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## Managing Medical Bills on the Brink of Bankruptcy

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Medical men who frequently go to law to recover fees generally lose more in the end than they gain; not only because such attempts to recover often prove fruitless, but because they excite prejudice and make influential enemies.

DANIEL WEBSTER CATHELL, *THE PHYSICIAN HIMSELF FROM GRADUATION TO OLD AGE* 292 (1925).

## I. INTRODUCTION

In the vast majority of health care interactions, patients in the United States—regardless of their insurance status—bear some direct financial liability to medical providers.<sup>1</sup> Whether they are not-for-profit hospitals or for-profit small businesses, health care providers cannot be indifferent to the collection of these obligations. Consultants in medical practice management have developed and marketed extensive advice for structuring all aspects of providers' interactions with patients to mimic commercial transactions in other retail service contexts.<sup>2</sup> This advice, if successful, shields providers from the public scrutiny of after-the-fact debt collection through lawsuits and liens.<sup>3</sup>

Medical practice management affects the study of the financial burden imposed by health care. In recent years, lawmakers and scholars have debated the role of medical problems in fueling personal bankruptcy filings. Some scholars measure medical-related bankruptcy using survey techniques. Skeptics of survey-based findings often cite studies of bankruptcy court records that yield more conservative estimates. Court record studies look for evidence of claims by creditors with medical identities in the documents that bankruptcy filers submit to the court.

A clash over these methods arose directly prior to the passage of the

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1. See *infra* Part II.A.

2. See, e.g., Anna Wilde Matthews, *Beyond Co-Pay: Surprise Bills at the Doctor's; To Ensure They Get Paid, Doctors Seek Entire Bill for Patient Share Upfront*, WALL ST. J., Aug. 5, 2009, at D1 (citing a doctor reporting that office staff had to train patients to see doctor visits like a trip to Walmart—"pay before leaving").

3. For scrutiny of that debt collection, see, for example, Mark A. Hall & Carl E. Schneider, *Patients as Consumers: Courts, Contracts, and the New Medical Marketplace*, 106 MICH. L. REV. 643 (2007); George A. Nation, III, *Obscene Contracts: The Doctrine of Unconscionability and Hospital Billing of the Uninsured*, 94 KY. L. J. 101 (2005).

Bankruptcy Abuse Prevention and Consumer Protection Act of 2005.<sup>4</sup> This bill was the most significant set of amendments to the Bankruptcy Code in a generation and substantially restricted debt relief for individual filers. Lawmakers who opposed the bankruptcy bill cited a 2005 study by Himmelstein, Thorne, Warren, and Woolhandler finding that approximately half of bankruptcies were medical-related.<sup>5</sup> Supporters of the bankruptcy bill countered with a court record analysis conducted within the Department of Justice (DOJ). According to the DOJ analysis, over half of the sample (54%) had no medical debt at all, the average medical debt among those with any such debt was under \$5,000, and medical debt comprised only 5.5% of the total unsecured debt of the sample.<sup>6</sup> More recently, debates about health care finance intensified public interest in the financial impact of medical bills and these methodological disputes. In the summer of 2009, Himmelstein et al. reported that 62% of personal bankruptcies could be construed as medical-related.<sup>7</sup> President Obama used medical bankruptcy rates as a rationale for health care reform.<sup>8</sup> Lawmakers held hearings on whether the current health care system is bankrupting American families. At one such hearing in July 2009, Representative John Conyers cited the

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4. Bankruptcy Abuse Prevention and Consumer Protection Act of 2005, Pub. L. No. 109-8, 119 Stat. 23 (2005).

5. *See infra* Part II.A.2.

6. *See infra* p. 265, tbl.1.

7. David U. Himmelstein, Deborah Thorne, Elizabeth Warren & Steffie Woolhandler, *Medical Bankruptcy in the United States, 2007: Results of a National Study*, 122 AM. J. MED. 741, 742 (2009).

8. President Obama cited the Himmelstein study during his campaign and has continued to reference the connection between medical bills and bankruptcy in statements to Congress. *See* BARACK OBAMA AND JOE BIDEN'S PLAN TO LOWER HEALTH CARE COSTS AND ENSURE AFFORDABLE, ACCESSIBLE HEALTH COVERAGE FOR ALL 1, 1 (2008), <http://www.barackobama.com/pdf/issues/HealthCareFullPlan.pdf> ("Over half of all personal bankruptcies today are caused by medical bills."). In an address to a joint session of Congress in early 2009, the President stated that "the crushing cost of health care . . . is a cost that now causes a bankruptcy in America every thirty seconds." President Barack Obama, Address to Joint Session of Congress (Feb. 24, 2009), available at [http://www.whitehouse.gov/the\\_press\\_office/remarks-of-president-barack-obama-address-to-joint-session-of-congress](http://www.whitehouse.gov/the_press_office/remarks-of-president-barack-obama-address-to-joint-session-of-congress). "In a letter to Democratic Senate leaders . . . the President said: 'Health-care reform is not a luxury. . . . [S]piraling premiums and out-of-pocket expenses are pushing [families] into bankruptcy and forcing them to go without the checkups and prescriptions they need.'" Catherine Arnst, *Study Links Medical Costs and Personal Bankruptcy*, BLOOMBERG BUSINESSWEEK, June 4, 2009, [http://www.businessweek.com/bwdaily/dnflash/content/jun2009/db2009064\\_666715.htm](http://www.businessweek.com/bwdaily/dnflash/content/jun2009/db2009064_666715.htm).

Himmelstein study as evidence that health care reform was urgently needed.<sup>9</sup> But a scholar from the American Enterprise Institute countered by citing the earlier DOJ court record analysis and its more modest assessment of the role of medical debt in bankruptcy.<sup>10</sup>

Here, we provide the first attempt to reconcile these competing methods of measuring medical burden, applying both the survey method and court record method to the same set of filers in a single dataset. Our dataset, the 2007 Consumer Bankruptcy Project (“2007 CBP”), is a nationally representative sample of people who filed for bankruptcy in early 2007. This dataset consists of hundreds of variables from court records, questionnaires, and telephone interviews. It was compiled by professors of law, medicine, and sociology at seven major research universities, including one of the authors of this Article.

The court record medical debt in our sample is patterned very consistently with the earlier DOJ sample. Someone who used the DOJ analysis to suggest that medical bills were not a problem in bankruptcy presumably would be nearly as happy to cite the court record analysis of our dataset.

However, when we compare the court record method and survey method as applied to the same dataset, court records routinely reflect smaller or even zero medical obligations for filers who report out-of-pocket expenses on the questionnaire. Indeed, one out of four respondents who explicitly reported medical bills as a reason for filing for bankruptcy has court records with zero identifiable medical debt.

After exploring several theories for these discrepancies, we observe that the deviations are quite consistent with filers’ medical bill management. In other words, due to credit use, the court record method is incapable of capturing some of the most significant medical obligations incurred before bankruptcy. For example, respondents who reported significant out-of-pocket expenses, but had little or no detectable medical debt in their court records, reported credit card and mortgage use for medical bills at significantly higher rates than other respondents.<sup>11</sup> Respondents who specifically cited medical bills as a reason for filing for bankruptcy mortgaged their homes to pay medical bills at *nearly four*

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9. See *Medical Debt: Is Our Healthcare System Bankrupting Americans: Hearing Before the Subcomm. on Commercial and Administrative Law of the H. Comm. on the Judiciary*, 111th Cong. 4 (July 28, 2009) (opening statement of Rep. John Conyers, Jr.), available at <http://judiciary.house.gov/hearings/pdf/Conyers090728.pdf>.

10. See *id.* at 10 (written testimony of Aparna Mathur, Research Fellow, American Enterprise Institute), available at <http://judiciary.house.gov/hearings/pdf/Mathur090728.pdf>.

11. See *infra* p. 276, fig.4.

*times* the frequency of other filers.<sup>12</sup> They also were more than a third more likely than other filers to use credit cards for medical bills.<sup>13</sup> These mortgages and credit card bills are invisible in the court record method because they bear no sign of medical identity. Thus, the court record method, by itself, produces an estimate of medical burden that is not merely more conservative across the board, but skewed.

The distortion in the court record method does not seem to apply to all demographic groups uniformly, probably due to factors we cannot directly measure, such as access to credit and access to health care. Thus, interesting patterns emerge when we disaggregate our national sample on the basis of age, race, sex, and housing tenure. Court records make some filers appear as if they had incurred distinctively high medical debt because they were less likely to use credit cards or mortgages for medical bills. For similar reasons, other groups of filers have quite similar medical debts in the court records even though they incurred very different amounts of medical obligation prior to filing. Again, significant variations in medical debt management alter the picture the court records provide.

The findings reveal the problems with relying exclusively on court records to measure the financial impact of medical care. They also provide another perspective on the financial end of medical practice with which this article began. As previously noted, non-legal writings advise how medical providers should manage the risk of transacting with patients, in part because these writers have long feared that patients will put doctors at the bottom of the priority list of bills to pay.<sup>14</sup> The respondents in the current study often were facing financial difficulties when they sought medical care.<sup>15</sup> Yet, by the time they filed for bankruptcy, respondents had considerably reduced providers' direct financial exposure. This suggests that even patients with modest incomes and high debt-to-income ratios feel a sense of responsibility to their doctors. Alternatively, they are responding to providers' encouragements to reduce their direct liability.

12. *See infra* p. 274, fig.3.

13. *Id.*

14. *See, e.g.*, DANIEL WEBSTER CATHELL, *THE PHYSICIAN HIMSELF FROM GRADUATION TO OLD AGE* 292 (1925). *See also* sources cited *infra* Part IV.

15. In telephone interviews with a large subset of respondents in our sample, 44% reported that they had seriously struggled financially for more than two years before filing for bankruptcy. An additional 27% reported serious struggling for more than one year. We do not have this information for all respondents in the sample, but the telephone survey subsample is not significantly different from the whole regarding variables such as filing status, chapter, total assets, total debts, priority debts, monthly income, and home value. *See infra* text accompanying note 100.

This Article proceeds with the following Parts. Part II.A offers background on out-of-pocket medical bills and medical practice management advice. It then contextualizes our study by reviewing the methodological and political dispute over measuring medical burden among bankruptcy filers. Part II.B describes our dataset, giving special attention to the new questions and variables that enabled this study. Part III reports our findings. Part IV highlights some implications of our study for understanding the burden of health care spending on families and medical practice management.

## II. BACKGROUND AND METHODOLOGY

### *A. Managing Out-of-Pocket Liability*

#### *1. In General*

For many reasons, today's health care finance system expressly imposes cost-sharing and direct patient liability on patients who are covered by health insurance.<sup>16</sup> According to The Coker Group, a health care industry consultant firm, 90% of patients owe money directly at the time of service.<sup>17</sup> Furthermore,

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16. See generally PAUL B. GINSBURG, ROBERT WOOD JOHNSON FOUND., HIGH AND RISING HEALTH CARE COSTS: DEMYSTIFYING U.S. HEALTH CARE SPENDING 19 (2008), available at <http://www.rwjf.org/files/research/101508.policysynthesis.costdrivers.rpt.pdf> (discussing consumer financial exposure as a method of controlling health care spending on low-value new technologies, assuming consumers have sufficient information); JONATHAN GRUBER, KAISER FAM. FOUND., THE ROLE OF CONSUMER COPAYMENTS FOR HEALTH CARE: LESSONS FROM THE RAND HEALTH INSURANCE EXPERIMENT AND BEYOND 1 (2006) (describing cost-sharing and reporting impact on utilization and health outcomes); MILLIMAN, 2008 MILLIMAN MEDICAL INDEX 9 (2008) (of the "\$15,609 total medical cost for a family of four under a PPO . . . the employee pays about \$6,167," \$2,675 of which is paid in cost-sharing at time of service); McKinsey & Company, *Why Americans Pay More for Health Care*, MCKINSEY Q., Dec. 2008, at 9 (noting that the "average" health care consumer pays 12% of the total cost directly out-of-pocket, in addition to 25% of the premium cost); Kaiser Fam. Found., *Snapshots: Health Care Costs: Distribution of Out-of-Pocket Spending for Health Care Services*, May 2006, <http://www.kff.org/insurance/snapshot/chcm050206oth.cfm> (noting that the average share paid out-of-pocket by non-elderly people with private insurance and any health spending in 2003 was 34%); Ann Kjos, *New Prospects for Payment Card Application in Health Care*, Federal Reserve Bank Philadelphia Payment Cards Center Discussion Paper 1 (Nov. 2008), available at <http://www.phil.frb.org/payment-cards-center/publications/discussion-papers/2008/D2008NovemberHealthCareCardApplication.pdf> ("[O]ut-of-pocket expenditures, which consumers pay directly to medical service providers, are not insignificant and are expected to grow from the current level of about \$269 billion.").

17. THE COKER GROUP, MAXIMIZING BILLING AND COLLECTIONS IN THE MEDICAL PRACTICE 41

obligations to be collected directly from patients represent, on average, 15-20% of a medical provider's receivables.<sup>18</sup> At least prior to the enactment of health care finance reform, the Centers for Medicare and Medicaid Services predicted continued increases in patient out-of-pocket payments.<sup>19</sup> In an analysis of a recent Medical Expenditure Panel Survey, the authors reported that a fifth of privately insured non-elderly families had out-of-pocket obligations exceeding 5% of their incomes.<sup>20</sup>

As an interesting sign of the times regarding direct medical obligations, a few years ago a bank started issuing a "Healthcare Visa Gift Card."<sup>21</sup> The website for the Visa card lists a variety of occasions for which such a gift might be appropriate.<sup>22</sup> Although new card orders are no longer being taken, the vendor of the cards called them a "hot new Christmas gift."<sup>23</sup> Gift-givers could get the card in amounts ranging from \$25 to \$5,000, and using the card would be fee-free for the recipient for eight months, after which the recipient would pay a monthly maintenance fee of \$1.50.<sup>24</sup> Existing cards may be used for health club membership and totally elective surgery as well as for dental care and co-pays at doctors' offices.<sup>25</sup>

Certainly many people with modest out-of-pocket obligations or higher

(2007).

18. Mitch Patridge & Doug Barry, *Compassionate Patient Financing Can Cure a Hospital's Financial Ills*, 32 J. HEALTH CARE FIN. 168, 171 (2006); Richard Haugh, *Financial Aid: From Direct Debits to New Loans, Patients Get New Ways To Pay Off Hospital Bills*, HOSP. & HEALTH NETWORKS, Nov. 2006, at 18. Patridge and Barry note that these receivables represent only 2-5% of net revenue due to insufficient collection practices. See Patridge & Barry, *supra*.

19. See Christopher J. Truffer et al., *Health Spending Projections Through 2019: The Recession's Impact Continues*, 29 HEALTH AFF. 522, 526 (2010) (noting a 4.8% average annual percentage growth for out-of-pocket payments over the projection period 2009-2019).

20. See GRUBER, *supra* note 16, at 11. This excludes insurance premiums. See, e.g., DIDEM BERNARD & JESSICA BANTHIN, MED. EXPENDITURE PANEL SURV., FAMILY-LEVEL EXPENDITURES ON HEALTH CARE AND INSURANCE PREMIUMS AMONG THE U.S. NONELDERLY POPULATION, 2004, 14, 15 (2007) (defining terms used in MEPS surveys).

21. See Givewell.com, Where To Use It, <http://www.givewell.com/where-to-use> (last visited Apr. 1, 2010) ("Promote happiness, give a Healthcare Visa Gift Card").

22. See Givewell.com, Occasions To Give, <http://www.givewell.com/occasions-to-give> (last visited Apr. 1, 2010).

23. *Medical Gift Cards Trendy*, HEALTH CARE COLLECTOR (Aspen Publishers, New York, N.Y.), Feb. 2008, at 11.

24. See Givewell.com, How It Works, <http://www.givewell.com/how-it-works/> (last visited April 2, 2010).

25. *Id.*

incomes pay immediately and without serious consequence. But contemporary studies continue to report that cost-sharing results in delinquent medical debt with some prevalence,<sup>26</sup> even for routine care.<sup>27</sup> Nationally representative studies estimate that tens of millions of households have accrued medical debt and/or have problems paying medical bills.<sup>28</sup> Concerns about medical debt are longstanding and have transcended the evolution of health care finance.<sup>29</sup>

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26. Many published papers and unpublished online policy briefs make this point. For recent examples, see ANDREW COHEN & CAROL PRYOR, IN DEBT BUT NOT INDIFFERENT: CHAPTER 58 AND THE ACCESS PROJECT'S MEDICAL DEBT RESOLUTION PROGRAM (2008), available at <http://www.accessproject.org/adobe/InDebtButNotIndifferent.pdf>; SIDNEY D. WATSON ET AL., LIVING IN THE RED: MEDICAL DEBT AND HOUSING SECURITY IN MISSOURI (2007), available at [http://www.accessproject.org/adobe/living\\_in\\_the\\_red.pdf](http://www.accessproject.org/adobe/living_in_the_red.pdf); Cathy Schoen et al., *How Many Are Underinsured? Trends Among U.S. Adults, 2003 and 2007*, 27 HEALTH AFF. w298, w304 tbl.4 (2008) (reporting that increasingly significant proportions of insured population pay out-of-pocket).

27. See, e.g., PAUL FRONSTIN & SARA R. COLLINS, EMPLOYEE BENEFIT RESEARCH INST., FINDINGS FROM THE 2007 EBRI/COMMONWEALTH FUND CONSUMERISM IN HEALTH SURVEY 9-10 (2008); WILLIAM LOTTERO ET AL., LOSING GROUND: ERODING HEALTH INSURANCE COVERAGE LEAVES KANSAS FARMERS WITH MEDICAL DEBT 10 (2006), available at [http://www.accessproject.org/adobe/losing\\_ground.pdf](http://www.accessproject.org/adobe/losing_ground.pdf) (nearly 60% with medical debt reported owing money for routine care); Jessica S. Banthin, Peter Cunningham & Didem M. Bernard, *Financial Burden of Health Care, 2001-2004*, 27 HEALTH AFF. 188 (2008) (studying out-of-pocket obligations plus premium costs across population); PETER J. CUNNINGHAM, CAROLYN MILLER & ALWYN CASSIL, LIVING ON THE EDGE: HEALTH CARE EXPENSES STRAIN FAMILY BUDGETS 3 (Ctr. for Studying Health Sys. Change, Res. Brief No. 10, 2008), available at <http://www.hschange.com/CONTENT/1034/1034.pdf> (explaining how trouble paying medical bills can result from non-catastrophic expenses).

28. In a Commonwealth Fund study, 72 million "working age" people and an additional 7 million over 65 had accrued medical debt and/or problems paying medical bills, an increase over earlier studies. See SARA R. COLLINS ET AL., LOSING GROUND: HOW THE LOSS OF ADEQUATE HEALTH INSURANCE IS BURDENING WORKING FAMILIES: FINDINGS FROM THE COMMONWEALTH FUND BIENNIAL HEALTH INSURANCE SURVEYS, 2001-2007, vii (Commonwealth Fund Issue Brief, 2008), available at <http://www.commonwealthfund.org/Content/Publications/Fund-Reports/2008/Aug/Losing-Ground--How-the-Loss-of-Adequate-Health-Insurance-Is-Burdening-Working-Families--8212-Finding.aspx>; see also Schoen et al., *supra* note 26 (reporting 16% were contacted by debt collectors about medical bills). In another study, 57 million people in 2007 (14 million more than in 2003) were in households with trouble paying medical bills. PETER J. CUNNINGHAM, TRADE-OFFS GETTING TOUGHER: PROBLEMS PAYING MEDICAL BILLS INCREASE FOR U.S. FAMILIES 2003-2007, 1 (Center for Studying Health Sys. Change, Tracking Rep. No. 21, 2008), available at <http://www.hschange.com/CONTENT/1017/1017.pdf>.

29. See, e.g., Jonathan Cohn, *This Won't Hurt a Bit: Health Care Reform for Dummies*, NEW REPUBLIC, Feb. 18, 2009, at 18 (reporting on the Committee on the Costs of Medical Care from the

Health policy researchers and patient advocates have articulated specific worries about how medical debt affects patients and their families. Prominent examples of such worries include the following: patients may self-ration medically necessary care and drugs;<sup>30</sup> medical providers may deny non-emergency care;<sup>31</sup> patients may self-ration important *non*-medical expenses;<sup>32</sup> providers or their designees may engage in harsh formal debt collection activity;<sup>33</sup> patients may experience adverse psychological consequences from fear about medical debt that in turn may aggravate health conditions;<sup>34</sup> certain demographic groups may be disproportionately impacted by cost-related or debt-related access problems;<sup>35</sup> and patients may experience pressures to convert

1930s and the concern that medical bills destabilize household finances); Editorial, *Most People Need No Aid To Pay the Doctor's Bill*, SATURDAY EVENING POST, Jan. 10, 1953, at 10, 12 (arguing that U.S. News story was an overreaction to data from academic study); *Special Report: Doctor Bills Pile Up: How Can Families Pay?*, U.S. NEWS & WORLD REP., Oct. 17, 1952, at 65-70 (reporting on academic study finding that one in five families had outstanding medical debt).

30. This point is frequently made. For a few recent entries to the literature, see, for example, PETER J. CUNNINGHAM & LAURIE E. FELLAND, *FALLING BEHIND: AMERICANS' ACCESS TO MEDICAL CARE DETERIORATES, 2003-2007*, 2 (Center for Studying Health Sys. Change, Tracking Rep. No. 19, 2008), available at <http://www.hschange.com/CONTENT/993/993.pdf> (noting cost was “most frequently cited—and growing—obstacle to care”); Cathy Schoen et al., *In Chronic Condition: Experiences of Patients with Complex Health Care Needs, in Eight Countries, 2008*, 28 HEALTH AFF. w1, w5 (2008) (discussing cost-related deterrence of treatment, particularly among U.S. patients); Robert W. Seifert & Mark Rukavina, *Bankruptcy Is the Tip of a Medical-Debt Iceberg*, 25 HEALTH AFF. w89, w90 (2006).

31. See, e.g., CUNNINGHAM, *supra* note 28, at 3 (“In 2007, about 10 percent of people with medical bill problems reported being denied care by medical providers directly as a result of their medical bill problems.”).

32. See, e.g., Cunningham et al., *supra* note 27, at 4-5 (discussing families who are late on mortgages and cut down other expenses due to medical bill problems); *id.* at 8 (discussing choice between medical bills and keeping children housed and fed); Robert W. Seifert, *Home Sick: How Medical Debt Undermines Housing Security*, 51 ST. LOUIS U. L.J. 325 (2007).

33. See generally Melissa B. Jacoby & Elizabeth Warren, *Beyond Hospital Misbehavior: An Alternative Account of Medical-Related Financial Distress*, 100 NW. U. L. REV. 535 (2006) (documenting concerns of patient advocates).

34. See, e.g., CAROL PRYOR, ANDREW COHEN & JEFFREY PROTAS, *THE ILLUSION OF COVERAGE 9* (2007), available at [http://www.accessproject.org/adobe/the\\_illusion\\_of\\_courage.pdf](http://www.accessproject.org/adobe/the_illusion_of_courage.pdf); Wilhelmine Miller, Elizabeth Richardson Vidgor & Willard G. Manning, *Covering the Uninsured: What Is It Worth?*, HEALTH AFF. W4-157, W4-162 (Web Exclusive Mar. 2004) (“The social stigma and psychological stresses of medical indigency, health care debt, and bill collection efforts are themselves burdensome.”).

35. See, e.g., ELIZABETH M. PATCHIAS & JUDITH WAXMAN, *WOMEN AND HEALTH COVERAGE:*

medical debt into third-party credit that could substantially increase the size of those bills and other consequences.<sup>36</sup>

The world looks different from the perspective of the medical practice management field. As the following paragraphs will illustrate, writers in this field focus on protecting health care *providers*, rather than patients, from unpaid debt. While scholars from many disciplines continue to debate whether medical care should be treated as an ordinary commodity,<sup>37</sup> those on the front lines of practical

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THE AFFORDABILITY GAP 5-6 (Commonwealth Fund Issue Brief, 2007), available at <http://www.nwlc.org/pdf/NWLCCommonwealthHealthInsuranceIssueBrief2007.pdf> (reporting on medical debt among people with health insurance).

36. See, e.g., SARA COLLINS ET AL., THE COMMONWEALTH FUND, THE AFFORDABILITY CRISIS IN HEALTH CARE: FINDINGS FROM THE COMMONWEALTH FUND BIENNIAL HEALTH INSURANCE SURVEY 32 (2004), available at [http://www.commonwealthfund.org/usr\\_doc/collins\\_biennial2003\\_723.pdf](http://www.commonwealthfund.org/usr_doc/collins_biennial2003_723.pdf) (one in five medical debtors had large credit card debt or home mortgage to pay medical bills); DEMOS & CTR. FOR RESPONSIBLE LEARNING, THE PLASTIC SAFETY NET: THE REALITY BEHIND DEBT IN AMERICA 56-57 (2005), available at [http://www.demos.org/pubs/PSN\\_low.pdf](http://www.demos.org/pubs/PSN_low.pdf) (reporting that medical bills contributed to credit card debt for 29% of low and middle income households); NAT'L CONSUMER LAW CTR., UNHEALTHY PURSUITS: HOW THE SICK AND VULNERABLE ARE HARMED BY ABUSIVE MEDICAL COLLECTION TACTICS, 36 (2005), available at <http://www.consumerlaw.org/news/content/medicaldebt.pdf> (suggesting that providers have encouraged patients to take on high-cost credit for bills); CINDY ZELDIN & MARK RUKAVINA, BORROWING TO STAY HEALTHY: HOW CREDIT CARD DEBT IS RELATED TO MEDICAL EXPENSES (2007), available at [http://www.demos.org/pubs/healthy\\_web.pdf](http://www.demos.org/pubs/healthy_web.pdf); Cunningham et al., *supra* note 27 (giving examples of credit card, mortgages, and personal loan use for medical bills); Brian Grow & Robert Berner, *Fresh Pain for the Uninsured: As Doctors and Hospitals Turn to GE, Citigroup, and Smaller Rivals To Finance Patient Care, the Sick Pay Much More*, BUS. WK., Dec. 3, 2007, at 34 (reporting on loan arranging for bills of patients who were unaware of the third-party arrangement); USA Today/Kaiser Family Foundation/Harvard School of Public Health, Health Care Costs Survey, Summary and Chartpack, Chart 3 (Aug. 2005), available at <http://www.kff.org/newsmedia/upload/7371.pdf> (reporting that 8% borrowed money or got second mortgages because of problems with paying medical bills). In a recent tracking survey, about one in ten respondents with problems paying medical bills reported that their providers suggested that they take out loans to meet their health care obligations. CUNNINGHAM, *supra* note 28. Two national publications recently cited Senator Grassley's concern that medical providers are "cozying up to banks, debt buyers, and credit card companies over patients' medical bills." Grow & Berner, *supra*, at 34 (quoting a statement that Senator Grassley provided to Business Week); *Overdose of Debt: Lenders Push Risky Credit for Everything from Cancer Care to Botox*, CONSUMER REPS., July 2008, at 14, 18 (reporting the same statement).

