgia to be a serious health condition"); *Holt v. Olmsted Tp. Bd. of Trustees*, 43 F. Supp. 2d 812, 823 (N.D. Ohio 1998) (noting claim by defendant that "aches and pains associated with Fibromyalgia do not rise to the level of a substantial limitation on a major life activity"); *Aquinas v. Federal Exp. Corp.*, 940 F. Supp. 73, 77 (S.D.N.Y. 1996) (noting that plaintiff's doctor calls fibromyalgia "very, very annoying").

116. *Johns-Davila v. City of New York*, No. 99 CIV. 1885, 2000 WL 1725418, at \*6-8 (S.D.N.Y. 2000) (noting plaintiff's claim "that fibromyalgia is a . . . condition . . . sensitive to atmospheric and environmental changes"); *Carter v. General Elec. Co.*, No. 98-C50239, 2000 WL 321663, at \*4 (N.D. Ill. 2000) (stating that "GE correctly notes that intermittent, episodic impairments are not disabilities under the ADA," but "that intermittent impairment that is a characteristic manifestation of an admitted disability must be accommodated").

117. *Wolz v. Deaton-Kennedy Co.*, No. 98-C6610, 2001 WL 699096, at \*5 (N.D. Ill. 2001) (noting defendant's acceptance of fibromyalgia as a recognized medical condition); *Walker v. Pepsi-Cola Bottling Co.*, No. CIV.A.99-748-JJF, 2000 WL 1251906, at \*17 (D. Del. 2000) (stating that plaintiff's alleged fibromyalgia constitutes an "impairment" under the ADA); *Winn v. Runyon*, No. 96-C3168, 1998 WL 565231, at \*3 n.5 (N.D. Ill. 1998) (stating that

—even though a number of courts recognize the inherently subjective nature of a fibromyalgia diagnosis.<sup>118</sup>

### B. The MCS Cases

Among the MCS cases, motions for summary judgment by the defendant were granted or affirmed in fourteen of seventeen cases (just over eighty percent). In only one case did a judge rule that the plaintiff with MCS had enough evidence of a disability to survive a motion for summary judgment.<sup>119</sup> These results are not startlingly different from those for fibromyalgia, but the cases themselves generate a much richer textual discussion of the nature of MCS than do the fibromyalgia cases. The reason for this difference is exemplified by the two cases on MCS that do not deal with requests for summary judgment, but rather for motions *in limine*: *Frank v. State of New York*<sup>120</sup> and *Treadwell v. Dow-United Technologies*.<sup>121</sup>

### C. Daubert and Emerging Diagnoses

The two motions were requests to exclude testimony by the plaintiffs' MCS experts under the *Daubert* expert witness standard. The *Daubert* standard developed in the mass toxic torts context and arose out of a case involving charges that the drug Benedictin caused birth defects.<sup>122</sup> The case raised the issue of the correct standard of reliability for the admission of expert scientific testimony. The district court had granted summary judgment to the defendant on the ground that while there was extensive research to support the defendant's claim that Benedictin did not cause birth defects, the expert testimony offered by the plaintiffs on the drug's

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fibromyalgia is a "clearly identifiable condition"); *Skorup v. Modern Door Corp.*, No. 3:95-CV-1006RP, 1997 WL 662507, at \*7 (N.D. Ind. 1997) (stating that fibromyalgia qualifies as an impairment under EEOC interpretive regulations).

118. *McPhaul v. Bd. of Comm'rs of Madison County*, 226 F.3d 558 (7th Cir. 2000) ("Fibromyalgia is a disease that is similar to chronic fatigue syndrome; its cause is unknown, there is no cure, and the symptoms are entirely subjective and usually involve chronic pain and fatigue."); *Wolz v. Deaton-Kennedy Co.*, No. 98-C6610, 2001 U.S. Dist. LEXIS 8462, \*21-\*22 (N.D. Ill. 2001) ("The condition is based entirely on the *patient's* subjective complaints.") (emphasis added).

119. *Davis v. Utah State Tax Comm'n*, 96 F. Supp. 2d 1271 (D. Utah 2000). Interestingly, this is a case in which a diagnosing physician stated in an affidavit that he did not diagnose the plaintiff with MCS because he did not believe MCS existed.

120. 972 F. Supp. 130 (N.D.N.Y. 1997).

121. 970 F. Supp. 974 (M.D. Ala. 1997).

122. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993).

harmful effects did not meet the required standard of “general acceptance” in the scientific community.<sup>123</sup> The Ninth Circuit Court of Appeals affirmed, citing *Frye v. United States*,<sup>124</sup> which stated that if a scientific expert testified to a conclusion, “the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.”<sup>125</sup> On appeal to the United States Supreme Court, the plaintiffs argued that Frye’s “general acceptance” test was superseded by the adoption of the Federal Rules of Evidence and asserted that their experts’ opinions should not have been excluded as unreliable.<sup>126</sup> The Supreme Court agreed that the Rules had superseded *Frye*, especially Rule 702, governing expert testimony. At the time, Rule 702 stated: “If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.”<sup>127</sup> The Court held that “the austere standard” of “general acceptance” under *Frye* was incompatible with the more permissive language of Rule 702.<sup>128</sup> That did not mean, however, that the Court was willing to open up trials to any and all expert testimony. The Court stated that under the Rules the trial judge was responsible for ensuring “that any and all scientific testimony or evidence admitted is not only relevant, but reliable.”<sup>129</sup> Scientific evidence and testimony admitted did not have to be “known to a certainty,” but did have to be supported by “good grounds”<sup>130</sup> based on the scientific method accepted in the appropriate field: “Rule 702’s ‘helpfulness’ standard requires a valid scientific connection to the pertinent inquiry as a precondition of admissibility.”<sup>131</sup> The Court recognized that at times there would be tension between scientific research, which was open to perpetual revision, and the demands of a trial, which required speed and finality in determinations.<sup>132</sup>

The Court was particularly concerned about the impact of allowing scientific experts to testify to still amorphous theories, because of their

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123. 727 F. Supp. 570, 572 (S.D. Cal. 1989).

124. 54 App. D.C. 46 (1923).

125. *Id.* at 47.

126. *Daubert*, 509 U.S. at 587.

127. FED. R. EVID. 702, *quoted in Daubert*, 509 U.S. at 588.

128. *Daubert*, 509 U.S. at 589.

129. *Id.* at 589.

130. *Id.* at 590.

131. *Id.* at 591-92.

132. *Id.* at 590.

unique ability to offer opinions from the stand based on secondary sources of knowledge, and because of the weight their opinions often carry:

Unlike an ordinary witness . . . an expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation. . . . Presumably, this relaxation of the usual requirements of firsthand knowledge—a rule which represents “a ‘most pervasive manifestation’ of the common law insistence upon ‘the most reliable sources of information. . . .’”—is premised on an assumption that the expert’s opinion will have a reliable basis in the knowledge and experience of his discipline.<sup>133</sup>

According to the Court, the correct response to the tension between science, reliability, and resolution was guided flexibility for the trial judge. The Court offered some general observations about factors that would bear on the inquiry into whether an expert’s testimony should be admitted. The observations developed into a non-dispositive four-prong test for expert witness reliability: whether theory or technique presented by the expert (1) can be and has been tested; (2) has been subjected to peer review and publication; (3) has a known or potential rate of error; and (4) has attained general acceptance in the pertinent scientific community.<sup>134</sup>

In 1999, in *Kumho Tire Co. v. Carmichael*,<sup>135</sup> the Court extended its ruling in *Daubert* to the admission of testimony of all expert witnesses, not just scientific experts. The *Kumho Tire* case involved the admission of the testimony of an expert on tire failure analysis. In extending its *Daubert* doctrine outside the realm of “hard science,” the Court noted that Rule

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133. *Id.* at 592 (citations omitted). There is a strong divergence between English and American law on the comparative treatment of expert and lay testimony. English courts will typically allow lay witnesses to present not only facts, but also opinions, based on their personal knowledge. American courts have been much stricter, and the expert/lay split has developed from early American courts:

[American courts] operated toward a broader presumption that an “opinion is not evidence.” This was a principle of convenience and efficiency. Since the jury was to assess credibility and draw rational inferences from the evidence, allowing a witness to say what inferences she drew from the evidence served no purpose. By contrast, if a witness had some “special skill” that would help the jury understand evidence that otherwise would be beyond its competency to interpret, opinion testimony would be allowed. Eighteenth and nineteenth century American courts did not establish bright lines on the issue of opinion testimony by the experts.

John V. Jansonius & Andrew M. Gould, *Expert Witnesses in Employment Litigation: The Role of Reliability in Assessing Admissibility*, 50 BAYLOR L. REV. 267, 271 (1998).

134. *Id.* at 593-94.

135. 526 U.S. 137 (1999).

702 made no relevant distinction between “scientific” knowledge and “technical” or “other specialized” knowledge,<sup>136</sup> and that it would be “difficult, if not impossible,” for judges to administer a rule that required them to differentiate between “scientific” and “technical” knowledge.<sup>137</sup> It also noted that, “[t]here is no clear line that divides the one from the others,”<sup>138</sup> and no evident break between the application of scientific principles and skill-based or experience-based observations. The Court emphasized, however, that the *Daubert* inquiry was to be a “flexible one . . . not . . . a definitive checklist or test.”<sup>139</sup> Too much depended on the unique circumstances of the particular case for the Court to issue an across-the-board rule for what was and was not admissible, and the type of scientific evidence used in the *Daubert* case would clearly not be available in every field and area in which expert testimony might be helpful to the fact-finders in a case.<sup>140</sup>

In the wake of *Daubert*, however, the flexible, open-ended inquiry the Supreme Court envisioned became an effective exclusionary tool in the hands of district court judges: Judges were more likely to scrutinize expert testimony before trial, and less likely to admit the testimony, in 1998 than in 1991.<sup>141</sup> *Daubert* and *Kumho* were expanded to encompass ever-broader categories of expert evidence, including clinical medical evidence.

In an article on the subject, Jean Eggen argues that courts have incorrectly applied *Daubert* to clinical medical evidence, which differs profoundly from the kind of scientific studies presented in *Daubert*.<sup>142</sup> Eggen states that while clinical medical evidence is “fundamentally

136. *Id.* at 147.

137. *Id.* at 148.

138. *Id.* at 148.

139. *Id.* at 150.

140. Effective December 1, 2000, Rule 702 was amended to incorporate the *Daubert* and *Kumho Tire* doctrines. Rule 702 now allows testimony to be admitted if “(1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.” FED. R. EVID. 702. Rule 702 does not codify *Daubert*, but references its factors in a Committee footnote. See FED. R. EVID. 702 advisory committee’s note § 702.4[2].

141. Jean Macchiaroli Eggen, *Clinical Medical Evidence of Causation in Toxic Tort Cases: Into the Crucible of Daubert*, 38 HOUS. L. REV. 369, 371 n.11 (2001); see also Lucinda M. Finley, *Guarding the Gate to the Courthouse: How Trial Judges Are Using Their Evidentiary Screening Role to Remake Tort Causation Rules*, 49 DEPAUL L. REV. 335 (1999) (arguing that federal judges, in exercising their gatekeeping capacity, have created exacting demands for scientific proof that place a higher burden on plaintiffs than did the previous standard).

142. Eggen, *supra* note 141, at 373-74.

scientific, as it is grounded in the discipline of medical science,” it is more in the nature of eyewitness testimony.<sup>143</sup> She describes the process by which physicians make a diagnosis in a clinical setting:

Several different thought processes contribute to the ultimate diagnostic decision in an individual case. First, the physician conducts a comparative analysis of the patient's illness in relation to known patterns of disease. Second, the physician applies certain diagnostic criteria to the patient to determine the probability that the diagnosis is one particular illness out of several. . . . Third, the physician undertakes a cause-and-effect analysis to determine if the appearance and progress of the disease in the patient is or has been consistent with generally known physiological or pathological information regarding the disease.<sup>144</sup>

Based on knowledge of the disease that the physician has developed through past experience and study, he will assess the patient's symptoms, come to a conclusion about causation and diagnosis, and testify to those conclusions at trial.<sup>145</sup>

The court's recognition of the validity of this process of diagnosis is especially important in cases in which a new illness or diagnosis is at the heart of the case. Eggen points out that while a physician may rely upon epidemiological or toxicological studies when available, relevant studies on a new condition may not exist, and time exigencies may press for a diagnosis.<sup>146</sup> In such a situation, the physician's training and prior experience with patients who have similar symptoms, not their review of current research, may be central to making a diagnosis.<sup>147</sup> If courts require “the physician [to] demonstrate reliance upon valid ‘hard scientific studies’” before they will admit clinical-based evidence at trial,<sup>148</sup> they create an “inadmissible *per se* standard that has the effect of excluding most clinical testimony of causation.”<sup>149</sup> This exact problem has arisen in the Fifth Circuit. In *Moore v. Ashland Chemical Inc.*, the Fifth Circuit affirmed a district court's decision that stated, in essence, that the technique of differential diagnosis is not sufficiently reliable to form the basis of testimony by a treating physician without reliance on traditional *Daubert*

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143. *Id.* at 390-91

144. *Id.* at 392.

145. *Id.*

146. *Id.* at 393.

147. *Id.* at 393-94.

148. *Id.* at 373.

149. *Id.* at 374.

hard science.<sup>150</sup> The district court focused on the reliability and relevancy of the studies underlying a physician's decision—or lack thereof—rather than the reliability of the physician's diagnostic process. Eggen points out that, “[I]n contrast, other courts have applied a different standard to clinical medical testimony.”<sup>151</sup> She notes that the Fourth Circuit has held that “properly conducted clinical diagnosis is a reliable basis for such testimony.”<sup>152</sup> The split in the circuits underscores the continuing debate about the correct level of scrutiny courts should apply to expert testimony about emerging diagnoses and is central to understanding the outcome of the MCS cases under the ADA.

#### *D. MCS and Daubert*

In both *Frank v. State of New York*<sup>153</sup> and *Treadwell v. Dow-United Technologies*,<sup>154</sup> trial court judges granted the defendants' motions *in limine* to exclude expert testimony about MCS. In *Frank*, after discussing various definitions of MCS put forth by the American College of Occupational and Environmental Medicine and the Federal Judicial Center's *Reference Manual on Scientific Evidence*, the trial court judge ruled that testimony about MCS was inadmissible as a matter of law under *Daubert*. In *Treadwell*, the trial court had already denied the defendant's motion for summary judgment on an ADA claim<sup>155</sup> before considering the motion to exclude testimony by the plaintiff's expert. Defendants argued that the expert, a doctor, would testify about four separate points that the defense felt should be excluded under *Daubert*: 1) that the plaintiff suffered from a condition known as multiple chemical sensitivity, 2) that MCS was recognized as a legitimate medical condition, 3) that the witness had the necessary expertise to make the diagnosis, and 4) that the plaintiff had contracted the condition as a direct and proximate cause of her exposure to a particular chemical while employed by the defendant.<sup>156</sup> The trial court judge, in applying *Daubert*, used a two-prong analysis: first, did the expert's testimony fall within the realm of “subjective belief or unsupported speculation,” and second, would the testimony assist the trier of fact in

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150. 151 F.3d 269 (5th Cir. 1998) (en banc).

151. Eggen, *supra* note 141, at 402.

152. *Id.* (discussing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262-63 (4th Cir. 1999)).

153. 972 F. Supp. 130 (N.D.N.Y. 1997).

154. 970 F. Supp. 974 (M.D. Ala. 1997).

155. *Treadwell v. Dow-United Technologies*, 970 F. Supp. 962 (M.D. Ala. 1997).

156. *Treadwell*, 970 F. Supp. 974, 979 (M.D. Ala. 1997).

understanding the evidence or determining a fact in issue?<sup>157</sup> The court adopted the position that “the science of MCS’s etiology has not progressed from the plausible, that is, the hypothetical, to knowledge capable of assisting a fact-finder, judge or jury.”<sup>158</sup> The court thus excluded the expert testimony on the diagnosis of MCS as well as any testimony related to clinical ecology.<sup>159</sup> While the plaintiff in *Treadwell* was allowed to proceed with her case under the ADA (though with limited evidence) other plaintiffs have not been so fortunate. In other cases, without the testimony of expert witnesses on MCS, plaintiffs were unable to prove key components of their claims, leading to summary judgment for the defendant.<sup>160</sup> No court that has directly considered a *Daubert* challenge to MCS evidence has allowed the expert evidence into the record.<sup>161</sup> When a

157. *Id.* at 980.

158. *Id.* at 982.

159. *Id.*

160. See, e.g., *Comber v. Prologue, Inc.*, No. CIV-JFM-99-2637, 2000 WL 1481300, at \*4-\*5 (D. Md. 2000) (“Were it admissible, evidence of this condition could strengthen [plaintiff’s] claim to be substantially limited in the major life activity of breathing. . . . Following a host of federal courts, the Court finds that Comber’s evidence on ‘multiple chemical sensitivity syndrome’ does not meet the Daubert standards of admissibility of scientific evidence for this case. . . . Prologue’s Motion in Limine to Exclude Any and All Evidence Related to ‘Multiple Chemical Sensitivity Syndrome’ is granted. Comber’s internist’s evidence would not be admissible at trial and cannot help Comber’s case to survive summary judgment.”). In another case, *Gabbard v. Linn-Benton Housing Authority*, 219 F. Supp. 2d 1130 (D. Or. 2002), the court explicitly noted the difficulties plaintiffs have confronted in this area:

To the court’s knowledge, no district court has ever found a diagnosis of multiple chemical sensitivity (“MCS”) to be sufficiently reliable to pass muster under Daubert. . . . Plaintiff Gabbard’s “case-by-case” approach, mentioned by some of these courts, is inapplicable here where the issue is whether or not evidence of MCS is admissible. Whether or not plaintiffs are “disabled” under the ADA or the Rehabilitation Act—which must be determined on a case-by-case basis—is not the focus of the inquiry; whether their treating physicians’ diagnoses of MCS is admissible evidence is. As have all other courts which have considered the issue, the court finds that such evidence must be excluded. . . . Because it lacks reliability, evidence of multiple chemical sensitivity syndrome cannot be used in support of plaintiffs’ cases. Further, a reasonable factfinder could not find that defendants’ use of particular chemicals was the cause of plaintiffs’ injuries. Defendant Linn-Benton Housing Authority’s motion in limine to exclude evidence (# 22) and defendant Oregon Department of Transportation’s motion for summary judgment (# 53) are therefore granted. Because the motions are dispositive of plaintiffs’ cases, these cases are dismissed.

*Id.* at 1134-35, 1141 (internal citations omitted).