37. Philip E. Tetlock, *Coping with Trade-Offs: Psychological Constraints and Political Implications*, in ELEMENTS OF REASON: COGNITION, CHOICE, AND THE BOUNDS OF RATIONALITY 251 (Arthur Lupia et al. eds., 2000) ("Liberals view the buying and selling of conventional medical

advice to providers largely proceed from the assumption of commercial exchange.<sup>38</sup> For the most part, a report published by the American Medical Association strongly emphasizes this theme, reminding doctors, “It’s your money—ask for it!”<sup>39</sup>

Medical practice management writings instruct providers on such matters as: how to get payments up front (including before services are rendered);<sup>40</sup> how to

services and, to some degree, legal services as suspect categories—people seem to be buying health, life, and justice—whereas conservatives are not bothered by such transactions.”); Mark A. Hall & Carl E. Schneider, *The Professional Ethics of Billing and Collections*, 300 JAMA 1806 (2008); Pamela Hartzband & Jerome Groopman, *Money and the Changing Culture of Medicine*, 360 NEW ENG. J. MED. 101 (2009); Marc A. Rodwin, *Medical Commerce, Physician Entrepreneurialism, and Conflicts of Interest*, 16 CAMBRIDGE Q. HEALTHCARE ETHICS 387 (2007); Deborah A. Stone, *The Doctor as Businessman: The Changing Politics of a Cultural Icon*, 22 J. HEALTH POL. POL’Y & L. 533 (1997).

38. See generally Hall & Schneider, *supra* note 37 (discussing model generally used by health care providers).

39. Specifically, The Coker Group report advises:

If, for some reason, the patient indicates an inability to make a payment, the staff member should call the billing manager . . . The manager should take the patient to a private room to discuss payment. The element of authority imposed by the billing or practice manager indicates that nonpayment is unacceptable. At the discretion of the manager, the patient may be allowed to leave without paying, but, preferably, with an agreed-upon plan for payment. In some cases, a fee should be charged if the patient is to be billed. . . . The long-range goal is to develop the understanding that arrangements for payments must be made in advance of the patient encounter. As with most matters related to credit and collection policy, it is essential to be consistent across the patient base. Consistent patterns of collection inform both the staff and the patients that direct patient payment is important. It’s your money—ask for it!

THE COKER GROUP, *supra* note 17, at 42-43.

40. See, e.g., Judy Capko, *Physicians Practice Pearls: You Earned It, Now Collect It*, PHYSICIANS PRAC., June 2007, available at <http://www.physicianspractice.com/index/fuseaction/articles.details/articleID/1008.htm> (recommending payments at time of service); Pamela Lewis Dolan, *Collecting the Patient Portion: Being Proactive, Early and Often*, AM. MED. NEWS, April 2, 2007, at 18 (citing health care consultant saying “‘Everyone needs to sign on that we are going to collect co-pays at the time of service.’ . . . The patient needs to be reminded over and over that this is the new system.”); Kim LaFontana & Kim Williams, *Practice Management Lab: Finding Success with Self-Pay*, PHYSICIANS PRAC., July/Aug. 2006, available at <http://www.physicianspractice.com/index/fuseaction/articles.details/articleID/858.htm> (referring to time of service as the “golden moment” for collecting payments from patients); Deborah Shapiro, *How To Address Patient Payments: Can’t Pay . . . Won’t Pay . . . Should Pay*, HEALTH CARE COLLECTOR (Aspen Publishers, New York, N.Y.), Mar. 2008, at 3 (“The best time to collect money from patients is before the service is rendered, or at least right after the service and before they walk out the door.”).

financially screen patients;<sup>41</sup> when to terminate or embargo patients for nonpayment;<sup>42</sup> how to physically arrange a medical office or hospital to encourage payment;<sup>43</sup> what color envelopes should be used for medical bill collection letters;<sup>44</sup> and even the optimal physical posture a staff member should

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41. For evidence of interest in financial screening of patients, see, for example, Emily Berry, *Taking a Financial History: Determining the Health of Your Patient's Credit Rating*, AM. MED. NEWS, Jan. 19, 2009, at 15; *Financial Triage: Innovative Ways That Hospitals Are Looking at Patient Finances*, BUS. WK., Nov. 20, 2008; Dave Hansen, *Giving Credit To Get What's Due: How Doctors Can Help Patients Pay the Bill*, AM. MED. NEWS, Jan. 21, 2008, at 15; *Overdose of Debt: Lenders Push Risky Credit for Everything from Cancer Care to Botox*, CONSUMER REPS., July 2008, at 14, 17 (reporting on hospitals' use of credit scores or credit reports, and Equifax's Payment Predictor system); *Maximizing Self-Pay Collections: Moving the Process Ahead*, HEALTH CARE COLLECTOR (Aspen Publishers, New York, N.Y.), Jan. 2009, at 10 (discussing how hospitals may wish to use credit scoring or reporting "to get a glimpse of the patient's financial situation"); Judy I. Veazie, *Point-of-Service Collections: When It's Too Late To Collect*, HEALTH CARE COLLECTOR (Aspen Publishers, New York, N.Y.), Feb. 2009, at 4, 5 (reporting the use of credit reports by providers to determine an approach for the self-pay portion of bills).

42. See, e.g., ROBERT J. SOLOMON, *THE PHYSICIAN MANAGER'S HANDBOOK: ESSENTIAL BUSINESS SKILLS FOR SUCCEEDING IN HEALTH CARE* 107-08 (2d ed. 2008) (proposing a sample collection plan, providing suspension of future appointments for a patient who misses two successive co-payments until payment is satisfied); THE COKER GROUP, *supra* note 17, at 41, 57 (recommending the dismissal of a chronic non-paying patient from a medical practice, particularly if it seems that the patient is not really in financial hardship); Dolan, *supra* note 40, at 18 (paraphrasing Jeff Peters, CEO of Health Directions, a Chicago-based consulting firm, "[t]here's no crime in telling patients their balance must be paid or arrangements for payment be made before they get another appointment"); Shirley Grace, *Physician Beware: 'The Dog Ate My Checkbook'*, PHYSICIANS PRAC., Feb. 2009, available at <http://www.physicianspractice.com/index/fuseaction/articles.details/articleID/1285.htm>; Wayne J. Guglielmo, *When Patients Can't Pay: You'll Collect More of What You're Owed—and Enhance Loyalty—If You Have a Payment Plan*, MED. ECON., June 3, 2005, at 49. One author compared conditioning treatment on payment for prior service to conditioning a future movie rental on payment for a prior rental. Curt Mayse, *Front Desk as Profit Center*, PHYSICIANS PRAC., Apr. 2005, available at <http://www.physicianspractice.com/index/fuseaction/articles.details/articleID/641.htm>.

43. See, e.g., Suz Redfean, *Pay Up, Self-Payer: Getting the Most from Patients Who Pay Out-of-Pocket*, PHYSICIANS PRAC., Mar./Apr. 2002, available at <http://www.physicianspractice.com/index/fuseaction/articles.details/articleID/293.htm> (recommending that offices be set up to require patients to pass the collections desk on the way to the exit).

44. See, e.g., *Ten Tips for Improving Collection Letters*, HEALTH CARE COLLECTOR (Aspen Publishers, New York, N.Y.), Mar. 2009, at 12 (recommending medical providers "[t]est pastel-colored envelopes that will stand out against other mail" and "the use of PS to emphasize. . . strongest points" relating to collection).

assume when attempting to collect from patients.<sup>45</sup> Sources recommend making a “game” out of billing for employees to maximize receipts<sup>46</sup> or motivating billing and collections employees with coffee cups, T-shirts, gift certificates, additional vacation days, or merit certificates.<sup>47</sup>

If doctors adhere to the advice with some success, they may be able to avert the need for formal and more public *ex post* debt collection efforts.<sup>48</sup> The practice management literature thus implicitly and explicitly encourages medical providers to shift the risk of patient default to third-party creditors: the common advice is, whenever possible, to “push the problem of nonpayment on to someone else.”<sup>49</sup>

45. *Collecting Assertively Is an Acquired Skill: Confidence and Empathy Are Key*, HEALTH CARE COLLECTOR (Aspen Publishers, New York, N.Y.), Dec. 2007, at 7, 8 (recommending “good posture—no slouching” while collecting medical bills in person or on the phone).

46. Dolan, *supra* note 40.

47. THE COKER GROUP, *supra* note 17, at 38.

48. See, e.g., Robert B. Avery et al., *An Overview of Consumer Data and Credit Reporting*, 89 FED. RES. BULL. 47, 67, 69 (2003) (using earlier data, estimating that medical bills accounted for 18.2% of court judgments on credit reports and 52.2% of collection agency actions).

49. Karen Caffarini, *Keeping Rubber Checks from Clogging Revenue Flow*, AM. MED. NEWS, Jan. 26, 2009, at 13; see also SOLOMON, *supra* note 42 (to make patient prioritize medical bills, “[r]emind the patient that he or she can use a credit card”); THE COKER GROUP, *supra* note 17, at 41; Jeffrey C. Levitt, *Transfer of Financial Risk and Alternative Financing Solutions*, 30 J. HEALTH CARE FIN. 21, 26 (2004) (“Likewise, medical providers would rather have another party take the financial exposure from patients rather than keep it on their own balance sheets. They are in the business of providing health care, not consumer financing.”); Patridge & Barry, *supra* note 18, at 169-170 (“Whether in the form of credit cards, bank loans, or the more widely used electronic paper-free funding programs, it is critical that the hospital offer reasonable options to the patient without placing additional financial burdens on the hospital, such as carrying long-term payment plans.”); Dolan, *supra* note 40 (reporting on consultant advising that medical practices should accept “all credit cards”); Mari Edlin, *A Fair Trade?: Make Payment Policies Fair and Legal*, PHYSICIANS PRAC., Nov. 2001, available at <http://www.physicianspractice.com/index/fuseaction/articles.details/articleID/270.htm> (citing practice manager saying: “We’re not a bank. Take out a loan or charge it.”); Guglielmo, *supra* note 42 (noting that experts suggest encouraging patients to put bill on credit card, rather than payment plan with provider, if patient is employed and not in particularly bad financial shape to “shift[ ] the credit burden . . . to the credit card company”); Pamela Moore, *Billing and Collections: Playing Hardball: Advice on Charging Interest and Late Fees on Past-Due Patient Accounts*, PHYSICIANS PRAC., Apr. 2008, available at <http://www.physicianspractice.com/index/fuseaction/articles.details/articleID/1142.htm>

(encouraging providers to get patients to use credit cards for balances, or to encourage patients to borrow money from companies like CareCredit so “patient can work out his troubles with someone else”); Redfearn, *supra* note 43 (citing consultant recommending that providers “forge relationships

Credit cards facilitate the expectation in the health care marketplace that the patient will resolve the self-pay portion of a medical bill in a “retail business” fashion at the time of service.<sup>50</sup> Health care is analogized to hotels and car rental businesses when authors recommend that medical providers take credit card imprints before seeing or treating the patient.<sup>51</sup> Health industry consultants have extended such analogies by recommending “sales finance programs similar to those offered by appliance and auto dealers” for particularly large out-of-pocket medical expenditures.<sup>52</sup>

Providers and hospitals commonly take credit cards notwithstanding the servicing fees they must pay,<sup>53</sup> and a Federal Reserve Payment Card Center researcher has noted that doctors’ offices more routinely include credit and debit card kiosks.<sup>54</sup> Not surprisingly, providers that have minimized ongoing patient receivables report a higher rate of identifying credit cards as an acceptable

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with local banks that can quickly arrange to grant small loans to patients”).

50. See Elizabeth S. Roop, *Debt Load: Building a Better Payment Plan (for Hospitals and their Patients)*, 82 HOSPITALS & HEALTH NETWORKS 46, 47 (June 2008) (reporting on how a medical facility “vigorously pursues upfront payments . . . [p]atients are given the opportunity to make a payment over the phone, which speeds collection for the hospital. A 20 percent discount is provided for up-front payments. . .”); Hansen, *supra* note 41; Kris Hundley, *As Medical Costs Grow, Creditors Get in the Game*, TAMPA BAY TIMES, Feb. 24, 2008, at 1D, available at 2008 WLNR 3634947 (referring to retail business model); Patrick Reilly, *Extracting Payment; Hospitals Try Collecting Before Patients Leave ER*, MOD. HEALTHCARE, Nov. 17, 2003, at 8; Veazie, *supra* note 41, at 4, 5 (“Point-of-service tools, including the acceptance of credit cards, are very important.”).

51. Nick A. LeCuyer & Shubham Singhal, *Overhauling the US Health Care Payment System*, MCKINSEY Q., June 2007, at 6 (Web Exclusive), available at <https://www.tipaaa.com/pdf/Overhauling%20the%20US%20Health%20Care%20Payment%20System-McKinsey%20Report.pdf> (offering hotel and car rental analogy); Jayne Oliva, *Consumer Directed Health Care: Zeroing in on Physician Practices*, PHYSICIAN EXECUTIVE, May/June 2005, at 66, 67 (“Today’s self-service generation will impel health care to mirror the banking industry” in terms of service delivery formats.).

52. LeCuyer & Singhal, *supra* note 51, at 6.

53. See, e.g., Jonathan G. Bethely, *Collecting Patients’ Share Up-Front Getting Easier*, AM. MED. NEWS, Feb. 27, 2006, at 1; Edlin, *supra* note 49 (noting that majority of physician offices accept credit cards); Levitt, *supra* note 49 (reporting that most hospitals accept credit cards for payment). *But see Credit Cards and Medical Expenses: Combination Creates Dilemma for Patients, Providers*, RECEIVABLES REP., Apr. 2007, at 3 (citing a *Hospital Accounts Receivable Analysis* survey in which only 47% of hospitals reported offering their patients the option of paying bills with credit cards).

54. Kjos, *supra* note 16.

method of payment (92.2%).<sup>55</sup> Although the total volume of credit card expenditures for medical bills remains murky, estimates are in the tens of billions and, at least before the implementation of the Credit Card Accountability, Responsibility, and Disclosure (CARD) Act of 2009, were expected to multiply.<sup>56</sup>

Issues surrounding medical billing and payment are complicated further in the context of emergency hospital care. The Emergency Medical Treatment and Active Labor Act, enacted in 1986, requires that hospitals provide services to anyone in need of emergency care, regardless of ability to pay.<sup>57</sup> With emergency room revenue (or any revenue) being important to a hospital's bottom line,<sup>58</sup> much management literature advises on how to effectively seek payment while complying with federal law. Experts emphasize prompt screening, and one notes, "[T]he best-performing hospitals ensure that a high percentage of [emergency department] patients are financially screened prior to discharge."<sup>59</sup> After a patient is stabilized, emergency department billing and collections practice thus resembles those practices already discussed. For instance, one consultant advises against an emergency department layout with multiple exits, which would enable patients to leave without discussing payment.<sup>60</sup> This same source cites the benefits of incentive programs for collections staff and lists credit card equipment as among the "nuts and bolts" of the emergency room collections process.<sup>61</sup>

Credit products designed and offered specifically for patient management of out-of-pocket medical costs present another avenue for shifting risk away from providers.<sup>62</sup> Medical providers typically do not bear legal liability for being

55. Dolan, *supra* note 40.

56. According to secondary reporting on a Visa USA study, credit cards were used for about a third (or \$86 billion in 2005) of paid out-of-pocket health expenditures. Kjos, *supra* note 16. McKinsey consultants recently offered a \$45 billion estimate in credit card self-pay health spending, but predicted a multiplication of this figure in the near future. LeCuyer & Singhal, *supra* note 51. Some of these estimates preceded the financial crisis.

57. 42 U.S.C. § 1395dd (2006). Emergency intake personnel are also prohibited from delaying treatment to inquire about a patient's ability to pay or insurance status. See § 1395dd(h).

58. For evidence that emergency room services are perceived as relatively unprofitable, see Jill R. Horwitz, *Making Profits and Providing Care: Comparing Nonprofit, For-Profit, and Government Hospitals*, 24 HEALTH AFF. 790, 792, exhibit 1 (2005).

59. Michael S. Friedberg, *Patient Access: A New Face for the Revenue Cycle*, HEALTH CARE FIN. MAN., March 1, 2007, at 90.

60. *Growing Focus on ED Collections: Here Are Tips*, HOSP. ACCESS MGMT., Apr. 1, 2009.

61. *Id.*

62. See, e.g., Milt Freudenheim, *Creating Financing: Medicine on Installment Plan: Doctors*

“arrangers” of credit.<sup>63</sup> By contrast, providers who directly extend credit may be required to comply with and face potential liability under federal truth-in-lending laws and regulations,<sup>64</sup> as well as state credit laws or deceptive practices

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*Offering Loans at 0%*, N.Y. TIMES, Aug. 30, 2007, at A1 (describing medical financing as “one of the fastest-growing parts of consumer credit, led by lending giants like Capital One and Citigroup and the Care Credit Unit of General Electric”); Grow & Berner, *supra* note 36 (referring to the “little-known medical debt revolution” and reporting that “[m]any patients say they don’t realize their debts are being shifted to such interest-charging middlemen as GE Money Bank”); Hansen, *supra* note 41. Recent examples of medical-specific credit products, designed largely to supplement insurance, include the CarePayment card by Aequitas Capital Management, Care Credit by General Electric, Capital One, Citigroup, Hospital Expense Loan Program (HELP Financial), U.S. Bank’s medical card, Complete Care, and MedKey Inc. See Schoen et al., *supra* note 26, at w307 (referring to medical debt as new growth industry); *Card Industry Looks To Seal a Health Care Payments Gap*, CARDS & PMTS (2007) (discussing CarePayment credit cards); Grow & Berner, *supra* note 36 (reporting on interest rates charged by medical credit providers, but noting that interest is not always charged when parties buy the debt at discount and expect to collect full amount); Hundley, *supra* note 50 (reporting on hospital relationships with medical credit providers and interest rates as compared to some in-house payment plans); *Overdose of Debt: Lenders Push Risky Credit for Everything from Cancer to Botox*, CONSUMER REPS., July 2008, at 14 (listing medical credit “pitches” to patients and doctors); MedKey Healthcare Finance, <http://www.medkeyinc.com> (last visited Apr. 8, 2010) (offering line of credit for medical bills, 90 days interest-free, 5.99% thereafter).

63. Federal consumer credit laws no longer include arrangers of credit under the Truth in Lending Act (TILA). *King v. Second City Constr. Co.*, 1997 U.S. Dist. LEXIS 15696, at \*9 (N.D. Ill. Sept. 30, 1997) (“At one time, the definition of creditor under the TILA and its implementing regulations included ‘arrangers of credit.’ However, that portion of the definition was deleted from both the statute and the regulations in 1982.”). We could find no evidence that state loan arranger or broker statutes have been applied to medical providers. For an example of a state broker statute, see, for example, IND. CODE ANN. § 23-2-5-3(e) (Lexis Nexis 2009) (defining a loan broker as “any person who, in return for any consideration from any source procures, attempts to procure, or assists in procuring, a loan from a third party or any other person, whether or not the person seeking the loan actually obtains the loan”).

64. 12 C.F.R. § 226.2(a)(17) (2008) (portion of regulation Z defining creditor as “a person (A) who regularly extends consumer credit that is subject to a finance charge or is payable by written agreement in more than 4 installments (not including a down payment), and (B) to whom the obligation is initially payable, either on the face of the note or contract, or by agreement when there is no note or contract”). See also *Bright v. Ball Memorial Hosp.*, 616 F.2d 328, 335 (7th Cir. 1980) (finding that a hospital can be “creditor” for purposes of TILA); James H. Backman, *Consumer Credit and the Learned Professions of Law and Medicine*, 176 B.Y.U. L. REV. 783 (1976); William D. Warren & Thomas R. Larmore, *Truth in Lending: Problems of Coverage*, 24 STAN. L. REV. 793, 819-20 (1972) (discussing refusal to exempt medical providers and other “professionals” from TILA, but noting some accommodations for installment payment practices); Edlin, *supra* note 49

statutes.<sup>65</sup> This divergence in legal consequences not only contributes to providers' reluctance to charge interest when they do extend credit,<sup>66</sup> but also increases the attractiveness of matching patients with specialty credit products.

Medical credit products are becoming integrated with health care finance more generally: some providers of insurance products or self-insuring companies

(recommending disclosures to comply with TILA if providers use payment plans); Gugliemo, *supra* note 42; Hansen, *supra* note 41; Moore, *supra* note 49 (recommending late fees rather than interest to ease TILA compliance); *Practice Pointers: When Patients Can't Pay*, MED. ECON., June 3, 2005 (discussing legal implications of falling within consumer credit definitions); Todd Stein, *Patients, Pay Up! You'd Better Have a Financial Policy*, PHYSICIANS PRAC., Mar. 2005, available at <http://www.physicianspractice.com/index/fuseaction/articles.details/articleID/629.htm> (warning providers that if they charge interest, they should have an attorney review their policy for compliance with lending laws: "Because the rules are complex, most practices choose not to charge interest on balances owed.").

65. See, e.g., *Anderson v. Southeast Ala. Med. Ctr.*, 381 So. 2d 68, 70 (Ala. Civ. App. 1979) (finding that defendant hospital was a "creditor" under ALA. CODE § 5-19-1(3) (1975), but not imposing finance charges for outstanding debt). See also Richard M. Alderman, *The Business of Medicine-Health Care Providers, Physicians, and the Deceptive Trade Practices Act*, 26 HOUS. L. REV. 109, 140 (1989).

66. The AMA Code of Medical Ethics, which is non-binding on physicians, suggests that providers notify patients of the possibility of charging interest in advance of treatment. See AMA Code of Medical Ethics, Opinion 6.08 (Interest Charges and Finance Charges) (1994), available at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion608.shtml>. But charging interest does not seem to be the norm among medical providers. See Edlin, *supra* note 49 (reviewing negative aspects of doctors imposing finance charges); Moore, *supra* note 49 (citing consultant characterizing charging interest as "touchy area" and discouraging it); Stein, *supra* note 64 ("[M]ost practices choose not to charge interest on balances owed."); Hansen, *supra* note 41 (citing a consultant reporting that "many" medical practices do not charge interest, but that "it is prevalent for expensive medical procedures" and another consultant saying that "it's common for physicians to collect bills without charging interest," and a practice group reporting that it charges 6% annual interest if the bill is unpaid for more than six months); Cheryl L. Toth, *Payment Plans for Patients: Better Collections for You*, PHYSICIANS PRAC., Jan./Feb. 2003, available at <http://www.physicianspractice.com/index/fuseaction/articles.details/articleID/365.htm> (discussing downsides of charging interest). For a recent controversial example, see Press Release, The Office of Attorney General Lori Swanson, Attorney General Lori Swanson Files Suit Against Allina Health System for Charging Usurious 18% Interest on Medical Debts (Jan. 22, 2009), <http://www.ag.state.mn.us/Consumer/PressRelease/090122AllinaInterest.asp> (alleging provider charged 18% interest on outstanding balances up to \$4,999 and 12% on balances from \$5,000 to \$9,999 in violation of Minnesota law); MINN. STAT. § 334.01(1) (2008) (stating the legal standard interest rate of 6% annually and maximum rate of 8%).

join with banks to offer lines of credit for the self-pay portion of bills.<sup>67</sup> Health savings accounts (HSAs), part of high-deductible health plans, may be directly linked with credit or debit cards.<sup>68</sup> The justification for offering adjunct credit products is to allow consumers to bridge the gap between large deductibles and more meager HSA contents.<sup>69</sup> Several companies have filed applications for business method patents for HSA payment systems with credit line components, suggesting significant investment in the combination of financing approaches.<sup>70</sup>

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67. See, e.g., Freudenheim, *supra* note 62, at A21 (“Big insurers, too, are devising new financing plans with various payback options.”); John Carroll, *Banks Give Insurers an Offer Most of Them Cannot Refuse*, MANAGED CARE, July 2006, <http://www.managedcaremag.com/archives/0607/0607.banks.html> (“Companies with self-funded or self-insured health plans started offering employees a line of credit” from a bank that is a subsidiary of UnitedHealth Group, “the OnePay Plan.”); *One Bill, OnePay: Pilot Program Simplifies Billing for Consumers and Physicians*, HUB MAG., 2006, [http://www.hubmagazine.net/pdfs/014909\\_OnePay.pdf](http://www.hubmagazine.net/pdfs/014909_OnePay.pdf) (discussing a pilot program in which the interest rate was set at the prime rate, and consumers made payment through payroll deductions). See generally E. Haavi Morreim, *High-Deductible Health Plans: Litigation Hazards for Health Insurers*, 18 HEALTH MATRIX 1, 30 (2008) (describing OnePay plan and potential problems); LeCuyer & Singhal, *supra* note 51 (recommending that insurance providers offer credit lines to policy holders); Sarah Rubenstein, *In New Health Plan, Patients Pay Their Share—Or Else*, WALL ST. J., Mar. 13, 2006, at B1.

68. See, e.g., Jennifer Roy, *HSA Lines of Credit*, HSA HEALTHLINE (Choice Fin., Fargo, N.D.), Nov. 2007, available at [http://www.choicefinancialgroup.com/hsa/healthline\\_newsletters/nov07.pdf](http://www.choicefinancialgroup.com/hsa/healthline_newsletters/nov07.pdf) (providing terms for Choice Financial’s line of credit); Chase Health Savings Account, Healthcare Line of Credit, [http://www.choicefinancialgroup.com/files/HSA\\_Guide.pdf](http://www.choicefinancialgroup.com/files/HSA_Guide.pdf) (last visited Apr. 9, 2010) (setting rate at 13.99% for interest rate on credit line); Provident Bank, Health Savings Account (HSA) Line of Credit, <https://www.mtb.com/personal/healthsavingsaccount/Pages/HSA.aspx> (last visited Apr. 9, 2010) (describing loans up to \$10,000 and encouraging use of line of credit as overdraft protection); Visa Health Savings Account Card, <http://usa.visa.com/personal/cards/prepaid/healthcare-card.html> (last visited Apr. 9, 2010) (combining line of credit with health insurance identification card, capability of accessing other accounts, and reimbursement arrangements); US Bank, Health Savings Solution Product Guide, <https://healthsavings.usbank.com/usbankhsa/forms/Health%20Savings%20Solution%20product%20guide.pdf> (last visited Apr. 9, 2010) (including line of credit); see also CARDS & PMTS, *supra* note 62; Tony Miller, *Getting on the Soapbox: Views of an Innovator in Consumer-Directed Care*, 25 HEALTH AFF. w549, w550 (2006); *Companies Offer Nation’s First Credit Line to Owners of Health Savings Accounts*, BUS. WIRE, June 27, 2005; Haugh, *supra* note 18, at 18.

69. See, e.g., *UMB Healthcare Services’ Dennis Triplett Offers Perspective on HSA Line of Credit Solution*, BUS. WIRE, Aug. 2, 2006, available at <http://www.allbusiness.com/banking-finance/banking-lending-credit-services-cash/5345119-1.html>.

70. See, e.g., Method for Maintaining & Providing Health Savings Accounts (HSAs), U.S. Patent Application No. 20060200397 (filed Sept. 7, 2006).

In summary, the current health care system features constant, regular financial transacting between providers and their patients regardless of patients' insurance status. The sizeable number of patients with difficulty handling self-pay obligations imposes additional financial risks on providers. The recommended approaches to managing these risks in light of legal and practical considerations encourage early payoff of health care providers and seek to avoid later direct legal enforcement to the extent possible.

The practices that providers adopt to shape their financial transacting affect the ways in which researchers can measure patients' medical burden. We turn to this matter in the following subsection, focusing specifically on the measurement of burden for people who have filed for bankruptcy.

## 2. *Measuring Medical Burdens of Bankruptcy Filers*

Researchers have differed in their methods of identifying medical bills and medical problems among people who file for bankruptcy.<sup>71</sup> Most bankruptcy studies use self-reported information in one form or another.<sup>72</sup> Elizabeth Warren, Jay Westbrook, and Teresa Sullivan honed the approach of using written questionnaires and other survey methods in the personal bankruptcy context.<sup>73</sup> With respect to medical problems, Warren, Himmelstein, Woolhandler, and Thorne wrote a paper that used data from the 2001 Consumer Bankruptcy Project ("2001 CBP") studying filers in five states. A key data source was written questionnaires, on which respondents could indicate whether they had out-of-pocket medical expenses of at least \$1,000 in the two years prior to bankruptcy, medical uses of second mortgages, and health insurance coverage. Respondents also could pick reasons for bankruptcy (including illness or injury) from a list of

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71. For literature reviews, see Melissa B. Jacoby, Teresa A. Sullivan & Elizabeth Warren, *Rethinking the Debates over Health Care Financing: Evidence from the Bankruptcy Courts*, 76 N.Y.U. L. REV. 375, 377 (2001) (summarizing earlier literature and referring to the bankruptcy system as an "overlooked source of information for purposes of the health care finance policy debates"); Melissa B. Jacoby, *The Debtor-Patient Revisited*, 51 ST. LOUIS U. L.J. 301 (2007) (distinguishing studies of debt from studies of medical-related financial problems).