161. See *Gabbard v. Linn-Benton Housing Auth.*, 219 F. Supp. 2d 1130, 1134 (D. Or.



direct challenge has not been raised, some courts have been willing to accept MCS as an impairment for the purposes of the ADA.<sup>162</sup>

In contrast, the issue of *Daubert* exclusion has never arisen in a fibromyalgia ADA case. This absence is notable not only because of significant parallels in the gaps of knowledge about fibromyalgia and MCS, but also because *Daubert* challenges have been used to exclude evidence about fibromyalgia in other areas of the law. A leading case is *Black v. Food Lion, Inc.*, a 1999 slip-and-fall trauma case out of the Fifth Circuit.<sup>163</sup> In *Black*, the court of appeals ruled that a magistrate judge erred in admitting the plaintiff's diagnosing physician's testimony about the cause of the plaintiff's fibromyalgia. The court of appeals held that the evidence should have been excluded because the physician had used clinical evidence to reach her conclusion; the opinion particularly objected to the lack of testing, peer review, or known rate of errors for the physician's methodology.<sup>164</sup> Other cases have reached similar conclusions.<sup>165</sup>

#### IV. QUESTIONS AND CONSIDERATIONS

Despite significant similarities between MCS and fibromyalgia,<sup>166</sup> and similarly dismal results under the ADA, the use of MCS under the ADA has generated a much more substantial legal dialogue than fibromyalgia, with far fewer cases. Courts are more likely to discuss and dissect the nature of MCS than they are of fibromyalgia, and ultimately, much more likely to reject its validity as a medical claim. Why?

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2002); *Coffey v. County of Hennepin*, 23 F. Supp. 2d 1081, 1086 (D. Minn. 1998) ("The Court has carefully examined the articles cited by Plaintiff, yet has failed to find an article or a medical association which opines that the methodology of diagnosing MCS has progressed to a point that it is scientific knowledge capable of assisting a fact-finder."); *Sanderson v. Int'l Flavors & Fragrances, Inc.*, 950 F. Supp. 981, 1001-02 (C.D. Cal. 1996) (excluding expert testimony on MCS because it does not represent "'scientific knowledge' under *Daubert*" and Fed. R. Evid. 702 and noting that it "has discovered no case in which MCS was recognized as a legitimate medical condition").

162. *Owen v. Computer Scis. Corp.*, No. 97-6272 (JEI), 1999 WL 43642 (D.N.J. 1999).

163. 171 F.3d 308 (5th Cir. 1999).

164. *Id.* at 313.

165. See *Vargas v. Lee*, 317 F.3d 498 (E.D. La. 2003); *Gross v. King David Bistro*, 83 F. Supp. 2d 597 (D. Md. 2000).

166. Both have no known etiology; both are diagnosed through a collection of subjective symptoms; neither can be diagnosed through objective medical evidence; both occur far more frequently in women than in men; and both have received greater recognition, as well as increased standardization in diagnostic techniques (though perhaps not at the same rate) over the past decade.

One possible explanation stems from the fact that there is a huge industry at stake in the battle over the legal recognition of MCS. Chemicals, of all kinds, play a key role in almost every aspect of modern American life. At the same time, a significant number of Americans now spend as much as ninety percent of their time in buildings with restricted ventilation,<sup>167</sup> and are continuously re-exposed to various levels of all sorts of chemicals. A study suggests that as many as a third of all Americans may be particularly sensitive to certain chemical odors.<sup>168</sup> The recognition of a plaintiff's development of MCS as a legitimate legal claim would place several large industries at risk of new legal liability. Ann McCampbell, a doctor who heads the Multiple Chemical Sensitivity Task Force of New Mexico, makes this argument with particular force, documenting tactics used by pharmaceutical and chemical industries in their war on MCS in and out of the courtroom and likening them to those used by the tobacco industry.<sup>169</sup>

Ultimately, the explanation is probably less sinister. While fibromyalgia is still a somewhat controversial diagnosis within the established field of rheumatology, environmental medicine as an entire field is still struggling to establish its place in the medical community.<sup>170</sup> The cases in which courts have excluded evidence about fibromyalgia have been tort cases in which causation was the key to determining liability, and there still exists a relative consensus in the medical community that there is no known cause for fibromyalgia.<sup>171</sup> Similarly, the wholesale exclusion of evidence about MCS may reflect the legal community's attunement to medical science's ongoing, blanket uncertainty about MCS. What echoes throughout the MCS cases is the Supreme Court's reminder in *Kumho Tire Co. v. Carmichael*: "[T]he presence of *Daubert's* general acceptance factor [does

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167. Kelley, *supra* note 25, at 489.

168. *Id.* (citing Claudia S. Miller, *Chemical Sensitivity: Symptoms, Syndrome or Mechanism for Disease*, 111 TOXICOLOGY 69, 71 (1996)).

169. See McCampbell, *supra* note 102.

170. Kelley, *supra* note 25, at 488.

171. Interestingly, while the case law recognizes that there is no consensus about fibromyalgia's cause, it does not recognize that there is a consensus about how to diagnose it: Despite the American College of Rheumatology's method for diagnosing fibromyalgia, that standard is not mentioned in a single ADA case. Instead, the information about fibromyalgia comes from a wealth of sources, including the Merck Manual, *Kocsis v. Multi-Care Mgmt., Inc.*, 97 F.3d 876 (6th Cir. 1996); on-line medical dictionaries, *Carter v. Gen. Elec. Co.*, 2000 U.S. Dist. LEXIS 3875 (N.D. Ill. 2000); and magazine articles, *Winn v. Runyon*, No. 96-C3168, 1998 U.S. Dist. LEXIS 13771 (N.D. Ill. 1998). It has not, however, come from one of the definitive sources in the field.

not] help show that an expert's testimony is reliable where the discipline itself lacks reliability . . . ."<sup>172</sup>

While this explanation relieves the exclusion of MCS of its menacing air, this exclusion remains deeply problematic, not only for MCS patients, but also for other patients with emerging diagnoses. If what the MCS case study exemplifies is that legal thought ultimately reflects medical acceptance, then the courts have effectively used *Daubert* to reinstitute the *Frye* standard of general acceptance. Alternatively, by tying *Daubert* testimony by a practicing physician to a requirement that the testimony be accompanied by "hard science," the courts have established a new standard that is equally high. Either may ultimately deny patients with emerging diagnoses protection under the ADA in exactly the same way the plaintiff was denied relief in *Comber v. Prologue, Inc.*<sup>173</sup>

If patients cannot present expert testimony about their conditions, they may be unable to prove facts that are significant for ADA claims. Even if their condition is ultimately recognized, plaintiffs may be denied relief for years or even decades while research develops, through defendants' effective use of the *Daubert* standard. MCS provides a clear example of this: There may be millions of Americans who suffer from the condition, but after at least a decade of intensive research since the Gulf War, an MCS plaintiff is as unlikely now to have the scientific or medical ammunition to survive a *Daubert* challenge as she were when the statute was first passed.

While the use of *Daubert* to exclude new diagnoses is troubling in cases involving liability based on diagnosis, it is particularly disturbing in cases that arise under laws like the ADA, in which diagnosis is not supposed to be central to a determination of liability. Unlike tort cases, liability under the ADA is not assigned based on how or why the plaintiff's condition developed, and liability is not tied to which specific condition afflicts the plaintiff. Any plaintiff who suffers from *any* condition that substantially limits a major life activity can claim protection under the ADA, regardless of the name for her condition.<sup>174</sup>

Once a plaintiff has demonstrated substantial limitation, the analysis shifts away from 'what' the plaintiff 'has' that qualifies her as disabled to whether or not she has been treated appropriately in relation to her disability. The fact that ADA liability is not meant to center around the

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172. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 151 (1999).

173. See *supra* note 160 and accompanying text.

174. See 42 U.S.C. § 12102(2) (2000) ("The term 'disability' means, with respect to individual—a physical or mental impairment that substantially limits one or more of the major life activities of such individual.").

named condition the plaintiff has, but rather around how the plaintiff is treated, is emphasized by the second and third ways in which a plaintiff can claim protection under the ADA. Beyond having an impairment that substantially limits a major life activity, plaintiffs may sue for ADA violations if they have a record of having such an impairment or are *regarded* as having such an impairment.<sup>175</sup> In other words, under the ADA, if a plaintiff can prove that the defendant treated her inappropriately based on the defendant's belief that the plaintiff had an impairment, it is not necessary for the plaintiff to actually *have* an impairment.

It is the ADA's apparently inclusive intent—manifested in both its legislative history and its language—that makes the use of *Daubert* exclusion in ADA cases especially problematic. In tort cases where liability is assigned based on diagnosis and attendant causation, it makes sense for courts to be cautious about new diagnoses; under the ADA, it does not. Analogizing an uncertain new diagnosis to misdiagnosis helps clarify why the exclusion of new or uncertain diagnoses is problematic. Consider the example of a person suing under the ADA who has been misdiagnosed with one “established” illness and is then re-diagnosed with another established illness. In a case where a plaintiff has been diagnosed with established condition X, and has been given protection under the ADA, it would make no sense for the court to later revoke protection if the plaintiff actually turned out to have established condition Y. Presumably, the plaintiff still has all the same limitations; she has just been given the wrong name for her condition. This example underscores that the condition's name, ultimately, should not matter in determining whether or not the plaintiff is protected under the ADA, because the plaintiff is equally limited whether she is told she has condition X or condition Y. Similarly, a plaintiff may have an emerging illness that doctors have difficulty diagnosing or naming, and yet the plaintiff may quite clearly be substantially limited in a major life activity, regardless of what name doctors eventually give her condition. The focus of litigation under the ADA should be on the phrase “substantially limited” and should look at a plaintiff's experience with the condition, not on the accuracy with which doctors can name the condition.

One solution to this problem, consonant with the original intent of the ADA, is suggested by language in some cases. In *Owen v. Computer Sciences Corp.*,<sup>176</sup> a defendant attempted to argue that MCS did not constitute a

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175. 42 U.S.C. § 12102 (2)(B)-(C) (2000).

176. *Owen v. Computer Scis. Corp.*, No. 97-6272 (JEI), 1999 U.S. Dist. LEXIS 12635 (D.N.J. 1999).

disability under the ADA.<sup>177</sup> In support of the argument that MCS was not a legitimate medical condition upon which a plaintiff could base a claim, the defendant highlighted numerous cases in which expert testimony about MCS had been excluded due to lack of existing scientific evidence on the diagnosis. The court chided the defendant:

The determination of whether an individual has a disability is not necessarily based on the name or diagnosis of the person's impairment, but rather on the effect of that impairment on the life of the individual. . . . The appropriate question before this Court is not whether [MCS] constitutes a per se disability under the ADA, as defendants argue, but whether Owen's condition is so severe that it substantially impairs a major life condition.<sup>178</sup>

The court reminded the defendant that—at least on this issue—the focus should not be on the technicalities of the ADA. Rather, the court would focus on the nature of the individual who claims protection under the statute's auspices and on that individual's story. This normative vision of the ADA, in combination with other features of the legal system, can guide courts out of the jaws of *Daubert* when cases involving new diagnoses arise.

In other cases, courts have indicated that the testimony of a plaintiff may be enough to establish the nature and severity of her condition for the purposes of the ADA.<sup>179</sup> Federal Rule of Evidence 701 allows lay witness testimony. Under Rule 701,<sup>180</sup> plaintiffs in ADA cases, because of their firsthand knowledge of their conditions, may offer opinions on matters normally “appropriate for expert testimony,”<sup>181</sup> so that even if expert

177. *Id.* at \*4.

178. *Id.* at \*4-\*5.

179. *Wolz v. Deaton-Kennedy Co.*, No. 98-C6610, 2001 WL 699096, at \*7 (N.D. Ill. 2001) (“[A]ll Wolz has is her testimony, but that is the very nature of fibromyalgia. The condition is based entirely on the patient's subjective complaints. Wolz does not have much, but she has enough to survive a motion for summary judgment.”)

180. Federal Rule of Evidence 701 reads:

If the witness is not testifying as an expert, the witness' testimony in the form of opinions or inferences is limited to those opinions or inferences which are (a) rationally based on the perception of the witness, and (b) helpful to a clear understanding of the witness' testimony or the determination of a fact in issue, and (c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702.

FED. R. EVID. 701.

181. *Holt v. Olmsted Tp. Bd. of Trustees*, 43 F. Supp. 2d 812, 819 (N.D. Ohio 1998).

testimony about a condition is excluded, a plaintiff can provide enough evidence of substantial limitation to shift adjudication forward to other components of the ADA. In *Holt v. Olmsted Township Board of Trustees*, the plaintiff was a woman who had been living with fibromyalgia for six years. The defendants filed a motion to strike a portion of her affidavit, in which she discussed her physical condition, as impermissible lay opinion. The court disagreed: "Plaintiff has personal knowledge of her condition and its symptoms. Testimony concerning her physical condition is also central to the factual issues in the instant matter [the ADA suit]. Therefore, those portions of the Affidavit in which Holt describes her physical condition . . . will not be stricken."<sup>182</sup> The court believed that Holt was qualified to testify about the limitations on her life that resulted from her illness, and was willing to accept the testimony as adequate to fulfill statutory requirements.

Blending the opinions in *Owen* and *Holt* provides a general guide to enable courts to allow the ADA to expand to accommodate new conditions and diagnoses, perhaps even before they have a name. If courts use a normative vision of the ADA that focuses on individual experience, as the law itself does, courts can admit plaintiffs' testimony about the nature of their conditions—and do so consistent with the Federal Rules of Evidence, even when experts are not allowed to testify about roughly the same topic. The only court to specifically consider the lay/expert split in a case involving MCS did just this: it admitted the lay testimony while excluding expert testimony on the same subject.<sup>183</sup> If other courts were to follow suit, it would allow even plaintiffs who cannot give their pain a name to give it the voice to which it is legally entitled.

#### CONCLUSION

Forty-three million is a large number, a number meant to impress onlookers with a sense of the enormity of the problem it represents. And yet, when it comes to the ADA, "43,000,000" has proven surprisingly restrictive. In a number of cases, the Supreme Court has used the number as a ceiling on the statute, rather than the floor that was intended; other courts have jealously policed the boundaries.

For illnesses discovered or developed after the passage of the ADA, the

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182. *Id.*

183. *Coffey v. County of Hennepin*, 23 F. Supp. 2d 1081, 1091 (D. Minn. 1998) ("The Court excludes any expert testimony regarding Multiple Chemical Sensitivities. However, lay witness testimony regarding the same will be considered.").

central question is whether they have been offered even the limited degree of protection the courts have extended to conditions that were well established in 1991. Several studies, including this one, suggest that they have not.<sup>184</sup> ADA claims brought by plaintiffs with both illnesses are dismissed at a higher rate than ADA cases as a whole. The courts have also effectively used the *Daubert* doctrine to exclude evidence of MCS, a new and controversial diagnosis. The logic applied in those cases could easily be applied to other developing diagnoses. The unwillingness of courts to admit evidence seems much more closely aligned with the rejected *Frye* standard than with the more permissive standard envisioned by the Supreme Court in *Daubert*. Even under existing law, however, if courts remain focused on the individual nature of adjudication under the ADA, and let ADA plaintiffs tell their stories, there is no reason that pains without a name should have any less of a chance in court than established conditions. All Americans with disabilities, be those disabilities named or not, should be given the chance to prove that they are one of the millions of disabled Americans that the ADA was enacted to protect.

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184. See studies cited *supra* note 25.





## CASE STUDY

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# How Can Resources Be Mobilized To Confront a Global Health Emergency?—An Introduction to the Problem

Peter Currie\*

A painful duality underlies the international response to the AIDS epidemic: Despite growing political momentum to address the crisis, current resources fall far short of those required to meet the global burden imposed by HIV/AIDS. In 2003, an estimated minimum of \$6.3 billion was needed to address the epidemic through programs of prevention, care, and treatment; an estimated \$14.9 billion will be needed by 2007.<sup>1</sup> Actual funding for HIV/AIDS in 2003 totaled around \$3.6 billion and is unlikely to increase at a rate adequate to meet projected need.<sup>2</sup> As millions continue to die, it is clear that the question of resource mobilization for HIV/AIDS has yet to be answered.

Five million people became infected with HIV in 2003, the worst year so far in the burgeoning epidemic.<sup>3</sup> The majority of these new infections occurred in sub-Saharan Africa, where HIV prevalence hovers around ten percent.<sup>4</sup> The spread of the virus has harmed the economies of many developing countries, draining them of workers and depressing their agricultural and industrial sectors, as well as damaging already strained education systems. In response to this stark reality both the World Health Organization (WHO) and the United Nations Joint Programme on HIV/AIDS (UNAIDS) have stressed the importance of mobilizing

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1. UNAIDS, REPORT ON THE STATE OF HIV/AIDS FINANCING, 6, 7 (June 25, 2003), [http://www.unaids.org/html/pub/governance/pcb03/pcb\\_14\\_03.03.2a\\_en.pdf.pdf](http://www.unaids.org/html/pub/governance/pcb03/pcb_14_03.03.2a_en.pdf.pdf) (last visited Dec. 24, 2003). Note that these figures represent funding for what UNAIDS has characterized as a “barebones” package of prevention, treatment, care and support.

2. TODD SUMMERS & JENNIFER KATES, THE HENRY J. KAISER FAMILY FOUND., GLOBAL FUNDING FOR HIV/AIDS IN RESOURCE POOR SETTINGS 1 (Dec. 2003).

3. UNAIDS, AIDS EPIDEMIC UPDATE (Dec. 2003), [http://www.unaids.org/wad/2003/Epiupdate2003\\_en/Epiupdate2003\\_en.pdf](http://www.unaids.org/wad/2003/Epiupdate2003_en/Epiupdate2003_en.pdf) (last visited Dec. 29, 2003).

4. *Id.*

resources to expand access to antiretroviral treatment.<sup>5</sup> In 2003, WHO and UNAIDS released the so-called “3 by 5” plan which sets the goal of providing three million people with HIV treatment by 2005.<sup>6</sup>

By what mechanisms will such ambitious goals be achieved? Government actors, non-governmental organizations, private foundations, and pharmaceutical companies have already taken steps to alleviate the burden imposed by HIV/AIDS. Notable among these efforts are the creation of the Global Fund to Fight AIDS, Tuberculosis and Malaria (“the Global Fund”), the production of generic antiretroviral medicines by nations such as Brazil, China, and India, and the negotiation of differential pricing plans to enable resource-poor nations to access costly antiretroviral therapy.

Individual wealthy nations are beginning to take steps to confront the crisis. The United States has recently emerged as a leading donor, allocating over one billion dollars to fight global HIV/AIDS in 2003.<sup>7</sup> In that same year the United States donated more than \$300 million to the Global Fund, with an additional \$322 million contributed by other G8 nations and private donors.<sup>8</sup> The Canadian government is considering a bill that would allow Canadian generic drug manufacturers to export inexpensive antiretroviral medicines to poor countries.<sup>9</sup>

Despite these positive developments, the current pace and scope of the world’s response to HIV/AIDS fall short of what is required.<sup>10</sup> Few developing countries have in place the systems, incentives and mechanisms

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5. Peter Piot, AIDS: The Need for an Exceptional Response to an Unprecedented Crisis, Presidential Fellows Lecture Before the World Bank (Nov. 20, 2003), [http://unaids.org/html/pub/media/speeches02/piot\\_worldbank\\_20nov03\\_en\\_pdf.pdf](http://unaids.org/html/pub/media/speeches02/piot_worldbank_20nov03_en_pdf.pdf) (last visited Dec. 31, 2003).

6. WORLD HEALTH ORG., EMERGENCY SCALE-UP OF ANTIRETROVIRAL THERAPY IN RESOURCE-LIMITED SETTINGS: TECHNICAL AND OPERATIONAL RECOMMENDATIONS TO ACHIEVE 3 BY 5, at 4 (Nov. 2003), [http://www.who.int/3by5/publications/documents/en/zambia\\_doc\\_final.pdf](http://www.who.int/3by5/publications/documents/en/zambia_doc_final.pdf) (last visited Jan. 5, 2004).

7. SUMMERS & KATES, *supra* note 2.

8. *Contributions to Date*, Global Fund to Fight AIDS, Tuberculosis and Malaria, *available at* <http://www.theglobalfund.org/en/files/pledges&contributions.xls> (last visited Jan. 5, 2004).

9. Heather Scofield & Paul Knox, *Big Drug Companies Embrace AIDS Plan*, GLOBE AND MAIL, Oct. 2, 2003, *available at* <http://www.globeandmail.com/servlet/story/RTGAM.20031002.udrug1002/BNStory/National/> (last visited Dec. 24, 2003).

10. UNAIDS, *supra* note 3.

to support a full-scale response to the crisis. International investment in capacity building and infrastructure are badly needed, as well as increased funds for antiretroviral treatment and other interventions. What can be done to mobilize the massive additional resources needed to truly confront this epidemic? The pieces included in the Case Study section of this issue of the *Yale Journal of Health Policy, Law & Ethics* offer a variety of strategies to invigorate global resource mobilization.

Stephen Lewis begins by highlighting the importance of the Global Fund.<sup>11</sup> As a participant in the efforts to establish the Global Fund, Special Envoy Lewis is keenly aware of the challenges that were overcome in creating the fund, and the potential of the fund to effectively distribute resources. He discusses the very real threat of bankruptcy currently facing the Global Fund, calling upon wealthy nations to contribute at a rate commensurate with their share of the world gross domestic product.

Asia Russell, Director of International Health Policy at the Health Global Access Project, then reviews the global HIV/AIDS policy of the current Bush administration, focusing on its failure to provide adequate support for the Global Fund.<sup>12</sup> Russell describes how, despite the political rhetoric in support of global AIDS spending, the White House has lobbied to decrease support for the Global Fund and has failed to encourage the development and use of cost-effective generic antiretroviral medications. Russell, too, calls for a resource mobilization framework in which wealthy countries contribute according to their overall wealth.

Linda Distlerath and Guy Macdonald, of the pharmaceutical company Merck & Co., recount the challenges and successes of the African Comprehensive HIV/AIDS Partnerships (ACHAP), a cooperative effort between Merck & Co., the Bill and Melinda Gates Foundation, and the government of Botswana.<sup>13</sup> Their story highlights the productive role that the private sector can play in funding practical solutions to confront the AIDS epidemic.

Finally, Mary Crewe, the Director of the Centre of the Study of AIDS at the University of Pretoria, offers a perspective from South Africa, the

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11. Stephen Lewis, *The Precarious Promise of the Global Fund*, 4 YALE J. HEALTH POL'Y L. & ETHICS 129 (2004).

12. Asia Russell, *The Bush Administration's Global AIDS Promises—and Praxis*, 4 YALE J. HEALTH POL'Y L. & ETHICS 133 (2004).

13. Linda Distlerath & Guy Macdonald, *The African Comprehensive HIV/AIDS Partnership—A New Role for Multinational Corporations in Global Health Policy*, 4 YALE J. HEALTH POL'Y L. & ETHICS 147 (2004).

nation most severely impacted by the epidemic.<sup>14</sup> She argues that western voices often dominate discussion of the extent and the means of responding to the epidemic, and these voices often either misconceive or misrepresent the challenges that Africa currently faces. She calls for greater attention to the moral and ethical aspects of international trade, so that globalization can become a vehicle for mobilizing resources to combat poverty and marginalization.

The diversity of the perspectives represented here reflects the complex nature of this problem; no single approach to resource mobilization is likely to overcome HIV/AIDS. Instead, the international community must continue to seek innovative strategies *and* must demonstrate the perseverance to implement those strategies effectively. As these authors show, there is considerable opportunity for imaginative solutions directed at reducing the global impact of the epidemic.

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14. Mary Crewe, *Spectacular Failure—A View from the Epicenter*, 4 YALE J. HEALTH POL'Y L. & ETHICS 157 (2004).

## The Precarious Promise of the Global Fund

Stephen Lewis\*

*The following is an abridged transcript of remarks delivered by Mr. Lewis on April 3, 2003 at a conference co-sponsored by the Center for Interdisciplinary Research on Aids (CIRA) and the Yale Journal of Health Policy, Law, and Ethics.<sup>1</sup> Mr. Lewis's speech opened a panel on global resource allocation, which asked: How best can the global community mobilize resources to combat HIV/AIDS in poor nations? This question inspired the Case Studies in this issue.*

When we reached the end of the 1990's, and the AIDS pandemic had been in place for virtually two decades, a great many people began to understand cumulatively that there was a profound moral default occurring in the world. The absence of resources was crippling the response to this global epidemic. The willingness to abandon, for example, the entire continent of Africa and to lose millions upon millions of lives unnecessarily had become one of the most repugnant and odious manifestations of western policy that could possibly be imagined. There was an intensive scurrying about to see whether something could be fashioned by way of a legitimate response. The amount of money coming from the western world as late as the final years of the 1990's was somewhere in the vicinity of two to three hundred million dollars a year—an amount so microscopic in terms of the need as to challenge levels of moral propriety.

Then, in April 2001, Kofi Annan, the Secretary General of the United Nations, floated an idea at the Abuja Summit on AIDS, Tuberculosis and Malaria, which seemed to have real promise. He recommended establishing a fund for AIDS, Tuberculosis and Malaria (the Global Fund) which would attempt to gather somewhere between seven and ten billion dollars a year in order to address the priorities of the pandemic. In the

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\* Stephen Lewis is the United Nation's special envoy for HIV/AIDS in Africa.

1. The editors of this Journal would like to thank the staff of CIRA for transcribing Mr. Lewis' speech, which was delivered extemporaneously. A version of these remarks was published in CIRA's Autumn 2003 Bulletin. Stephen Lewis, *The Global Fund: Does It Have a Future?*, CIRA NOTES, Autumn 2003, at 12.

subsequent eighteen months, the Global Fund raised a total of \$2.1 billion spread over four years from the major donor nations, drastically short of the goal. We were failing. The inability to gather the consciousness and resources of the developed world, given the possibilities of the Global Fund, was a dreadful shock to everyone.

The Global Fund was designed to create a new multilateral, financial vehicle. The Global Fund's Board of Directors would include representatives from countries of the developed and developing world, from non-governmental organizations, from groups of people living with AIDS, and from the private sector. A Country Coordinating Mechanism (CCM) within a country would bring together all interested parties including the government, community-based organizations, faith-based organizations, non-governmental organizations, the diplomatic community, the United Nations community, and associations of people living with HIV/AIDS. This CCM would fashion a proposal that was representative of the panoply of needs in the country rather than simply representing government priorities, and the Global Fund would not accept a proposal unless the proposal was broadly representative of a whole range of needs. The Fund would run the proposal through a technical review committee that would appraise its inherent worth and recommend its approval (or not) by the Board. Ultimately the proposal, in whole or in part, would be accepted or would be returned with suggested alterations. It was an artful, pretty intelligent, quite committed vehicle for disbursing sufficient amounts of money where that money was needed most—at the community level—rather than simply through the apparatus of the government.

The Global Fund has had lots of problems. It took a long time to get going (it didn't have an executive director until the middle of 2002), to hire staff, and to put its processes in place. It is resented by some governments that regard it as being too slow in making the necessary disbursements. And the romantic, idyllic idea of NGO participation was somewhat limited in practice. But even within those general constraints, the Fund stood and stands as probably the best multilateral channel we have for obtaining and distributing large amounts of money to confront the pandemic. Of the \$2.1 billion that has so far been apportioned, some sixty percent of funds are used to combat AIDS, with other funds going to tuberculosis and malaria. Some sixty percent of funding is going to Africa, which is an appropriate distribution in light of Africa's needs. Fifty percent of funding is going to treatment, fifty percent to prevention and other forms of behavior change. Altogether this is a pretty rational and thoughtful distribution of the money.



Now we find ourselves in April of 2003 and suddenly the Global Fund is effectively facing bankruptcy. How is it possible that we could have gone this far into the pandemic and fashioned a vehicle for fundraising, initiated by the Secretary General of the United Nations, only to have it reach a dead end in a relatively brief period of time? The Global Fund needs \$14.5 billion to cover the resource needs of 2003, 2004 and 2005. It is between \$12.5 and \$13 billion dollars short of that target. President Bush, in his otherwise admirable proposition to provide \$10 billion in new money over five years to combat global AIDS, decided that only ten percent of the new money would go to the Global Fund—meaning \$200 million a year.

If you assigned an amount of money which should go to the Global Fund from the United States based on the American proportion of world gross domestic product (which is the kind of formula that most of us use when we apportion the financial responsibilities of various countries), then the United States should be providing somewhere around \$1.5 billion a year, not \$200 million a year. For whatever reason, we continue to resist obdurately the proposition that there is some responsibility for responding to the ravages of the pandemic in Africa and in the world. As a result, all of the western countries are in a shambles around their contributions. Everyone is short and very few are showing an inclination to do anything about it.

I beg you to look at the implications for a moment. In Africa, close to thirty million people are infected. Of those thirty million, probably at least six million should have treatment now. We're lucky if three hundred thousand (five percent) are in treatment in tiny pockets here and there on the landscape of the various countries. This calamitous shortfall results in the death, completely and totally unnecessarily, of huge numbers of people. Why should people die needlessly? What kind of international society are we fashioning? What's happened to the moral anchors of the world? How is it possible to come to the year 2003 and still not be willing to respond?

The thing that always distresses me most is the large numbers of young women I meet (in Africa the pandemic disproportionately and savagely targets women) with their children in tow. They say to me, "Mr. Lewis, who's going to look after my children when I die?" They say, "You have treatment in your country and people are allowed to live. Why can't we have the drugs for treatment?" I never know how to answer that question, because it bespeaks a double standard in this world so excruciating as to be beyond definition. If there is anything that will give the world a sense of moral compass again it will be the fashioning of resources to respond to a

pandemic that is killing more than two million people on the African continent alone every year, unnecessarily.

# The Bush Administration's Global AIDS Promises—and Praxis

Asia Russell\*

*In other words, we want to join you in the war against the pandemic of AIDS. We want to be on your side in a big way. . . . I believe we have a responsibility—my country has got a responsibility. We are a great nation, we're a wealthy nation. We have a responsibility to help a neighbor in need, a brother and sister in crisis. And that's what I'm here to talk about.*

—President George Bush, 2003<sup>1</sup>

## INTRODUCTION

In Senegal on July 7, 2003, President Bush began his five-country, five-day tour of sub-Saharan Africa, the region most devastated by the AIDS pandemic.<sup>2</sup> Mr. Bush's public statements during his brief time in Africa characterized the United States as a global leader, willing and able to confront global AIDS.<sup>3</sup> The President's Emergency Plan for AIDS Relief (PEPFAR), a bilateral program announced during Mr. Bush's 2003 State of the Union address, was held up as evidence of the United States' commitment. PEPFAR will commit approximately \$10 billion in new money and \$15 billion total over five years to global AIDS treatment and prevention in twelve African and two Caribbean countries.<sup>4</sup> PEPFAR's

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\* Director of International Health Policy, Health Global Access Project (HealthGAP).

1. Pres. George W. Bush, Remarks to the AIDS Support Organization (TASO) Centre at Entebbe, Uganda (July 11, 2003), <http://www.state.gov/p/af/rls/rm/22366.htm> (last visited Dec. 16, 2003).

2. UNAIDS, REPORT ON THE GLOBAL HIV/AIDS EPIDEMIC 22 (July 2002).

3. See, e.g., Bush, *supra* note 1; Jim Fisher-Thompson, *Bush Welcomed Exuberantly in Botswana*, WASH. FILE (International Information Programs, U.S. State Dep't), July 10, 2003, available at <http://usinfo.state.gov/regional/af/potus2003/a3071002.htm> (last visited Dec. 16, 2003).

4. Pres. George W. Bush, State of the Union at the U.S. Capitol (Jan. 28, 2003), available at <http://www.whitehouse.gov/news/releases/2003/01/20030128-19.html> (last visited Dec. 27, 2003).

clinical goals are to avert seven million new HIV infections, start two million people on antiretroviral treatment, and extend care to ten million HIV affected people. The initiative also described a plan to set United States contributions to the Global Fund To Fight AIDS, Tuberculosis, and Malaria (Global Fund) at \$200 million per year starting in 2004.<sup>5</sup> These are welcome steps, but they are countered by other United States actions that undermine vital multilateral AIDS interventions, likely with a negative impact on the viability and success of the President's own program.

For example, during President Bush's visit to Botswana, he remarked that "the average citizen cares deeply about the fact that people are dying in record numbers because of HIV/AIDS. We cry for the orphan. We care for the mom who is alone. We are concerned about their plight, and therefore, will respond as generously as we can."<sup>6</sup> However, less than one week after President Bush's return from his five-country tour of Africa, White House officials began obstructing the efforts of Congressional appropriators to increase United States funding of the Global Fund for fiscal year 2004 to a maximum of \$1 billion, an amount beyond the \$200 million requested by President Bush.<sup>7</sup> The recently appointed clinical director of PEPFAR and the current director of the Office of National AIDS Policy, Dr. Joe O'Neill, made a series of arguments in letters to Congressional leadership, claiming that insufficient infrastructure exists to absorb the additional \$1 billion authorized by Congress, despite extensive evidence to the contrary.<sup>8</sup>

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5. Press Release, The White House, Fact Sheet: The President's Emergency Plan for AIDS Relief (Jan. 29, 2003), *available at* <http://www.whitehouse.gov/news/releases/2003/01/20030129-1.html> (last visited Dec. 29, 2003).

6. Pres. George W. Bush, Remarks by President Bush and President Mogae of Botswana in a Photo Opportunity (July 10, 2003), *available at* <http://usinfo.state.gov/regional/af/potus2003/a3071002.htm> (last visited Dec. 13, 2003).

7. *See, e.g.*, Letter from Dr. Joseph O'Neill, Director, Office of National AIDS Policy, to Rep. Jim Kolbe, US House of Representatives (July 16, 2003), *available at* <http://www.globalaidsalliance.org/oneillmemo.html> (last visited Dec. 29, 2003); Letter from Dr. Joseph O'Neill, Director, Office of National AIDS Policy, to Bill Frist, Majority Leader, U.S. Senate (July 17, 2003), *available at* <http://www.oneworld.net/article/view/66291> (last visited Dec. 29, 2003).

8. *See* Physicians for Human Rights, A Health Action AIDS Briefing Paper: Administration Claims that \$3 Billion Cannot Be Effectively Used To Fight Global HIV/AIDS Are Mistaken (July 31, 2003), *at* <http://www.phrusa.org/campaigns/aids/briefing080403.html> (last visited Nov. 10, 2003); *see also* PROGRAMME COORDINATING BOARD, UNAIDS, FINANCIAL RESOURCES FOR HIV/AIDS

A second example of United States actions thwarting global efforts to combat the HIV/AIDS pandemic was on display just two weeks prior to President Bush's departure for Africa, when U.S. trade negotiators attending a World Trade Organization (WTO) informal ministerial meeting in Sharm el-Sheikh, Egypt, continued their longstanding opposition to a straightforward, economically viable WTO deal. This deal would have focused on how poor countries with insufficient domestic drug manufacturing capacity could obtain exported, low-cost generic versions of patented medicines, including medicines for HIV and its complications.<sup>9</sup> Bush stated during his 2003 State of the Union address that "the cost of [anti-HIV medication] has dropped from \$12,000 a year to under \$300 a year," a price reduction which "places a tremendous possibility within our grasp. . . . [s]eldom has history offered a greater opportunity to do so much for so many."<sup>10</sup> Only generic manufacturers offer antiretroviral prices as low as \$300 per year. Despite Bush's tacit endorsement of procurement of generics as part of his own plan, his trade negotiators were blocking a WTO agreement that would increase access to generic medicines in poor countries.

These examples signal the pattern of contradiction between word and deed, between best practice and political calculation, which currently characterizes White House policies on global AIDS and access to affordable medicines. President Bush's Administration now readily acknowledges the magnitude of the global AIDS crisis, although earlier comments by President Bush during a debate with Al Gore, in which Bush stated that Africa would not be a priority for his Administration, cast a long shadow over his presidency.<sup>11</sup> This shift in rhetoric did not happen by accident. Public pressure including coalition protests, non-violent civil disobedience, and other forms of grassroots activism and policy work forced the White House to express a commitment to scaling up the United States government's response to the crisis.<sup>12</sup> Grassroots pressure also

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PROGRAMMES IN LOW- AND MIDDLE-INCOME COUNTRIES OVER THE NEXT FIVE YEARS (Nov. 28, 2002), available at [http://www.public-info.org/Pages/PagesDossiers/FINANCEMENT%20VIH/PCB13\\_FinancialResources\\_en.doc](http://www.public-info.org/Pages/PagesDossiers/FINANCEMENT%20VIH/PCB13_FinancialResources_en.doc) (last visited Dec. 16, 2003).

9. *U.S. Government, Industry, Wrestle with New Approach to TRIPS and Health*, INSIDE U.S. TRADE, June 27, 2003.

10. Bush, *supra* note 4.

11. Derrick Z. Jackson, *No Bush Gaffes, but Plenty of Holes*, BOSTON GLOBE, Oct. 13, 2000, at A23.

12. See e.g., Jon Cohen, *Tough Challenges Ahead on Political and Scientific Front*, 297 SCIENCE 312 (2002); Manny Fernandez, *Protesters Take AIDS Message to the White House*, WASH. POST,

helped reverse more than a decade of United States government opposition to funding access to life-saving antiretroviral treatment.<sup>13</sup>

Unfortunately these changes have translated neither into full support for the Global Fund nor an end to White House obstruction of pro-public health trade policies that facilitate robust generic competition. The Administration's AIDS policies are more likely to be guided by the perceived political risk associated with supporting effective interventions than by the evidence base supporting the need for such interventions. This piece will focus on one such intervention, the Global Fund, and will examine efforts by the Administration, despite its promises, to avoid effective implementation of the Global Fund.

#### THE GLOBAL FUND— AN EMERGENCY RESPONSE FORGED BY INTERNATIONAL PRESSURE

During the last four years, international AIDS activism focused attention on the tremendous gap in access to affordable HIV treatment that renders AIDS a death sentence for 95% of the world's 42 million HIV positive people, and a chronic, manageable illness only for the remaining 5%.<sup>14</sup> AIDS activists criticized what they identified as the etiology of a deadly "medical apartheid" that creates two standards of clinical care—one for the rich and one for the poor. Activists highlighted:

- Pharmaceutical company pricing policies, which bear little relation to the cost of bringing a drug to market;
- Resistance to integration of "First World" standards for clinical care into the impoverished settings relied upon by the world's poor;
- Trade policies, enforced by the United States, that block poor countries from using compulsory licenses<sup>15</sup> and other

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Nov. 27, 2002, at A8.