72. Most general population studies that include bankruptcy-related questions use self-reported information. See, e.g., CUNNINGHAM, *supra* note 28; USA Today/Kaiser Family Foundation/Harvard School of Public Health, *supra* note 36; APARNA MATHUR, AM. ENTER. INST., MEDICAL BILLS AND BANKRUPTCY FILINGS (2006), [http://www.aei.org/docLib/20060719\\_MedicalBillsAndBankruptcy.pdf](http://www.aei.org/docLib/20060719_MedicalBillsAndBankruptcy.pdf).

73. TERESA A. SULLIVAN, ELIZABETH WARREN & JAY LAWRENCE WESTBROOK, AS WE FORGIVE OUR DEBTORS (1989) (describing filers from 1981).

pre-coded options.<sup>74</sup> The 2001 CBP undertook follow-up telephone surveys with a subset of the filers that reviewed out-of-pocket costs and medical diagnoses in greater detail.<sup>75</sup> Himmelstein and his coauthors analyzed that dataset and concluded in their first paper that nearly half of bankruptcies met at least one criterion for characterization as a “major medical bankruptcy” and more than half met a slightly more expansive definition of “any medical bankruptcy.”<sup>76</sup>

Published in the peer-reviewed journal *Health Affairs* as a web exclusive, the Himmelstein paper was released just as Congress was restarting deliberations on a major bill to restrict bankruptcy relief. Senator Grassley, a sponsor of that bill, requested that a division of the DOJ (the Executive Office for United States Trustees) determine the validity of the Himmelstein findings.<sup>77</sup> Assistant Attorney General William Moschella submitted a short letter and summary reporting the frequency and amounts of medical debt detectable in court records in a sample of “no-asset” chapter 7 cases.<sup>78</sup> Those figures are reprinted in Table 1 in Part III; as noted in the introduction, Attorney General Moschella’s letter and summary conveyed that the medical debt impact was modest. The letter closed

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74. David Himmelstein et al., *Illness and Injury as Contributors to Bankruptcy*, HEALTH AFF. W5-67 (Web Exclusive Feb. 2, 2005).

75. *Id.* at W5-69. Among the respondents who participated in telephone interviews and said they had medical reasons for bankruptcy, the average amount of out-of-pocket expense (excluding premiums) in the year leading to bankruptcy was over \$3,500. Out-of-pocket expense since illness onset averaged approximately \$12,000. *Id.*

76. *Id.* at W5-66. Other studies have used the same data for analysis, *see, e.g.*, Jacoby & Warren, *supra* note 33 (reanalyzing 2001 CBP data to show different ways to measure medical-related bankruptcy), or adopted similar survey instruments for use on different populations. *See* WATSON, *supra* note 26 (using some CBP questions to study Missouri debtors); Ezekial Johnson & James Wright, *Are Mormons Bankrupting Utah? Evidence from the Bankruptcy Courts*, 40 SUFFOLK U. L. REV. 607 (2007) (replicating methods, finding that 61% in study of filers in Utah reported that medical problems contributed to their bankruptcy filings).

77. 151 CONG. REC. S2053, S2078 (Mar. 4, 2005) (reprinting Letter from William E. Moschella, Assistant Att’y Gen., U.S. DOJ, to Charles E. Grassley, U.S. Sen. (Feb. 10, 2005)). The letter characterized the Himmelstein et al. definitions of medical bankruptcy as “very broad” and highlighted that the article’s broader definition of medical bankruptcy included drug addiction and uncontrolled gambling, *id.*, although those factors were nominal additions to the overall count.

78. For a description of the distinction between an “asset case” and a “no-asset case,” *see* Dalié Jiménez, *The Distribution of Assets in Consumer Chapter 7 Bankruptcy Cases*, 83 AM. BANKR. L.J. 795 (2009). An asset case is one in which there is property to distribute to unsecured creditors after secured creditors are paid any allowed secured claims and the debtor retains exempt property. *Id.* at 798. Accordingly, in a “no-asset case,” debtors have no unencumbered non-exempt assets for distribution to unsecured creditors. *Id.* at 797.

by stating, “[T]he conclusion that almost 50 percent of consumer bankruptcies are ‘medical related’ requires a broad definition and *generally is not substantiated* by the official documents filed by debtors.”<sup>79</sup>

Assistant Attorney General Moschella’s observation is based on the following method: whether coders could find holders of claims that had demonstrably medical names on “Schedule F,” a list of claims that bankruptcy filers must submit to the court.<sup>80</sup> On Schedule F, debtors list the amount of non-priority unsecured claims (claims owed to general creditors who lack collateral for these debts) owed at the time of filing and the identity of the holders of such claims at that time. The DOJ’s summary of findings correctly noted that using Schedule F would exclude bills owed on the date of bankruptcy to a creditor with a non-medical name, but neither the summary nor cover letter highlighted or explained the relevance of this limit for those who would be unfamiliar with the ramifications.<sup>81</sup>

The court record method was not without precedent. Early studies of the bankruptcy system under the 1978 Bankruptcy Code used court records to start examining filers and the system.<sup>82</sup> Over time, researchers interested in the circumstances of bankrupt families began to identify pros and cons to using court records.<sup>83</sup> As studies of bankruptcy filers have evolved and use of consumer credit for various household purposes has grown substantially, so have the

79. *See supra* note 77 (emphasis added).

80. *See* Official Bankruptcy Forms, Schedule F: Creditors Holding Unsecured Nonpriority Claims (Dec. 2007), available at [http://www.uscourts.gov/rules/BK\\_Forms\\_1207/B\\_006F\\_1207f.pdf](http://www.uscourts.gov/rules/BK_Forms_1207/B_006F_1207f.pdf). *See also supra* note 77.

81. *See supra* note 77. After the Bankruptcy Abuse Prevention and Consumer Protection Act was enacted, the Director of the United States Trustee Program was circumspect about what could be gleaned from Schedule F about medical burden. He observed that the Program did not have “definitive data” on the amount of medical debt owed by bankruptcy filers and that, even with data-enabled forms that the Program hoped to develop, medical debt would be difficult to measure through those forms. *Hearing on Working Families in Financial Crisis: Medical Debt and Bankruptcy*, 110th Cong. 4-5 (2007) (statement of Clifford J. White III, Director, Executive Office for United States Trustees), available at <http://judiciary.house.gov/hearings/July2007/white070717.pdf>. White’s testimony cited 2003 data in which 46% of the filers in no-asset chapter 7 cases included medical debt on Schedule F, about 78% of them reported debt less than \$5,000, and fewer than 1% of the cases represented more than one third of the total medical debt. *See id.* at 4.

82. Examples include SULLIVAN ET AL., *supra* note 73 (regarding filers from 1981); Susan D. Kovac, *Judgment-Proof Debtors in Bankruptcy*, 65 AM. BANKR. L.J. 675 (1991) (describing filers from 1985-1986).

83. *See, e.g.*, Jacoby et al., *supra* note 71 (reviewing these concerns).

number of objections to measuring medical burden with court records.<sup>84</sup>

Nonetheless, certain U.S. senators characterized the DOJ response as a debunking of the Himmelstein study's finding that medical problems contributed to about half of bankruptcies. Senator Grassley issued a press release strongly suggesting that assertions of high percentages of medical-related bankruptcies were "myth."<sup>85</sup> Senator Sessions also used the DOJ study to suggest that these percentages were a "fiction."<sup>86</sup>

84. *See, e.g.*, 151 CONG. REC. S6010 (May 26, 2005) (reprinting Letter from David Himmelstein, Assoc. Professor of Med., Harvard Med. Sch., et al. to Charles E. Grassley, U.S. Senator (Feb. 14, 2005)). This letter identified a list of debts that likely would be excluded from the analysis cited in the Moschella letter as well as the implications of including only no-asset chapter 7 cases.

85. Senator Grassley said:

Make no mistake, misrepresentations about this legislation have been running rampant by those who oppose any meaningful bankruptcy reform. I've been in politics a long time, and I know that political criticism is never inhibited by ignorance. For instance, the statistical analysis in the U.S. Trustee's office examined over 5000 bankruptcy cases and found that under one-half listed medical debts of any sort. And those filers who did list medical debts, on average, listed under \$5000 in medical debts. So much for the myth that most bankruptcies are driven [sic.] medical costs. The fact is there are abusers out there. The fact is S. 256 doesn't harm bankrupts with large medical debts. Let's stop the abuse. Let's return to common sense. Let's enact bankruptcy reform now, before the abuse gets worse.

Press Release, Opening Statement of Senator Chuck Grassley at the Bankruptcy Reform Hearing (Feb. 10, 2005), [http://grassley.senate.gov/news/Article.cfm?customel\\_dataPageID\\_1502=9716](http://grassley.senate.gov/news/Article.cfm?customel_dataPageID_1502=9716).

86. Senator Sessions said:

This is what the United States Trustee Program found in a much more extensive survey. . . They were asked to survey the filings in their districts to find out what you list on your filing as your debts, who you owe. You actually list who it is. So, if it is a doctor bill, it is on there. If you don't put it on there you don't wipe out that debt and you remain obligated to pay it, so everybody puts every debt they have on the list so it can be wiped out when they file bankruptcy. What they found was, this professional study of 5,000 cases, not interviewing debtors but looking at what they put on their form, they found that only slightly more than 5 percent of the total unsecured debt reported in those cases was medically related. Only 5 percent was medically related. This is not 50 percent of the cases in bankruptcy being caused by medical—only 5 percent of them, of the total debt, was medical. . . . For some people there is no doubt that medical debts are a cause for bankruptcy. I do not doubt that. But this idea that . . . we ought to assume that there is no fraud and abuse in bankruptcy and the idea that everybody is in bankruptcy because of medical debts is just not so.

It is just not; it is a fiction. We need to get it out of our heads.

151 CONG. REC. S2077 (daily ed. Mar. 4, 2005). Senator Cornyn echoed the sentiments, saying:

First, let me say to my friend, the Senator from Alabama, how much I appreciate his eloquence on this bill and his very successful attempt to explain to the American people,

Likewise, academic critics of the Himmelstein study highlighted the DOJ findings and lent credence to the court record method as a valid and useful measure of medical bill burden.<sup>87</sup> Within a lengthier critique of the Himmelstein study, two health care finance experts included a full paragraph identifying the DOJ findings as a counterpoint.<sup>88</sup> They used the DOJ findings to illustrate that medical debt is only a small proportion of bankruptcy filers' financial obligations.<sup>89</sup> In written testimony for a congressional hearing, a law professor described and cited the DOJ findings for the proposition that only a few cases have sufficiently high medical debt for it to be properly characterized as a cause of bankruptcy.<sup>90</sup>

By 2009, interest in the scope of the medical bankruptcy problem intensified. Early in the year, then-President-Elect Obama's economic agenda included making it easier for people in medical-related bankruptcies to receive a discharge of debt.<sup>91</sup> In the summer of 2009, Himmelstein, Thorne, Warren, and Woolhandler released a new study estimating that 62% of bankruptcy filings could be counted as medical-related.<sup>92</sup> That study's release dovetailed with debates on health care finance reform. In late July 2009, the House Judiciary Committee called a hearing to discuss whether the health care system was bankrupting American families. Representative Conyers cited the 2009

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as well as to us, what is at stake here, and to knock down some myths that are being used to try to worry people when, in fact, there is no reason for people to be worried about this legislation.

*Id.*

87. These writings also identified a range of other criticisms, unrelated to the data sources, which are beyond the scope of this Article.

88. David Dranove & Michael Millenson, *Medical Bankruptcy: Myth Versus Fact*, 25 HEALTH AFF. w78 (2006) (citing DOJ study and conclusion without qualifications).

89. *Id.*

90. *Working Families in Financial Crisis: Medical Debt and Bankruptcy: Hearing Before the Subcomm. On Commercial and Administrative Law of the H. Comm. on the Judiciary*, 110th Cong. 27-29, 32 (July 17, 2007) (statement of Todd J. Zywicki, Professor, George Mason Univ. Sch. Of Law).

91. See Posting of Sarah Rubenstein to Wall St. J. Health Blog, *Obama Aims To Help Patients Wipe Away Medical Debts*, <http://blogs.wsj.com/health/2009/01/07/obama-aims-to-help-patients-wipe-away-medical-debts/> (Jan. 7, 2009, 2:06PM EST) (citing The Obama-Biden Plan, [http://change.gov/agenda/economy\\_agenda](http://change.gov/agenda/economy_agenda) (last visited Apr. 2, 2010) ("Obama and Biden will create an exemption in bankruptcy law for individuals who can prove they filed for bankruptcy because of medical expenses. This exemption will create a process that forgives the debt and lets the individuals get back on their feet.")).

92. Himmelstein et al., *supra* note 7.

Himmelstein study as evidence that health care finance reform was urgently needed.<sup>93</sup> But a witness at the hearing from the American Enterprise Institute returned to the DOJ findings, which she described as the “closest comparable survey,” to cast doubt on Himmelstein’s findings.<sup>94</sup>

No one has systematically examined the DOJ’s court record method and why exactly it differs from the Himmelstein study’s findings. We undertake that examination here by imposing both methods on, and collecting both types of information from, a single population.

### *B. Data for the Current Study*

We analyze information from the 2007 Consumer Bankruptcy Project (“2007 CBP”), a nationally representative study of approximately 2,500 personal bankruptcy cases.<sup>95</sup> The response rate to the questionnaire portion was 50%.<sup>96</sup> Respondents and non-respondents shared similar characteristics on variables such as income, debt, assets, monthly expenses, and prior bankruptcies.<sup>97</sup> The dataset has a slight underrepresentation of chapter 13 cases, which we correct with weighting when necessary.<sup>98</sup> The median age of a filer in the 2007 CBP is 43, older than the median in the general U.S. population.<sup>99</sup> Median household income

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93. *Medical Debt: Is Our Healthcare System Bankrupting Americans: Hearing Before the Subcomm. on Commercial and Administrative Law of the H. Comm. on the Judiciary*, 111th Cong. 4 (July 28, 2009) (opening statement of Rep. John Conyers, Jr.), available at <http://judiciary.house.gov/hearings/pdf/Conyers090728.pdf>.

94. *Id.* at 6-7 (written testimony of Aparna Mathur, Research Fellow, American Enterprise Institute), available at <http://judiciary.house.gov/hearings/pdf/Mathur090728.pdf>.

95. Robert M. Lawless et al., *Did Bankruptcy Reform Fail? An Empirical Study of Consumer Debtors*, 82 AM. BANKR. L.J. 349, 391 (2008) (describing the methods of the 2007 CBP).

96. *Id.* at 392.

97. *Id.* at 396.

98. The average Schedule F medical debt is significantly higher for chapter 7 filers than chapter 13 filers, but there was no chapter-related difference in the *likelihood* of reporting medical debt on Schedule F. In addition, the median Schedule F medical debt for chapter 7 and chapter 13 filers is not significantly different (\$1,698 for chapter 7 filers versus \$1,384 for chapter 13). Filers in the two chapters also had a similar distribution of Schedule F debts (as well as questionnaire expense) across the range, with the differences skewing the averages likely coming largely from the group of filers with Schedule F medical debts \$10,000 and above. Thus, for most of our analysis, we combine the two kinds of cases without weighting, but indicate where we have used weighting.

99. Deborah Thorne, Elizabeth Warren & Teresa A. Sullivan, *The Increasing Vulnerability of Older Americans: Evidence from the Bankruptcy Court*, 3 HARV. L. & POL’Y REV. 87, 92 (2009). The median age in the general population in 2007 was only 36.1. *Id.* at 93, fig.1.

of the sample is less than \$28,000.<sup>100</sup> Median net worth is substantially negative (nearly -\$24,400).<sup>101</sup> About half were homeowners when they filed for bankruptcy, and among them, median mortgage debt was just over \$100,000.<sup>102</sup>

Respondents completed written questionnaires that included demographic information and other information about their pre-bankruptcy circumstances.<sup>103</sup> For all respondents, the 2007 CBP also extracted information on approximately 200 variables from court records, many of which are debtor-supplied under penalty of perjury. The 2007 CBP conducted follow-up telephone surveys with approximately 1,000 respondents within a year after they filed for bankruptcy.<sup>104</sup>

The approach taken in this Article is unique in several respects. First, we approximate the DOJ method of identifying medical debts from Schedule F in the court records.<sup>105</sup> This enables replication and closer scrutiny of the DOJ court record method. Second, we are able to isolate filers who specifically identified medical *bills* as a reason for bankruptcy as compared to lost income or the other ways medical problems can contribute to financial distress.<sup>106</sup> In addition, we use

100. Lawless et al., *supra* note 95, at 359, 404. The mean was under \$31,000. *Id.* at 404. In terms of income distribution, about 85% of the 2007 CBP respondents had incomes below the U.S. national median household income in 2007 (undifferentiated by household size), and more than three in ten had incomes below the “poverty rate” for a family of four. For national median income figures, see CARMEN DENAVAS-WALT, BERNADETTE D. PROCTOR & JESSICA SMITH, INCOME, POVERTY, AND HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2007, 5, 7 (2008), available at <http://www.census.gov/prod/2008pubs/p60-235.pdf>. For the poverty guidelines, see U.S. Dept. of Health & Human Servs., The 2006 HHS Poverty Guidelines, <http://aspe.hhs.gov/POVERTY/06poverty.shtml> (last visited Apr. 10, 2010). The income distribution of bankruptcy filers in the 2007 CBP is shown in Lawless et al., *supra* note 95, at 360 fig.2.

101. Lawless et al., *supra* note 95, at 371, 405.

102. *Id.* at 365.

103. *Id.* at 399-402 (reproducing questionnaire).

104. *Id.* at 396. As was previously noted, the telephone survey subsample is not significantly different from the whole regarding variables such as “filing status, filing chapter, total assets, total debts, priority debts, monthly income, [and] home value.” *Id.* at 396 n.177.

105. The specific codebook instruction was as follows:

This number represents the sum of debts that appeared to be owed to medical providers. Debts were counted as medical debts if they were owed to hospitals, doctors, labs, nursing homes and other treatment facilities, pharmacies, medical collection agencies, and anything else that looked related to health, medical, wellness, or sickness.

106. Jacoby & Warren, *supra* note 33, at 563 (2006) (discussing the importance of income effects of illness or injury). Notably, for this Article, we are not seeking a comprehensive count of cases that could be construed as medical bankruptcies. In this respect, our study is distinct from the aim of Himmelstein et al., *supra* note 7. Still, the explicit “medical bill reason” for bankruptcy

a more detailed series of questions about out-of-pocket medical expenses that reveal respondents' medical bill management techniques. Specifically, the questionnaire asked whether respondents were directly responsible for medical bills uncovered by insurance within the two years leading up to the bankruptcy filing.<sup>107</sup> Respondents who said "yes" were asked additional follow-up questions:

How did you, or a spouse or partner, pay for the medical bills or prescriptions that were not covered by insurance? Did you: Check all that apply: Pay with a cash, check, or debit card; Pay with a regular credit card; Pay with a medical credit card (such as CitiHealth Card, CareCredit, or MediCredit); Pay with money from a home equity loan or line of credit; Agree to a payment plan with the medical provider; Something else (please specify).

The latter questions help us scrutinize the absence of a medical bill from the court records and offer a window into the management practices explored in Part II.A. For this Article, we report findings for all of the responses, and primarily discuss the options that most directly relate to discrepancies between the court record method and the survey method: cash, credit card, and home equity loans.<sup>108</sup> Also, whereas prior surveys asked only whether respondents incurred more than \$1,000 in out-of-pocket expenses, respondents in this study were asked to identify the amount that they paid out-of-pocket within specified ranges: less than \$1,000; \$1,000-\$5,000; \$5,001-\$10,000; and more than \$10,000. This greater specificity enables a better comparison to the court record method and facilitates a more in-depth analysis of medical burden. Overall, our innovation is to deploy both the survey method and the court record method on the same dataset, and to use new methods of analysis to undertake this comparison.

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helps identify filers who are likely to have some non-trivial obligation. If court records are a useful source of information about medical burden, then we at least should be able to find evidence of substantial medical bills in the records of these respondents.

107. The exact language of question 18 was: "During the TWO years before the bankruptcy, were you, or a spouse or partner, FINANCIALLY responsible for ANY medical bills, INCLUDING prescription medication or co-payments, that were NOT covered by insurance" (emphasis in original). The question did not ask the respondent to indicate the specific source of the cost (doctor, hospital, prescription drugs, etc.).

108. A more in-depth evaluation of payment plans and "something else" (other forms of payment for medical bill payment not discussed in this Article) will be reported in a separate paper.

## III. ANALYSIS AND FINDINGS

We start by reporting Schedule F medical debt. The left column of Table 1 replicates the information the DOJ reported to Congress. The middle column represents our 2007 CBP data limited to no-asset chapter 7 cases (liquidation cases) to most closely match the DOJ sample. The right column represents the 2007 CBP full core sample that also includes chapter 13 (repayment plan) cases.

TABLE 1: DOJ AND 2007 CBP SAMPLE COMPARISONS

DOJ Sample (No-Asset 7s Closed Between 2000 and 2002, Excluding N.C. & Ala.)	2007 CBP Sample (No-Asset 7s Only)	2007 CBP Sample (7s and 13s)
<i>All Cases</i>		
<i>N=5,203</i>	<i>N= 1,719</i>	<i>N=2,438</i>
<b>54%</b> listed no medical debt.	<b>48.4%</b> listed no medical debt ( <b>50.6%</b> if including cases with missing data).	<b>49.8%</b> listed no medical debt ( <b>50%</b> if including cases with missing data).
Medical debt accounted for <b>5.5%</b> of the total general unsecured debt.	Medical debt accounted for <b>6.2%</b> of the total general unsecured debt (\$5,851,877 of \$93,095,955).	Medical debt accounted for <b>5.6%</b> of the total general unsecured debt (\$7,727,494 of \$136,353,023).
<b>90.1%</b> reported medical debts less than \$5,000.	<b>86.2%</b> reported medical debts less than \$5,000 ( <b>88.6%</b> if inflation-adjusted to \$5,734).	<b>88%</b> reported medical debts less than \$5,000 ( <b>92.3%</b> if inflation-adjusted to \$5,734).
<b>1%</b> of cases accounted for <b>36.5%</b> of all medical debt.	<b>1%</b> of cases accounted for <b>37.3%</b> of all medical debt.	<b>1%</b> of cases accounted for <b>35.4%</b> of all medical debt.
Less than <b>10%</b> of all cases represented <b>80%</b> of all medical debt.	<b>10%</b> of all cases represented <b>80.3%</b> of all medical debt.	<b>10%</b> of all cases represented <b>79.8%</b> of all medical debt.

<i>Cases with Any Schedule F Medical Debt</i>		
<i>N=2,391</i>	<i>N=853</i>	<i>N=1,271</i>
Among the cases with medical debt, the average medical debt was <b>\$4,978</b> per case ( <b>\$5,709</b> in 2007 dollars).	Among the cases with medical debt, the average medical debt was <b>\$7,483</b> per case.	Among the cases with medical debt, the average medical debt was <b>\$6,313</b> per case (weighted by case type).
<b>78.4%</b> reported medical debt below \$5,000 (average of <b>\$1,212</b> for this group).	<b>73.4%</b> reported medical debt below \$5,000; <b>76.3%</b> with inflation adjustment (average of <b>\$1,405</b> for this group).	<b>76.1%</b> reported medical debt below \$5,000; <b>78.8%</b> with inflation adjustment (average of <b>\$1,394</b> for this group).
<b>21.6%</b> of cases accounted for <b>80.9%</b> of all medical debt. <sup>109</sup>	<b>21.6%</b> of cases accounted for <b>82.4%</b> of all medical debt. <sup>110</sup>	<b>21.6%</b> of cases accounted for <b>81.3%</b> of all medical debt. <sup>111</sup>
Medical debt accounted for <b>13.0%</b> of the total general unsecured debt.	Medical debt accounted for <b>12.3%</b> of the total general unsecured debt.	Medical debt accounted for <b>12.2%</b> of the total general unsecured debt.

Table 1 shows that the application of the court record method to the 2007 CBP dataset produces results that are very close to the DOJ results. With respect to the differences, Table 1 indicates that our court records include a slightly greater proportion of cases with Schedule F medical debt than the DOJ sample. Also, our sample’s average medical debt, as indicated by the court records, is higher than the DOJ sample’s, even after adjusting the numbers for inflation using the Consumer Price Index. These increases are consistent with rising medical costs (at a rate that is outpacing inflation) and self-pay obligations during the 2000s. Furthermore, because the DOJ reported neither median debt nor a distribution of the larger debts, it is possible that a small number of large debts explain the differences in averages.<sup>112</sup> In Figure 1, we report the distribution of the 8% of our sample with more than \$10,000 in Schedule F medical debt,

109. We do not know why the DOJ reported this measure, but we replicate it in this Table.

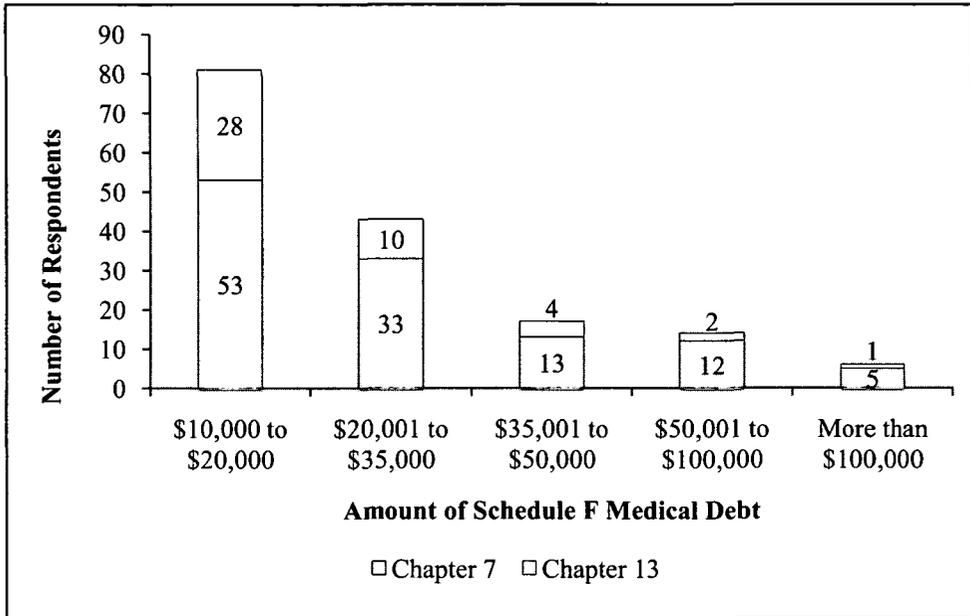
110. Additionally: 1% of cases account for 2.9% of the total medical debt, 10% of cases account for 67.4% of the total medical debt, and 20% of cases account for 81.4% of the total medical debt.

111. Again, we offer more figures: 1% of cases account for 2.5% of the total medical debt, 10% of cases account for 65.3% of the total medical debt, and 20% of cases account for 80% of the total medical debt.

112. We did not cap or remove outliers (disclosed in Figure 1 and note 113) because we found no evidence that the data in the DOJ report capped or excluded outliers. Earlier analyses by U.S. Trustee researchers appear to include the biggest Schedule F medical debts. See Ed Flynn & Gordon Bermant, *The Class of 2000*, AM. BANKR. INST. J., Oct. 2001, at 20 (reporting that “medical debt-figures were highly skewed by a few debtors with enormous medical debts.”).