13. John Donnelly, *Prevention Urged in AIDS Fight: Natsios Says Fund Should Spend Less on HIV Treatment*, BOSTON GLOBE, June 7, 2001, at A8; Sabin Russell, *AIDS Activists in Uproar over Official's Remarks on Africa*, S.F. CHRON., June 8, 2001, at A5.

14. INTERNATIONAL HIV TREATMENT ACCESS COALITION, A COMMITMENT TO ACTION FOR EXPANDED ACCESS TO HIV/AIDS TREATMENT 3 (2002), available at [http://www.who.int/hiv/pub/arv/who\\_hiv\\_2002\\_24.pdf](http://www.who.int/hiv/pub/arv/who_hiv_2002_24.pdf) (last visited Dec. 16, 2003).

15. "Compulsory licensing" refers to government authorization for the manufacturing of a patented product without the consent of the patent holder, breaking a patent monopoly and resulting in competition among suppliers, and subsequently driving down prices. Compulsory licensing is permitted according to guidelines set out in many trade agreements, including the WTO's Agreement on Trade-Related Aspects of Intellectual

mechanisms to promote access to cheaper generic versions of essential medicines;

- The need for wealthy donor countries to pay their fair share, as calculated by country wealth and global need, toward closing the massive gap in financing AIDS treatment, prevention, and care.

From 1999 until 2001, pressure from the emerging global social movement<sup>16</sup> for treatment access forced initial changes in U.S. trade policy regarding patents and access to affordable medicines.<sup>17</sup> Generic competition was facilitated, which in some cases helped reduce the prices offered by proprietary pharmaceutical companies for important drugs.<sup>18</sup> And the definition of the minimum standard for a comprehensive response to HIV disease management in poor countries was revolutionized.<sup>19</sup> For the first time, the human right of universal access to HIV treatment was being expressed not as a radical idea, but as part of a comprehensive clinical response to the disease.

At the same time, Brazil's program of universal HIV treatment access—made possible by government provision of low-cost, generic HIV medicines—was dramatically reducing morbidity and mortality. Data from Brazil clearly demonstrated that delivering triple combination therapy in a resource poor setting worked.<sup>20</sup> From 1996 to 2002, Brazil experienced a 40-70% reduction in AIDS-related mortality.<sup>21</sup> Treatment access was linked with a reduction in stigma, increased hope, more rapid uptake of HIV testing, and potentially a reduction in infectiousness—the latter related to

Property Rights, and the North American Free Trade Agreement (NAFTA).

16. See *supra* note 13 and accompanying text.

17. See Exec. Order No. 13,155, 65 Fed. Reg. 30,521 (May 12, 2000).

18. See Barton Gellman, *Death Watch: The Global Response to AIDS in Africa*, WASH. POST, July 5, 2000, at A1; Barton Gellman, *A Turning Point that Left Millions Behind*, WASH. POST, Dec. 28, 2000, at A1; Barton Gellman, *An Unequal Calculus of Life & Death*, WASH. POST, Dec. 27, 2000, at A1.

19. See Ariel Pablos-Mendez, *AIDS Care Is Learnt by Doing It*, 79 BULL. WORLD HEALTH ORG. 1153 (2001); HARVARD UNIVERSITY, CONSENSUS STATEMENT FOR ANTIRETROVIRAL TREATMENT OF AIDS IN POOR COUNTRIES (Apr. 4, 2001), available at [http://www.cid.harvard.edu/cidinthenews/pr/consensus\\_aids\\_therapy.pdf](http://www.cid.harvard.edu/cidinthenews/pr/consensus_aids_therapy.pdf) (last visited Dec. 16, 2003).

20. Tina Rosenberg, *Look at Brazil*, N.Y. TIMES MAG., Jan. 28, 2001, at 26.

21. WORLD HEALTH ORG., FACT SHEET NO. 274: GLOBAL AIDS TREATMENT EMERGENCY (Sept. 2003), available at <http://www.health.fgov.be/WHI3/krant/krantarch2003/kranttekstsept3/030924m02a-who.htm> (last visited Dec. 16, 2003).

increased control of viral load as a result of powerful and effective combination antiretroviral therapy.<sup>22</sup> Finally, generic competition in Brazil and India reduced the cost of antiretroviral treatment from \$15,000 per year to \$700 per year, and then to less than a dollar per day—beating the “best offers” of brand name companies and showing the world that anti-HIV treatment was economically feasible.<sup>23</sup>

On April 26, 2001, United Nations Secretary General Kofi Annan called for the creation of a Global Fund which would serve as a “war chest” to attract the billions in new resources needed to fight AIDS and other infectious diseases with both treatment and prevention. Annan’s remarks echoed those of activists fighting for realization of the right to access to affordable, life-saving medicines: “[T]here has been a world-wide revolt of public opinion. People no longer accept that the sick and dying, simply because they are poor, should be denied drugs which have transformed the lives of others who are better off.”<sup>24</sup>

The Global Fund is structured differently than other responses to AIDS. Rather than an unresponsive bureaucracy, the Global Fund is designed to be a streamlined mechanism driven by country-level demand to attract resources and fund effective programs. Proposals incorporating antiretroviral treatment would be explicitly eligible for Global Fund grants, unlike many bilateral funding streams that refused to fund HIV treatment, deeming it not “cost effective.”<sup>25</sup> The Global Fund was to be guided by best practices as determined by science and human rights rather than the dictates of foreign policy as established by one donor country or another.

For example, the Global Fund would not require that countries procure brand name drugs. On the contrary, Global Fund policy supports procurement of the lowest cost medicines, whether brand name or generic.<sup>26</sup> Likewise, effective prevention interventions such as

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22. Thomas Quinn et al., *Viral Load and Heterosexual Transmission of Human Immunodeficiency Virus Type 1*, 342 NEW ENG. J. MED. 921 (2000).

23. C. Perez-Casas et al., *Untangling the Web of Price Reductions: A Pricing Guide for the Purchase of ARVs for Developing Countries*, MÉDECINS SANS FRONTIÈRES (Apr. 24, 2003), available at <http://www.accessmed-msf.org/documents/untangling4thapril2003.pdf> (last visited Dec. 16, 2003); see also *Clinton Group Gets Discount For AIDS Drugs*, N.Y. TIMES, Oct. 24, 2003, at A8.

24. U.N. Secretary General Kofi Annan, Address to the African Summit on HIV/AIDS, Tuberculosis, and Other Infectious Diseases (Apr. 26, 2001), available at <http://www.cptech.org/ip/health/abuja/annan04262001.html> (last visited Dec. 16, 2003).

25. INTERNATIONAL HIV TREATMENT ACCESS COALITION, *supra* note 14, at 12.

26. GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS, AND MALARIA, GUIDELINES FOR PROPOSALS (March 2003), available at <http://www.theglobalfund.org/en/apply/proposals> (last visited Dec. 16, 2003).



comprehensive sex education, harm reduction strategies, condom access, and needle exchange, while controversial in the United States, are supported by the Global Fund precisely because they are proven to be effective. In contrast, the White House favors funding for “abstinence-only” HIV prevention efforts, which educate about abstinence as a sole intervention, rather than incorporating it as part of a comprehensive framework of HIV prevention options. Abstinence education alone has not been proven effective in preventing HIV transmission, but is strongly supported by extreme religious conservatives.<sup>27</sup>

In 2001, the United States pledged to donate a mere \$200 million dollars as a “down payment” to the Global Fund. In response to a call for an international effort to raise the \$7 to \$10 billion annually needed to turn back the tide on this disease, and to launch the first comprehensive funding mechanism to address the related pandemics of AIDS, tuberculosis and malaria, the United States gave a sum that totaled about a fifth of what it spends on one cruise missile, or the budget of one Hollywood blockbuster. Activists raised the possibility that, without sufficient funding, the Global Fund would be unable to show clear clinical results, thus shielding donors ad infinitum from committing the billions needed for HIV treatment programs. The remaining Group of Seven leading industrialized countries (G7) announced contributions even lower than that of the United States, adding to the funding crisis. Activism had created a promising and independent multilateral emergency funding mechanism committed to supporting treatment access, but G7 donors, lining up behind the mediocre commitment from the United States, were refusing to fund it in proportion to their wealth.

#### FUNDING THE GLOBAL FUND

On May 27, 2003, before departing for the G8 Summit in Evian, President Bush signed into law an authorizing bill, the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003. This new law authorized expenditures of up to \$3 billion for global AIDS programs in 2004, including \$1 billion for the Global Fund, as long as the \$1 billion from the United States did not exceed 33% of total Global Fund contributions.<sup>28</sup> By July, President Bush’s initial 2004 budget request asked

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27. Emily Wax, *Ugandans Say Talk, Not Abstinence Will Win AIDS War; Bush Likely to Hear Dissent on Policy*, WASH. POST, July 9, 2003, at A18; Tina Rosenberg, *On Capitol Hill, Ideology Is Distorting an African AIDS Success*, N.Y. TIMES, April 28, 2003, at A30.

28. H.R. 1298, 108th Cong. (2003) (enacted).

for only \$2 billion for global AIDS spending. Furthermore, only \$200 million of this amount was earmarked for the Global Fund, despite having approved \$1 billion in the authorizing bill. This represented a one-third *decrease* in the United States contribution to the Global Fund—from \$350 million in 2003 to \$200 million in 2004.<sup>29</sup>

During Congressional consideration of the 2004 authorizing bill, the White House lobbied aggressively to undermine amendments that would increase contributions to the Global Fund. Instead of allowing appropriators to increase funding for global AIDS programs, the White House intervened, opposing any proposal that would provide more than \$200 million for the Global Fund in 2004. Ultimately, \$500 million in appropriations for the Global Fund passed the House, with a looming veto threat from the President.<sup>30</sup> Following the work of House-Senate Conferees, Congress approved \$2.4 billion in global AIDS spending, \$550 million allocated for the Global Fund—far less than the \$1 billion President Bush promised to the Global Fund when he signed the authorizing bill, but incrementally more than the \$200 million advocated by the White House.<sup>31</sup>

The White House defended its reduced contribution to the Global Fund by arguing that the nascent infrastructure of poor countries would be unable to absorb an additional \$1 billion. This argument flies in the face of available data.<sup>32</sup> The Bush Administration's resistance to the Global Fund is motivated not by logic and facts but by political considerations. In reality, the cash-strapped Global Fund is the only funding mechanism currently operational that has the capacity to absorb—and accountably award—such sums. Religious conservatives and Congressional and White House officials have criticized the Global Fund as being unaccountable to American taxpayers.<sup>33</sup> But the United States Health and Human Services Secretary

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29. U.S. STATE DEP'T, U.S. GOVERNMENT SUPPORT FOR THE FIGHT AGAINST HIV/AIDS (June 18, 2003), *available at* <http://www.state.gov/g/oes/rls/fs/2003/21742.htm> (last visited Dec. 29, 2003).

30. Jim Abrams, *House Approves \$17.1B Foreign Aid Measure*, ASSOCIATED PRESS, July 24, 2003; Sheryl G. Stolberg, *House Wrangles Over Level of Spending on Global AIDS*, N.Y. TIMES, July 23, 2003, at A9.

31. The Bush Administration recently proposed a 63% reduction in funding for the Global Fund for fiscal year 2005—from the \$550 million approved for 2004 to \$200 million. U.S. Dep't of State and Int'l Assistance Programs, Budget of the United States Government, Fiscal Year 2005 (Feb. 2, 2004).

32. *See supra* note 8.

33. *See* Press Release, Office of Congressman Joe Pitts, Rep. Pitts Decries Committee Action on HIV/AIDS Bill (April 2, 2003), *available at*

Tommy Thompson is the Chair of the Global Fund's Board, and the Global Fund is subjected to regular audits by the General Accounting Office.<sup>34</sup> This is unlike traditional bilateral funding programs, whose quantitative clinical accomplishments are frequently inscrutable, severely limiting accountability.<sup>35</sup>

#### THE GLOBAL FUND AND THE BUSH AIDS INITIATIVE: COMPLEMENTS OR ADVERSARIES?

The United States has refused to promise an annual contribution to the Global Fund that represents a fair share of the overall financial need of the Fund. This refusal is illogical and immoral. If the Global Fund falters and is unable to fund significant quality HIV proposals, in particular proposals that fund HIV treatment, the success of the administration's own PEPFAR program will also be compromised. Unlike PEPFAR, which will not be able to show results for years, the Global Fund is the one mechanism that is actually equipped to responsibly absorb a \$1 billion contribution, as well as the billions in donations from other donors that the United States contribution will leverage.

G7 countries have already promised to spend between \$7 and \$10 billion each year fighting AIDS in low and middle-income countries, as one of a series of targets committed to by all United Nations members.<sup>36</sup> UNAIDS projects that funding needs in poor countries will reach \$10.5 billion by 2005, and will reach \$15 billion by 2007<sup>37</sup>—and this is without taking into account the funding needed to build and develop human and non-human infrastructure. Global AIDS spending in poor countries from all sources is estimated to be \$4.7 billion—with only \$1.6 billion, or 34%,

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<http://www.house.gov/pitts/press/releases/030402r-AIDSbillIR.htm> (last visited Dec. 16, 2003).

34. U.S. GEN. ACCOUNTING OFFICE, *THE GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS AND MALARIA HAS ADVANCED IN KEY AREAS, BUT DIFFICULT CHALLENGES REMAIN* (May 2003), available at <http://www.gao.gov/new.items/d03601.pdf> (last visited Dec. 16, 2003).

35. See Derek Link & Mark Harrington, *Exploring the American Response to the AIDS Pandemic*, Treatment Action Group Report (July 2000); see also U.S. GEN. ACCOUNTING OFFICE, U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT FIGHTS AIDS IN AFRICA, BUT BETTER DATA NEEDED TO MEASURE IMPACT (March 2001), available at <http://www.gao.gov/new.items/d01449.pdf> (last visited Dec. 3, 2003).

36. U.N. G.A., Special Session on HIV/AIDS, *Declaration of Commitment* (June 2001), available at <http://www.un.org/ga/aids/docs/aress262.pdf> (last visited Dec. 16, 2003).

37. UNAIDS, *FACT SHEET, MEETING THE NEED* (Sept. 1, 2003), available at <http://www.unaids.org/Unaid/EN/media/fact+sheets.asp> (last visited Nov. 10, 2003).

from the combined multilateral and bilateral commitments of the seven wealthiest countries in the world.<sup>38</sup> Current spending patterns mean funding goals, and clinical goals whose fulfillment is dependent on money, will be unmet as long as donor neglect continues.<sup>39</sup>

Examples of the potential synergy of the Global Fund and PEPFAR generate additional arguments for the immediate full funding of both programs by the United States. A multilateral mechanism like the Global Fund is a necessary part of an effective response to the AIDS catastrophe. Multilateral mechanisms pool donor efforts, are less affected by country politics, have low overhead costs relative to bilateral aid, and support the coordination of international efforts. The lessons learned from meaningful cooperation between civil society and government in Global Fund grant writing and program implementation will be essential to PEPFAR's attainment of its clinical goals, in particular the goal of treating two million people with antiretrovirals by 2008.<sup>40</sup>

The White House appears willing, for now, *not to object* to the use of PEPFAR money to purchase generic versions of medicines.<sup>41</sup> What is unclear is whether in the future, in order to respond favorably to pressure from the pharmaceutical industry lobby, the United States will develop a procurement policy for PEPFAR that *de facto* excludes most generic suppliers, for example by subjecting suppliers to unnecessarily high standards that do not increase patient safety but do eliminate generic companies from eligibility. Likewise, it is unclear whether PEPFAR will

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38. KAISER FAMILY FOUND., FACT SHEET, GLOBAL HIV/AIDS SUPPORT FROM G8 COUNTRIES, (May 2003), *available at* <http://www.kff.org/hivaids/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14377> (last visited Dec. 16, 2003).

39. Press Release, United Nations, Two Years After Historic Session on HIV/AIDS, New Reports Show Progress but Member Nations Fall Short of Goals (Sept. 22, 2003), *available at* <http://www.un.org.in/News/2003/pr/pr166.html> (last visited Dec. 16, 2003).

40. PEPFAR is already imposing artificial, external restrictions on funding for civil society mobilization—an intervention that is a critical element of successful HIV treatment scale-up efforts. *See* CTRS. FOR DISEASE CONTROL, RAPID EXPANSION OF ANTIRETROVIRAL THERAPY PROGRAMS FOR HIV-INFECTED PERSONS IN SELECTED COUNTRIES IN AFRICA AND THE CARIBBEAN UNDER THE PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF, *available at* <http://www.cdc.gov/od/pgo/funding/04080.htm> (last visited Dec. 20, 2003). The Global Fund, in contrast, permits CCM applicants to make independent determinations regarding the proportion of spending needed to support civil society involvement in building local demand for treatment access.

41. *See* Bush, *supra* note 4. Bush's mention of the cost of generics suggests this lack of objection.

solicit direct in-kind donations of medicine to offset additional costs and therefore favor the procurement of brand name pharmaceuticals, despite a resounding international consensus that in-kind donations of chronically administered medicines decrease program sustainability.<sup>42</sup>

The Global Fund is providing grantees with funding used to procure low-cost, generic antiretroviral medicines. This ensures that finite resources will be used in a way that will benefit the greatest number of sick and dying people, while increasing international acceptance of the procurement of generic HIV medicines.<sup>43</sup> Without adequate funding, the ability of the Global Fund to set independent standards in the critical area of drug procurement will likely be undermined by the competing political interests of the private sector, to the detriment of people living with HIV.

#### OVERCOMING WHITE HOUSE RESISTANCE TO EFFECTIVE RESPONSES TO THE AIDS CRISIS

An essential test of the commitment of the United States and other wealthy donor countries to winning the war against AIDS is whether they are committed to providing adequate levels of funding to pay for the interventions—prevention, care, and treatment—that are the weapons in this war. Donor nations are currently failing this test. A new paradigm in resource mobilization, built on the mutual commitment of all partners to contribute equitably to interventions that will most wisely use limited resources for prevention and treatment, is desperately needed. The current “supply-driven” system, where donor countries capriciously decide when they will give and how much, has increased doubt that the international community will commit the money needed to close the massive *existing* funding gap, much less mobilize the *additional* finances needed to expand and build new infrastructure.

During the sixth Board Meeting of the Global Fund, donor countries on the board rejected proposals to require contributors to give based on

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42. See, e.g., Alain Guilloux & Suerie Moon, *Hidden Price Tags: Disease Specific Drug Donations, Costs and Alternatives*, MÉDECINS SANS FRONTIÈRES, DRUGS FOR NEGLECTED DISEASES WORKING GROUP (2001).