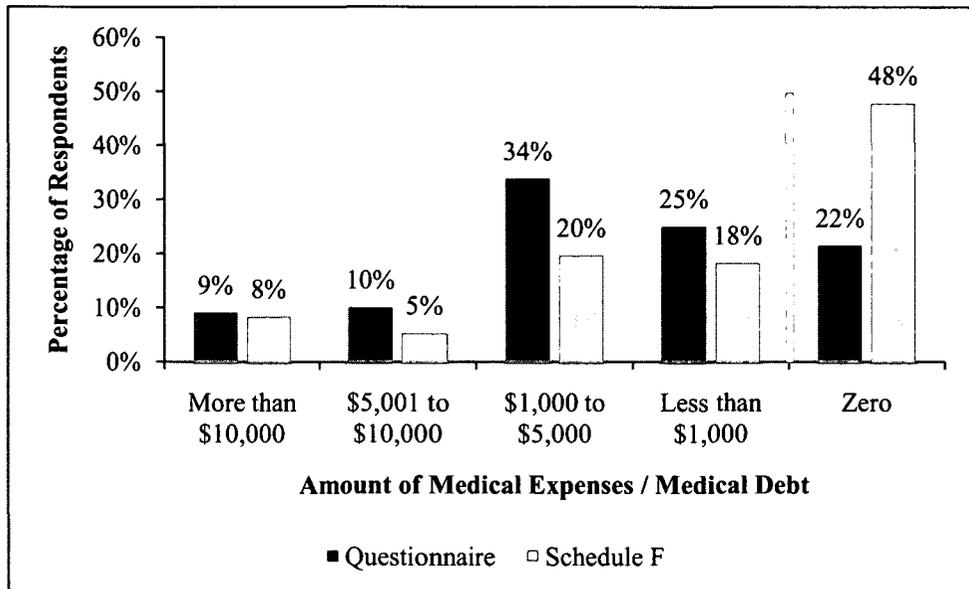
subdivided by chapter of bankruptcy filing.<sup>113</sup>

**FIGURE 1: COURT RECORD MEDICAL DEBT OVER \$10,000**



Now that we have verified the similarities between the DOJ and 2007 CBP court records, we assess how well the court record method reflects pre-bankruptcy out-of-pocket expenses. To be included in a court record count of medical bills, a bill must have several qualities. It must be outstanding on the date of the bankruptcy filing. The filer must know about the bill to report it. Finally, the holder of the claim must be identifiable as medical to a third-party coder. Figure 2 displays medical expense of the 2007 CBP sample as indicated on the questionnaire (the survey method) and on Schedule F (the court record method). Importantly, the questionnaire asked only about expenses within two years prior to filing, whereas court records include claims incurred at any time before filing. This comparison thus suppresses even greater potential differences between the measures.

113. Of the filers with Schedule F medical debts over \$100,000, four were just over this amount. Two had over \$500,000. Three of these six filers were under twenty-five years old.

**FIGURE 2: QUESTIONNAIRE-DERIVED MEDICAL EXPENSES AND SCHEDULE F MEDICAL DEBT**

As Figure 2 shows, respondents had consistently lower levels of Schedule F medical debt than out-of-pocket medical expenses incurred within two years prior to filing.<sup>114</sup> The darker columns in Figure 2, which represent the questionnaire responses, show that nearly eight of ten respondents reported *some* out-of-pocket expenses within two years before filing, whereas medical debt could be found in the court records of only about five of ten respondents.

We examined the level of congruence between the court record and questionnaire measures in various ways. We established the Cronbach's alpha between the two variables, which is 0.609.<sup>115</sup> This level of congruence between the two measures is low enough to merit concern about the validity of using one

114. As illustrated by Figure 1, the distributions of the two measures are different. Written questionnaire expense forms a unimodal distribution, with a peak at \$1,001 to \$5,000. Schedule F medical debt manifests a different pattern, with about half the respondents having zero Schedule F medical debt, and greater than eight out of ten reporting \$5,000 or less.

115. Cronbach's alpha is a measurement of how well two or more variables "hang together," or whether they measure a single latent construct. It is a measure of the reliability or consistency between the items at hand and is computed through the equation:  $\alpha = \frac{N \cdot \bar{c}}{\bar{v} + (N-1) \cdot \bar{c}}$ , where N is the number of items,  $\bar{c}$  is the interitem covariance, and  $\bar{v}$  is the average variance of the items. At the most basic level, Cronbach's alpha allows a researcher to evaluate how well one variable can replace another variable.

of these measures as a stand-in for the other.<sup>116</sup>

Next, we engaged in a filer-by-filer comparison of the two measures, which can be explained as follows. First, we compared the dollar value of the court record and survey measures for each filer. Doing this, we identified about a third of respondents in our sample (32%) who reported expenses on the questionnaire based on the survey method, but who had no medical debt in their court records. Documenting precise declines in dollar amounts when neither number is zero is more difficult because the questionnaire asked for an estimate of expense by category rather than an exact dollar amount. But we conservatively estimate that an additional 56% of the sample had less Schedule F medical debt than questionnaire-reported expenses.<sup>117</sup>

Our second filer-by-filer approach was to subtract a categorized measure of Schedule F medical debt from the questionnaire medical expenses category for each respondent.<sup>118</sup> For each case, this produced a nine-point scale ranging from

116. Generally, for comparing groups, a Cronbach's alpha of 0.70 to 0.80 or higher allows one to substitute one variable for another or to create a composite variable using the two measures. See J. Martin Bland & Douglas G. Altman, *Statistics Notes: Cronbach's Alpha*, 314 BRIT. MED. J. 572, 572 (1997).

117. To calculate the differences between questionnaire-reported medical expense and Schedule F medical debt for this particular finding, we subtracted each individual's reported expense from Schedule F medical debt, allowing us to compare the two reporting processes in a "pair-wise" manner. We needed to estimate a dollar amount for expense because the questionnaire asked only for categories of expenses. To estimate, we took the middle point of each expense category and used that to calculate the difference. For example, for the category \$1,000 to \$5,000, each respondent who reported expenses in that range was assigned a dollar debt amount of \$3,000.50. For those who reported "more than \$10,000" in expense, we assigned a dollar amount of \$15,000 for purposes of this analysis. We believe that this is a particularly conservative estimate, given that on Schedule F, only half of the medical debts over \$10,000 were also under \$20,000. See *supra* p. 267, fig. 1. To prevent these respondents from skewing the average difference between the two measures, we coded anyone who reported "more than \$10,000" in expenses on the questionnaire *and* reported more than \$10,000 in debt on Schedule F as having zero difference between the the two measures. Again, this allows our measure to be conservative.

118. The initial categories of expense, consistent with the ranges on the questionnaire, are coded as follows: "zero" means no expense, "1" means under \$1,000; "2" represents expense between \$1,000 and \$5,000; "3" means expense between \$5,001 and \$10,000; and "4" represents more than \$10,000. Subtracting the category of Schedule F debt from the category of questionnaire expense indicated by each respondent yields a number between "-4" and "+4." These numbers thus take on a meaning different from the original codes. For example, "zero" indicates the same category of expense on both measures, whether that category is no medical bills or over \$10,000 in medical bills. When we use numbers in the appendices and going forward, we are referring to the result of this subtraction.

“-4” to “+4”. A “-4” signifies that an individual had more than \$10,000 in Schedule F medical debt and no questionnaire-reported expenses. A “+4” signifies that an individual had more than \$10,000 in expenses on the questionnaire but no Schedule F medical debt. Appendix A shows the distribution of cases along this scale.

Most respondents fell within the same category of expenses under both measures or had more survey expenses than court record medical debt.<sup>119</sup> About one-fifth of the sample clearly had out-of-pocket expenses that were at least \$1,000 more than their Schedule F medical debt, and often the difference was more than \$5,000 or more than \$10,000.<sup>120</sup> Cases fitting this description reveal most clearly the difficulties of relying on only court records; they also present the most interesting questions of how these households managed to reduce medical obligations in the midst of financial problems.

Although the additional analysis using this scale focuses on this fifth of respondents, we must emphasize that this is not a comprehensive count of people with serious medical burden. Some respondents with very significant medical

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119. In the group of cases on the negative side of the scale, Schedule F medical debt exceeded the questionnaire reports of expense. We strongly suspect that these cases can be explained by the timing: the questionnaire asked for out-of-pocket expense only within the two years prior to filing. By contrast, Schedule F captures debts older than two years. Some particularly big debts are likely to be older. Notably, the presence of some cases with Schedule F debt older than two years and no recent out-of-pocket expense slightly dampens the discrepancy between these two measures of medical burden. A small number of such cases may not only raise the Schedule F medical debt averages, but also could make the highest dollar category of medical bills (*see supra* p. 268, fig.2) seem more consistent across measures than it really is. Although we believe this to be the dominant explanation, particularly for the cases in the “-4” and “-3” categories, we offer several others as well. While completing the exact dollar amounts on Schedule F, respondents may have been more likely to have been consulting direct documentation and to be completing the paperwork with a lawyer. A debtor who estimated even a few dollars less on the questionnaire could create a discrepancy when this measure was compared with Schedule F medical debt. Most discrepancies on the negative side of the scale are within a one or two point difference, and thus potentially are of smaller amounts. Also, some medical providers impose interest and/or finance charges. A respondent may have recalled and reported only principal on the questionnaire, while Schedule F lists the legally collectible debt that includes these additional amounts. Finally, although the coding error rate in this study was very low, error remains a possible explanation. For the rate, see Lawless et al., *supra* note 95, app.

120. We refer here to categories “+2,” “+3,” and “+4,” which represent having out-of-pocket expenses of at least \$1,000 more, \$5,001 more, or \$10,001 more, respectively, than Schedule F medical debt. The 20% figure is premised on missing variables being included in the total count. *See infra* app. A.

bills do not have verifiable discrepancies between the court record and survey measures. The most populous group of filers, whose expenses fall within the same category on both measures (as indicated by a “zero”), is very diverse regarding the amounts of medical debt these respondents faced both before and during bankruptcy. For example, 11% of all respondents who are a “zero” had over \$10,000 of expenses in both the questionnaire and Schedule F. Such a respondent may have owed \$50,000 in medical bills beforehand and could either continue to owe those bills to a provider or have reduced them to some amount above \$10,000 identifiable as medical bills on Schedule F. An additional 4% had between \$5,000 and \$10,000 of medical expenses on both measures.<sup>121</sup> The average Schedule F medical debt for this “zero” group is just under \$5,000, suggesting that individuals could, in fact, have paid thousands of dollars towards their medical debt while still occupying the same category of expenses on the two measures. Cases that are a single category greater as recorded by the survey method compared to the court record method (a “+1” in Appendix A) also mask a wide range of dollar differences and significant medical obligations for the same reasons.<sup>122</sup>

With respect to the fifth of the sample with the biggest verifiable discrepancies between the measures, a variety of possibilities could explain why the same debtor reported a large amount of medical expenses in the questionnaire but had little (or no) identifiable Schedule F medical debt. There is the standard problem that some medical providers or their debt collectors do not have medical-sounding identities that court record coders can discern.<sup>123</sup> Also, having more questionnaire-reported medical expenses than Schedule F medical debt could reflect that individuals on the brink of bankruptcy paid off some or all of their medical bills.<sup>124</sup> Such payoff would not necessarily signify a lack of

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121. Forty percent of those who have the same category of medical expense on the questionnaire and medical debt on Schedule F had no out-of-pocket medical expenses or medical debt.

122. Those respondents that fall in the “+1” category have, on average, just under \$1,000 in Schedule F medical debt and are most likely to report less than \$1,000 in out-of-pocket expenses in the two years prior to filing. However, like the “zeros,” these individuals could easily have large differences in the amount of expense and Schedule F medical debt. For example, some respondents indicated more than \$10,000 in expense and reported between \$9,000 and \$10,000 in medical debt on Schedule F. It is possible that they had \$10,001 in expenses and only paid off \$100 of that debt, putting them in one category lower, but it also is possible that respondents had \$25,000 in expenses and paid \$15,100 off those expenses off prior to bankruptcy.

123. *See infra* note 152.

124. *See generally* Christopher Tarver Robertson, Michael Hoke & Richard Egelhof, *Get Sick, Get Out: The Medical Causes of Home Mortgage Foreclosures*, 18 HEALTH MATRIX 65, 90-92

financial burden from the bills; money is fungible and financially distressed families constantly make difficult choices about how to juggle expenses. Those filers most concerned with maintaining relationships with doctors could have fought very hard to pay these expenses while defaulting on other major obligations or satisfying those obligations using credit cards.<sup>125</sup> We can test the payoff hypothesis by looking at how the filers report managing their medical expenses, paying careful attention to the reported use of cash or cash equivalents.

In addition, some existing medical bills might simply be missing from Schedule F. This could be due to inadvertence,<sup>126</sup> a mistaken belief that insurance would fully cover a pre-bankruptcy procedure,<sup>127</sup> or a more intentional effort to hide the bankruptcy from a provider (who, if not listed, may not hear about the case) to avoid a feared disruption in health care.<sup>128</sup> The possibility that these circumstances explain the complete disappearance of a medical bill can be explored in part by looking at cases in which complete payoff would be most unlikely due to the size of the bills.

As the literature review suggested, reporting more expenses on the questionnaire than medical debt on Schedule F also could be due to the use of a credit card, home equity loan, or less formal borrowing to finance part or all of medical bills. In such an instance, out-of-pocket medical expenses, even if not paid fully by the time of filing bankruptcy, would not appear as Schedule F medical debt. Or, Schedule F medical debt would be lower in amount while debt to other creditors would likely be higher.

Discrepancies also could reflect that people overly attribute their financial problems on questionnaires to medical issues, which seem like a socially acceptable basis for overindebtedness.<sup>129</sup> Due to the methods employed here, this is less likely to explain the discrepancy in this study. The discrepancy reflected in

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(2008) (reporting statements of foreclosure defendants that they had reallocated money intended for their mortgages toward medical bills).

125. It also is possible that providers gave respondents significant discounts for prompt payment that remain invisible to us, although those payments could have come from another credit source.

126. *See, e.g., In re Hocum*, 119 B.R. 723 (Bankr. D.S.D. 1990) (granting debtor's post-discharge request to amend Schedule F to include accidentally omitted \$262.94 hospital bill that had been assigned to debt collector).

127. For example, in one case, the debtor originally failed to list a medical debt on Schedule F because he thought Medicare would fully cover his cataract operation. He amended Schedule F once he realized his error. *See In re Nosler*, 2007 WL 4322315 (Bankr. M.D. Fla. Aug. 2, 2007).

128. *See Jacoby et al., supra* note 71, at 383.

129. *See id.* at 384-85 for discussions of overmedicalization generally.

Figure 2 and the text is based on a purely factual question about out-of-pocket obligation not covered by insurance. The 2007 CBP questionnaire did not ask people about “medical *debt*,” which could be susceptible to inconsistent interpretations. Thus, the survey method variable for out-of-pocket expenses is straightforward. In addition, when respondents were asked to indicate their reasons for filing for bankruptcy—the place where overmedicalization would be most suspected—they did not merely check every available reason for filing that might be sympathetic. Indeed, only three out of ten respondents explicitly indicated medical bills as a reason for bankruptcy, even though far more reported substantial out-of-pocket medical expenses and had other indicators of distress.<sup>130</sup> In other words, it is possible that respondents have assigned too little responsibility to their medical problems for their financial downfall.<sup>131</sup> Even the greatest skeptics of the studies by Himmelstein et al. would be unlikely to suggest that the three out of ten people who reported medical bills as a reason for bankruptcy lacked any medical liability.

To begin our assessment of the possible explanations for discrepancies between the court record and survey methods, we look at the raw percentages on the use of cash, credit cards, and home equity loans for people with any medical expenses not covered by insurance.<sup>132</sup> These absolute percentages of credit usage presumably are dampened by the proximity to bankruptcy when some filers already have consumed their available credit.<sup>133</sup> But the overall frequency is less

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130. Respondents in our sample selected an average of 4.33 reasons for filing out of a total of 19. Respondents who included the medical bill reason had a slightly higher average (5.75), but this can be explained by the fact that there was a strong association between reporting medical bills as a reason and the other medical reasons on the list of responses. For more information about the indication of medical reasons for filing, see *infra* p. 281, fig.6.

131. Jacoby & Warren, *supra* note 33.

132. The percentages in Figure 3 vary slightly from those in Appendix B because the questionnaire variables had fewer missing data points. Appendix B looks at these variables in combination with the court record variables, which reduced the number of observations. Also, Appendix B shows the difference in home equity loan use if one includes all who reported expense regardless of housing tenure.

133. We do not know the credit limits of our respondents. Because credit limits are not regularly reported in the general population, studies have used various techniques to estimate them. See ROBERT B. AVERY ET AL., AN OVERVIEW OF CONSUMER DATA AND CREDIT REPORTING, FED. RES. BULL. 58 (Feb. 2003), available at <http://www.federalreserve.gov/pubs/bulletin/2003/0203lead.pdf>. The most common approach is to use the highest balance ever reported as the credit limit. Using this technique, Avery et al. found in their 2003 paper that about 25% of revolving accounts in the general population had a credit limit below \$1,000; 41% had a credit limit between \$1,000 and \$4,999; and only a very small percentage had a credit limit of \$25,000 or more. *Id.*

important than the circumstances under which respondents used credit. Figure 3 shows medical bill payment methods broken down by those respondents who reported that medical bills were a reason that they filed for bankruptcy and those who did not. This breakdown demonstrates that respondents who indicated medical bills as a reason for filing use regular credit cards and home equity loans at a much higher level. In this Figure, the vertical axis shows the percentage of respondents with medical expenses.<sup>134</sup> The horizontal axis is a breakdown of the use of different methods of paying medical bills.

**FIGURE 3: METHODS OF MANAGING MEDICAL BILLS**

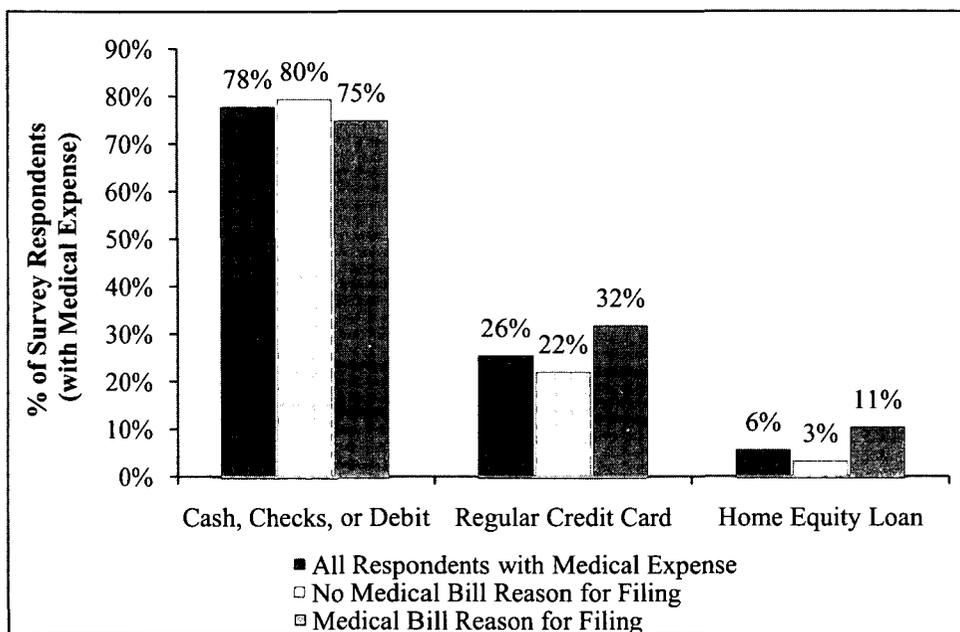


Figure 3 illustrates that those who reported medical bills as a reason for bankruptcy said they used home equity for medical bills nearly four times as frequently as the other respondents, and had a higher rate, by more than a third, of using credit cards to pay medical bills.<sup>135</sup> The markedly higher use of home

Looking at the overall profile of revolving accounts, the average credit limit was about \$4,500. *Id.*

134. Here, as before, we examine only those respondents who indicated having any out-of-pocket medical expense in the two years prior to filing for bankruptcy.

135. Differences between those with a medical bill reason for filing and those without a medical bill reason for filing are statistically significant ( $p$ -value  $\leq .05$ ) for use of both credit cards

equity loans and credit cards to pay medical bills among those who reported medical bills as a reason for filing is of particular importance to our analysis. If an individual pays for medical care with a credit card or home equity loan, then these expenses will not be identified as medical bills in court records. The data presented in Figure 3 thus support a more nuanced and multi-instrument approach to evaluating the effect of medical debt on bankruptcy filings.

We also examined the congruence between medical obligations captured by the court record and survey methods depending on whether respondents listed a medical bill reason for bankruptcy. Respondents who identified this reason for filing for bankruptcy had, on average, twice the difference between survey medical expenses and Schedule F medical debt as those who did not identify medical bills as a reason for filing.<sup>136</sup> And, as noted in the introduction, over one quarter (27%) of those who identified a medical bill reason for bankruptcy had zero Schedule F medical debt, rendering them invisible in the court record method.

To explore further the possible explanations for reduced or invisible medical debt using the court record method, we look at the medical bill management of respondents based on the levels of discrepancy between the two methods of measurement.<sup>137</sup> Appendix B reports all of our results as well as whether the differences are statistically significant using a traditional ANOVA test.<sup>138</sup> Figure 4 shows three important methods of responding to medical bills. It reports these in groups that had increasing amounts of difference between the court record and survey methods. If paying off medical bills in full were the explanation for the decline or disappearance of medical bills by the time of bankruptcy, we would expect to see high rates of reporting use of cash and cash equivalents by

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and home equity loans. All differences, when tested across the three groups—1) all respondents with medical expenses, 2) those with a medical bill reason for filing, and 3) those without a medical bill reason for filing—are statistically significant with an ANOVA test. However, we cannot identify which of the differences are causing that statistical significance. ANOVA is an “ANalysis Of VAriance” test, which compares group means by analyzing comparisons of variance estimates to determine whether the differences in means are statistically significant.

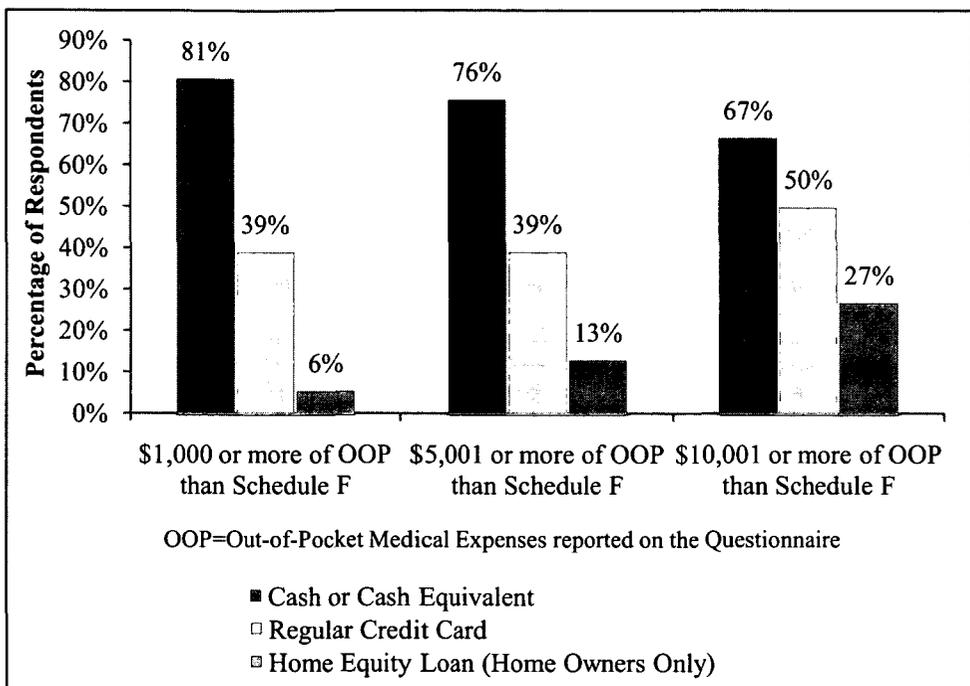
136. The difference is statistically significant. Overall, all respondents reported just over half of a category more of medical expense than of Schedule F medical debt. Those who listed medical bills as a reason for filing had, on average, approximately three-quarters of a category more of medical expense than Schedule F medical debt. Those who did not indicate medical bills as a reason for filing had less than 0.4 of a category more medical expense than Schedule F medical debt.

137. *See supra* text accompanying notes 118-122.

138. As these variables are coded as “Yes” or “No” variables, the frequency can be essentially understood as the percent of respondents in the group replying affirmatively to the question.

respondents with the biggest gaps. Figure 4 and Appendix B show a pattern of slightly decreasing use of cash, with the lowest frequency of cash usage reported by those who reported over \$10,000 of medical expenses on the questionnaire but had no Schedule F medical debt.<sup>139</sup> The pattern in Figure 4 suggests that having lower Schedule F medical debt is not due to individuals paying off medical bills completely with cash, debit cards, or checks before filing for bankruptcy.

**FIGURE 4: USE OF CASH, CREDIT CARDS, AND HOME EQUITY LOANS FOR MEDICAL BILLS, BY GAP IN MEASURES**



By contrast, Figure 4 illustrates a positive relationship between the reported use of a regular credit card to pay medical bills and the difference between the reported expenses on the questionnaire and Schedule F medical debt.<sup>140</sup> This is

139. The difference in use of cash, debit cards, and checks is statistically significant to the 0.002 level. Using the ANOVA method of testing the differences in the groups does not allow us to identify *which* differences are statistically significant, but does allow us to demonstrate that the overall patterns of use vary enough to be statistically significant.

140. The differences in use of a regular credit card for medical bills are statistically significant

consistent with the concern that debts transferred to credit cards become minimized or invisible in court record studies.<sup>141</sup>

Filers with significantly greater out-of-pocket expenses than Schedule F medical debt also indicated use of home equity loans with much greater frequency.<sup>142</sup> This is especially true for those with at least \$10,001 more in expenses than Schedule F medical debt; over a quarter of this group used home equity loans to pay medical debts. This is in sharp contrast to the overall rate of 5.8% who used a home equity loan to pay off medical debt among all homeowners in the 2007 CBP.

Appendix C displays the comparative medical bill management for the group of respondents with more than \$10,000 in expenses reported on the questionnaire and zero Schedule F medical debt. Members of this small group would have had to expend significant effort to pay off \$10,000—or much more—completely in cash before bankruptcy. Also, this biggest of possible differences between the measures would be less likely to be due to forgetfulness about medical bills, partial payoff of medical bills, seeking to hide their bankruptcy cases from providers, or other such explanations. Respondents in this group reported using home equity loans for medical bills at over four times the frequency of everyone else; they also reported using credit cards twice as often as everyone else.

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to the <0.001 level. Like anyone reporting medical expense on the questionnaire, the group that reported over \$10,000 of debt on Schedule F and zero expense on the questionnaire would have skipped the question about managing out-of-pocket expense and thus had the “lowest” use of all methods of payment.

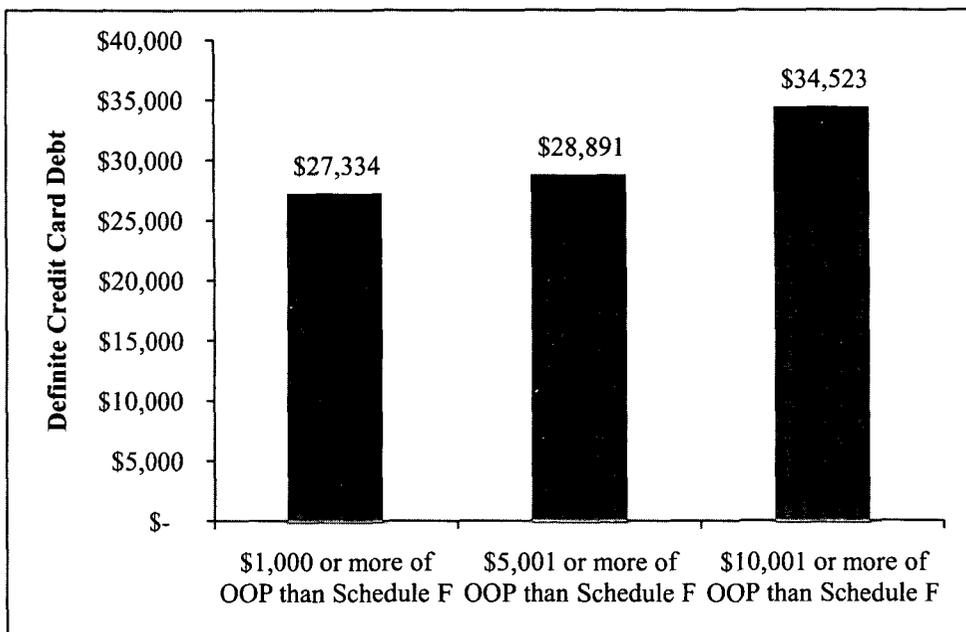
141. As another measure, when we isolated and compared the Schedule F medical debt of those who indicated using credit cards for medical bills from those who did not so indicate, the credit card users reported lower average and median medical debts. However, credit card users had nearly twice the amount of credit card debt. Credit card users had \$5,264 average Schedule F medical debt versus \$6,841 for non-credit card users. We also compared medians: those who used credit cards to pay medical bills had a median Schedule F medical debt of \$1,473, compared to \$1,791 for those who did not use a credit card. The difference is significant to the 0.05 level. Those who reported using a regular credit card to pay for medical expenses filed, on average, \$31,853 in credit card debt on Schedule F, compared to \$15,792 in credit card debt for those who did not use a regular credit card to pay medical expenses.

142. Figure 4 portrays the percentages of those who owned a home and used a home equity loan for medical expenses; if we look at all filers, (i.e. not just those who owned a home in the last five years) we see a similar pattern, but smaller numbers. For example, 19% of those in the highest group report using a home equity loan, compared to 3% of those reporting the same amount on both measures. The differences exhibited using either methods of measurement are statistically significant to the 0.0001 level. All data on the individual breakdown of use of home equity loans are available in Appendix B.

Generally, filers with the greatest amounts of out-of-pocket expenses but zero Schedule F medical debt had a much higher rate of reporting that they shifted obligations to alternate creditors that are undetectable as medical on court records.

To further corroborate these findings, we looked at the amount reported on Schedule F of claims owed to *credit card* lenders (as opposed to claim holders with medical identities).<sup>143</sup> Figure 5 reports the results.

**FIGURE 5: AVERAGE SCHEDULE F CREDIT CARD DEBT, BY GAP IN MEASURES**



As Figure 5 shows (and is reported more fully in Appendix D) the amount of Schedule F credit card debt grows as the gap increases between the survey and court record methods of identifying medical obligation.<sup>144</sup> The filers represented

143. It can be difficult to identify credit card debt because of the variety of ways debt can be listed on Schedule F. Although we would get the same results either way as the next footnote explains, we used a very conservative, lower bound definition of credit card debt by using only debt in which the listing contained the words “credit card,” “card,” “revolving credit,” “charge account,” or closely similar terms. Also, any listing that contained brand name words for a credit card, such as “Visa,” “MasterCard,” or “Discover,” was counted as *definitely* credit card debt.

144. This result is obtained with the “definitely credit card” variable, but the same pattern

in Figure 5—the fifth of the sample with verifiably higher out-of-pocket expenses than Schedule F medical debt—had much greater average credit card debts than the \$19,006 average credit card debt of all filers in the sample, and also had higher median credit card debts than the median of the overall sample. Again, this suggests that those with less Schedule F medical debt are not necessarily paying off medical debt with ease, but rather are shifting medical bills to alternate forms of credit.<sup>145</sup> These findings also support the story that bankruptcy filers in our sample made their medical providers a higher priority than other types of creditors. As money is fungible, these individuals went into bankruptcy with lower medical debt but higher levels of credit card debt.<sup>146</sup> In addition to the court record information on credit card usage, we find a parallel trend regarding home mortgages. As the gap grows between the questionnaire medical expenses and Schedule F medical debt, so do the amounts of secured claims against filers' residences.<sup>147</sup> This generally corroborates filers' reporting of home equity use for medical bills.

We explored other indicators that might shed light on why medical expenses are not appearing on Schedule F. The 2007 CBP questionnaire asked respondents to indicate whether they engaged in a variety of methods to “make ends meet” during the previous two years.<sup>148</sup> We were interested in whether respondents with

emerged when we conducted the same analysis with the “probably credit card” variable, as well as with the two measures combined.

145. The pattern is the same for both chapter 7 and chapter 13 cases, but the amounts in chapter 7 cases are higher for cases fitting the two left-most columns on Figure 5.

146. These results are consistent with an earlier analysis of no-asset chapter 7 cases by researchers at the Executive Office for United States Trustees (in DOJ), in which Schedule F credit card debt levels were particularly high among filers with no observable medical debt on Schedule F. See Ed Flynn & Gordon Bermant, *Credit Card Debt in Chapter 7 Cases*, AM. BANKR. INST. J., Dec. 2003/Jan. 2004, at 20 (credit card debt of those with no Schedule F medical debt was higher than those with Schedule F medical debt and “was more than twice as high as for debtors who listed at least \$5,000 in medical debt”); see also MICHELLE M. DOTY ET AL., SEEING RED: THE GROWING BURDEN OF MEDICAL BILLS AND DEBT FACED BY U.S. FAMILIES (Commonwealth Fund Issue Brief, 2008), available at <http://www.commonwealthfund.org/Content/Publications/Issue-Briefs/2008/Aug/Seeing-Red--The-Growing-Burden-of-Medical-Bills-and-Debt-Faced-by-U-S--Families.aspx>.

147. Home owners with the highest level of difference between medical expenses and Schedule F medical debt (i.e. at least \$10,001 more in medical expenses than Schedule F medical debt) also have the highest level of secured claims against their residences, a dollar figure which declines as the difference between medical expenses and Schedule F medical debt decreases..

148. The questionnaire asked: “During the TWO years before the bankruptcy, did EITHER you or a spouse or partner DO, or TRY TO DO, any of the following things in order to make ends

increasingly greater questionnaire-reported expenses than Schedule F medical debt were more likely to report “Consolidated debts with a credit card or new loan” or “Put necessities on the credit card (for example, food or monthly bills)” as coping options. As Appendix E shows, those with higher expenses than Schedule F medical debt were more likely to say that they put necessities on the credit card.<sup>149</sup>

Finally, we turn back to filers’ stated reasons for bankruptcy, which in Figure 6 are broken down based on the size of the difference between the court record and survey measures of expenses. This helps determine the consequences of relying exclusively on the court record method to measure medical-related financial burden. As Figure 6 shows and Appendix F reports more fully, as the gap between the court record and survey measures grows, so does the percentage of respondents who indicated medical bills as a reason for filing for bankruptcy (the left-most column in each grouping). These findings suggest that the court record method particularly under-represents medical bill problems for filers who reported medical reasons for filing for bankruptcy.

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meet? (Check all that apply.)” Possible responses were: “Worked more hours or got another job; Cashed out or borrowed from a retirement, a 401k, a pension account or life insurance; Refinanced your home, took out a home equity loan or line of credit, or took out a debt consolidation loan that was secured by your home; Sold your house; Asked creditors, such as landlords or credit card companies, to work with you on the payments; Sold or pawned a car, furniture, or other personal property; Consolidated debts with a credit card or new loan; Used a payday loan business (for example, Check to Cash) or car title lender to borrow money or take a cash advance; Put necessities on the credit card (for example, food or monthly bills); Accepted or borrowed money from family or friends; Accepted or borrowed money from a religious group or charity; or Something else.”

149. They were not more likely to say that they consolidated debt on a credit card or new loan, but it is not obvious that respondents would conceptualize moving medical bills to credit cards as a consolidation.

**FIGURE 6: MEDICAL-RELATED REASONS FOR FILING FOR BANKRUPTCY, BY GAP IN MEASURES**

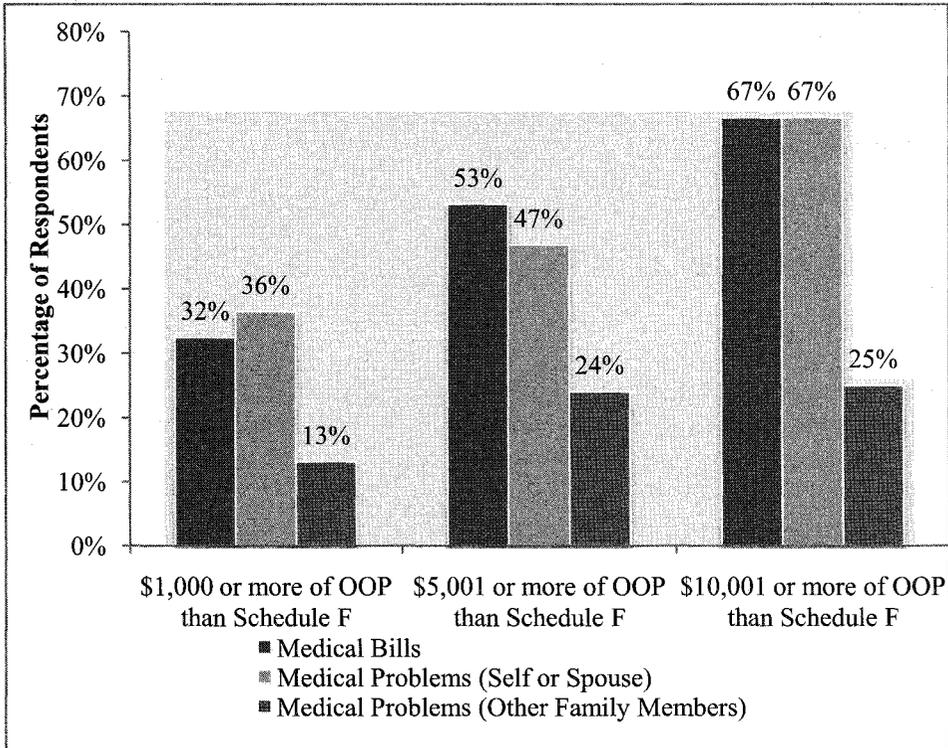


Figure 6 presents the distribution of individuals who said that medical bills, medical problems of self or spouse, or medical problems of other family members were a reason for filing. Again, this distribution is categorized by the difference between the medical expenses reported on the questionnaire and the amount of medical debt reported on Schedule F. Note that two-thirds of respondents with more than \$10,000 in medical expenses on the questionnaire and zero medical debt on Schedule F reported that medical bills were a reason for filing for bankruptcy. Thus, Figure 6, like Figure 3, shows that those most affected by medical debt are less likely to show up in a court records study.<sup>150</sup> Had we conducted our study relying entirely on court records as the DOJ did in 2005, our medical debt count would not have included a single member of this

150. While the number of cases that fall into the category of \$10,000 or more expenses reported on the survey and zero Schedule F medical debt is small (19 cases in our sample), this group represents a very conservative method of analyzing medical debt in bankruptcy.

group.<sup>151</sup> For the other respondents represented on Figure 6, a study relying exclusively on the court record method would have significantly understated their medical burden.

The analysis for this project has limits. First, as noted earlier, any attempt to code medical debts from court records risks the omission of providers or related parties with no obvious health care designation in its name; our study is no exception.<sup>152</sup> This limit is consistent with our conclusion that multi-instrument studies are preferable to exclusive reliance on court records for some kinds of research questions. Second, the questionnaire did not ask respondents to identify the precise type of health care that they received, precluding a correlation of type of care and medical bill management for the full sample.<sup>153</sup> Third, the nature of the data collection ultimately required that we compare a continuous variable (Schedule F medical debt) with a categorical one (pre-bankruptcy out-of-pocket expenses) based on dollar ranges. The categories are the most precise measures available for out-of-pocket estimates for the full dataset. Fourth, the variables are drawn considerably from self-reported questionnaire data and thus face the same challenges as other interview and questionnaire studies.<sup>154</sup> But to emphasize, this limit applies to the court records as well. This is not a situation in which a debtor

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151. The same pattern holds for illness of self or partner as a reason for filing. Familial medical problems were noted as a cause of bankruptcy by a smaller group of filers, but show similar patterns: 25% of the group with the biggest gap between medical expenses and Schedule F medical debt selected familial medical problems as a reason for bankruptcy, compared to 10.7% of the sample population. A full breakdown of the distribution into these categories is available in Appendix F.

152. For example, CSI Financial Services “takes over” a patient’s account and offers extended payment plans, but the hospital takes back the debts upon a patient’s default on a payment plan. Haugh, *supra* note 18, at 18. Neither CSI Financial Services nor the banks doing the interim financing would be detected as medical on Schedule F under most coding protocols. Some bulk medical debt buyers do not have medical-sounding names. See generally *In re Andrews*, 394 B.R. 384 (Bankr. E.D.N.C. 2008) (discussing bulk buyers in a different context).

153. Diagnosis information was collected via telephone interview and thus is available only for the subset of respondents who participated in that portion of the study.

154. Those who conduct research relying on interview and questionnaire data have long struggled with two principal issues. First, the nature of human response introduces a higher degree of error into the data. See John Bound, Charles Brown & Nancy Mathiowetz, *Measurement Error in Survey Data*, in HANDBOOK OF ECONOMETRICS 3705 (2001). Second, asking questions about finances and health, two private topics, might introduce additional error. See Marianne Bertrand & Sendhil Mullainathan, *Do People Mean What They Say? Implications for Subjective Survey Data*, 91 AM. ECON. REV. 67, 68 (2001). In the context of our analysis, however, we believe that our findings contribute meaningfully to our understanding of an otherwise unexplained discrepancy.

says one thing while a court or creditor says another; in many consumer bankruptcy cases, nearly all of the documents in the court records are submitted by the debtor. Fifth, this study is designed to analyze bankruptcy filers. This means that we cannot directly comment on how non-filers deal with their medical bills.<sup>155</sup> Sixth, we compare court records and questionnaire data for a sample that was drawn in 2007, whereas the DOJ sample was collected in the early 2000s.<sup>156</sup> We cannot prove, of course, that a survey conducted in the early 2000s on the sample captured by the DOJ would replicate our results. But, as Table 1 illustrates, our Schedule F data and the DOJ data (reported in Table 1) are similarly patterned.

We also should take care to note some significant demographic patterns in expense and medical bill management that affect the accuracy of relying only on court records.<sup>157</sup> For example, homeowners and non-homeowners had equal frequency of identifiable Schedule F medical debt, as well as similar distributions across the dollar ranges of Schedule F medical debt.<sup>158</sup> But on the questionnaire, homeowners were more likely to report incurring expenses within the two years prior to filing (81% versus 73%) and had a different distribution of expenses than non-homeowners. Homeowners also were more likely to report using credit cards—and, of course, home equity loans—for medical bills than non-

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155. We see glimpses of a difference between the bankruptcy population and the general population. For example, in the tracking survey of the Center for Studying Health System Change, more than half of respondents who reported problems paying medical bills said that providers suggested that they undertake payment plans. CUNNINGHAM, *supra* note 28, at 3. Even among bankruptcy filers who identified medical bills as a reason for bankruptcy, only about a third reported being in payment plans directly with their providers; it is possible that providers suggested plans to more of them. We will discuss provider payment plans in more depth in a separate paper.

156. *See supra* p. 265, tbl.1. Medical costs rose at a rate outpacing inflation generally in the 2000s, and self-pay obligation did as well. Although our literature review focuses largely on more recent publications, we do not believe that medical practice management advice was qualitatively different in the first half of the decade. *See Jacoby & Warren, supra* note 33. We do not know of a theory on which the enactment of the 2005 bankruptcy amendments would affect our results.

157. We found few statistically significant differences in the average amount of Schedule F medical debt among those with differing education levels, gender, race, or living arrangements. We also tested for a variety of demographic differences in medical bill management—for instance, age, race, gender, homeownership, and marital status—and again many were not significant. For example, we did not find a significant difference in bill management between respondents who indicated that they lived with a permanent partner and those who lived alone.

158. The homeownership variable includes everyone who reported owning a home within five years prior to filing.

homeowners.<sup>159</sup> A stand-alone analysis of the court records would blunt these differences.

We encountered a similar phenomenon regarding medical expenses among petitioners who identified as African American versus petitioners who identified as white.<sup>160</sup> In our sample, there was not a statistically significant difference between African American petitioners and white petitioners in the frequency or average amount of Schedule F medical debt.<sup>161</sup> But on the questionnaire, African American petitioners reported lower levels of out-of-pocket medical expenses than most other petitioners, and African American petitioners with medical expenses were much less likely to use credit cards or home equity loans (but just as likely to use cash) for the bills they did incur.<sup>162</sup> African American petitioners

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159. Nearly three out of ten (27.9%) of those petitioners who owned a home in the five years prior to bankruptcy reported using a regular credit card to pay their medical bills, compared to 17% of those who did not own a home. As previously noted, 5.8% of homeowners used a home equity loan to pay medical bills. Strangely, 1.2% of filers who said they did not own a home at any time in the prior five years selected this option on the questionnaire. It is possible that the language of the selection led them to believe that this option included lines of credit not secured by homes. Or, they may have used someone else's home as collateral. In any event, this difference, like the difference in credit card usage, is statistically significant to the <0.001 level.

160. The written questionnaire asked respondents to indicate the group with which they identified, with the options of "African American or Black, Asian American, Hispanic or Latino/a, White or Caucasian, Other (please specify), or none." The questionnaire asked for the same information about partners of respondents. For the comparisons, we included in our measure African American respondents who reported no partner (57%) or identified his or her partner as African American (31%), which is the great majority of the respondents who identified as African American.

161. Among households with African American petitioners, 49.4% listed medical debt on Schedule F, compared to 52.6% of white filers. Households with African American petitioners listed smaller average medical debt (\$5,688 per household) than did white filers (\$6,513). But both of these differences are outside the standard levels for statistical significance. Households with African American petitioners, however, had a lower median Schedule F medical debt (\$1,349) than white petitioners (\$1,746), and this difference is significant to the 0.05 level. The DOJ report used averages, not medians, and thus would not have captured this difference.

162. 76% of African American respondents reported using cash to pay medical bills, versus 77% percent of white respondents, a difference that is not statistically significant. African American petitioners with medical expense were much less likely than white petitioners to report using a credit card to pay medical bills (11.3% versus 30.1%). This difference persists when we examine the use of home equity loans to pay off medical expense (1.7% versus 5.3%), and when we focus on only those who owned homes some time within the five years prior to filing (2.2% versus 6.9%). The difference in credit card and home equity loan use (including either measurement) is significant to the <0.001 level.

also had significantly less general credit card debt in their court files than other respondents. Looking at the patterns across the distribution of both measures of medical burden, it appears that African American petitioners in our sample were less likely than white petitioners to have reduced or eliminated medical bills owed directly to providers by the time they got to bankruptcy. We cannot control for the variables that might be driving this finding, such as differences in access to medical care and credit.<sup>163</sup> Whatever the explanation, Schedule F and the court record method are somewhat more (though not perfectly) reflective of the pre-bankruptcy burdens of African American respondents in this sample than they are of the pre-bankruptcy burdens of white filers.

A final example comes from the small group of youngest filers: households with at least one petitioner under twenty-five. The youngest filers reported having Schedule F medical debt with much greater frequency than any other age group or all other age groups combined. In addition, on average, households in which at least one of the filers was under twenty-five had an average medical debt on Schedule F of \$13,263, compared to an average of \$5,846 for all other age groups.<sup>164</sup> Yet, relying on this finding alone would overstate young filers' relative likelihood of having out-of-pocket medical expenses in the two years prior to filing, and may speak instead to their lack of financing options. These filers were less likely than other households to report using a regular credit card for medical bills and had less general credit card debt in their files overall.<sup>165</sup> They were also more likely to report using a provider payment plan or doing

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163. As noted earlier, we tested for a variety of other differences based on race and sex relating to medical bills and medical bill management, and they were not significant. According to one prior study, African American families are three times as likely as white families to file for bankruptcy, but their reasons for filing are similar. See Elizabeth Warren, *The Economics of Race: When Making It to the Middle Isn't Enough*, 61 WASH. & LEE L. REV. 1777, 1779 (2004).

164. Although the youngest filers had a much higher average Schedule F medical debt than everyone else, the difference between the medians (\$1,672 for the youngest versus \$1,590 for the older filers) is not statistically significant, suggesting that a small number of the youngest filers with huge Schedule F medical debts skews the average. We see a glimpse of this in Figure 1, where three out of the six filers with Schedule F medical debts over \$100,000 were under the age of twenty-five. On a filer-by-filer basis, the very youngest respondents were also much more likely to have the same category of medical expense on both measures than everyone else (46% versus 36%).

165. Among households in which either petitioner was under twenty-five years old, 18.9% reported using credit cards for medical bills, compared to 24% of all other petitioners. This difference is not statistically significant. These youngest filers also had a lower frequency of home equity loan use for medical bills (2.1% versus 4.2% for all other petitioners), but this difference is outside traditional levels for statistical significance.

“something else” about a medical bill, which often meant waiting to discharge the bill in bankruptcy.<sup>166</sup> Both of these latter options increase the likelihood of a pre-bankruptcy medical bill showing up as Schedule F medical debt. Likewise, a much greater proportion of bankrupt households with younger women petitioners (34 and younger) retained direct obligation that appeared as Schedule F medical debt than other groups. But such households were less likely to use a regular credit card or a home equity loan for medical bills and much more likely than others to use a provider payment plan or “something else” as compared to other households.<sup>167</sup>

These demographic observations warrant further study with additional controls. But this preliminary look reveals another layer of complexity that seems to be disregarded by those who rely exclusively on court records to measure medical debt burden.

#### IV. DISCUSSION

This Article is the first to demonstrate through detailed systematic analysis that the DOJ’s court record method, standing alone, is an unreliable measure of the financial burden of illness or injury faced by bankruptcy filers. In our nationally-representative sample of filers, the court record method produced a skewed undercount of medical bills and failed to account for filers with significant medical hardship who had no debt on Schedule F that could be identified as medical. The shifting of medical obligations to creditors with non-medical identities played a large role in the discrepancy between court record and survey information, particularly for respondents with the largest verifiable gaps in measures. Absent changes to the forms on which information about debts is collected, the DOJ court record methodology should not be used to measure the financial burden of health care on bankrupt families.

The demographic assessment suggests that court records better reflect medical bills for some groups of filers than for others. Yet court records, standing alone, are not well-suited to distinguish these filers on the relevant demographic

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166. Petitioners under twenty-five years of age with out-of-pocket expense reported provider payment plans 27.4% of the time, compared to all other petitioners, who reported payment plans 22.8% of the time. 21% of the younger petitioners reported doing “something else” to handle expenses, compared to 9.5% of all other petitioners. Both of these differences are statistically significant to the 0.005 level.

167. Looking at the use of credit, the difference between the groups is significant to the <0.001 level using a standard ANOVA test. The difference in use of “something else” is also statistically significant to the <0.001 level, while the difference in the use of cash is too small to be statistically significant.

criteria such as age and racial identity. Furthermore, lawmakers and scholars who have been relying on the DOJ court record study have made no public efforts to draw such distinctions.

The clock cannot be turned back to 2005, when the DOJ analysis enabled lawmakers to vote with a clearer conscience in favor of the Bankruptcy Abuse Prevention and Consumer Protection Act of 2005 and against amendments that members of Congress proposed to protect people with medical problems from certain harsher effects of the bill.<sup>168</sup> However, our study should guide the use and interpretation of these kinds of studies in other contexts.

In combination with other methods, the court record method has unappreciated utility to shed light on the impact of patients' bankruptcies on *providers*. Consistent with the medical practice advice reviewed in Part II, health care consultants are concerned that "the last bill people pay is often their healthcare debt."<sup>169</sup> One might have thought that families headed to bankruptcy court would overwhelmingly defer dealing with their medical bills. However, in our national sample, due to filers' payment and credit activities between the time of treatment and the time of bankruptcy, fewer bankruptcy filings directly affected medical providers, and for substantially smaller amounts. Nearly 80% of bankruptcy filers had received medical services or goods resulting in some self-pay obligation within two years before they filed for bankruptcy—while many already were struggling financially. And yet despite their financial hardship, a third of filers with medical obligation had managed to protect their providers entirely from the bankruptcy process, and many others reduced the dollar amount of the obligation.<sup>170</sup> Some filers who reported the largest possible out-of-pocket

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168. See, e.g., Melissa B. Jacoby, *Bankruptcy Reform and the Cost of Sickness: Exploring the Intersections*, 71 MO. L. REV. 903, 908 n.21 (2006) (reviewing failed medical-related amendments to the 2005 Act). We recognize that the legislation as a whole had been pending in various forms since 1997, and lawmakers across the political spectrum were evidently responsive to credit industry pressure to enact it. See generally Melissa B. Jacoby, *Negotiating Bankruptcy Legislation Through the News Media*, 41 HOUS. L. REV. 1091, 1118 (2004).

169. Robert Czerwinski & Peter M. Friend, *Selling Written-Off A/R*, HEALTHCARE FIN. MGMT., Sept. 2008, at 128, 130; see also *A New World of Health Care: More Patients Seek Help with Bills*, HEALTH CARE COLLECTOR (Aspen Publishers, New York, N.Y.), Nov. 2008, at 1 (citing an industry expert saying, "As everyone knows, we are often the last bill people pay. I thought it was telling this past month when we heard people say they had to buy books, pay school fees, or pay for their kids' participation in sports so they could not pay the hospitals. Why? Other folks won't let you in without paying, but hospitals will.").

170. In theory, preferential transfer law polices eve-of-bankruptcy payoffs of creditors, including medical providers. See, e.g., 11 U.S.C. § 547 (2006); *Cruse v. Hannibal Health Care Sys.* (*In re Watkins*), 325 B.R. 277 (Bankr. E.D. Mo. 2005) (applying preference law and ruling for

expenses within the two years prior to filing had no medical providers as creditors in the court records. Schedule F also includes debt older than two years, which increases the debt captured by the court record method. This suggests that our study is a fairly conservative measure of providers' reduction of exposure to their patients' bankruptcies within the two years prior to filing. Thus, a better way to use the court record method is combined with other sources to reveal the extent to which medical providers extricate themselves from the process and consequences of patients' bankruptcies.

## V. CONCLUSION

Regardless of whether they are insured, nearly all patients have direct monetary dealings with their medical providers. A body of advice and technological tools help providers manage risks associated with this financial exposure. The advice and tools encourage the use of third-party credit. Our study demonstrates how these practices affect the empirical study of medical burden on patients. In our sample, an exclusively court record study does not merely produce a more conservative measure of medical burden; it hides or diminishes cases in which medical bills were particularly significant.