43. The presence of more than one or two medicine suppliers is the factor most strongly associated with low medicine prices. See Stéphane Lucchini et al., *Decrease in Prices of Antiretroviral Drugs for Developing Countries: From Political “Philanthropy” to Regulated Markets?*, in *ECONOMICS OF AIDS AND ACCESS TO HIV/AIDS CARE IN DEVELOPING COUNTRIES, ISSUES AND CHALLENGES* 169 (J.P. Moatti et al., Agence Nationale de Recherches sur le Sida eds., 2003), available at [http://www.iaen.org/files.cgi/11088\\_part\\_1\\_n7\\_Luchini.pdf](http://www.iaen.org/files.cgi/11088_part_1_n7_Luchini.pdf) (last visited Dec. 3, 2003).

their fair share of global need. This decision imperils the “demand-driven” ethos of the Global Fund—where recipient countries’ resource gaps define the Global Fund’s outstanding funding needs. Advocates will be forced to communicate conflicting messages—that G7 countries should contribute proportionately to their wealth, but poor country applicants must submit substantial requests for funding, regardless of the stinginess of donor nations. Ultimately, this stinginess will exacerbate what the Global Fund’s Technical Review Panel has already described as the “shyness” of applicants in requesting funding for antiretroviral treatment, a historically neglected intervention.<sup>44</sup>

The most promising models for resource mobilization have been suggested elsewhere.<sup>45</sup> These support a framework in which the financial burden of each donor country is calculated proportionately to its wealth and to overall financial need, as determined by transparent analyses. Such a model of “equitable contribution” would require donors to commit prospectively to a regular, agreed upon schedule, so that continuity of care in poor countries would be assured and sustainable, short-term and long-term planning by government, care providers, people living with HIV, and other experts would be possible. In this manner, donors’ obligations would be determined based on what people with HIV and people at greatest risk of infection need, rather than what donors independently determine they are willing to commit—the latter being the hallmark of the current, unsuccessful global AIDS resource mobilization framework. The promises made by donor countries to correct the global AIDS funding crisis will continue to be broken, so long as donors resist a coherent, transparent, and equitable framework for their contributions.

In the last four years, international demand for access to HIV treatment for all has helped catalyze a dramatic shift in the rhetoric of decision makers in the United States, as well as other donor countries. The United States now claims it is willing to lead the fight against the global AIDS epidemic. But the promises of the current Administration are worth little without a commitment to full, sustained funding for mechanisms that work, particularly the Global Fund as discussed above, and full support for trade policies that prioritize public health and access to affordable generic

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44. GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS, AND MALARIA, SIXTH BOARD MEETING, REPORT OF THE SECRETARIAT AND THE TECHNICAL REVIEW PANEL ON ROUND 3 PROPOSALS (Oct. 15-17, 2003).

45. See, e.g., Marie-Josée Mbukenakamwe, Address at the Second International AIDS Society Conference on HIV Pathogenesis and Treatment (July 13, 2002), *available at* <http://www.actupparis.org/article1205.html> (last visited Dec. 29, 2003).

medicines over the commercial interests of the proprietary pharmaceutical industry.





# **The African Comprehensive HIV/AIDS Partnerships—A New Role for Multinational Corporations in Global Health Policy**

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Merck & Co., Inc.**

## **MERCK'S COMMITMENT TO GLOBAL HEALTH**

While some scholars have argued that companies should only serve the immediate financial goals of their stockholders, Merck and Co., Inc., one of the world's leading research-based pharmaceutical firms, has long taken a different position when it comes to alleviating the impact of disease in the developing world. All major pharmaceutical firms have an obligation to offer assistance when social, political, and economic conditions make it impossible for patients to receive life-saving therapies. On a practical level, there are clearly constraints: Merck's primary role in global health is to discover, produce and distribute innovative drugs and vaccines to address unmet medical needs worldwide. Merck and other pharmaceutical firms must have the resources – including investor support – necessary to continue performing that role. Merck's research programs to develop safe, effective vaccines for HIV/AIDS, rotavirus, and human papillomavirus attest to its commitment to address diseases of global magnitude for all people regardless of their economic situation. However, Merck recognizes that bringing new drugs and vaccines through regulatory approval and into

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†† Merck & Co., Inc., operates in most countries outside the United States as Merck Sharp & Dohme (MSD). The authors are grateful to Dr. Donald de Korte (ACHAP), Dr. Helene Gayle (the Bill & Melinda Gates Foundation), and Prita Pillai (ACHAP) for their assistance.

the marketplace does not necessarily result in people having access to life-prolonging medicines, especially in those regions of the world where the health care infrastructure is inadequate and poverty overwhelming. In these regions, Merck and other large producers should help remove the barriers that stand between patients and the therapies they need.

Multinational pharmaceutical companies thus share with the governments of the developed nations and international institutions a complex social obligation. In meeting those obligations, Merck invests not only in the expected – with a research and development budget for 2003 exceeding three billion dollars—but also in the social goods that enable access to medicines and health care around the world. Improving global health by investing in human, physical and intellectual capital saves lives and can also stimulate the economic development necessary to pull communities and countries out of poverty. This in turn shapes a more favorable environment for multinational companies like Merck to continue pursuit of new drugs and vaccines against diseases yet unconquered. In the long term, the company believes, these social investments serve the best interests of its stockholders as well as those of people living in developing societies. This strategy explains Merck's partnership with the government of Botswana and the Bill & Melinda Gates Foundation—the African Comprehensive HIV/AIDS Partnerships (ACHAP)—an ongoing effort to combat that nation's leading health crisis.

#### THE AFRICAN COMPREHENSIVE HIV/AIDS PARTNERSHIPS

Merck's AIDS research program has spanned more than fifteen years, yielding two antiretroviral drugs and a promising HIV/AIDS experimental vaccine in early human clinical trials.<sup>1</sup> Realizing the challenges in access to HIV/AIDS medicines in the developing world—especially in sub-Saharan Africa—Merck has entered into numerous partnerships with governments, international organizations, foundations, other corporations and non-governmental organizations (NGOs) as it attempts to deal effectively with the global HIV/AIDS pandemic.

It was in this context that Merck decided to launch a comprehensive program of HIV/AIDS prevention, care, treatment and support in one

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1. LOUIS GALAMBOS & JANE ELIOT SEWELL, *CONFRONTING AIDS: SCIENCE AND BUSINESS CROSS A UNIQUE FRONTIER* (1999); *see also* Press Release, Merck & Co., Merck's Investigational HIV Vaccine Candidate To Be Studied In Collaborative Clinical Trial To Begin in 18 Cities Around the World (Sept. 19, 2003), [http://www.merck.com/newsroom/press\\_releases/research\\_and\\_development/2003\\_0919.html](http://www.merck.com/newsroom/press_releases/research_and_development/2003_0919.html) (last visited Dec. 10, 2003).

country in sub-Saharan Africa. The enormity of the pandemic seemed to be creating institutional and political gridlock.<sup>2</sup> Meanwhile, people were dying prematurely and HIV infections were continuing to spread. Merck set out to create a pilot program, which—if successful—could provide guidelines for other developing nations, for international organizations, for foundations, and for the governments of developed countries that ultimately would have to bear the tremendous cost of any comprehensive plan. To be successful, this program had to be implemented in cooperation with an African government that had the political will to mount an integrated fight against HIV/AIDS. If these conditions were met, an additional bolus-type infusion of funding, drugs and technical assistance could have both an immediate and long-lasting impact.<sup>3</sup>

Merck, which was willing to commit \$50 million toward such an effort through the Merck Company Foundation, sought other potential funding partners from the business, public sector and foundation world. Most companies and other institutions were skeptical of a partnership focused on just one country, but the Bill & Melinda Gates Foundation was willing to invest in this still undefined program. By late 1999, the Gates Foundation was already committed to expanding its global health programs, including those in HIV/AIDS, and it brought to the partnership strong financial support and substantial expertise.<sup>4</sup> Together, the Gates Foundation and Merck set out to develop a program that would encourage others in the pharmaceutical industry, in governments, and in foundations to act swiftly to stem this deepening crisis.

The two partners set out to focus these resources on one country, something that neither international organizations nor the governments of

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2. HANNAH E. KETTLER, *NARROWING THE GAP BETWEEN PROVISION AND NEED FOR MEDICINES IN DEVELOPING COUNTRIES* (2000); MÉDECINS SANS FRONTIÈRES, *FROM DURBAN TO BARCELONA: OVERCOMING THE TREATMENT DEFICIT* (2002), *available at* [http://www.doctorswithoutborders.org/publications/reports/2002/fdtb\\_07-2002.pdf](http://www.doctorswithoutborders.org/publications/reports/2002/fdtb_07-2002.pdf) (last visited Dec. 10, 2003); UNAIDS & HARVARD SCH. OF PUB. HEALTH, *LEVEL AND FLOW OF NATIONAL AND INTERNATIONAL RESOURCES FOR THE RESPONSE TO HIV/AIDS, 1996-1997* (1999). For a discussion of the delay in United States assistance, see Jeanne Cummings, *African Aid Slowed Amid U.S. Wrangling*, WALL ST. J., July 11, 2003, at A4.

3. *See, e.g.*, UNAIDS, *ACCELERATING ACTION AGAINST AIDS IN AFRICA* (2003) (discussing the importance of leadership in Botswana).

4. Press Release, Bill & Melinda Gates Foundation, The Bill & Melinda Gates Foundation, Merck & Co., Inc., and the Republic of Botswana Launch New HIV Initiative (July 10, 2002), <http://www.gatesfoundation.org/GlobalHealth/HIVAIDSTB/HIVAIDS/Announcements/Announce-243.htm> (last visited Dec. 22, 2003).

donor nations could easily do based on their chartered mandates or traditional modes of international aid. After reviewing the impact of HIV/AIDS in various sub-Saharan countries, the level of health care infrastructure and demonstration of political will and government commitment, Gates and Merck realized that one country stood out: Botswana. Politically stable and known for good governance, Botswana had the important advantage of strong leadership by President Festus Mogae, who was deeply committed to fighting the epidemic ravaging his country. With 35.4% of the adult population infected, Botswana has the world's highest reported HIV rate. A small country with a record of strong economic growth during its first 35 years of independence, Botswana had not yet felt the full impact of the epidemic, but HIV/AIDS clearly was threatening its very existence.<sup>5</sup>

After meeting with representatives of Merck and the Gates Foundation in July 2000, President Mogae agreed to launch the African Comprehensive HIV/AIDS Partnerships, a public-private collaboration between the Government of Botswana, Merck, and the Bill & Melinda Gates Foundation. President Mogae commented, "We should have started yesterday."<sup>6</sup>

#### THE DEVELOPMENT, IMPLEMENTATION AND IMPACT OF ACHAP

To be successful, the new program needed substantial resources and a commitment to transparency and accountability. Merck and the Bill & Melinda Gates Foundation each dedicated fifty million dollars to ACHAP over a five-year period. In addition, Merck is donating its HIV medicines to the Government of Botswana's antiretroviral (ARV) therapy program and is assisting with the development and management of the ACHAP organization. A board of directors, which has primary responsibility for transparency and accountability, oversees these funds: authorizing budgets, approving proposals and providing direction on strategy and operations. Dr. Donald de Korte, former managing director of Merck's subsidiary in South Africa, headed up the operation in Botswana, managing a core team of twenty, complemented by consultants seconded to ministries and

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5. NATIONAL AIDS COORDINATING AGENCY, STATUS OF THE 2002 NATIONAL RESPONSE TO THE UNGASS DECLARATION OF COMMITMENT ON HIV/AIDS: GOVERNMENT OF BOTSWANA COUNTRY REPORT (2003), *available at* <http://www.naca.gov.bw/documents/REPORT%2012%20Mar%2031%202003%201711%20Hours.pdf> (last visited Dec. 22, 2003) [hereinafter "2002 NATIONAL RESPONSE TO THE UNGASS DECLARATION OF COMMITMENT ON HIV/AIDS"].

6. Interview with Festus Mogae, President, Botswana (July 2000).

sectors.<sup>7</sup>

Relations between the two United States partners and the government of Botswana were crucial to success. Under pressure to act quickly and decisively, there were disagreements about what should be done and how it should be accomplished—especially in the early development of the formal operational relationships between the partners. In the pressure cooker of the pandemic, cultural differences emerged over efficiency, over changes that were needed in relatively rigid social systems and methods of delivering services, and over operational paradigms that had political but not medical saliency. Breaking down functional boundaries seemed natural to planners attuned to corporate reengineering and fast-track mechanisms, but not always to political leaders sensitive to local patterns of behavior and status.<sup>8</sup>

With some grinding and a great deal of good will, however, these problems were turned into relatively minor impediments in the overall progress of ACHAP. There was from the beginning a solid consensus about the nature of the crisis and the need to move forward as quickly as due diligence, available personnel and government procedures allowed. As a result, during its first three years, ACHAP was able to keep a tight focus on three specific objectives: 1) building institutional capacity; 2) strengthening the health care system, including prevention and treatment services; and 3) creating and expanding community initiatives for HIV/AIDS education and the care and support for people living with the infection.

#### ACHAP-SUPPORTED PROGRAMS IN BOTSWANA

ACHAP's effort in capacity-building includes programs expanding and fortifying human resources and those providing technical advice and support. ACHAP assisted in the elaboration of Botswana's national HIV/AIDS strategy, including the development of a national monitoring and evaluation system and the provision of a needs assessment toolkit that will guide future HIV/AIDS interventions at the district level. ACHAP has trained more than 500 government, NGO and other key players on project

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7. For details on the organization and direction of ACHAP, see <http://www.achap.org>. See also Tracey Naledi, *The African Comprehensive HIV/AIDS Partnerships: A Model for Allocating Resources in the Developing World* (May 2003) (unpublished manuscript, on file with ACHAP).

8. See Naledi, *supra* note 7. See also NATIONAL AIDS COORDINATING AGENCY, *THE NATIONAL HIV/AIDS STRATEGIC FRAMEWORK 2003-2009* (2003); 2002 NATIONAL RESPONSE TO THE UNGASS DECLARATION OF COMMITMENT ON HIV/AIDS, *supra* note 5.

development, monitoring and evaluation, leadership skills and proposal development, media training and computer skills. Many of these areas of capacity-building are not HIV/AIDS specific, but they provide some of the fundamental underpinnings to support Botswana's national strategic framework for HIV/AIDS.

In the technical area, HIV/AIDS training programs for care and treatment—both in the classroom through the Harvard AIDS Institute and in the clinic with HIV experts from hospitals in Europe and the United States—have been provided to over 1200 health care workers, with the aim of reaching all Botswana's medical personnel by the end of 2003. A number of other ACHAP programs focus on skill-building for HIV/AIDS education as a means to increase awareness and knowledge and to destigmatize the disease. For example, a distance-learning initiative conducted in collaboration with the UN, Botswana TV and the Botswana Ministry of Education is reaching teachers in more than 400 schools.<sup>9</sup>

*Key ACHAP interventions within the national strategic framework include:*

- A program establishing the relationship between alcohol abuse and HIV transmission and a related effort aimed at the development of behavior change communication through market segmentation;
- A program introducing routine and diagnostic HIV testing to increase rapidly the number of people knowing their status;
- Education programs on condoms to dispel misconceptions about HIV/AIDS; a project to install more than 10,500 dispensers providing free condoms throughout the country;
- A program providing small grants to fund community-based initiatives;
- Support for the construction of health resource centers at hospitals and daycare facilities for orphans;
- Programs involving an array of support and counseling services, including faith-based services, pre-and post-test counseling, leadership development, the establishment of district responses to mobility, and interventions emphasizing youth prevention and blood safety.<sup>10</sup>

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9. *Teacher Capacity-Building Programme*, African Comprehensive HIV/AIDS Partnerships, at <http://www.achap.org/TCBP.htm> (last visited Nov. 10, 2003).

10. GOVERNMENT OF BOTSWANA, MINISTRY OF HEALTH, *DAWN: CHALLENGES AND LEARNINGS OF ARV IMPLEMENTATION IN BOTSWANA* (2003); African Comprehensive HIV/AIDS Partnerships, at <http://www.achap.org> (last visited Dec. 10, 2003).

Several months after the initiation of ACHAP, President Mogae decided to offer antiretroviral (ARV) treatment to all those in Botswana for whom it was clinically indicated. To support this bold effort, ACHAP secured the pro bono services of McKinsey & Company, a management consultant firm, to work with the government in the planning and development of a government-run ARV program. Since the program's launch in January 2002, ACHAP has continued to support this crucial initiative with technical, managerial, and human resources, including resources to increase the capacity of laboratories nationwide, to install an IT-based patient management system, to train teams of health care workers in the hospitals and clinics, to build drug storage facilities and clinics, and to launch an aggressive information, education, and communications campaign. This style of bottom-up and top-down infrastructure development has been critical to the success of the ARV plan.

The program, which is called *Masa* ("dawn" in Setswana), had enrolled more than 12,000 patients by September 2003. Although most of the Botswana still do not know their HIV status and the cultural stigma of infection continues to be a serious problem, *Masa* is already the largest government-sponsored ARV treatment program in Africa. Adherence to the drug plan has been greater than 85%, and 85% of the patients on the therapy have achieved complete viral suppression after six months.<sup>11</sup>

Rapid expansion of the program is now underway, with more sites for treatment under development.<sup>12</sup> Meanwhile, new initiatives will strengthen blood safety practices, develop additional disease prevention programs for highly mobile populations, address the high risk practices of traditional healers and integrate them into mainstream prevention, treatment and care efforts, and mobilize private firms in Botswana to provide HIV/AIDS services for their employees and families, as well as for the communities where they conduct business.

#### ACHAP: BOTSWANA'S LESSONS

ACHAP has been successful to date in large part because it is fully integrated with the government's strategy, because it is able to leverage the benefits of the private sector to support public health aims, and because the development of its strategy is locally driven. ACHAP is enhancing local capacity through the transfer of managerial, leadership and technical skills

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11. Ernest Darkoh, *The Masa Antiretroviral Therapy Program in Botswana*, Presentation to the Bill and Melinda Gates Foundation (September 24, 2003).

12. *See id.*

to Botswana's citizens. By being fully integrated, it is able to build on existing systems and structures. By developing specific, realistic goals, ACHAP is fostering an environment characterized by individual and institutional accountability and is optimizing resource allocation. The struggle to develop an effective infrastructure, to build the requisite human resource capacity, and to transform deep-set cultural values will go on for many years. But already, ACHAP and the Government of Botswana have made significant progress in developing a comprehensive and sustained national response to HIV/AIDS.

The ACHAP experience demonstrates the importance of implementing reforms in one particular country and in every part of that country, on the regional and the local level. All medicine, like politics, is ultimately local. ACHAP built essential relationships with crucial partners and stakeholders, those with responsibilities and accountabilities within the country. With some effort, private-sector effectiveness has been achieved in public organizations. As this experience indicates, the international, the national, and the local elements can be aligned. This can be done despite inadequate numbers of qualified staff, high attrition rates due to illness and death, underdeveloped monitoring and evaluation expertise, and an insufficient infrastructure to accommodate the large number of patients that need treatment.

What are the key principles that might be applicable to such partnerships in other countries? We feel there are five attributes that warrant consideration:

- ACHAP is an independent yet fully engaged entity solely devoted to supporting a national response to HIV/AIDS through the *timely* development, implementation, management and evaluation of programs. ACHAP has a tight focus and has operated with specific deadlines and realistic goals, full accountability, and a high degree of transparency.
- ACHAP has been able to leverage private sector management and foundation resources in a government-led planning and implementation process. This is a true partnership, not a lopsided alliance dominated by one or more of the participants. ACHAP is a *de facto*, as well as a *de jure*, partnership.
- ACHAP is fully integrated with government processes and procedures and has never attempted to operate independently of the government of Botswana. This is perhaps easier to accomplish with a public-private partnership than it would be with a government-to-government program, with agency rules, legislatures, and executives on both sides of the program. Tight



integration means that ACHAP's desire to be fast and efficient must be tempered—and occasionally frustrated—by the government's bureaucracy. Still, there is a lesson here for the developed nations that will perforce pick up the programs that ACHAP has helped launch.

- ACHAP has been able to help the government of Botswana identify, acquire, and employ the resources and technical expertise (sometimes through management consultants) needed to build training programs and the institutional and human capacity that the country lacked. The United States partners' global contacts and experience with health-related programs were critical to these initial infrastructure- and capacity-building activities.
- ACHAP's determination to be efficient and results-driven has enabled the partnership to build both individual and institutional accountability in its complex, locally based program. Good financial and organizational management, honed in the foundation and corporate worlds, enabled this partnership to achieve substantial, measurable results within three years.

The ultimate measure of the success of ACHAP will be the extent to which the goals of the Government of Botswana can be achieved: reduction in the incidence of HIV and alleviation of the burden of HIV/AIDS on the people, their communities and their country. It will be several more years before this effort can be fully evaluated. In the meantime, the ACHAP partners—Merck, the Gates Foundation, and the government of Botswana—are committed to sharing their experiences so that others engaged in the struggle against HIV/AIDS in the developing world can learn from the work of this unique public-private partnership. The success to date suggests that there truly is hope for all those in sub-Saharan Africa infected and affected by HIV.



# Spectacular Failure—A View from the Epicenter

Mary Crewe\*

*The question these billions ask is—what are you doing you in whom we have placed our trust, what are you doing to end the deliberate and savage violence against us that, everyday, sentences many of us to a degrading and unnecessary death!*

—President Thabo Mbeki, U.N. Millennium Summit, 2000<sup>1</sup>

## INTRODUCTION

In 2000, at the XIII International AIDS Conference in Durban, Jeffrey Sachs spoke of the “shocking disregard” shown by the international community in its failure to respond to the AIDS epidemic.<sup>2</sup> “How could the world,” he asked, “have stood by for the first 20 years of this pandemic, letting it reach 35 to 40 million people before any real funding started?”<sup>3</sup> Two years later, at the XIV International AIDS Conference in Barcelona, speakers again decried the world’s inaction; Dr. Peter Piot, Executive Director of the Joint United Nations Programme on HIV/AIDS (UNAIDS), lamented, “Why are only 30,000 Africans getting antiretroviral treatment, when a hundred times that number need it?”<sup>4</sup>

It was at the Barcelona Conference that an inspiring call was issued to

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1. South African President Thabo Mbeki, Statement at the U.N. Millennium Summit (Sept. 7, 2000), <http://www.anc.org.za/ancdocs/history/mbeki/2000/tm0907.html> (last visited Jan. 7, 2004). See generally Tim Trengove Jones, CTR. FOR THE STUDY OF AIDS, *Who Cares? AIDS Review 2001*, <http://www.csa.za.org/filemanager/list/3/> (last visited Jan. 7, 2004) (discussing Mbeki’s speech at the U.N. Millennium Summit).

2. Jon Cohen, *Companies, Donors Pledge to Close Gap in AIDS Treatment*, 289 SCIENCE 368, 368 (2000) (quoting Sach’s comments at the XIII International AIDS Conference).

3. *Id.*

4. Peter Piot, *Keeping the Promise*, Address at the Opening Ceremonies of the XIV International AIDS Conference (July 7, 2002), [http://www.hivandhepatitis.com/2002conf/14th\\_aids/4.html](http://www.hivandhepatitis.com/2002conf/14th_aids/4.html) (last visited Jan. 7, 2004).

make antiretroviral (ARV) treatment available to three million people in the developing world by the end of 2005.<sup>5</sup> Providing treatment to three million—when twenty million are infected—does not seem like an ambitious plea. Yet, even this somewhat modest goal is unlikely to be reached, given the ongoing failure to mobilize international resources for the provision of HIV/AIDS drugs in the developing world. Just a few months ago, on the very day the World Health Organization launched its 5.5 billion dollar so-called “three by five” plan to meet the treatment challenge outlined in Barcelona in 2002,<sup>6</sup> speculation about the organization’s inability to meet the plan’s financial requirements began to appear in the media<sup>7</sup>—leaving many to wonder whether the next International AIDS Conference will be yet another reprise of the previous two.

At the very least, the implications of this failure to mobilize resources will need to be recognized at the upcoming 2004 International AIDS Conference in Bangkok. The responsibility for the largely avoidable deaths that have resulted from this failure must be laid firmly where it belongs. Unfortunately, it belongs everywhere: Responsibility lies with the international community, particularly the wealthy G8 countries which have been unwilling to adequately support the Global Fund on AIDS, Tuberculosis and Malaria. It lies with the United Nations, which has failed to exercise decisive leadership. It also lies with governments in Africa, which have not met their obligations to their own citizens. Finally, and most generally, responsibility for these catastrophic losses lies within an approach towards globalization and development that lacks a moral foundation, and in doing so, often pits economics against ethics. These failures have combined to produce one of the greatest betrayals and tragedies of all time.

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5. Thomas H. Maugh, *Bleak AIDS Conference Reports Deliver a Global Reality Check*, L.A. TIMES, July 15, 2002, at A3.

6. See Gautam Naik, *U.N. Agency Sets \$5.5 Billion Plan To Fight AIDS: World Health Organization Aims to Distribute Drugs To 3 Million by End of 2005*, WALL ST. J., Dec. 1, 2003, at B4, available at <http://www.aegis.com/news/wsj/2003/WJ031201.html> (last visited Dec. 17, 2003).

7. See, e.g., *id.*; *WHO Launches Campaign To Give Life-Extending Drugs to 3 Million with AIDS by 2005*, Africa Recovery, at <http://www.un.org/ecosocdev/geninfo/afrec/newrels/wtoaids.htm> (last visited Jan. 6, 2004).

## AFRICAN AIDS—THE EPICENTER OF THE CRISIS

The statistics describing the HIV/AIDS epidemic are well known and need little elaboration, but a brief reminder is timely. No region has been harder hit by AIDS than sub-Saharan Africa, which is home to over seventy percent of those infected by HIV—nearly thirty million adults and children in the region are living with HIV.<sup>8</sup>

Why have African countries been so badly affected? What are the factors influencing individual and community vulnerability? The answers to these questions are many, and have triggered sometimes heated debate among economists, social development experts, epidemiologists and behavioral scientists. Among the many responsible factors are the legacies of colonialism and neo-colonialism, poverty and economic underdevelopment, the effects of structural adjustment, the failure of rural agriculture, continuing gender inequalities, lack of good quality education, differences in sexual behavior and political indifference and denial.<sup>9</sup> These conditions, combined with the world's inability—or perhaps unwillingness—for many years to talk about the Africa of AIDS, have made HIV/AIDS the most serious threat the continent has yet faced.<sup>10</sup> More than twenty million Africans have died—many at the height of their productive and reproductive years—stretching the medical, educational and welfare capacity of states beyond their limits, undermining development efforts and casting a shadow over the future of the continent.<sup>11</sup>

Ensuring access to essential ARV medications and health education would have an enormous impact on the rate and pace of the epidemic in Africa, on the ability of people, families and communities to deal with HIV and AIDS, and on the ability of Africa to meet development challenges and ultimately to take its rightful place in the world. There is currently an unprecedented international interest in the African epidemic. Much is written about the need for treatments and the urgent need to mobilize resources to secure the provision of ARV drugs, but thus far little has come of this.

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8. See UNAIDS, AIDS EPIDEMIC UPDATE (Dec. 2003), *available at* [http://www.unaids.org/wad/2003/Epiupdate2003\\_en/Epi03\\_03\\_en.htm#TopOfPage](http://www.unaids.org/wad/2003/Epiupdate2003_en/Epi03_03_en.htm#TopOfPage).

9. Mary Crewe & Peter Aggleton, *Racism and HIV/AIDS in Africa*, 10 S. AFR. J. INT'L AFF. 140 (2003).

10. *Id.* at 141.

11. See CAROLYN BAYLIES ET AL., AIDS, SEXUALITY AND GENDER IN AFRICA 1 (2000); *HIV/AIDS in Africa*, The World Bank, at <http://www.worldbank.org/afr/aids/> (last visited Jan. 6, 2004).

From the ground, it seems clear that we have not yet answered the simple question “Does the international community care about African AIDS?”<sup>12</sup> Inspiring declarations and promising protocols are relatively easy to draft. Indeed, in recent years, increased commitments at the international, regional and domestic levels toward the realization of human rights related to HIV/AIDS, including improved access to treatment, have been enthusiastically adopted.<sup>13</sup> Yet, in the end, it is concrete actions that count. And to date, there has been regrettably little action to demonstrate the concern of the United Nations, the international community, and even of many of Africa’s sovereign governments. From the epicenter of the pandemic it is with disbelief that one comes to realize the stark reality of international trade and intellectual property agreements, and how these are allowed to trump creative and imaginative plans to quickly develop treatment routes, which hold the potential to save lives and to vest real meaning in the many existing political statements.<sup>14</sup>

Since 1996, people with HIV and AIDS who live in well-resourced countries have benefited from taking a combination of HIV ARV drugs. These drugs have resulted in an enormous decrease in the number of people dying from AIDS-related illnesses.<sup>15</sup> Many people who were seriously

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12. Jones, *supra* note 1, first asked this question in reviewing the response of the international community.

13. Key among these are the Declaration of Commitment on HIV/AIDS, the Millennium Development Goals, General Comment Fourteen of the Committee on Economic, Social and Cultural Rights, and resolutions by the Commission on Human Rights on the right to the highest attainable standard of health and access to medication. There is growing recognition that fundamental principles of human rights dictate that essential medical goods, services and information should not only be universally available, acceptable and of good quality, but also within physical reach and affordable for all.

14. The impact of trade negotiations on the accessibility of drugs in the developing world is of tremendous concern to many public health advocates. See, e.g., Brook Baker, *U.S. Trade Negotiations with the South African Customs Union Undermine Access to Medicines and Violate U.S. Law* (July 7, 2003), at

<http://www.cptech.org/ip/health/trade/sacu/hgap07072003.html> (last visited Jan. 7, 2004);

Press Release, Health GAP, “Free Trade” Costs Lives: Access to Medicines, the AIDS Crisis, and the Free Trade Area of the Americas (June 2003),

[http://www.healthgap.org/press\\_releases/03/0603\\_HGAP\\_FTAA.pdf](http://www.healthgap.org/press_releases/03/0603_HGAP_FTAA.pdf) (last visited Jan. 7, 2004); see also

Ellen ‘t Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT’L L. 27 (2002).

15. Senegal and Uganda are countries where effective education programs have

ill have been able to return to work. Yet, most Africans living with HIV/AIDS do not have the opportunity to make such decisions about their health and to exercise choice about which medications to use. Despite a significant decline in the prices of principal ARVs in Africa, these life-sustaining drugs remain out-of-reach for more than ninety-five percent of those whose lives they would save.<sup>16</sup>

One is tempted to ask if an underlying racism towards Africa lies beneath the complacency that allows this treatment gap to persist and even to grow. As in colonial times, do the lives of Africans not matter when profits and trade are at stake? Is the failure to mobilize international resources for the provision of drugs to the developing world—thereby creating large-scale denial of treatment—colonialism of a special kind? There is a great deal of rhetoric about providing treatments in Africa, which slides between myth and reality.<sup>17</sup> Arguments are raised about the economic viability of AIDS treatments in Africa, about the greater effectiveness of prevention, about the danger of starting treatments that cannot be sustained potentially leading to the development of resistant viruses, and about Africa's weak and underdeveloped health infrastructure.<sup>18</sup> These concerns are seldom raised in Europe or in North America, and it is particularly incomprehensible that the lack of infrastructure should still be an argument when we now have so much data available on the viability of treatment in resource poor settings.<sup>19</sup> Much of the resistance to large-scale funding of programs to combat HIV/AIDS in Africa is grounded in a discourse about the continent's inadequacy, its corruption, its poor governance, and its need for technical assistance and capacity building. Even "development agencies" have rightly drawn criticism for exaggerating and constructing many of the so-called problems

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worked, coupled in some cases with treatment programs. Botswana remains a very interesting example of treatment access that to date seems to be having little impact on the epidemic and stigma.

16. See, e.g., Robert Walgate, *As AIDS Drug Prices Plummet for Third World, Questions Still Abound*, THE SCIENTIST, Apr. 3, 2001, at <http://www.biomedcentral.com/news/20010403/04/>.

17. See Hans Bingswanger, *Willingness to Pay for AIDS Treatments: Myths and Realities*, 362 LANCET 1152 (2003).

18. See *id.*

19. See, e.g., Jennifer Singler & Paul Farmer, *Treating HIV in Resource-Poor Settings*, 288 JAMA 1652 (2002); see also Justice Edwin Cameron, Opening Address at AIDS in Context Conference, University of Witwatersrand, South Africa (Apr. 4, 2001) (transcript available at the South African History Archive).

that keep African countries from “developing.”<sup>20</sup> While there is some truth to the criticisms—there are *some* examples of corruption, *some* poor governance—the fact that these examples have taken over the discourse can be seen as the arrival of the new colonialists, whose language silences the voices of the continent and in doing so treats Africa as if it were one homogenous whole, a move which fails to acknowledge many areas of success and advancement.

Given the host of current statements of international commitment and intent regarding provisions for HIV/AIDS,<sup>21</sup> one cannot help but return to the simple question: What has gone wrong? Why have promises been made but not kept?<sup>22</sup> Why does it seem that Africa is simply not important enough for the commitments to be translated into sustained action—for serious work to begin with governments to develop ARV programs and care initiatives? Perhaps the answer lies in a new accomplice to the familiar specter of colonialism: the phenomenon of globalization. In this modern world of globalization, people are only as important as the financial and trade returns they give to the world order, and Africa, with her stumbling economies and falling share of the world trade exports, does not offer enough in return. Indeed, most Africans are worse off now than they were twenty-five years ago and sub-Saharan Africa has the world’s lowest rate of economic growth.<sup>23</sup> Compounding this problem are the annual debt repayments of the continent, which if channeled into HIV/AIDS drugs would provide more than the projected amounts needed to address the epidemic effectively.<sup>24</sup> These economic conditions foment a dangerous relationship between the new trends of globalization and old attitudes of colonialism, whereby the suffering of those afflicted with diseases such as

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20. See JAMES FERGUSON, *THE ANTI-POLITICS MACHINE: “DEVELOPMENT,” DEPOLITICIZATION, AND BUREAUCRATIC POWER IN LESOTHO* (1990).

21. See *supra* note 13.

22. At the Barcelona Conference in 2002, Peter Piot poignantly and aptly remarked, “Together, we have moved beyond the point where world leaders have ignored our pleas. The promises have been made. Now, they need to be kept.” Piot, *supra* note 4. For a discussion of the delays in Bush’ promised emergency AIDS funds, see, for example, Linda Bilmes, Op-Ed, *A Poor Start for Bush’s Aids Programme*, FIN. TIMES, July 7, 2003, available at <http://www.informationclearinghouse.info/article4043.htm> (last visited Jan. 7, 2004).

23. For an expanded discussion, see AFRICA IN CRISIS: NEW CHALLENGES AND POSSIBILITIES (Tunde Zack-Williams et al. eds., 2002).

24. The debt repayment figures for Africa exceed the amount needed by the Global Fund on AIDS, TB and Malaria. See Peris Jones, When “Development” Devastated: Donor Discourses, Access to HIV/AIDS Treatment in Africa and Reconstituting the Terrain of Development, Seminar at the University of Pretoria Department of Sociology (May 2003).



AIDS becomes an economic condition for the “developers” to overcome. True, Africa’s economic development challenges are formidable, and the ferocity of the AIDS epidemic both exacerbates these issues and gives an important urgency to them, but to meet these challenges the nature of the engagement of the Western nations with African countries must change. Globalization needs to have an ethical dimension added to it—a moral foundation from which it will serve to address, as a priority, the issues of poverty and marginalization and not to intensify them.<sup>25</sup>

### CONCLUSION

The failure of the international community to mobilize the resources needed to ensure that Africans have access to treatment is an affront to all humanity, not just to the millions of people living with HIV who at the very least would like to be able to exercise choice with regard to treatment options. From the financial and political capitals of the world it is easy to romanticize poverty and local attempts to deal with it. And it is easy, while not confronted daily with the reality of this epidemic to debate about international trade, security issues, profits and the costs of intellectual property and research.

No matter how much anguish is expressed, no matter how many times the reality of the suffering is exposed and the deaths mourned, what counts is that those with the capacity and the resources to act to save millions of people, have not. It is hard not to read this response as underpinned by racism, a callous lack of real concern, and a spectacular failure of commitment to the rights, dignity and life of all Africans.

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25. See Ethical Globalization Initiative, at <http://www.egiinitiative.com> (last visited Dec. 17, 2003).



## BOOK REVIEWS

### **The High Cost of Prescription Drugs: The Price of Success?**

**H. Jeffrey Lawrence, M.D.\***

*The Big Fix: How the Pharmaceutical Industry Rips Off American Consumers.* By Katharine Greider. New York: PublicAffairs, 2003. Pp. 189.

*Magic Cancer Bullet: How a Tiny Orange Pill Is Rewriting Medical History.* By Daniel Vasella with Robert Slater. New York: HarperBusiness, 2003. Pp. 258.

Two recent books provide radically different perspectives on the pharmaceutical industry. *The Big Fix* by Katharine Greider<sup>1</sup> is squarely in the muckraking tradition of Jessica Mitford,<sup>2</sup> while the *Magic Cancer Bullet* by Daniel Vasella<sup>3</sup> with Robert Slater is a business insider's view on modern drug development. *The Big Fix's* subtitle—"How the Pharmaceutical Industry Rips Off American Consumers"—captures its theme. By contrast, Dr. Vasella develops the notion that modern drug development is

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1. KATHARINE GREIDER, *THE BIG FIX: HOW THE PHARMACEUTICAL INDUSTRY RIPS OFF AMERICAN CONSUMERS* (2003).

2. For one example of Jessica Mitford's investigative work on the American funeral industry, see JESSICA MITFORD, *THE AMERICAN WAY OF DEATH* (1963).

3. DANIEL VASELLA WITH ROBERT SLATER, *MAGIC CANCER BULLET: HOW A TINY ORANGE PILL IS REWRITING MEDICAL HISTORY* (2003).

incredibly complex and expensive, and drug companies take big risks that need to be rewarded with big profits. While opposite in viewpoint, the books share key characteristics. Both are short tomes targeting the lay public. Both put a sharp focus on the issues of fair marketing and pricing practices for prescription drugs. And, by ignoring the potential of physicians to serve as agents of change, both fail to provide concrete steps to alleviate the problem of prescription drug costs in America.