The health care finance debate intensified the interest in medical bills among financially distressed families such as those found in the bankruptcy system, and the interest in this subject will not subside anytime soon. Our study urges caution in using the DOJ court record analysis or other such studies to measure patient medical debt on a standalone basis. It also casts doubt on efforts to refute survey studies based on court documents alone. Absent changes to the forms on which filers report their debts, or, perhaps, substantial changes in medical bill

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trustee to recover execution on bond for payment of medical bills subject to state court judgment). Although the law is not uniform, some courts find that a creditor is vulnerable to preference attack even if the debtor simply substitutes another creditor (for example, a credit card or credit card convenience check) to pay the antecedent debt. *See, e.g., In re Marshall*, 550 F.3d 1251 (10th Cir. 2008); *In re Wells*, 382 B.R. 355 (6th Cir. BAP 2008); *Flatau v. Walman Optical Co. (In re Werner)*, 365 B.R. 283 (Bankr. M.D. Ga. 2007). But for a variety of legal and practical reasons, preference law is unlikely to have an effect on medical bill payment pre-filing in most consumer bankruptcy cases. First, the preference period is relatively short (ninety days, as mentioned) unless the beneficiary is an insider. 11 U.S.C. § 547(b)(4) (2006) (setting 90-day preference period generally and one year look-back period for insiders). Second, recipients of transfers of value less than \$600 have an absolute statutory defense to preference actions in consumer bankruptcy cases, and thus case trustees would not pursue such cases. § 547(c)(8). Third, providers have a defense if they accepted payment in the ordinary course of business, which Congress in 2005 defined broadly to protect more payment recipients. § 547(c)(2).

management, court records alone reveal very little about the burden of medical bills on financially distressed families. At best, when used in combination with other instruments, such records help to shed light on the impact of patient bankruptcy on health care providers—an important but distinct matter.



**APPENDIX A: DISTRIBUTION OF DIFFERENCE BETWEEN QUESTIONNAIRE-REPORTED OUT-OF-POCKET EXPENSES AND SCHEDULE F MEDICAL DEBT**

	Number	Percent
Four categories more on Schedule F than on the questionnaire (-4)	19	0.78
Three categories more on Schedule F than on the questionnaire (-3)	26	1.07
Two categories more on Schedule F than on the questionnaire (-2)	96	3.93
One categories more on Schedule F than on the questionnaire (-1)	224	9.18
Same category of medical debt on Schedule F and the questionnaire (0)	834	34.18
One category more on the questionnaire than on Schedule F (+1)	584	23.93
Two categories more on the questionnaire than on Schedule F (+2)	373	15.29
Three categories more on questionnaire than on Schedule F (+3)	79	3.24
Four categories more on the questionnaire than on Schedule F (+4)	36	1.48
Missing either questionnaire or Schedule F data (excluded from analysis)	169	6.93
Total	2440	100

APPENDIX B: MEDICAL BILL MANAGEMENT, BY GAP IN MEASURES

	Pay with cash, check, or debit card	Pay with a regular credit card	Pay with a medical credit card	Agree to a payment plan with the medical provider	Something else	Pay with money from a home equity loan or other line of credit	Pay with money from a home equity loan or other line of credit (Home owners only)
	Percent (SD)	Percent (SD)	Percent (SD)	Percent (SD)	Percent (SD)	Percent (SD)	Percent (SD)
-4	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
-3	87.5% (0.342)	12.5% (0.342)	0.0% (0)	12.5% (0.342)	12.5% (0.342)	6.3% (0.25)	7.7% (0.277)
-2	90.4% (0.298)	13.5% (0.345)	1.9% (0.139)	26.9% (0.448)	7.7% (0.269)	1.9% (0.139)	2.9% (0.171)
-1	78.5% (0.412)	11.4% (0.319)	2.7% (0.162)	28.2% (0.452)	12.8% (0.335)	2.0% (0.141)	3.1% (0.175)
0	73.6% (0.441)	19.3% (0.395)	1.4% (0.119)	31.7% (0.466)	13.8% (0.345)	3.0% (0.172)	4.2% (0.200)
+1	82.5% (0.380)	25.2% (0.434)	2.6% (0.158)	19.7% (0.398)	9.1% (0.288)	4.8% (0.214)	5.8% (0.234)
+2	81.0% (0.393)	39.1% (0.489)	4.3% (0.203)	23.6% (0.425)	7.8% (0.268)	4.6% (0.209)	5.7% (0.232)
+3	76.0% (0.430)	39.2% (0.491)	3.8% (0.192)	27.8% (0.451)	12.7% (0.334)	10.1% (0.303)	13.1% (0.340)

+4	66.7% (0.478)	50.0% (0.507)	0.0% (0)	22.2% (0.422)	19.4% (0.401)	19.4% (0.401)	26.9% (0.452)
Total	79.0% (0.407)	26.0% (0.438)	2.6% (0.159)	25.1% (0.434)	10.8% (0.310)	4.5% (0.207)	5.9% (0.236)
Prob > F	0.0020	0.0000	0.2612	0.0013	0.0465	0.0001	0.0001

**APPENDIX C: MEDICAL BILL MANAGEMENT OF THOSE WHO REPORTED MORE THAN \$10,000 IN QUESTIONNAIRE MEDICAL EXPENSES AND ZERO SCHEDULE F MEDICAL DEBT**

	Pay with cash, check, or debit card	Pay with a regular credit card	Pay with a medical credit card	Something else	Agree to a payment plan with the medical provider	Pay with money from a home equity loan or other line of credit	Pay with money from a home equity loan or other line of credit (Home owners only)
	Percent	Percent	Percent	Percent	Percent	Percent	Percent
All other respondents (SD)	73% (0.45)	23% (0.42)	2% (0.15)	10% (0.30)	23% (0.42)	4% (0.19)	5% (0.225)
\$10,001 more reported on Questionnaire than on Schedule F (SD)	67% (0.48)	50% (0.51)	0% (0.00)	19% (0.40)	22% (0.42)	19% (0.40)	27% (0.452)
Probability > F	0.4218	0.0002	0.000	0.3465	0.9054	0.0029	0.0000

**APPENDIX D: DEFINITE CREDIT CARD DEBT REPORTED ON SCHEDULE F, BY GAP IN MEASURES**

	Mean (standard deviation)
-4	\$15,148.75 (24950.728)
-3	\$14,518.50 (25589.335)
-2	\$9,754.48 (16860.425)
-1	\$13,457.91 (20811.045)
0	\$15,075.98 (22072.988)
+1	\$19,892.82 (26959.325)
+2	\$27,334.37 (34652.081)
+3	\$28,890.91 (32613.587)
+4	\$34,523.00 (27361.75)
<b>Total</b>	<b>\$18,837.03 (27361.75)</b>
Prob > F	0.0000

## APPENDIX E: CREDIT CARDS TO MAKE ENDS MEET, BY GAP IN MEASURES

	<b>Put necessities on the credit card (for example, food, or monthly bills)</b>	<b>Consolidated debts with a credit card or new loan</b>
	Percent (standard deviation)	Percent (standard deviation)
-4	47.4% (0.513)	36.8% (0.496)
-3	42.3% (0.504)	15.4% (0.368)
-2	40.6% (0.494)	17.7% (0.384)
-1	40.2% (0.491)	25.0% (0.434)
0	52.3% (0.5)	31.4% (0.464)
+1	56.5% (0.496)	37.3% (0.484)
+2	65.7% (0.475)	46.1% (0.499)
+3	64.6% (0.481)	43.0% (0.498)
+4	75.0% (0.439)	47.2% (0.506)
<b>Total</b>	54.5% (0.498)	34.7% (0.476)
<b>Prob &gt; F</b>	0.0000	0.0000

**APPENDIX F: MEDICAL REASONS FOR FILING FOR BANKRUPTCY, BY GAP IN MEASURES**

	<b>Medical or health care bills, including prescription medications</b>	<b>Medical problems experienced by you or your spouse or partner</b>	<b>Medical problems of other family members (such as children or parents)</b>
	Percent (standard deviation)	Percent (standard deviation)	Percent (standard deviation)
-4	21.1% (0.419)	26.3% (0.452)	5.3% (0.229)
-3	26.9% (0.452)	30.8% (0.471)	3.8% (0.196)
-2	22.9% (0.423)	29.2% (0.457)	8.3% (0.278)
-1	25.0% (0.434)	28.6% (0.453)	8.9% (0.286)
0	27.9% (0.449)	28.9% (0.454)	9.0% (0.286)
+1	25.2% (0.434)	31.0% (0.463)	10.6% (0.308)
+2	32.4% (0.469)	36.5% (0.482)	13.1% (0.338)
+3	53.2% Z(0.502)	46.8% (0.502)	24.1% (0.43)
+4	66.7% (0.478)	66.7% (0.478)	25.0% (0.439)
<b>Total</b>	28.9% (0.453)	31.9% (0.466)	10.7% (0.31)
<b>Prob &gt; F</b>	0.0000	0.0000	0.0002



# **Can I Tell You the Truth? A Comparative Perspective on Regulating Off-Label Scientific and Medical Information**

**John E. Osborn\***

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“We have met the enemy and he is us.”

Walt Kelly, creator of Pogo.

## I. INTRODUCTION

American pharmaceutical manufacturers are under siege. Even casual observers of this sector recognize the severe challenges to the prevailing business model: declining research productivity; heightened regulatory focus on safety and comparative outcomes with a correspondingly low number of new product approvals; decreasing market capitalization of mature companies; increasing product liability claims; evolving price restraints in the face of increasing managed care market power; and the looming uncertainty of the effects of federal health care reform. But, in fact, the single greatest threat to the pharmaceutical industry may be the policy environment within the United States, which is restricting the ability of companies to speak truthfully with physicians about their products.<sup>1</sup>

During the past decade drug companies have endured intrusive government investigations of their business practices, particularly with respect to the marketing and promotion of their products. Firms face extraordinary civil and criminal liability if they discuss or otherwise attempt to influence prescribing other than for the indications approved by the U.S. Food and Drug Administration (FDA). There are now well more than one hundred ongoing civil and criminal investigations involving the U.S. Department of Justice (DOJ) and units of the U.S. Department of Health and Human Services (HHS), as well as associated investigations run by state attorneys general.<sup>2</sup> Billions of dollars in

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1. This article addresses the public policies associated with the regulation of pharmaceutical manufacturers' communications with physicians. This includes discussions between field sales representatives, who work for a manufacturer and seek to promote or “detail” the manufacturer's product, and physicians and their office staff. This article is not concerned with so-called “direct to consumer” advertising, in which manufacturers attempt to communicate directly with current or prospective patients about the benefits of using a drug.

2. In a recent speech at the National Health Care Fraud Summit, U.S. Attorney General Eric Holder noted that “[i]n 2009, the Justice Department reached an all-time high in the number of health care fraud defendants charged, more than 800. We also obtained more than 580 convictions.

civil and criminal penalties have been paid to date for alleged wrongdoing,<sup>3</sup> and

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And on the civil enforcement front, our health care fraud recoveries last year under the False Claims Act exceeded a stunning \$2.2 billion dollars.” Eric Holder, U.S. Attorney Gen., Address at the National Summit on Health Care Fraud (Jan. 28, 2010) (transcript available at <http://www.justice.gov/ag/speeches/2010/ag-speech-100128.html>). See also *infra* note 21 and accompanying text.

3. Publicly disclosed civil settlement and criminal plea agreements have outlined in great detail allegations against nearly all of the major pharmaceutical companies, including Abbott (which paid \$622 million in 2003 to settle a federal investigation into its sales and marketing practices), AstraZeneca (\$355 million in 2003 and \$520 million in 2010), Bayer (\$97.5 million in 2008), Bristol-Myers Squibb (\$499 million in 2006), Cephalon (\$425 million in 2007), Eli Lilly (\$1.415 billion in 2009), Merck (\$670 million in 2008), Pfizer (\$2.3 billion in 2009), Pfizer/Warner-Lambert (\$430 million in 2004), Schering-Plough (\$345 million in 2004), Serono (\$704 million in 2005), and Takeda/Abbott Pharmaceuticals joint venture (\$875 million in 2001). See Gardiner Harris, *Abbott To Pay \$622 Million To End Inquiry Into Marketing*, N.Y. TIMES, June 27, 2003, at C1; Press Release, Dep’t of Justice, AstraZeneca Pharmaceuticals LP Pleads Guilty to Healthcare Crime; Company Agrees To Pay \$355 Million To Settle Charges (June 20, 2003), [http://www.justice.gov/opa/pr/2003/June/03\\_civ\\_371.htm](http://www.justice.gov/opa/pr/2003/June/03_civ_371.htm); Eric Holder, U.S. Attorney Gen., Remarks at the AstraZeneca Settlement Announcement (Apr. 27, 2010) (transcript available at <http://www.justice.gov/ag/speeches/2010/ag-speech-100427.html>); Press Release, Dep’t of Justice, Bayer Healthcare To Pay U.S. \$97.5 Million To Settle Allegations of Paying Kickbacks to Diabetic Suppliers (Nov. 25, 2008), <http://www.justice.gov/opa/pr/2008/November/08-civ-1050.html>; Barnaby J. Feder, *Bristol Says U.S. Inquiry Is Settled*, N.Y. TIMES, Dec. 22, 2006, at C1; Press Release, Dep’t of Justice, Biopharmaceutical Company, Cephalon, To Pay \$425 Million & Enter Plea To Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), <http://www.justice.gov/civil/ocl/cases/Cases/Cephalon/Cephalon%20Press%20Release.pdf>; Press Release, Dep’t of Justice, Eli Lilly and Company Agrees To Pay \$1.415 Billion To Resolve Allegations of Off-label Promotion of Zyprexa (Jan. 15, 2009), [http://www.justice.gov/civil/ocl/cases/Cases/Eli\\_Lilly/Lilly%20Press%20Release%20Final%2009-civ-038.pdf](http://www.justice.gov/civil/ocl/cases/Cases/Eli_Lilly/Lilly%20Press%20Release%20Final%2009-civ-038.pdf); Press Release, Dep’t of Justice, Merck Agrees To Pay \$399 Million To Resolve Allegations of Improper Medicaid Billing and Improper Inducements to Healthcare Professionals (Feb. 7, 2008), <http://www.justice.gov/usao/pae/News/Pr/2008/feb/steinkrelease.pdf>; Press Release, Dep’t of Justice, Justice Department Announces Largest Health Care Fraud Settlement in Its History (Sept. 2, 2009), <http://www.justice.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Pfizer/Pfizer%20-%20PR%20%28Final%29.pdf>; Press Release, Dep’t of Justice, Warner-Lambert To Pay \$430 Million To Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion (May 13, 2004), [http://www.justice.gov/opa/pr/2004/May/04\\_civ\\_322.htm](http://www.justice.gov/opa/pr/2004/May/04_civ_322.htm); Press Release, Dep’t of Justice, Schering-Plough To Pay \$345 Million To Resolve Criminal and Civil Liabilities for Illegal Marketing of Claritin (July 30, 2004), [http://www.justice.gov/opa/pr/2004/July/04\\_civ\\_523.htm](http://www.justice.gov/opa/pr/2004/July/04_civ_523.htm); Press Release, Dep’t of Justice, Serono To Pay \$704 Million for the Illegal Marketing of AIDS Drug (Oct. 17, 2005), [http://www.justice.gov/opa/pr/2005/October/05\\_civ\\_545.html](http://www.justice.gov/opa/pr/2005/October/05_civ_545.html); Press Release, Dep’t of Justice, TAP Pharmaceutical Products Inc. and Seven Others Charged with Health Care Crimes; Company Agrees To Pay \$875 Million To Settle

many billions more surely will be paid in the coming years, on top of the costs of the investigations themselves and the potential further liability that may stem from related private class actions brought by plaintiffs' counsel. The concomitant media and political scrutiny has irreparably harmed the reputation of the industry.<sup>4</sup> If the history of Western civilization may be seen as one long battle pitting order against freedom, the government's effort to curtail off-label speech might be dismissed as a minor skirmish on the outskirts of town. However, this issue is anything but minor in policy terms. The eventual outcome will have significant implications for the practice of medicine, the development of new drugs, and the public health.

Physicians may prescribe FDA-approved drugs and biological products for any therapeutic use that is appropriate in their medical judgment.<sup>5</sup> While the prevalence of off-label prescribing is difficult to estimate, there is little doubt that in oncology<sup>6</sup> and pediatrics<sup>7</sup> off-label prescribing is exceedingly common. Off-

Charges (Oct. 3, 2001), <http://www.justice.gov/opa/pr/2001/October/513civ.htm>.

4. A recent survey indicated that the industries that the greatest numbers of people believe should be "more regulated" are oil, pharmaceutical and drug, health insurance, managed care, and tobacco companies. THE HARRIS POLL, BANKS SEEN AS NEEDING MORE REGULATION FOR SECOND YEAR 1 (2009), available at <http://news.harrisinteractive.com/profiles/investor/NewsPDF.asp?b=1963&ID=34987&m=r>.

5. The Food, Drug and Cosmetic Act does not limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. Such "unapproved" or, more precisely, "unlabeled" uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature.

*Use of Approved Drugs for Unlabeled Indications*, 12 FDA DRUG BULL. 4 (1982).

6. See Am. Soc'y of Clinical Oncology, *Reimbursement for Cancer Treatment: Coverage of Off-Label Drug Indications*, 24 J. CLINICAL ONCOLOGY 3206, 3206 (2006); see also Daniel B. Klein & Alexander Tabarrok, *Do Off-Label Drug Practices Argue Against FDA Efficacy Requirements?*, 67 AM. J. ECON. & SOC. 743 (2008) (for a recent survey of physician perspectives on the arguably anomalous dichotomy that exists between the FDA's regulation of unapproved products and the absence of regulation of unapproved indications or uses of approved products); Bryan Cote, *Compendia: The Bridge Between FDA Approved Indications and Off-Label Usage*, ONCOLOGY BUS. REV., Jan. 2008, at 10, 11, available at [http://www.oncbiz.com/documents/OBR\\_0108\\_Compendia.pdf](http://www.oncbiz.com/documents/OBR_0108_Compendia.pdf) (estimating that approximately 60% of cancer drugs are used off-label); Richard A. Epstein, *Cancer Patients Deserve Faster Access to Life-Saving Drugs*, WALL ST. J., May 2-3, 2009, at A11.

7. See Alicia T. F. Bizzano et al., *Off-Label Prescribing to Children in the United States Outpatient Setting*, 9 ACAD. PEDIATRICS 81 (2009).

label prescribing often is driven by factors beyond the control of the manufacturer,<sup>8</sup> such that in some therapeutic areas off-label uses are the customary, preferred treatments and are publicly declared to be such on patient advocacy group websites and elsewhere.<sup>9</sup> Some arms of the government, such as the military, actively encourage off-label use by purchasing and providing drugs specifically intended for off-label use.<sup>10</sup> Moreover, the Centers for Medicare and Medicaid Services (CMS) authorize government reimbursement of products for off-label uses based upon the submission by manufacturers of medical information about such use.<sup>11</sup> Indeed, many drugs appear to have legitimate off-label uses that only become evident over time through physician practice and post-approval clinical studies.<sup>12</sup>

Off-label prescribing<sup>13</sup> has engendered passionate debate in recent years.

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8. See *infra* text accompanying notes 109, 110, 113, 116, and 118.

9. Even though no drugs have been expressly approved for the treatment of multiple sclerosis (MS)-related fatigue, Cephalon's Provigil (modafinil) is one of the "medications commonly used in the treatment of MS," according to the National Multiple Sclerosis Society. The MS Society's website notes that the clinical experience of some physicians treating patients with MS has shown "significant benefit [of Provigil] for many patients with MS-related fatigue." National Multiple Sclerosis Society, About MS, <http://www.nationalmssociety.org/about-multiple-sclerosis/what-we-know-about-ms/treatments/medications/modafinil/index.aspx> (last visited Mar. 29, 2010).

10. For example, the U.S. military conducted a number of clinical studies examining aviator performance and pilot sustained alertness while taking Provigil (modafinil). See Memorandum from the U.S. Dep't of the Air Force (Dec. 2, 2003) (stating that "[m]odafinil, a 'Go Pill', is now approved for management of aircrew fatigue"), available at <http://www.hep.af.mil/HEPF/Policy/modafinil.pdf>.

11. See DEP'T OF HEALTH & HUMAN SERVS., CHARTER: MEDICARE EVIDENCE DEVELOPMENT & COVERAGE ADVISORY COMMITTEE (Nov. 12, 2008), available at <http://www.cms.hhs.gov/FACA/Downloads/medcaccharter.pdf>.

12. See discussion of Cephalon's Provigil (modafinil) in text associated with footnotes 101-108.

13. The term "off-label" includes new, un-FDA-approved indications or uses for a product, potential side effects or safety concerns, dosing regimens to enhance efficacy in certain circumstances, or any other product-related information that was not known or fully developed and appreciated at the time of product approval. See generally Scott D. Danzis, *Off-Label Communications and Prescription Drugs*, in ETHICS AND THE PHARMACEUTICAL INDUSTRY 184 (Michael A. Santoro & Thomas M. Gorrie eds., 2005). "Off-label use may originate from a presumed drug class effect, extension to milder forms of an approved indication, extension to related conditions (the use of the antiasthmatic montelukast [Singulair] for chronic obstructive pulmonary disease), expansion to distinct conditions sharing a physiological link (the use of the antidiabetic drug metformin to treat polycystic ovarian syndrome), or extension to conditions whose symptoms overlap with those of an approved indication." Randall S. Stafford, *Regulating Off-Label Drug Use—Rethinking the Role of the FDA*, 358 NEW ENG. J. MED. 1427, 1427 (2008).

Some have suggested that the government adopt policies to limit physician prerogative to prescribe for unapproved uses. They argue that, at least in certain cases, the risks associated with off-label prescribing are unacceptable, and that the integrity of the drug regulatory system is undermined if there are effectively two different regimes under which some uses are authorized only after rigorous testing and approval while others are wholly unregulated.<sup>14</sup> Others fear that increased scrutiny would signal a marked shift toward federal oversight, away from the longstanding practice of state regulation of the practice of medicine.<sup>15</sup> Indeed, some have said that off-label prescribing should be encouraged to advance public health in the face of a moribund agency approval process that is underfunded, overwhelmed, and incapable of timely reviewing and approving new indications at a pace consistent with medical developments.<sup>16</sup> Regardless of one's perspective, it is undeniable that off-label prescribing is a critical component of the practice of medicine in America.<sup>17</sup>

Yet under current law, drug manufacturers may not *promote* their products for off-label uses. The enforcement of off-label promotion restrictions has precipitated far more controversy and consternation than off-label *prescribing*. Although the commercial motivations of drug manufacturers are readily apparent, some believe there is no need to restrict off-label promotion as manufacturers ultimately are deterred from advertising off-label uses by the threat of substantial tort liability for misrepresentation and harm to patients. Others point out that while labeling may be amended to include new information about a drug, invariably there will be occasions in which the company is in possession of truthful, non-misleading scientific and medical information that

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14. See Muriel R. Gillick, *Controlling Off-Label Medication Use*, 150 ANNALS INTERNAL MED., 344, 345-46 (2009) (arguing that the costs and risks inherent in prescribing certain biotechnology products suggest the government should limit physicians' discretion to prescribe off-label and instead apply the national cost determination method used by the CMS); see also Rebecca Dresser & Joel Frader, *Off-Label Prescribing: A Call for Heightened Professional and Government Oversight*, 37 J.L. MED. & ETHICS 476 (2009).

15. See Federation of State Medical Boards, FSMB Mission, Vision, Core Values and Goals, <http://www.fsmb.org/mission.html> (last visited Mar. 29, 2010) (providing background information on the state regulation of physicians in the United States).

16. At least one former senior FDA official contends that the agency cannot possibly approve proposed modifications to existing labeling, let alone keep labeling current on all approved products, at the pace required to keep up with scientific advances and changes in medical practice. See Scott Gottlieb, *Stop the War on Drugs*, WALL ST. J., Dec. 17, 2007, at A21.

17. See U.S. GEN. ACCOUNTING OFFICE, OFF-LABEL DRUGS: INITIAL RESULTS OF A NATIONAL SURVEY 22, 23-26 (Feb. 1991), available at <http://www.dtic.mil/cgi-bin/GetTRDoc?AD=ADA270395&Location=U2&doc=GetTRDoc.pdf>.

will not be included in the current, approved labeling.<sup>18</sup> The most extreme position contends that the current ban on off-label promotion should be modified substantially or even scrapped, since it significantly increases the cost of drug development, inhibits the rate of adoption of effective new uses of approved products, and limits the full dissemination to prescribing physicians of useful medical information.<sup>19</sup> Others contend that restricting off-label promotion ensures public safety by preventing pharmaceutical companies from spreading false or misleading information about their products in the pursuit of profits.<sup>20</sup>

These perspectives and practices serve to demarcate the wide bounds of a vigorous policy debate over the significance and validity of truthful medical and scientific information that is not included in the FDA-approved label. Notwithstanding this backdrop of widespread, prevailing medical practice and the importance of new medical and scientific information, the FDA and the DOJ have increased dramatically their enforcement activities in this area, and apparently will continue to do so in the coming years.<sup>21</sup> What should we make of

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18. See *infra* text accompanying notes 97-100.

19. See Alexander T. Tabarrok, *Assessing the FDA via the Anomaly of Off-Label Drug Prescribing*, 5 INDEP. REV. 25, 26-27 (2005), available at [http://www.independent.org/pdf/tir/tir\\_05\\_1\\_tabarrok.pdf](http://www.independent.org/pdf/tir/tir_05_1_tabarrok.pdf).

20. See Stafford, *supra* note 13; see also Donna T. Chen et al., *U.S. Physician Knowledge of the FDA-Approved Indications and Evidence Base for Commonly Prescribed Drugs: Results of a National Survey*, 18 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 1094 (2009).

21. See Mike Scarcella, *DOJ Ready for Fraud Attack*, NAT'L L.J., Aug. 10, 2009, at 1; see also Carrie Johnson, *A Backlog of Cases Alleging Fraud: Whistle-Blower Suits Languishes at Justice*, WASH. POST, July 2, 2008, at A1 (reporting that over 900 cases are pending with about one-half concerning health care companies); John R. Wilke, *Cases, Fines Soar in Fraud Probes of Drug Pricing*, WALL ST. J., June 7, 2005, at A1 (quoting then Assistant Attorney General Peter Keisler to the effect that there were then more than 150 outstanding investigations involving approximately 500 products); Michael K. Loucks, First Assistant U.S. Attorney, Address from the 2007 Medical Device Congress: Trends in Prosecutions and So-Called Off-Label Promotion Issues (Nov. 26, 2007) (PowerPoint presentation accompanying comments available at <http://www.ehcca.com/presentations/pharmaaudio20071126/loucks.pdf>). In the presentation, Mr. Loucks summarized various factors that he examines in determining whether a prospective case brought to the attention of his office might be worth further inquiry, including the extent of the total product market for FDA-approved uses; whether sales representatives promote the product to physicians who do not treat patients having the FDA-approved condition; whether the company otherwise "targets" such doctors by paying bonuses to sales representatives that take into account sales outside of the FDA-approved uses; or whether such sales are included in company annual objectives. In summary, any drug that has apparent off-label utility could trigger an investigation. This perspective led a leading health care lawyer to observe, "I don't think that a company that has legitimate off-label sales has a safe harbor anymore." Michael McCaughan, *Off-Label Sales in Jeopardy: Rx Industry Fights for Clarity*, RPM REP., Dec. 2007, at 4, 13 (quoting Scott Bass, Sidley Austin LLP).

this phenomenon? Where off-label prescribing is ineffective or ill-advised, the FDA has a legitimate, compelling interest in protecting the public health by ensuring that companies do not transmit false or misleading information, or otherwise encourage off-label prescribing when there is no underlying medical basis. But where the challenged off-label information is truthful, what is the public interest in forbidding it? The billions of dollars in corporate fines flowing into government coffers or absorbed by legal fees, which might otherwise be put to good use in discovering new medicines, compel us to question the wisdom of government policy in this area. What regulatory scheme will best ensure that physicians are fully informed, yet minimize the potential for exaggeration or embellishment so that the public health is not harmed? How should government regulators best respect the recognized constitutional rights of companies to speak truthfully about their medical discoveries, while ensuring that they speak accurately and fairly?

This article contends that the government's de facto policy of limited rulemaking and broad enforcement by threat of criminal prosecution is not the optimal way in which to develop an appropriate regulatory equilibrium: ideally, one that is efficient, effective, and equitable. The article begins with a summary of the law and public policy concerning off-label prescribing and promotion in the United States. After a brief discussion of the regulatory norms that judges and scholars have long recommended as important in establishing an appropriately balanced regulatory enforcement framework, it evaluates the current regulatory environment in the United States and concludes that there are significant deficiencies related to the absence of clarity, transparency, judicial review, and policy congruity. The article then presents several product-specific case studies that illustrate especially anomalous outcomes or challenging quandaries engendered by prevailing government policy. Following this critique of U.S. policy, the article summarizes the alternative approach of self-regulation now prevailing in the United Kingdom. Finally, it considers which model is likely to be more effective in facilitating appropriate, ethical business behavior by industry, and to that end it makes a number of policy recommendations for changes in U.S. regulatory policy and practice. The animating theme of this article and its policy recommendations is that while pharmaceutical companies have a profoundly important duty to act in a manner that is medically and ethically appropriate, communicating truthful, non-misleading scientific and medical information supports sound medical practice and should not subject companies to civil or criminal liability.<sup>22</sup>

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22. To be clear, this article is not primarily about commercial free speech and the tension between the First Amendment to the U.S. Constitution and FDA regulations that limit companies

In considering this subject, I am reminded of the stone statue at the apex of the Federal Triangle district in Washington, D.C. The statue is meant to portray a heroic figure—government authority—who restrains with every ounce of strength a wild stallion—unbridled capitalism—poised to break free at any moment and gallop down the boulevard. Unquestionably, there is a vital role for government in preventing the worst excesses of business, but where is the line across which excess occurs; who should make the determination; and what should be the penalty for crossing that line?

## II. REGULATING OFF-LABEL SCIENTIFIC AND MEDICAL INFORMATION IN THE UNITED STATES: A CONCISE HISTORY

The Food, Drug and Cosmetic Act of 1938, as amended (the “FDCA” or the “Act”)<sup>23</sup> provides the statutory framework under which the FDA regulates the sale and marketing of drugs in the United States. The Act does not address directly the communication of off-label information. Instead, a series of statutory provisions, as interpreted by the FDA, serve to proscribe off-label promotion and marketing. Specifically, the Act grants the FDA substantial authority to determine the safety and efficacy of all “new” drugs prior to marketing, and to regulate a new drug’s proposed “labeling” to ensure that it is not false or misleading.<sup>24</sup> Labeling is defined under the Act to include all tangible material that accompanies a drug.<sup>25</sup> Once a drug has been approved by the FDA, the Act specifies that the drug’s labeling may not “suggest” that it be used for any new condition that has not been approved by the FDA.<sup>26</sup> FDA regulations restrict company activities in this area to a much greater extent than the FDCA’s statutory scheme. For example, the FDA defines “labeling” to include virtually anything that a company or its employees might produce or present,<sup>27</sup> even if the material in question does not accompany the drug. As such, the Act’s prohibition of false or misleading labeling is transformed by the agency into an effective prohibition on any advertisement, promotional message, or discussion that is not “consistent with” the approved product labeling,<sup>28</sup> or otherwise concerns any use

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from communicating truthful and non-misleading scientific and medical information. Much has been written on this subject, and although the commercial free speech issue is relevant here, the primary focus of this article concerns regulatory policy.

23. Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-399 (2006).

24. § 352(a).

25. § 321(m), (p).

26. §§ 321(p), 355(a), (b), (j). The agency also must approve any new uses prior to marketing by the company.

27. Food and Drugs, 21 C.F.R. § 202.1 (2009).

28. The FDA interprets its various regulations to prohibit any communication to physicians or

that has not been approved expressly by the FDA,<sup>29</sup> regardless of whether it is truthful or accurately reflects good medical practice.

The FDCA also makes it a crime to introduce into interstate commerce a drug that is “misbranded.” The Act defines misbranding as making false or misleading statements in the labeling, or failing to include in the labeling “adequate directions for use.”<sup>30</sup> This regulation makes eminent sense on its face; if a manufacturer includes demonstrably false information in the label, it certainly is mislabeled or “misbranded” in common parlance. However, FDA regulations have extended this seemingly straightforward statutory provision by introducing the concept of “intended use.” A manufacturer’s intended use includes all uses objectively intended by the drug manufacturer based upon statements made in labeling, in advertisements, or in written or oral statements by company representatives, and if the FDA-approved labeling does not cover each “intended use” then a drug also is deemed to be misbranded.<sup>31</sup>

The collective effect of these regulations is as follows: a drug is approved by the FDA for a specific use; if there is to be a new intended use or if the intended

other health care providers by drug company representatives of information that is not “consistent with” the approved product labeling. *See* FDA Response to Comments on Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64074, 64085 (Dec. 3, 1997) (“Under the act, the regulated industry cannot promote its products for unapproved uses, or . . . in ways not consistent with approved labeling.”); *see also* FDA Warning Letter from Thomas W. Abrams, Dir., Div. of Drug Mktg., Adver. & Commc’n, FDA, to Cary Rayment, President and Chief Executive Officer, Alcon, Inc. (Oct. 20, 2006) *available at* <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm053637.pdf>; FDA Warning Letter from Michelle Safarik & Jialynn Wang, Regulatory Review Officers, Div. of Drug Mktg., Adver. & Commc’n, FDA, to Elizabeth M. Zola, Assoc. Dir., Regulatory Affairs, Ross Products Div., Abbott Laboratories (July 15, 2005), *available at* <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm054809.pdf>; FDA Warning Letter from Thomas W. Abrams, Dir., Div. of Drug Mktg., Adver. & Commc’n, FDA, to Adrain Adams, President, Kos Pharmaceuticals, Inc. (July 13, 2001), *available at* <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM166441.pdf>.

29. As suggested above, this broad prohibition is not set forth in any single regulation, but effectively stems from reading the combination of 21 U.S.C. § 355(a) (2006) (requiring that the FDA approve a product and its labeling prior to introducing it into interstate commerce) and the regulation found at 21 C.F.R. § 202.1(e)(4) (limiting the marketing and promotion of drugs in a manner inconsistent with their approved uses).

30. 21 U.S.C. § 352(f)(1) (2006).

31. 21 C.F.R. § 201.128 (2009).

use otherwise changes, then a manufacturer must demonstrate safety and efficacy for that new intended use and obtain FDA approval for modified labeling that properly reflects this new intended use; if a manufacturer provides information to physicians or other health care providers that is not consistent with the existing, approved product labeling, then the manufacturer has established a new intended use without obtaining FDA approval, and therefore is unable to provide to physicians and consumers the requisite instructions for using the product for this unapproved indication; the company therefore has violated the law by introducing a “misbranded” product into interstate commerce. Many regard this interpretation as awkward at best and untenable at worst.<sup>32</sup>

A company may be liable not only under the FDCA but also under the federal False Claims Act (FCA).<sup>33</sup> The FCA makes it unlawful to file a false claim with the government, or to make a false statement that leads to making a false or fraudulent claim paid or approved by the government.<sup>34</sup> Liability under the FCA is determined on the basis of the labeling in effect at the time the off-label speech occurs. This appears to be the case even if the information is truthful, and even if the FDA subsequently approves the promoted indication. The interpretation and application of the FCA to off-label promotion challenges are particularly interesting as they go directly to the relevance of the truthfulness of the medical or scientific information: drug companies do not themselves file claims for payment with the government; instead, manufacturers sell their

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32. In fact, the actual labeling may be entirely accurate with respect to the directions of use for the product as it is commonly used, but manufacturers may be charged with misbranding if they are *aware* of substantial off-label use, and are unable to unilaterally modify the labeling to correct the situation. *See* Memorandum of Law in Support of Motion for Preliminary Injunction at 10-11, *Allergan, Inc. v. United States*, No. 09-1879 (D.D.C. Oct. 1, 2009). *But see* *Smoking Everywhere, Inc. v. U.S. FDA*, No. 09-771, -- F. Supp. 2d --, 2010 WL 129667, at \*9 (D.D.C. Jan. 14, 2010) (rejecting the FDA’s contention that product testimonials established the manufacturer’s broader intended use to treat nicotine withdrawal symptoms, when the overwhelming focus of the promotional materials was to support the use of the product only as a nicotine substitute).

33. *See* 31 U.S.C. § 3729 (2006). The False Claims Act imposes liability of three times the government’s loss plus civil penalties for each false claim presented. In response to evidence of substantial fraud in defense contracting, health care, and other areas involving government payments, Congress in 1986 modified a Civil War-era statute to enhance the law’s whistleblower—or *qui tam*—features. In so doing, Congress enabled citizens with evidence of fraud with respect to government contracts and programs to sue, on behalf of the government, in order to recover the funds. As an incentive to file a *qui tam* case, the citizen whistleblower or “relator” may be awarded a portion of the funds recovered, typically between 15-25%. A *qui tam* suit initially remains under seal for at least sixty days during which time government determines whether to join the action. 31 U.S.C. § 3730 (2006).

34. 31 U.S.C. § 3729(a)(2).

products to wholesale distributors, who in turn sell to pharmacies and other providers, who in turn file claims with the government. Therefore, one might reasonably conclude that liability under the FCA for drug manufacturers would follow only if they make a false statement. However, at least one federal court has found otherwise, ruling that a violation of the FDCA for off-label promotion is sufficient to establish liability under the FCA, whether or not the underlying promotional statements were false.<sup>35</sup>

This regulatory framework establishes the FDA's fundamental authority in determining the flow of information from drug companies to physicians and patients.<sup>36</sup> But this authority is not unlimited. The *Washington Legal Foundation* cases of the late 1990s<sup>37</sup> established that the Constitution limits the FDA's ability to control the dissemination of truthful, non-misleading scientific and medical

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35. United States *ex rel.* Franklin v. Parke-Davis, 147 F. Supp. 2d 39 (D. Mass. 2001). The court's ruling that the FCA does not require both a false statement and a false claim also is significant for construction of the statute. *But see infra* text accompanying note 88.

36. In the early 1990s, it was common to hear drug company executives say to the firm's commercial group (without a trace of shame or irony): "If you don't get one or two warning letters a year, then you really aren't doing your job." It is difficult to imagine that FDA officials were unaware of this cavalier attitude, and over time it seems they became determined to do something about it. Many observers trace the heightened attention on the problems of off-label promotion to the reign of former FDA Commissioner, Dr. David A. Kessler, who was appointed to the post in 1991. During his time at the agency, he opposed legislation that would have modified labeling for an approved product if a particular off-label use was common practice among clinicians for at least five years, and he generally expressed concerns about physician prescribing decisions that were based on anecdotal experience. *See Protecting and Promoting Public Health: Hearing on S. 1477 Before the S. Comm. on Labor and Human Resources*, 104th Cong. (1996) (statement of Dr. David A. Kessler, Comm'r, FDA), available at <http://www.fda.gov/NewsEvents/Testimony/ucm115101.htm>. These sentiments may have influenced many of those still at the agency or working in policy positions in HHS. Regardless, the FDA's focus on preserving its institutional prerogatives is evident in multiple court filings and public statements. Agency officials have made clear that they are extremely reluctant to acknowledge the truthfulness of safety and efficacy claims without final approval to that effect, and that, in its view, manufacturer dissemination of off-label information is "inherently misleading," even though that same information is not misleading when others do the disseminating. *See Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 67 (D.D.C. 1998), *vacated on other grounds*, *Wash. Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000). However, courts have not always agreed. "In asserting that any and all scientific claims about the safety, effectiveness, contraindications, side effects, and the like regarding prescription drugs are presumptively untruthful or misleading until the FDA has had the opportunity to evaluate them, FDA exaggerates its overall place in the universe." *See id.*

37. *See Friedman*, 13 F. Supp. 2d at 51; *Wash. Legal Found. v. Henney*, 128 F. Supp. 2d 11 (D.D.C. 2000), *dismissed and vacated in part*, 202 F.3d 331 (D.C. Cir. 2000).

information, at least in the form of peer-reviewed journal articles, medical textbooks, and sponsorship of continuing medical education programs. In this line of cases, an FDA guidance that would have limited the dissemination of peer-reviewed journal articles and medical textbook reprints (so-called enduring materials) were struck down as an unconstitutional infringement of commercial free speech under the Supreme Court's test articulated in *Central Hudson v. Public Service Commission of New York*.<sup>38</sup> Subsequently, the FDA avoided a permanent injunction against enforcement of the guidance by stipulating that the ruling merely established "safe harbors" under which manufacturers could be assured that their activities would not be challenged, and that "nothing in [the Food and Drug Administration Modernization Act of 1997 (FDAMA)] provides the FDA with independent authority to regulate manufacturer speech."<sup>39</sup>

Despite the agency's wide authority, some critics have faulted the FDA for failing to more aggressively enforce the off-label promotion rules and limit abuses by drug manufacturers.<sup>40</sup> Consequently, the government has increased significantly the number of enforcement actions in this area in recent years, which may be traced to a seminal case involving the Parke-Davis unit of Warner Lambert and its drug Neurontin (gabapentin). Neurontin was approved by the FDA in 1994 as an adjunctive treatment for seizures associated with epilepsy. However, Parke-Davis was accused of developing and executing a promotional campaign to spur prescriptions for the treatment of pain and a series of psychiatric disorders, including anxiety and depression. To accomplish this, Parke-Davis employed a legion of technical medical writers who penned prospective journal articles in support of the purported off-label utility, and then paid physicians to put their names on the articles as authors.<sup>41</sup> Parke-Davis also

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38. 447 U.S. 557 (1980). In *Central Hudson*, the U.S. Supreme Court established a four-part test to determine the constitutionality of allowing government regulation of commercial speech: whether the commercial speech to be regulated is lawful and not misleading; whether there is a substantial government interest at stake; if so, whether the proposed regulation advances the asserted substantial government interest; and whether the proposed regulation is more extensive than necessary to serve the interest. *See id.*

39. *Henney*, 202 F.3d at 336.

40. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, PRESCRIPTION DRUGS: FDA'S OVERSIGHT OF THE PROMOTION OF DRUGS FOR OFF-LABEL USES 16 (July 2008), available at <http://www.gao.gov/new.items/d08835.pdf>. This report found that between 2003 and 2007 the FDA received approximately 277,000 submissions of promotional material as required under the law, but the agency could not provide data on the number of pieces actually reviewed, the extent to which they identified regulatory violations, the length of the review process, or the status of reviews. To date, there is no systematic means by which the FDA determines which promotional pieces will be reviewed thoroughly.

41. *See* Natasha Singer, *Medical Papers by Ghostwriters Pushed Therapy*, N.Y. TIMES, Aug.

hired “medical liaisons” as an adjunct sales force to solicit doctors to prescribe off-label, one of whom subsequently brought a *qui tam* action against the company alleging violations of the False Claims Act. Particularly damning were excerpts from a sales presentation in which a manager equated off-label prescriptions to “money,” dismissed alleged safety concerns as unworthy of consideration, and directed sales representatives to promote off-label.<sup>42</sup> Pfizer, having acquired the Parke-Davis unit through its acquisition of Warner-Lambert, eventually settled these allegations for \$430 million.<sup>43</sup> In this matter, the government effectively announced<sup>44</sup> its intention to focus on off-label promotion as a separate, actionable violation of the FDCA and the FCA. The case is notorious in that its salacious details show the industry at its worst in employing aggressive sales tactics and adopting marketing messages that diverge not only

4, 2009, at A1 (regarding recent allegations related to this practice).

42. John Ford, a Parke-Davis marketing manager, reportedly encouraged the company’s medical liaisons to promote Neurontin for off-label uses for which there was no apparent scientific or medical basis:

I want you out there every day selling Neurontin. . . . We can’t wait for them to ask, we need to get out there and tell them up front. . . . That’s where we need to be, holding their hand and whispering in their ear, Neurontin for pain, Neurontin for monotherapy, Neurontin for bipolar, Neurontin for everything.

DISCLOSURE OF INFORMATION BY RELATOR DAVID P. FRANKLIN PURSUANT TO 31 U.S.C. § 3730 B(2), 11 (1996), *available at* <http://dida.library.ucsf.edu/pdf/rab00a10>.

43. *See* Press Release, Dep’t of Justice, Warner-Lambert To Pay \$430 Million To Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion (May 13, 2004), [http://www.justice.gov/opa/pr/2004/May/04\\_civ\\_322.htm](http://www.justice.gov/opa/pr/2004/May/04_civ_322.htm). In a more recent case, Eli Lilly was accused of illegally promoting its drug Zyprexa (olanzapine). Zyprexa, the first in a new class of so-called atypical antipsychotics, was approved by the FDA in 1996 for the treatment of schizophrenia and in 2005 for the treatment of bipolar disorder. Following FDA approval of the second indication, the record suggests that Eli Lilly shifted its marketing strategy such that its sales representatives would indicate to general practitioners that Zyprexa was appropriate for elderly patients suffering from depression or dementia. In announcing its settlement, the government emphasized the primacy of the FDA’s role, suggesting that any information provided by companies outside of the FDA-approved message would necessarily “undermine the integrity of the doctor-patient relationship and place innocent people in harm’s way.” Eli Lilly settled these allegations in early 2009 for \$1.415 billion. Press Release, Dep’t of Justice, Eli Lilly and Company Agrees To Pay \$1.415 Billion To Resolve Allegations of Off-label Promotion of Zyprexa (Jan. 15, 2009), [http://www.justice.gov/civil/oclcases/Cases/Eli\\_Lilly/Lilly%20Press%20Release%20Final%2009-civ-038.pdf](http://www.justice.gov/civil/oclcases/Cases/Eli_Lilly/Lilly%20Press%20Release%20Final%2009-civ-038.pdf).

44. *See* Press Release, Dep’t of Justice, Warner-Lambert To Pay \$430 Million To Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion, *supra* note 43.

from the information contained in the approved label, but also from established medical science.

Since the Parke-Davis settlement, the federal government's policy in this area has been that significant off-label prescribing will be regarded with suspicion, and any discourse with physicians about pharmaceutical and biological drug characteristics not included in the FDA-approved labeling will lead, at the least, to a very intrusive and expensive investigation. Key government prosecutors have confirmed that it does not matter whether or not the questionable speech is truthful or misleading, so long as it is "off-label."<sup>45</sup>

### III. THE PUBLIC POLICY IDEAL AND REGULATORY NORMS

Government regulates the behavior of business by developing rules, and then monitoring and enforcing compliance with those rules, preferably in a fair and consistent manner.<sup>46</sup> American courts acknowledge that agencies have broad discretion to engage in *ad hoc* enforcement actions should they wish to make an example of a firm or an industry in order to affect policy, but they also emphasize the benefits inherent in the development of clear rules under a transparent rulemaking process.<sup>47</sup> In fact, courts have long preferred this extensive, explicit

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45. When asked at an industry sponsored panel if he regards it significant that the off-label information in question is truthful, Assistant U.S. Attorney Loucks replied: "I would say this from an investigator's or prosecutor's perspective, I don't know that it matters much that the off-label promotion activity might be entirely truthful and accurate, it's still off-label." Michael Loucks, Assistant U.S. Att'y in the Dist. of Mass., National Pharma Audioconference: Lessons of Bristol Myers-Squibb's \$515 Million Settlement for Off-Label Promotion, Kickbacks and Drug Pricing (Nov. 26, 2007) (transcript on file with author).

46. There is an extensive academic literature concerning the effectiveness of regulation and choices involving rulemaking and enforcement. In a leading law and economics analysis, Fenn and Veljanovski conclude that economic efficiencies result, and corresponding harm is minimized, when government agencies use their discretion to negotiate with firms rather than applying across-the-board enforcement sanctions. P. Fenn & C.G. Veljanovski, *A Positive Economic Theory of Regulatory Enforcement*, 98 *ECON. J.* 1055 (1988); see also William M. Landes & Richard A. Posner, *The Private Enforcement of Law*, 4 *J. LEGAL STUD.* 1 (1975); A. Mitchell Polinsky, *Private Versus Public Enforcement of Fines*, 9 *J. LEGAL STUD.* 105 (1980); see generally A READER ON REGULATION (Robert Baldwin, Colin Scott & Christopher Hood eds., 1998). Of course, rulemaking and enforcement do not necessarily represent a choice of one form of regulation over another. By definition, there must be rules before there can be enforcement, and even under the most elaborate set of rules there will be those who do not adhere to them who must be subject to enforcement actions as a result. In some areas of U.S. law (for example, securities law) there is relative emphasis placed on clear articulation of rules, and in others there is relative emphasis on selective enforcement.

47. See, e.g., *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C.

rulemaking process as one that at once is consistent with due process and rule of law principles, and provides more effective notice to, and engagement with, the regulated industry in question.<sup>48</sup>

An optimal regulatory regime is fair to the regulated parties, accomplishes the government interests at stake while being sensitive to related legal and policy interests, and minimizes the costs for government and industry. Scholars are quick to praise those normative values that they believe to be associated with proper rulemaking and enforcement, such as clarity, including what some have referred to as accessibility (meaning that the rules are easily interpreted and applied to concrete, real world situations without excessive difficulty or effort); transparency of the rulemaking process; congruity of the rules with other, related legal and regulatory policy preferences and values; and adherence to due process principles, including notice to, and engagement with, the regulated party.<sup>49</sup> On this point, prominent regulatory theorists have proposed thinking about regulation and optimal regulatory strategy as a cascading series of choices, perhaps as a pyramid, where enforced self-regulation (industry rules with government oversight) would be employed, and only where this approach has failed demonstrably should government resort to state regulation with discretionary or mandatory punishment.<sup>50</sup>

On the other hand, legal scholars and social scientists in Britain and America have written extensively in recent years about the problems associated with rules and rulemaking. In this regard, there is near unanimity that much of the trouble lies in the challenge inherent in the ambiguity of the English language.<sup>51</sup> Beyond

Cir. 1993) (notice and comment to affected parties of proposed rules is preferable to “ad hocery” of enforcement actions).

48. See, e.g., *Whisenhunt v. Spradlin*, 464 U.S. 965, 969 (1983) (Brennan, J., dissenting from denial of certiorari) (arguing that the due process clause demands “that government articulate its aims with a reasonable degree of clarity”); *Morton v. Ruiz*, 415 U.S. 199, 231 (1974) (“[T]he agency must, at a minimum, let the standard be generally known so as to assure that it is being applied consistently . . . .”); *SEC v. Chenery Corp.*, 332 U.S. 194 (1947) (holding that the SEC may pursue enforcement actions, but must allow for notice, participation, and transparency).

49. See generally ROBERT BALDWIN & MARTIN CAVE, *UNDERSTANDING REGULATION: THEORY, STRATEGY, AND PRACTICE* (1999); BRONWEN MORGAN & KAREN YEUNG, *AN INTRODUCTION TO LAW AND REGULATION: TEXT AND MATERIALS* (2007); ANTHONY OGUS, *REGULATION: LEGAL FORM AND ECONOMIC THEORY* (1994) (regarding normative values associated with rulemaking and enforcement). On the importance of accessibility, see Colin S. Diver, *The Optimal Precision of Administrative Rules*, 93 *YALE L.J.* 65 (1983).

50. See IAN AYRES & JOHN BRAITHWAITE, *RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE* (1992).

51. Regulation can fail because of the nature of rules and the nature of language. JULIA BLACK,

this, the American inclination for the heavy hand of law enforcement and criminal sanction, combined with the prospective application of mandatory exclusion from federal reimbursement programs, has fostered a regulatory environment that largely fails to meet the critical norms praised by courts and commentators.

#### IV. THE AMERICAN EXPERIENCE

In the United States, the regulation of off-label medical and scientific communication is inconsistent with the ideals outlined above. In recent enforcement actions, the government has appeared unable or unwilling to distinguish among lawful off-label prescribing by physicians, the communication by companies to physicians and health care providers of truthful and non-misleading speech, the communication by companies of false or misleading information, and clear financial impropriety that may be associated with that communication. Prosecutors have interpreted ambiguous rules to develop innovative but untested legal theories to compel breathtaking settlements and plea agreements. The political and legal dynamic at work here effectively ignores important free speech rights that have been recognized by American courts and the FDA, and threatens the prerogative of doctors to practice medicine by limiting access to the most recent scientific and medical developments. Although there are standards for determining whether corporate malfeasance should be treated as a civil or criminal matter, the process is far from transparent and the standards and associated calculation of financial penalties are not interpreted consistently.

##### *A. The Absence of Clear Rules*

With so much at stake, the laws and regulations applicable to the promotion and marketing of drugs and devices ought to be very clear. Companies understand that drug advertisements and other promotional material and statements must be truthful and not misleading. Company sales representatives understand that they may not tell doctors that an approved drug is good for a particular condition unless the FDA approves its use based upon the submission of valid scientific and medical information.

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RULES AND REGULATORS 5-45 (1997). "Transparency is usually bought at the price of incongruity . . ." Diver, *supra* note 49, at 91. Diver suggests that the dilemma for the rule maker and the enforcer is how best to strike the proper balance between specificity or transparency, and the discretion that must be applied under varying factual circumstances to reach fair and consistent enforcement. For a discussion of rules and their role in limiting government discretion, see ROBERT BALDWIN, RULES AND GOVERNMENT (1995).

But beyond these broad guidelines, not much else is clear.<sup>52</sup> Under current FDA regulations and the agency's interpretation of them, it remains unclear where to draw the line between impermissible off-label promotion and the ostensibly permissible exchange of scientific information. One might say ostensibly, because the FDA has acknowledged several well-known "exceptions" over the years that allow manufacturers to speak about off-label use in certain limited circumstances. For example, manufacturers commonly respond to unsolicited requests for information on off-label uses from health care professionals,<sup>53</sup> announce the results of clinical studies concerning a new use for an approved drug,<sup>54</sup> and provide financial support for scientific and educational activities, provided that they do not influence the content of such activities.<sup>55</sup> Yet the FDA has never outlined its perspective on these matters in a definitive, comprehensive way. Moreover, at times the agency has suggested that it may not continue to recognize these exceptions.<sup>56</sup> The only certainty is that the FDA will

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52. *But see The View from FDA: An Interview with Robert Temple on Off-Label Promotion*, RPM REP., Dec. 2007 (quoting Dr. Robert Temple) ("No, I don't think [the rules are] confusing. They're not always followed, but I don't think there's any confusion about it. Companies aren't allowed to do it. It is as clear as it could be."). However, in the interview, Dr. Temple did acknowledge some ambiguity and confusion related to companies' sponsorship of and influence over content presented in medical education programs. *Id.*

53. *See* Citizen Petition Regarding the Food and Drug Administration's Policy on Promotion of Unapproved Uses of Approved Drugs and Devices, 59 Fed. Reg. 59,820, 59,823 (Nov. 18, 1994) (indicating that FDA policy allows companies to disseminate information in response to unsolicited requests).

54. 21 C.F.R. §§ 312.2(a), 312.7(a), 812.7 (2009).

55. *See* Decision in *Washington Legal Foundation v. Henney*, 65 Fed. Reg. 14,286 (Mar. 16, 2000) (stating that manufacturers may provide resources for continuing medical education if they comply with statutory provisions).