Much of what is covered in Greider's *The Big Fix*, in eight chapters with titles such as "Drugs R Us" and "Patent Shenanigans," is old territory—the rapid rise in expenditures on prescription drugs in the United States, the high profits of pharmaceutical firms, questionable patent manipulations, aggressive marketing practices to physicians and the general public, and the arcane pricing structure of pharmaceuticals. Many of the issues discussed are important and compelling. There is little question that the cost of medication is putting a heavy economic burden on elderly and poor Americans, by some estimates consuming fourteen percent of the average Social Security benefit.<sup>4</sup> The common practice of developing "me-too" drugs—with high price tags but only modest improvements in convenience and/or toxicity—are described.<sup>5</sup> Greider discusses the byzantine pricing practices of American pharmaceutical companies, with consumer costs that drive the elderly to take bus trips to Canada for cheaper medicines.<sup>6</sup>

Perhaps the most critical ethical issue concerning the pharmaceutical company relates to their marketing practices. Greider cites estimates that the drug industry devotes one-quarter to one-third of its sales dollars to marketing,<sup>7</sup> amounts that may exceed the costs of research and development. Like other consumer advocates, she finds these expenditures excessive and largely responsible for the high cost of prescription drugs. However, the pharmaceutical industry has persistently disputed these estimates,<sup>8</sup> and it is difficult, if not impossible, to find firm figures to support either position. That being said, it is hard to believe that

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4. Frank Davidoff, *The Heartbreak of Drug Pricing*, 134 ANNALS INTERNAL MED. 1068 (2001).

5. GREIDER, *supra* note 1, at 47-48.

6. *Id.* at 22-23.

7. *Id.* at 64.

8. See, e.g., Melody Petersen, *Increased Spending on Drugs Is Linked to More Advertising*, N.Y. TIMES, Nov. 21, 2001, at C1 (noting that "[t]he big drug companies . . . objected" to a study suggesting a link between advertising and the high cost of prescription drugs and "said that their research showed no direct link between advertising and rising drug expenses").

marketing costs cannot be reduced substantially, given that U.S. consumers paid in excess of \$145 billion in 2000 on prescription drugs.<sup>9</sup>

So why does the pharmaceutical industry devote such large sums of money to advertising? Drug companies are not foolish, and they would not spend billions of dollars on marketing if the medications sold themselves. The medical literature bears out Greider's contention that meetings with drug representatives and the provision of free samples do influence the prescribing practices of physicians and the likelihood that they will request that a new drug be added to their hospital formulary.<sup>10</sup> She also points out that even young idealistic doctors in training are susceptible to the pharmaceutical industry's direct marketing practices, which include giving physicians gifts of expensive meals, books, medical equipment, and even luggage and resort vacations.<sup>11</sup> The Pharmaceutical Research and Manufacturers of America (PhRMA) recently adopted a new Code on Interactions with Healthcare Professionals, which significantly limits gift-giving and entertainment to physicians, but the code is purely voluntary.<sup>12</sup> Hospitals, HMOs, and many medical professional organizations have also adopted stricter codes of ethics that impose limits on the interactions between health care workers and pharmaceutical representatives.<sup>13</sup> But much more could be done. These new codes do not address the issue of direct advertising to consumers on television, radio and magazines. Patients do go to their doctors and ask for the "purple pill" even if they do not know what medical conditions it treats. If large medical organizations and HMOs lobbied government and industry to end direct advertising to the public, direct marketing could be severely curtailed.

What should drive the proper selection of prescription medicines if

9. Davidoff, *supra* note 4.

10. Lisa D. Chew et al., *A Physician Survey of the Effect of Drug Sample Availability on Physicians' Behavior*, 15 J. GEN. INTERNAL MED. 478 (2000); Mary-Margaret Chren & C. Seth Landefeld, *Physicians' Behavior and Their Interactions with Drug Companies A Controlled Study of Physicians Who Requested Additions to a Hospital Drug Formulary*, 271 JAMA 684 (1994); Marilyn Y. Peay & Edmund R. Peay, *The Role of Commercial Sources in the Adoption of a New Drug*, 26 SOC. SCI. MED. 1183 (1988).

11. Michael A. Steinman et al., *Of Principles and Pens: Attitudes and Practices of Medicine Housestaff Toward Pharmaceutical Industry Promotions*, 110 AM. J. MED. 551 (2001).

12. Press Release, PhRMA, PhRMA Adopts New Marketing Code (Apr. 19, 2002), <http://www.phrma.org/mediaroom/press/releases/19.04.2002.390.cfm>.

13. *Gifts to Physicians from Industry*, 265 JAMA 501 (1991); Susan L. Coyle, *Physician-Industry Relations Part 1: Individual Physicians*, 136 ANNALS INTERNAL MED. 396 (2002); Susan L. Coyle, *Physician-Industry Relations Part 2: Organizational Issues*, 136 ANNALS INTERNAL MED. 403 (2002).

advertising is not to be trusted? Modern medical education has promulgated the paradigm of evidence-based medicine.<sup>14</sup> In this model, standards of therapy are derived from hard clinical science in the form of well-designed controlled trials that are sufficiently powered to provide convincing statistical evidence that one treatment is superior to another. In an ideal world, all medical decisions would be based on such evidence. The “winning” drug would be chosen by unbiased clinical trials, and there would be no use for advertising. In this world, physicians would simply prescribe the best drug. So why does this model not work in the real world? To a large degree it is because the U.S. Food and Drug Administration (FDA) typically does not require new drugs to be tested against existing treatments. Instead, it requires only that they be tested against placebos.<sup>15</sup> This is an easier benchmark to meet, as it merely requires that the new drug be effective, but not necessarily better than standard therapy. Drug companies, however, have little financial incentive for head-to-head trials with other effective therapies if they are not required for FDA approval and if one company stands to lose the contest. Thus the controlled trials needed to decide the best therapy are often never performed.

While she argues powerfully, Katharine Greider’s credentials, as well as her scholarship, are skimpy at best. Her terse biosketch on the book cover describes her as a newspaper reporter and free-lance magazine writer with articles focusing on health and medical topics. She lists no footnotes or references anywhere in her book, and her sources are listed in a brief two-page description at the very end. Her book, which runs a mere 180 pages, is published by PublicAffairs, a notable source of alternative and self-acknowledged gadfly journalism.

In contrast, Daniel Vasella, as chairman and chief executive officer of Novartis, one of the largest pharmaceutical companies in the world, has clear-cut qualifications as a business leader in the pharmaceutical industry. He also has a potentially very exciting story to tell in his book, *Magic Cancer Bullet*, published by HarperBusiness. As the subtitle of the book claims, this book sets out to recount “how a tiny orange pill is rewriting medical history.” He provides his personal perspective on the development of the first anticancer therapy which is targeted to a specific molecular lesion. The drug is imatinib (trade name Gleevec), and the disease it treats is chronic myelogenous leukemia (CML). Imatinib is the first commercially

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14. See David L. Sackett et al., *Evidence Based Medicine: What It Is and What It Isn't*, 312 BRIT. MED. J. 71 (1996).

15. Marcia Angell, *The Pharmaceutical Industry — To Whom Is It Accountable?*, 342 NEW ENG. J. MED. 1902 (2000).

available “molecular” therapy for cancer, and it is designed to inhibit the kinase function of the mutant fusion protein Bcr-Abl that drives the myeloproliferative process underlying the pathogenesis of CML.<sup>16</sup>

Vasella’s book is largely a narrative of Novartis’s involvement in the initial clinical testing of imatinib, an account sprinkled with vignettes about some of the first patients to take the drug. He devotes relatively little time or credit to the years of NIH-funded academic research that made the development of imatinib, and indeed most other modern pharmaceuticals, possible.<sup>17</sup> He describes a number of key scientists in the company who oversaw the synthesis of the compound and the early clinical trials, as well as the anxiety they experienced manufacturing enough of the drug for the anticipated need and monitoring the early reports of clinical testing. Those early trials were dramatically positive, with a large majority of patients with CML showing excellent responses to imatinib, which is a simple oral medication with relatively few side effects.<sup>18</sup> Based on those initial studies, the FDA rapidly approved imatinib for the treatment of CML, and it is now the standard therapy for the stable phase of the disease.<sup>19</sup>

This book is primarily intended to be a “good news” story for patients with leukemia and their families, and not a treatise on public health policy toward the pharmaceutical industry. Nonetheless, Dr. Vasella presents this success story as evidence that large drug companies, driven by the profit motive, are the best hope for the development of effective new therapies. He invokes a business model he calls “innovation management,” a model that “assumes that the private sector is the most capable of carrying out innovative drug discoveries.”<sup>20</sup> This premise is a little difficult to accept in the case of imatinib, given the pioneering work of numerous academic researchers that led to imatinib’s discovery. His arguments for free enterprise, scattered throughout the narrative, are simplistic and underdeveloped: “We must be able to protect our patents for drugs; otherwise there will be no incentive for our scientists to be innovative . . . . And we must structure our prices high enough to assure a return on investment

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16. See VASELLA WITH SLATER, *supra* note 3, at 27.

17. Jeff Gerth & Sheryl G. Stolberg, *Drug Makers Reap Profits on Tax-Backed Research*, N.Y. TIMES, April 23, 2000, at A1.

18. Brian J. Druker et al., *Efficacy and Safety of a Specific Inhibitor of the BCR-ABL Tyrosine Kinase in Chronic Myeloid Leukemia*, 344 NEW ENG. J. MED. 1031-32. (2001).

19. For a discussion of imatinib’s FDA approval process, see VASELLA WITH SLATER, *supra* note 3, at 137-67.

20. VASELLA WITH SLATER, *supra* note 3, at 92.

sufficient to support ongoing research and development.”<sup>21</sup>

Dr. Vasella believes that Novartis took enormous risks to develop imatinib. Unfortunately, however, his view is not well supported by the facts. The effectiveness of imatinib in preclinical tests in cell lines<sup>22</sup> and mouse models<sup>23</sup> of CML was impressive, early clinical trials went very smoothly, and FDA approval took a record-setting two and a half months. He repeatedly sounds the message that he continued to push for the drug’s development, even though he feared the market for it would be too small to make a profit for Novartis, because he thought it was in the best interest of the patients.<sup>24</sup> While these are noble sentiments, they ring a little false when one recognizes that imatinib has significant activity in three other rare malignancies—gastrointestinal stromal tumors (or GISTs),<sup>25</sup> hypereosinophilic syndrome,<sup>26</sup> and certain forms of chronic myelomonocytic leukemia,<sup>27</sup> and is now being tested in a variety of common tumors, such as prostate cancer.<sup>28</sup> Gleevec has also helped establish Novartis as one of the premier oncology franchises leading the targeted therapy drive of the future. So Gleevec may yet make money for Novartis.

The last chapter of the book, cleverly entitled “Success Management,” is largely devoted to justifying the pricing and patent practices of the pharmaceutical industry. Vasella talks in fair detail about the pricing issues for Gleevec, citing an unreferenced claim that the average cost of research and development for a new drug is about \$880,000,000.<sup>29</sup> Other authors have put the figure closer to \$500,000,000.<sup>30</sup> He provides no figures for the

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21. *Id.* at 18.

22. Brian J. Druker et al., *Effects of a Selective Inhibitor of the Abl Tyrosine Kinase on the Growth of Bcr-Abl Positive Cells*, 2 NATURE MED. 561 (1996).

23. Nicholas C. Wolff & Robert L. Ilaria, Jr., *Establishment of a Murine Model for Therapy-Treated Chronic Myelogenous Leukemia Using the Tyrosine Kinase Inhibitor STI571*, 98 BLOOD 2808 (2001).

24. See, e.g., VASELLA WITH SLATER, *supra* note 3, at 15-16.

25. Heikki Joensuu et al., *Management of Malignant Gastrointestinal Stroma Tumours*, 3 LANCET ONCOLOGY 655 (2002).

26. Jan Cools et al., *A Tyrosine Kinase Created by Fusion of the PDGFRA and FIP1L1 Genes as a Therapeutic Target of Imatinib in Idiopathic Hypereosinophilic Syndrome*, 348 NEW ENGLAND J. MED. 1201 (2003).

27. Magnus K. Magnusson et al., *Activity of STI571 in Chronic Myelomonocytic Leukemia with a Platelet-Derived Growth Factor Beta Receptor Fusion Oncogene*, 100 BLOOD 1088 (2002).

28. VASELLA WITH SLATER, *supra* note 3, at 27-28.

29. VASELLA WITH SLATER, *supra* note 3, at 175.

30. Davidoff, *supra* note 4.



research and development dollars expended by Novartis to develop imatinib itself, and states that they based their pricing for Gleevec (\$2,200/month) on the cost of alpha interferon, another standard drug used to treat CML.<sup>31</sup> My Veterans Affairs hospital pays \$1,432 for a month's supply of imatinib; by comparison, hydroxyurea, another oral medication used to control CML, costs less than \$20/month.<sup>32</sup> Vasella quite correctly points out the inequities in Medicare reimbursement that preclude payment for oral cancer drugs and force many elderly patients with CML to pay for their medication out of their own pockets.<sup>33</sup> This Medicare policy will seem increasingly dated as more molecular therapies are introduced, replacing toxic intravenous medications with simpler oral therapies with fewer side effects. While Vasella and Novartis should be applauded for initiating a patient support program for those individuals who cannot afford the medication,<sup>34</sup> several other pharmaceutical companies already have similar policies for expensive cancer medications.<sup>35</sup>

Reading these two books back to back is reminiscent of the old saw about the statistician who would say that a person with one foot in a bucket of ice water and the other foot in a bucket of boiling water was, on average, comfortable. Read together the books do not provide a balanced perspective on the problems of the pharmaceutical industry, nor any guidance as to how change could best be effected. As of this writing, President Bush had just signed a Medicare prescription drug benefit into law,<sup>36</sup> but its value to consumers is delayed and remains uncertain. Until there is an effective national health policy for prescription drugs, the licensed health care providers who can prescribe expensive life-saving medications represent the most effective agents for near-term change. These providers need to find the will to 1) pressure drug companies to

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31. VASELLA WITH SLATER, *supra* note 3, at 179.

32. Information regarding spending at the author's Veterans Affairs hospital is on file with the author. For information about the pricing of hydroxyurea, see *Hydroxyurea*, DestinationRx, at <http://www.destinationrx.com/prescriptions/refine.asp?BrandName=Hydroxyurea> (last visited Jan. 8, 2004).

33. VASELLA WITH SLATER, *supra* note 3, at 126.

34. *Id.* at 179.

35. For a list of other pharmaceutical companies providing such programs, see *Indigent Patient Programs*, The Nutrition Advisor, at <http://www.nutritionadvisor.com/indigent.htm?source=overture#research> (last visited Jan. 16, 2004).

36. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

reduce or eliminate Direct-To-Consumer advertising, 2) resist the aggressive marketing practices directed at them, 3) use evidence-based medicine wherever possible to assure more cost-effective (and cost-saving) prescribing, and 4) press Congress to pass legislation requiring comparative drug trials before FDA licensing.<sup>37</sup>

If marketing practices are to be reduced substantially, those marketing practices must be made to fail. For health care professionals who need more moral support to take on these challenges, they would do well to go to the website of the non-profit group No Free Lunch,<sup>38</sup> a devoted group of physicians endeavoring to limit the influence of pharmaceutical marketing on prescribing practices. At that website, physicians and medical students can get concrete suggestions on actions they can take to aid in that endeavor and are invited to take the following public pledge: "I . . . pledge to accept no money, gifts, or hospitality from the pharmaceutical industry; to seek unbiased sources of information and not rely on information disseminated by drug companies; and to avoid conflicts of interest in my practice, teaching, and/or research."<sup>39</sup> Neither Greider nor Vasella discuss the important role that physicians could play in the near term in creating change in pharmaceutical pricing. To paraphrase the closing comment in Greider's book, if the perspective of a large drug company is "*Who is going to stop me?*"<sup>40</sup> physicians must say "*We will.*"

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37. Angell, *supra* note 15.

38. *Just Say No to Drug Reps*, No Free Lunch, at <http://www.nofreelunch.org/> (last visited Jan. 6, 2004). The website invites readers to protest drug-company sponsored meals to their Department Chairs and/or Program Directors and to give talks on the subject of drug-company influence on prescribing practices, using slide show presentations created by No Free Lunch. *What Can You Do?*, No Free Lunch, at <http://www.nofreelunch.org/todo.htm> (last visited Jan. 6, 2004).

39. *Take the Pledge*, No Free Lunch, at <https://ironclad.secure-orders.net/nofreelu/pledge.htm> (last visited Jan. 6, 2004).

40. GREIDER, *supra* note 1, at 174.

## American Meat: A Threat to Your Health and to the Environment

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*Slaughterhouse Blues: The Meat and Poultry Industry in North America.* By Donald D. Stull and Michael J. Broadway. Belmont, CA: Thomson/Wadsworth, 2003. Pp. 172.

In 1923 Mrs. Cecile Steele of Delaware received 500 chicks instead of the fifty she had ordered to restock her flock of laying hens. When she decided to keep all 500 chicks and found she could turn a profit selling them as food, the era of “big chicken” was born on the eastern shore of Maryland.<sup>1</sup> In *Slaughterhouse Blues: The Meat and Poultry Industry in North America*,<sup>2</sup> anthropologist Donald Stull and social geographer Michael Broadway team up to investigate the impact of the unprecedented changes that followed in the poultry industry and similar changes that occurred in the beef and pork industries.

*Slaughterhouse Blues* is an important book and should be of interest to all who care about sustainable agriculture, the future of rural communities, and the health and environmental consequences of the current industrial agricultural system. The book is an excellent introduction to the important links between public health and food production. The authors frame the larger issue in the book’s preface:

Canada and the United States are urban societies and, despite our collective dependence upon agriculture, most North Americans have lost

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1. DONALD D. STULL & MICHAEL J. BROADWAY, *SLAUGHTERHOUSE BLUES: THE MEAT AND POULTRY INDUSTRY IN NORTH AMERICA* 38 (2003). “Big Hog” developed only in the latter part of the twentieth century, *id.* at 57-60, and “Big Beef” developed slowly from the late nineteenth century and through the twentieth century, *id.* at 27-35.

2. STULL & BROADWAY, *supra* note 1.

any connection to their agrarian heritage. Yet, if we do not understand where our food comes from and how it gets to our table, who produces it and . . . at what cost, we stand to jeopardize the very food supply that sustains us. . . . [W]hat we eat has real consequences for workers, communities, and the environment.<sup>3</sup>

Stull and Broadway proceed to analyze the industrialization of meat and poultry production systems over the last 150 years along with the sociological consequences of these changes on workers and communities. While the authors' discussion of the industrialization of the meat and poultry industry is excellent, they fail to fully explore two important issues introduced in the opening chapter: 1) the fact that current per capita meat consumption in the United States exceeds nutritional needs and 2) the fact that industrial agriculture and animal production systems are unsustainable, inequitable, and injurious to public health and the environment. Despite this, *Slaughterhouse Blues* is an outstanding introduction to the social and environmental consequences of industrial meat and poultry production at the start of the twenty-first century—problems too long ignored by the public health community.

The book's first chapter, "Setting the Table," lays out the authors' central thesis. They contend that the industrialization of agriculture, specifically meat and poultry production, has resulted in a few very large producers, huge concentrated animal production facilities, the selection of animal breeds for quick growth, negative health and environmental consequences, and a changed rural America. By providing ostensibly cheap meat and poultry, this system has also contributed to increased per capita consumption of meat and poultry.<sup>4</sup>

Since most Americans have never visited a feedlot, a slaughterhouse, or a concentrated animal feeding operation (CAFO), the authors provide important, vivid descriptions both of the conditions inside these facilities and of the consequences of these conditions for workers and communities. The current food system produces inexpensive food, but at enormous costs that are passed on to workers, the public, and to future generations; these are the economic externalities of the current food production system. Increasingly, this scenario of concentrated animal production is being replicated in countries around the world, especially as U.S. environmental regulations become more stringent, U.S. communities organize to block construction of new factory farms in their neighborhoods, and more states adopt state-wide moratoriums against building additional CAFO facilities.

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3. *Id.* at xvi-xvii.

4. *Id.* at 19-20.

The development of animal production systems in the twentieth century has followed a model of increased efficiency, where corporate profit is maximized and there is very little regulation. The industry has not given adequate attention to worker safety, public health, and animal welfare concerns, despite the enormous impact that these systems may potentially have on the public's health. The health of workers is affected by air pollution, repetitive motion diseases, industrial accidents, and direct contact with ill or diseased animals.<sup>5</sup> Those living near the feeding lots and CAFO facilities may be exposed to air and water pollution and may suffer psychological stress associated with odors, noise pollution, and other factors.<sup>6</sup> The authors mention concerns for the public at large that include food poisoning and an increase in antibiotic resistant infections resulting from the widespread and inappropriate use of antibiotics in animal feed.<sup>7</sup>

In the early chapters of the book, the authors trace the history of beef, pork, and poultry production in the United States, giving colorful examples from history and their own first-hand experiences touring slaughterhouses and factory farms and interviewing slaughterhouse workers and factory farm contract growers. The authors also provide a thorough and interesting discussion of forces, such as the development of railroads and refrigeration, which have contributed to the geographical and corporate concentration of meat and poultry production into vertically integrated industries and the concomitant decline of family farms and independent operators.

In *Slaughterhouse Blues*, the authors document the increasing concentration and intensification seen in all three industries—beef, pork, and poultry. Only four companies now control eighty-one percent of the beef market, fifty-nine percent of the pork market, and fifty percent of poultry production.<sup>8</sup> Vertical integration began in the poultry industry in the 1960s. Corporate giants such as Tyson and Purdue now control all stages of chicken production, from breeding chickens, hatching chicks, and growing the chickens, to processing and shipping finished cuts of poultry to the supermarket. Increasingly, they are producing value-added,

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5. Richard Fenske & Nancy Simcox, *Agricultural Workers*, in OCCUPATIONAL HEALTH: RECOGNIZING AND PREVENTING WORK-RELATED DISEASE AND INJURY 729 (Barry S. Levy & David H. Wegman eds., 4th ed. 2000); NL Sprince et al., *Risk Factors for Agricultural Injury: A Case-Control Analysis of Iowa Farmers in the Agricultural Health Study*, 9 J. AGRIC. SAFETY & HEALTH 5 (2003).

6. Steve Wing et al., *Environmental Injustice in North Carolina's Hog Industry*, 108 ENVTL. HEALTH PERSPS. 3 (2000).

7. STULL & BROADWAY, *supra* note 1, at 20.

8. *Id.* at 158.

prepared cuts of poultry as well. This same pattern was adopted by the hog industry beginning in the 1980s in North Carolina—the number of hogs raised increased five-fold between 1982 and 1997, while the number of hog farms fell from over 11,000 to about 3000.<sup>9</sup> The authors show how this same pattern of hog production is now occurring elsewhere in the United States and in Canada and is being adopted by the beef and dairy industries as well.

The dramatic change from small farms raising a few hundred head of cattle, hogs, or chickens to the large, vertically integrated CAFOs and slaughterhouses of today has many consequences. In *Slaughterhouse Blues*, Stull and Broadway focus on the social changes rural communities experience as their family farmers are forced out of business and as towns are forced to cope with an influx of immigrants who work at the new plants. Ordinary people living in rural communities are not included in the decision to attract industrial animal producers to their doorsteps, in determining the location of the new CAFOs, or in reaping the tax breaks and other benefits of their presence. But while ordinary people are not included in these decisions, they suffer the consequences. As the authors note, “[A]s farm size increases, so does rural poverty.”<sup>10</sup>

Communities must cope with the increased demand for services accompanying the rapid influx of migrant and low-wage earners, including demand for low-cost housing, social services, and more schools.<sup>11</sup> The authors point out that communities are often unprepared for these realities and lack the resources to deal with these problems when they do occur. By way of example, they cite the town of Brooks in Alberta, Canada. Based on their studies of other towns’ experiences, the authors of *Slaughterhouse Blues* advised the town not to allow a beef processing plant to be constructed there, but the town’s leaders rejected that advice. After the fact, those town leaders sadly admitted that the overall impact of the new plant was negative despite the promises of economic development, jobs, and prosperity that the corporation had made prior to the plant’s construction.<sup>12</sup> The authors describe their frustration in trying to help communities deal with the social changes brought by these large meat packing facilities: “And while we nod knowingly as community members tell us our predictions came true, we are invariably humbled and disappointed by the rigidity of the industry and the inability of local

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9. *Id.* at 58.

10. *Id.* at 149.

11. *Id.* at 122.

12. *Id.* at 124.

communities to do more than mitigate its social and economic costs.”<sup>13</sup>

The authors’ research focuses on the changes that take place in a community once a large meatpacking plant or CAFO is constructed. Knowledge about the social and economic consequences of industrial agriculture should aid local governments in making informed decisions for their communities and will also help community members hold governments accountable. An equally important area of research, given less attention in *Slaughterhouse Blues*, is documentation of the factors that make an area attractive for industrial animal production. These factors may include lack of environmental regulations, tax incentives by county or city government, infrastructure such as roads built at local government expense, available land, and the proximity of transportation, markets, and slaughterhouses. Further research to identify the specific factors that lead large companies to choose a particular region or community for a plant would explain much about the growth of industrial animal production.<sup>14</sup>

Another area where more research is needed is assessment of the full impact of the odor, noise, water pollution, air pollution, and transmission of antibiotic resistance on the physical and mental health of people living near CAFOs. Three studies have shown increased rates of both physical and mental illness among people living near CAFOs, but further investigation is required in order to understand the specific components of CAFO emissions that are contributing to the many reported illnesses.<sup>15</sup>

As the authors note, locating CAFOs or slaughterhouses in areas where the residents are predominantly poor and/or from minority groups raises concerns about environmental justice. *Slaughterhouse Blues* discusses the seminal work of Steve Wing and colleagues in North Carolina who have documented that CAFO facilities in North Carolina are sited disproportionately in poor, nonwhite communities that lack the political power to resist.<sup>16</sup> While the permitting process for siting CAFOs varies by state and county, and may include environmental considerations such as water use and manure management, health and justice concerns for communities are rarely included in the permitting process.

In chapter five, the authors mention, but do not elaborate on, the serious impact of large concentrations of animals on the environment, nearby residents, and the public at large. The current industrial food

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13. *Id.* at 126.

14. *Id.* at 42.

15. Steve Wing & Susanne Wolf, *Intensive Livestock Operations: Health and Quality of Life Among Eastern North Carolina Residents*, 108 ENVTL. HEALTH PERSPS. 233 (2000).

16. Steve Wing et al., *supra* note 6; *see also* STULL & BROADWAY, *supra* note 1, at 59.

production system causes environmental effects that ultimately lead to public health problems and, therefore, warrant increased attention from public health professionals. Irreplaceable fossil aquifers are being drawn down for irrigation of feed crops; pesticides and fertilizers used to grow animal feed contaminate water and soil; and ocean fisheries are being depleted to produce feed for factory farmed poultry, pork, and fish.<sup>17</sup> Animal feed additives, such as antibiotics and heavy metals including arsenic, end up in manure that is spread on fields, and manure from lagoon spills, leaks, and excess land applications contaminate waterways.<sup>18</sup>

Stull and Broadway provide a good discussion of the astounding amount of manure produced by hog CAFOs. Since hogs produce up to four times as much solid waste as an average person, a CAFO of 5000 hogs is equivalent to a city of 20,000 with no sewage treatment plant. The total amount of animal manure produced annually in the United States is 12.4 billion tons. The authors discuss how difficult it is to safely store and dispose of all that waste. Hog waste “lagoons” are prone to having leaks and can overflow during storms, thereby polluting streams, rivers, and drinking water wells with massive amounts of raw manure.<sup>19</sup>

Cropland application of manure, the standard disposal practice, often saturates the land with more phosphorous and nitrogen than crops can utilize or the soil can retain. In addition, land application may not be as safe as the authors of *Slaughterhouse Blues* imply. Since the growers usually do not know what ingredients are included in the feed, they also do not know what is in the manure produced by the chickens or hogs. Manure may contain antibiotics, bacteria—such as *Salmonella*—that may be resistant to those same antibiotics, arsenic, and other additives.<sup>20</sup>

The use of antibiotics as “growth promoters” in feed has caused concern among many health organizations including the World Health Organization and the U.S. Centers for Disease Control and Prevention.<sup>21</sup>

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17. JOHN DAVENPORT ET AL., *AQUACULTURE: THE ECOLOGICAL ISSUES* 10-18 (2003).

18. Lars Jensen et al., *Antimicrobial Resistance Among Pseudomonas spp. and the Bacillus cereus Group Isolated from Danish Agricultural Soil*, 26 ENV'T INT'L. 581 (2001); I. Krapac et al., *Impacts of Swine Manure Pits on Groundwater Quality*, 120 ENV'T POLLUTION 475 (2002).

19. Steve Wing et al., *The Potential Impact of Flooding on Confined Animal Feeding Operations in Eastern North Carolina*, 110 ENVTL. HEALTH PERSPS. 387 (2001).

20. NAT'L RESEARCH COUNCIL, *BIOSOLIDS APPLIED TO LAND* (2002), available at <http://www.nap.edu/books/0309084865/html/> (last visited Jan. 18, 2004); D. Rutherford et al., *Environmental Fate of Roxarsone in Poultry Litter. Part II. Mobility of Arsenic in Soils Amended with Poultry Litter*, 37 ENVTL. SCI. & TECH. 1515 (2003).

21. Press Release, World Health Organization (WHO), Council and Parliament Prohibit Antibiotics as Growth Promoters (July 22, 2003), at



Over seventy percent of all antibiotics in the United States are used in animal production, including many identical to those used to treat humans. The emergence of resistant strains of bacteria in animals jeopardizes the future usefulness of these powerful agents against human disease.<sup>22</sup>

The effect of the industrial animal production system on the farmers who actually raise the animals is an important issue, but the authors discuss it only briefly. The authors do not address the nearly feudal system of contracts where “growers” commit to build chicken houses or swine confinement facilities to company specifications, and the company provides the chicks or piglets, their feed, and their medications. In a system where growers essentially become serfs on their own land, the company owns the chicks or piglets from start to finish and rewards those who produce in larger quantities and achieve a higher than average ratio of animal weight per feed input. However, the company does not own the manure or any dead or sick animals; instead, the growers remain responsible for disposing of these wastes. The margin of profit for the growers is extremely slim, and they often actually lose money but continue in the business because of huge debts incurred for building the chicken or swine facilities in the first place.<sup>23</sup>

Increased productivity is the stated goal of industrial animal production, but at what cost? The authors of *Slaughterhouse Blues* suggest that the costs of that increased productivity may be significant; they discuss the economic impact of CAFOs and disassembly plants in the chapter entitled, “There’s No Such Thing as a Free Lunch.” However, their analysis omits a full discussion of the externalized costs of industrial animal production and the inherent non-sustainability of the system. The root of the problem with industrial animal production is that the industry does not pay for the true costs of the system. Instead these costs are externalized—passed on to workers as low wages; imposed on communities as increased social services, over-crowded schools, and additional taxpayer-funded

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[http://www.keepantibioticsworking.com/News/News.cfm?news\\_ID=349](http://www.keepantibioticsworking.com/News/News.cfm?news_ID=349) (last visited Nov. 5, 2003); *Frequently Asked Questions About NARMS*, Centers for Disease Control and Prevention (CDC), at <http://www.cdc.gov/narms/faq.htm> (Dec. 29, 2003).

22. STULL & BROADWAY, *supra* note 1, at 151; MARGARET MELLON ET AL., HOGGING IT!: ESTIMATES OF ANTIMICROBIAL ABUSE IN LIVESTOCK 63 (2001).

23. The authors have engaged in personal communication with many animal farmers, and this information is on file with the authors. An insightful conference on this topic, entitled “The Chicken: Its Biological, Social, Cultural and Industrial History: From Neolithic Middens to McNuggets,” was held at Yale University in New Haven, Connecticut in May 2002.

infrastructure; and left to the future as polluted waterways, depleted aquifers, toxic residues from agrichemicals used in feed production, depletion of non-renewable fossil fuels, and the diversion of crops suitable for human consumption to the inefficient conversion of grain into meat. These externalities are not included in the market prices. Chickens are now raised in half the time to twice the size they were in 1926 and cost the consumer a fraction of what they cost per pound in 1926 (ten dollars per pound in today's dollars), but they still yield a profit for the corporations.<sup>24</sup> Meanwhile, the short and long-term human and environmental costs are generally not acknowledged, understood, or addressed by consumers or policy makers; instead, they are absorbed by current and future generations. Profits are privatized while health risks and environmental costs are socialized.

Stull and Broadway paint a picture of an industry crying out for regulation. Upton Sinclair, by drawing attention to conditions in the slaughterhouses of the early twentieth century in *The Jungle*, stimulated passage of legislation such as the Federal Food and Drugs Act of 1906 (the "Wiley Act").<sup>25</sup> Sinclair's original intent was to stir empathy for the plight of workers, rather than to arouse concerns about the safety of food, although reform was needed in the latter area as well. Unions finally succeeded in improving wages and working conditions by mid-century, only to have conditions deteriorate as the meat industry increasingly recruited non-union workers from minority groups and immigrants who lacked the power or know-how to alleviate their condition. Today, unions are once again helping to change the food industry. For example, the United Food and Commercial Workers (UFCW) union won a settlement with Perdue Farms in which 25,000 poultry workers were awarded ten million dollars.<sup>26</sup>

Stull and Broadway point out that consumption of meat has increased, without addressing the important fact that current meat consumption in the United States far exceeds nutritional needs. However, they do contend that increased consumption of meat is the driving force of the whole system. In their first chapter, "Setting the Table," they lay out key United States Department of Agriculture (USDA) figures on average meat consumption in the United States to illustrate how it has changed during the last century. In the year 2000, the average American ate ninety-one

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24. STULL & BROADWAY, *supra* note 1, at 38.

25. Pub. L. No. 59-384, 34 Stat. 768 (1906); see STULL & BROADWAY, *supra* note 1, at xiii.

26. *\$10 Million Back Pay Award for Poultry Workers a Victory; But Too Many Employers Still Breaking Wage Laws*, LRA Online, at <http://www.laborresearch.org/story2.php/197> (May 14, 2002).

pounds of chicken per year compared with fourteen pounds per year in 1926 and twenty-one pounds per year in 1930. Annual beef consumption doubled from 48.6 pounds per capita in 1930 to a high in 1970 of 113.7 pounds per capita

But do we need all that animal fat and protein? The authors refer to the obesity epidemic in the United States, and they discuss some of the changes in the American food industry, such as the prevalence of fast food and “supersizing,” and other changes in the American lifestyle that may contribute to this epidemic.<sup>27</sup> This excess consumption of saturated fat, mostly from animal products such as meat and high fat dairy, deserves more attention as a health, equity, and environmental problem. Saturated fat consumption is a major contributor to the high prevalence of cardiovascular disease in developed countries, and an emerging problem among the affluent in developing countries as well.<sup>28</sup> Current meat consumption in the United States averages 220 pounds per person per year, supplying nearly double the amount of protein we need.<sup>29</sup>

In the section “Feed People, Not Cows!” the authors make the very important observation that producing poultry and meat is an inefficient way to produce calories and nutrients for the human diet.<sup>30</sup> Lester Brown of World Watch argues further that world food production capacity cannot produce enough grain to meet world food needs if more people adopt the high meat diet of the average person in the United States. The amount and type of meat in the diet determines the total amount of grain needed. The United States has the highest per capita grain consumption in the world at about 900 kilograms of grain per capita per year.<sup>31</sup> The more meat a person consumes, the more grain that person will indirectly consume per year since grain must be fed to cattle, pigs or poultry first. On average it takes seven kilograms of grain to produce one kilogram of beef, four

27. STULL & BROADWAY, *supra* note 1, at 147-49.

28. THE NUTRITION TRANSITION: DIET AND DISEASE IN THE DEVELOPING WORLD 1-5 (Benjamin Caballero & Barry M. Popkin eds., 2002) [hereinafter THE NUTRITION TRANSITION].

29. The American Heart Association recommends no more than six ounces of cooked lean meat per day for protein needs or 136.9 pounds per year. *Eating Plan: Meat, Poultry and Fish*, American Heart Association, at <http://www.americanheart.org/presenter.jhtml?identifier=1084> (last visited Jan. 18, 2004).

30. STULL & BROADWAY, *supra* note 1, at 18.

31. W. W. NORTON & CO., STATE OF THE WORLD, 1999: A WORLD INSTITUTE REPORT ON PROGRESS TOWARD A SUSTAINABLE SOCIETY 120 (1999). Italy and Taiwan are in the middle at 400 and 300 kilograms average per capita grain consumption respectively, and India is at 200 kilograms per capita. These figures are current as of 1990. *Id.*

kilograms of grain for one kilogram of pork, and two kilograms of grain to produce one kilogram of poultry. It is much more efficient for humans to ingest the grain protein directly.

The United States is exporting both the methods of industrial animal production and the retail outlets to fuel an increased appetite for meat—and in many countries laws governing occupational health and environmental protection are much weaker than they are here. More in-depth research is needed to document fully how the consolidation and concentration of animal production has impacted the environment, communities, and health. Solutions to these problems will likely include government regulation and enforcement, as well as better-informed consumer choices. Since both depend on an informed public, we concur with the authors' views in the closing statement of their last, "Food for Thought":

Each of us chooses the food we eat, and our choices shape prevailing systems of production, processing, and packaging. The challenge for those concerned about developing a sustainable agricultural system, one that respects land, producers, harvesters, and processing workers is to show consumers the connection between the food they eat and the prevailing industrial production system. Only if we make that connection will more people demand changes in their food and how it is produced. It is to that end, that we offer this book.<sup>32</sup>

This volume is an important contribution to our understanding of the many connections between the food we eat and the industrial production system that creates that food. Anyone concerned about food security, environmental justice, and intergenerational equity with regard to use of the earth's non-renewable resources should read this book. We also hope *Slaughterhouse Blues* will stimulate much needed research to document more completely the adverse health effects of high rates of meat consumption and the adverse environmental and public health effects associated with the industrial animal production system that is needed to satisfy America's insatiable desire for large amounts of cheap meat.

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32. STULL & BROADWAY, *supra* note 1, at 158.