56. In fact, some of the exceptions specified are not true "safe harbors" in that "[g]uidance documents do not establish legally enforceable rights or responsibilities." 21 C.F.R. § 10.115(d)(1) (2009). The agency's perspective is evinced in its recent attempt to balance First Amendment and public health concerns. *See* Guidance for Industry on Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices; Availability, 74 Fed. Reg. 1,694 (Jan. 13, 2009), *available at* <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm> (Draft Guidance). (The author was a member of an industry working group that advocated for the development and adoption of this guidance.) The Draft Guidance was criticized by prominent members of Congress and consumer advocates for permitting companies to distribute off-label information that will put "the public at risk for ineffective and dangerous uses of drugs." Letter from Henry A. Waxman, Chairman, House Comm. on Oversight & Gov't Reform, House of Representatives, to Andrew C. von Eschenbach, Comm'r, FDA (Nov. 30, 2007),

consider company efficacy claims to be truthful and not misleading if they are found to be such by the agency and are included in approved labeling.<sup>57</sup>

Even if the rules were comprehensive, practical, and clearly articulated, the situation is complicated considerably by the potential application of the First Amendment and its explicit protection of speech. However, following the *Washington Legal Foundation* cases, no federal appellate court and very few other federal district courts have had the occasion to opine on the question of whether the FDA's policy of prohibiting the dissemination of truthful, non-misleading off-label scientific and medical information is unconstitutional. As such, it is not clear whether the views set forth in the *Washington Legal Foundation* cases will be adopted broadly, or whether the First Amendment will be applied to protect other forms and manners of speech related to off-label information.<sup>58</sup>

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available at [http://online.wsj.com/public/resources/documents/waxmanletter\\_113007.pdf](http://online.wsj.com/public/resources/documents/waxmanletter_113007.pdf).

The Draft Guidance also was criticized by industry for reneging on earlier "safe harbor" commitments. See Letter from Daniel J. Popeo, Chairman, Wash. Legal Found., and Richard A. Samp, Chief Counsel, Wash. Legal Found., to FDA (Apr. 21, 2008), available at <http://www.wlf.org/upload/Reprints%20Guidance-%20WLF%20Comments.pdf>. In its comments, the Foundation criticized the agency for failing to address broadly the underlying First Amendment commercial free speech prerogative. "It is inexplicable for FDA to be issuing a Draft Guidance in this area without any explanation regarding what it views as the extent of manufacturers' First Amendment rights." *Id.* at 5. Some of these criticisms were addressed by the FDA in the final guidance. For example, although the Draft Guidance purported to offer manufacturers a bona fide safe harbor for the dissemination of peer-reviewed journal articles, it limited its application to cases where there has not been any unlawful promotion of the product. However, in the final guidance, the agency modified its language; while it may challenge companies that promote illegally, it will not hold companies responsible for the contemporaneous dissemination of journal articles. Finally, the Draft Guidance required that any journal articles disseminated under the safe harbor be limited to those that summarize "adequate and well-controlled clinical investigations." The FDA's final guidance does not contain this limitation.

57. See Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices; Availability, 74 Fed. Reg. 1,694. Some viewed the Draft Guidance as a distinct "relaxation" of the prior level of FDA scrutiny of drug company promotion, especially in comparison with the core principles of the FDA Modernization Act of 1997. This statute allowed for dissemination of journal articles, but only where manufacturers were communicating about drugs as to which they were seeking label expansion and had submitted the article to the agency in advance. See Stafford, *supra* note 13, at 1429. Conversely, others noted that the guidance, even in final form, was relatively narrow in that it only allowed the dissemination of materials that were "written, edited, excerpted, or published specifically for, or at the request of" the manufacturer. See *supra* Good Reprint Practices.

58. In *United States v. Caputo*, 288 F. Supp. 2d 912 (N.D. Ill. 2003), the district court

The quandary for industry executives and their counsel can be reduced to one word: accessibility. The rules are not reasonably well appreciated and susceptible to practical application. How should companies apply the broad commandment that forbids off-label promotion to the daily routine of interacting with prescribing physicians? Consider a few concrete business situations that illustrate the inadequacy of current FDA rules and regulations: may sales representatives present their message to any physician, so long as it is consistent with the approved labeling, or must all physicians to whom the message is presented have patients who suffer from the on-label indication? Is it “consistent with” the approved labeling to discuss the likely mechanism of action of the active compound if the mechanism is not disclosed in the labeling? May companies sponsor what have been known as “independent” continuing medical education programs, and if so how should they be structured? May a company engage a physician as a bona fide consultant without being seen as improperly influencing prescribing decisions, and if so how should it determine fair market value compensation for the services rendered? May a company offer advice on reimbursement for off-label uses, either to a physician, to a physician office staff,

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considered whether the First Amendment shielded defendants from liability for promoting a medical device in a form that had never been approved by the agency. In finding that it did not, Judge Castillo distinguished *Washington Legal Foundation* by noting that the communication at issue in that case was limited to the dissemination of peer-reviewed journal articles and the sponsorship of continuing medical education programs, while accepting defendants’ First Amendment argument in *Caputo* would necessarily allow much greater leeway for manufacturers to promote off-label. “[P]ermitting Defendants to engage in *all* forms of truthful, non-misleading promotion of off-label use would severely frustrate the FDA’s ability to evaluate the effectiveness of off-label uses.” *Id.* at 922. As another data point, Judge Saris of the U.S. District Court in Boston had occasion in 2007 to express her views at a hearing in which the drug manufacturer Schering-Plough Corporation was sentenced for violating the Food, Drug and Cosmetic Act for, among other things, promoting off-label and misleading the FDA. In contrast to Judge Castillo, Judge Saris explicitly rejected the *Washington Legal Foundation* principles. “I do not accept that there is a First Amendment right to market something that does not get FDA approval,” she said. Michael K. Loucks, First Assistant U.S. Attorney, Address from the 2007 Medical Device Congress: Trends in Prosecutions and So-Called Off-Label Promotion Issues (Nov. 26, 2007), available at <http://www.ehcca.com/presentations/pharmaaudio20071126/loucks.pdf> (quoting Judge Saris in Schering Sales Corporation sentencing hearing). See also *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002) (ban on advertising of compounded drugs is unconstitutional because it did not satisfy Central Hudson test); *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999); *United States v. Caronia*, 576 F. Supp. 2d 385, 394 (E.D.N.Y. 2008) (noting “unsettled” constitutional law, and despite the fact that the speech in question was not inherently misleading, a pharmaceutical sales representative is not entitled to dismissal on First Amendment grounds of case alleging FDCA violations for “misbranding” based upon improper off-label promotion).

to a private payer, or to a state pharmacy and therapeutics committee? May a company express any level of ambition or prospect for an unapproved use lest it be accused of embracing an off-label marketing strategy? FDA regulations simply do not address these and other questions associated with the promotion and sale of prescription pharmaceuticals.

Some cases are rather stark and unsympathetic. In the Neurontin matter, there does not appear to be any valid contention that the company's sales and marketing efforts were predicated on the communication of truthful, non-misleading information that just happened to be outside the FDA-approved labeling. Many cases are not so straightforward, however. The complexities of medicine, health care practices, and the contemporary commercial enterprise suggest that in many situations, FDCA violations may or may not have occurred depending upon the subjective interpretation of myriad factors. The FDA has an obligation to develop and promulgate comprehensive guidance on promotional activities, medical education, and physician consulting engagements. Instead, the agency has issued a series of warning letters in response to complaints and its own observations as to apparent violations. The alleged infractions range from the outrageous (lying about efficacy, denying safety issues) to the sublime (the height or boldness of typefaces used in a marketing brochure makes it misleading). The letters are specific to the facts of each case and are a poor substitute for a general regulatory framework or code of conduct of the sort that has been promulgated by other federal government agencies.<sup>59</sup> Moreover, the FDA's approach has facilitated a cynical approach by many companies that choose to employ intellectual gymnastics to distinguish their practices from many a narrowly crafted warning letter.

FDA warning letters would be more useful if they were issued with reference to a broad but detailed code of conduct. For example, the U.S. Securities and Exchange Commission (the "SEC" or the "Commission") promulgates detailed regulations and provides further guidance to companies on disclosure issues through its "No Action" letters. No Action letters necessarily are fact-specific as well, but they are intended to supplement a comprehensive framework of securities laws, rules, and regulations. As the Commission notes:

An individual or entity who is not certain whether a particular product, service, or action would constitute a violation of the federal securities law may request a "no-action" letter from the SEC staff. Most no-action letters describe the request, analyze the particular facts and circumstances involved, discuss applicable laws and rules, and, if the staff grants the request for no action,

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59. The FDA publishes its warning letters to the public. See U.S. Food and Drug Administration, Warning Letters, <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm> (last visited Mar. 29, 2010).

concludes that the SEC staff would not recommend that the Commission take enforcement action against the requester based on the facts and representations described in the individual's or entity's original letter. The SEC staff sometimes responds in the form of a no-action letter to requests for clarification of the legality of certain activities.<sup>60</sup>

The FDA deserves credit for issuing its recent—albeit belated—guidance which attempts to address in a comprehensive manner the practice of disseminating reprinted articles from peer-reviewed journals.<sup>61</sup> The agency has characterized the guidance as the FDA's "current thinking" on the topic and notes that the guidance was made necessary due to the expiration of Section 401 of the Food and Drug Administration Modernization Act of 1997 (FDAMA), which had previously provided a safe harbor for the industry on reprint practices.<sup>62</sup> However, unlike the previously existing FDA Notice clarifying that FDAMA and its implementing regulations merely constituted a safe harbor,<sup>63</sup> the most recent guidance explicitly permits the dissemination of off-label scientific and medical information under certain circumstances, regardless of whether the company is pursuing a new indication and without requiring that companies submit the material to be disseminated in advance for review.<sup>64</sup> Many appreciate the guidance as an initial, if halting, step toward enhanced regulatory clarity to better guide industry practice, inform physicians, and enhance compliance.

#### *B. The Lack of Transparency in the Rulemaking and Enforcement Process*

In addition to enacting rules and regulations that are comprehensive and reasonably clear, government should ensure that the process for both the adoption and the enforcement of rules is transparent. The U.S. government has failed on both accounts. In its adoption of rules and regulations, the FDA largely has failed to address forthrightly the evident tension between the First Amendment and its regulations proscribing the communication of truthful and non-misleading information not contained in approved labeling. Moreover, as the DOJ has assumed a higher degree of involvement in developing cases alleging civil and

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60. U.S. Securities and Exchange Commission, No Action Letters, <http://www.sec.gov/answers/noaction.htm> (last visited Mar. 29, 2010).

61. See Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices; Availability, 74 Fed. Reg. 1,694.

62. See *id.*

63. See *Decision in Washington Legal Foundation v. Henney* 65 Fed. Reg. 14,286 (Mar. 16, 2000).

64. See *id.*

criminal violations under the FDCA and the FCA, the investigation, consideration, and resolution of these cases also have become less transparent.

With respect to the development of rules, the FDA has shied away from engaging in an open process in which it attempts to reconcile the competing interests of commercial free speech and regulatory prerogative. Perhaps the best example concerns the agency's response to the *Washington Legal Foundation*<sup>65</sup> opinions. The nearest the agency came to providing comprehensive rules on the dissemination of off-label scientific and medical information was its 1996 policy guidance, which sought to limit the use by companies of peer-reviewed journal articles and medical textbooks.<sup>66</sup> This guidance subsequently was found to be unconstitutionally broad in a preliminary ruling issued by a federal district court in the *Washington Legal Foundation* cases.<sup>67</sup> The FDA was presented with a clear choice: it could have contested the ruling on appeal, or it could have modified and reissued its guidance in reaction to the decision. As noted above, until very recently the agency did neither, instead declaring that its guidance (as well as similar statutory language) merely provided a safe harbor for companies.<sup>68</sup> As such, any failure by companies to follow the guidance was not necessarily a violation of the law. However, the agency retained its general authority under which it could challenge manufacturers. Absent the adoption of a bona fide safe harbor for companies to rely upon in disseminating these kinds of materials, manufacturers still face potential civil and criminal liability. In light of this revised posture, the appellate court had no legal basis to provide its opinion on the underlying question, thereby ensuring that the law in this area would remain ambiguous. Based upon deposition and other testimony offered by FDA officials in the course of the litigation, it seems evident that the agency was displeased with the court's decision, yet there was no public attempt to address the important policy issues raised by the case.

In 2002, shortly after the Supreme Court's decision in *Thompson v. Western*

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65. See *Wash. Legal Found. v. Henney*, 128 F. Supp. 2d 11 (D.D.C. 2000), *dismissed and vacated in part*, 202 F.3d 331 (D.C. Cir. 2000).

66. See Advertising and Promotion; Guidances, 61 Fed. Reg. 52,800 (Oct. 8, 1996).

67. See *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 72-74 (D.D.C. 1998), *vacated on other grounds*, *Wash. Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000); *Wash. Legal Found. v. Henney*, 56 F. Supp. 2d 81 (D.D.C. 1999), *dismissed and vacated in part*, 202 F.3d 331 (D.C. Cir. 2000).

68. See Decision in *Washington Legal Foundation v. Henney*, 65 Fed. Reg. 14,286. The FDA subsequently published a Request for Comment on First Amendment Issues several years after the *Washington Legal Foundation* cases concluded, and though it received numerous comments it has not yet taken action in response. See Request for Comment on First Amendment Issues, 67 Fed. Reg. 34,942 (May 16, 2002).

*States Medical Center*,<sup>69</sup> which held that the FDA's proposed ban on advertising of compounded drugs was unconstitutional because it did not satisfy the *Central Hudson* commercial free speech test, the FDA published a notice<sup>70</sup> requesting public comments on the First Amendment issues raised by this and other cases, and how it might properly regulate commercial speech within the bounds permitted by the Constitution. The agency's request suggested it might well be prepared to engage with industry and commentators on a more transparent basis. The questions themselves were important: how can the agency advance public health with fewer restrictions on speech? What can the FDA do to limit speech on off-label uses of approved drugs? Does industry practice lead to over-prescribing? Does the First Amendment allow for more limits on claims made in labels than those made in advertisements?<sup>71</sup> There were a large number of responses to this request. Some were critical of the agency, but others praised it for soliciting views and prompting public debate. Yet despite the public response, the FDA failed to take action, publish its views, or otherwise seek to resolve the questions raised by *Thompson*.

With respect to enforcement, the process has become less transparent over time, particularly with the increased involvement of the DOJ. The DOJ has long been involved in the investigation and prosecution of possible violations of the FDCA through the Civil Division and its Office of Consumer Litigation. However, in recent years certain U.S. Attorneys' Offices, notably those in Boston and Philadelphia, have developed innovative legal theories on misbranding and the FCA premised on the primacy of FDA regulatory authority and the impropriety of drug company off-label communication. These offices have managed their cases without any apparent policy coordination. Accordingly, there is an absence of transparency in terms of ascertaining standards as to whether there has been wrongdoing by a company, whether a case is treated as a criminal or civil matter, and what level of financial penalty should be levied if there has been wrongdoing. Additionally, it is unclear whether and to what extent a company's history of alleged wrongdoing or, conversely, its record of cooperation and good behavior, will lead to greater or lesser penalties. Absent judicial review and without a comprehensive code of written standards, companies are left to digest and interpret the implications of the most recent civil settlement and criminal plea agreements. These periodic pronouncements effectively constitute silent or implicit rulemaking, in which an agency acts as

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69. 535 U.S. 357 (2002).

70. Request for Comment on First Amendment Issues, 67 Fed. Reg. 34,942.

71. See Lester M. Crawford, Jr., *Commercial Speech and Public Health: Request for Comment*, 288 JAMA 36 (2002).

both rule maker and adjudicator.<sup>72</sup>

While the Department's prosecution guidelines are set forth in the United States Attorneys' Manual,<sup>73</sup> it has resisted extending these general guidelines to provide written policy direction with respect to off-label promotion cases. In correspondence between the Washington Legal Foundation (WLF) and the DOJ occurring in 2004 and 2005, WLF urged senior Department officials to develop such guidelines related to the investigation and disposition of cases involving the communication of truthful, non-misleading speech.<sup>74</sup> WLF argued that more precise standards would serve two important purposes: they would inform the industry as well as guide prosecutors. The Department declined the invitation and rejected the notion that any additional policy guidelines were needed. Then Assistant Attorney General for the Civil Division Peter D. Keisler responded that "the Department does not have theoretical views regarding off-label promotion of products subject to regulation by the Food and Drug Administration . . . . The Department applies the law to the facts of actual cases and, as a result, there is no need for pure analysis of off-label promotion."<sup>75</sup>

Further, while the DOJ has established corporate criminal culpability guidelines in a series of written memoranda drafted and revised by successive Deputy Attorneys General Thompson, Holder, and McNulty during the Bush administration which are used to determine whether or not to charge corporations with criminal violations of the law,<sup>76</sup> it is left to individual prosecutors and field supervisors to determine whether a corporation's conduct actually warrants criminal or civil treatment. Has the corporation cooperated meaningfully with the prosecuting office in its investigation and review? Has the corporation agreed to conduct its own investigation and waive any attorney-client privilege claims that

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72. This consolidation of authority arguably is inconsistent with the underlying purpose of the Administrative Procedure Act, 5 U.S.C. §§ 551-559 (2006). The Act requires that those agencies that develop administrative rules establish independent procedures for determining if the rules have been violated. Here, DOJ interprets and applies the FDCA and FCA provisions, and enforces them through the settlement process with minimal judicial review, as discussed in the text below.

73. DEP'T OF JUSTICE, UNITED STATES ATTORNEYS' MANUAL (1997), *available at* [http://www.usdoj.gov/usao/eousa/foia\\_reading\\_room/usam](http://www.usdoj.gov/usao/eousa/foia_reading_room/usam).

74. Letter from Daniel J. Popeo, Gen. Counsel, Wash. Legal Found., and Richard A. Samp, Chief Counsel, Wash. Legal Found., to James B. Comey, Deputy Attorney Gen., Dep't of Justice (Mar. 24, 2005) (on file with author).

75. Letter from Peter D. Keisler, Assistant Attorney Gen., Civil Div., U.S. Dep't of Justice, to David Price, Senior Vice President, Legal Affairs, Wash. Legal Found. (Oct. 5, 2004) (on file with author).

76. *See, e.g.*, Memorandum from Paul J. McNulty, Deputy Att'y Gen., to Heads of Dep't Components, U.S. Attorneys (2006), *available at* [http://www.usdoj.gov/dag/speeches/2006/mcnulty\\_memo.pdf](http://www.usdoj.gov/dag/speeches/2006/mcnulty_memo.pdf).

might otherwise apply in providing the prosecutors with the results of said investigation? Does the improper marketing and promotional activity suggest that it was the result of conscious corporate wrongdoing, or merely the result of a limited number of renegade sales representatives? And how should prosecutors make this determination? Prosecutors in the various U.S. Attorneys' Offices around the country may apply these standards in different ways and give different weight to the factors presented. Furthermore, given that meaningful review and oversight from senior officials in the Department present political sensitivities when reserved for the late stages of a delicate and complicated negotiated settlement, it is difficult to achieve transparency or consistency under the current process.<sup>77</sup>

As an example, consider reconciling the criminal treatment accorded Eli Lilly in the 2003 case involving the alleged off-label promotion of Evista (raloxifene HCl) for a treatment subsequently approved by the FDA with the civil treatment of Bristol Myers-Squibb in 2007 for alleged promotional impropriety involving its drug Abilify (aripiprazole). As another example of disparate interpretation, some U.S. Attorneys' offices have begun to suggest in negotiations that drug company sales representatives are violating the law by "selling the side effects." The implication is that presenting possible adverse reactions seen by other physicians in their patients who have taken the drug for an off-label use, the company is effectively (if discreetly) promoting the product for that off-label use. This focus also suggests that prosecutors will take a dim view of companies whose sales representatives visit physicians who do not prescribe on-label.

In effect, the absence of clear guidelines in this area makes it exceedingly difficult to defend the company effectively.<sup>78</sup> This stems from a lack of clarity in

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77. See Barry Meier, *Justice Dept. and Prosecutors Are Said To Have Disagreed on OxyContin Case*, N.Y. TIMES, July 31, 2007, at C4. In the absence of formal Department prosecutorial guidelines, some comfort might be taken from evidence that senior officials are providing policy oversight to the settlement of those cases prepared by U.S. Attorneys in this area. Published reports indicated that senior Department officials initially disagreed with local prosecutors over the noteworthy criminal plea agreement involving Purdue Pharma and three of its senior executives, though the recommendations of the U.S. Attorney for the Western District of Virginia eventually were accepted. This would seem to represent the kind of responsible policy oversight that we would expect of senior officials in any cabinet agency. However, the Department was criticized for what some regarded as an inappropriate attempt to politicize an investigation by an otherwise independent U.S. Attorney.

78. The involvement of various state Attorneys General offices presents added challenges and complexities, which makes it difficult for companies to develop global settlements with all relevant federal and state authorities. Some states have developed "anti-fraud" revenue objectives into their

the rules themselves and from a lack of transparency in the application and enforcement of the rules. It arises in the context of establishing—or refuting—a causal link between off-label prescribing and the company’s marketing of the product in question. In my experience, there is no evident willingness to engage on the question of whether the allegedly improper promotion has actually led physicians to prescribe off-label. Once counsel enters into settlement discussions, the government will emphasize the statutory bases of criminal and civil liability. For example, the FCA provides a civil penalty of up to three times the amount that was falsely claimed from the government.<sup>79</sup> On the criminal side, the government may apply a multiplier of up to two times the amount of the corporate gain or the government loss. However, these multipliers are only meaningful if the underlying base amount (which represents the alleged level of “inappropriate” off-label prescriptions) is derived in a fair and transparent manner.

Some advocates have encouraged DOJ officials to seek advice from the FDA prior to initiating investigations in order to determine whether the drug in question is being prescribed outside the approved labeling for medically appropriate reasons.<sup>80</sup> The FDA retains oversight responsibility for regulating the communication of scientific and medical information and, as such, holds institutional prerogative and memory. DOJ officials may well consult with the FDA in developing a sophisticated medical and clinical perspective on specific cases and in developing a broad policy approach to cases, but it is not evident that they are doing so. Indeed, the perspective of former FDA policymakers suggests that it does not occur other than at the investigatory level.<sup>81</sup>

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annual budgets, creating an incentive to push for a particular outcome regardless of the underlying circumstances and federal policy imperatives. *See New York Will Exceed Medicaid Fraud Recovery Target for Fiscal Year 2008*, BNA’S HEALTH CARE DAILY REP., Sept. 19, 2008, [http://news.bna.com/hdn/HDLNWB/split\\_display.adp?fedfid=108](http://news.bna.com/hdn/HDLNWB/split_display.adp?fedfid=108) (subscription access; on file with author) (describing how in exchange for federal monies granted in 2006, New York committed to recover hundreds of millions of dollars in Medicaid fraud and abuse in the state system).

79. 31 U.S.C. § 3729(a) (2006).

80. *See* Scott Gottlieb, Resident Fellow, American Enter. Inst. for Pub. Policy Research, *Off-Label Uses of Approved Drugs: Medicine, Law & Policy* (May 21, 2008) (video available at [http://www.usdoj.gov/dag/speeches/2006/mcnulty\\_memo.pdf](http://www.usdoj.gov/dag/speeches/2006/mcnulty_memo.pdf)); *see also* Scott Gottlieb, *From FDA, a Good Framework for Distributing Information on Off-Label Uses*, HEALTH AFF. ONLINE, Apr. 23, 2008, <http://healthaffairs.org/blog/2008/04/23/from-fda-a-good-framework-for-distributing-information-on-off-label-uses>.

81. Perhaps not so much at the investigatory level either. A recent GAO report concluded that the FDA had failed to develop adequate performance measures and otherwise to properly manage its primary investigatory unit, the Office of Criminal Investigations (OCI). *See* U.S. GOV’T ACCOUNTABILITY OFFICE, *FOOD AND DRUG ADMINISTRATION: IMPROVED MONITORING AND*

More extensive FDA involvement would not necessarily change the dynamic, approach, or outcome of these cases. Government officials, whether political appointees or career service, generally have strongly held policy perspectives and are inclined to use their authority to advance their personal ambitions, and to protect and strengthen the respective prerogatives and preferences of the institutions they serve. This is entirely natural, but it is troubling in light of the relatively limited bargaining power that companies possess when faced with the threat of prosecution, the sanction of exclusion, vicarious liability for executives, the costs of defense, and the prospect of public disclosure of inflammatory documents. The best way to limit the unintended impact of political motivations would be to establish a regulatory system based upon a clear understanding of the rules that provides notice to, and engagement with, the regulated parties, and then to apply the rules consistently and transparently.

### *C. The Paucity of Federal Judicial Review*

Article III of the Constitution established judicial authority to interpret the law, and in so doing, provide a check on the power of the executive and legislative branches of government. The deficiencies outlined above, an absence of clarity in the regulations and an absence of transparency in rulemaking and enforcement, can be remedied by the courts. But there have been relatively few cases litigated by the drug companies accused of impropriety. This hesitancy to contest allegations occurs because firms are cognizant of a 1998 revision to a rule issued by the HHS Office of Inspector General (OIG). The revised rule significantly altered the legal landscape by expanding the authority of the OIG to exclude drug manufacturers from receiving federal health reimbursement monies if they are found to have engaged in significant financial or other impropriety.<sup>82</sup>

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DEVELOPMENT OF PERFORMANCE MEASURES NEEDED TO STRENGTHEN OVERSIGHT OF CRIMINAL AND MISCONDUCT INVESTIGATIONS (2010). However, this report will not necessarily result in senior FDA officials injecting additional medical and clinical perspective into the investigatory process. Instead, it seems likely to expand the potential criminal exposure of drug companies and their executives in cases of alleged off-label promotion. In response to the GAO Report, the FDA is developing criteria to increase the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible corporate officials accountable. Letter from Margaret A. Hamburg, FDA Comm'r, to Senator Charles E. Grassley (Mar. 4, 2010), *available at* <http://grassley.senate.gov/about/upload/FDA-3-4-10-Hamburg-letter-to-Grassley-re-GAO-report-on-OCI.pdf>.

82. See Health Care Programs: Fraud and Abuse; Revised OIG Exclusion Authorities

Prior to this, only those institutions that provided services directly to patients (such as hospitals, hospices, day care providers, and diagnostic service providers) could be excluded or “debarred” from federal financing program eligibility.

In issuing this expanded rule, the OIG noted that they “would not expect that manufacturers would often be convicted and subject to mandatory exclusion.”<sup>83</sup> Drug companies receive a large portion of their total revenue and earnings from reimbursements under the federal Medicare and Medicaid programs, and to lose this would irrevocably cripple a company. Indeed, it is often said that no sane company would ever challenge in court allegations that, if proven, would result in a felony conviction and certain exclusion. In effect, companies that negotiate settlements with the government to resolve allegations of illegal off-label promotion can reasonably expect that the OIG will not exercise its discretion to exclude the company from continuing to receive federal reimbursement funds; companies that challenge the government’s allegations in court clearly put the company at risk of extinction as a felony conviction carries with it automatic exclusion.<sup>84</sup>

It is difficult to overstate the immense impact that this seemingly technical clarification has had on the development of the legal and regulatory landscape. As a practical matter, companies accused of wrongdoing *must* cooperate and resolve the matter by settlement. They cannot realistically challenge the government in court either on the facts, the underlying theories of liability, or whether the charges alleged are compatible with the Constitution or even consistent with FDA regulations themselves. The risk/reward calculus is skewed dramatically in favor of settlement when a loss would jeopardize the firm’s viability by forfeiting government reimbursement for its products. As a result,

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Resulting from Public Law 104-191, 63 Fed. Reg. 46,676 (Sept. 2, 1998).

83. See Health Care Programs: Fraud and Abuse; Revised OIG Exclusion Authorities Resulting from Public Law 104-191, 63 Fed. Reg. at 46,679.

84. See Dan Levine, *Marketing Tactics Put Johnson & Johnson Under DOJ Microscope*, NAT’L L.J., Dec. 3, 2009, available at [http://www.law.com/jsp/article.jsp?id=1202436012057&Marketing\\_Tactics\\_Put\\_Johnson\\_Johnson\\_Under\\_DOJ\\_Microscope](http://www.law.com/jsp/article.jsp?id=1202436012057&Marketing_Tactics_Put_Johnson_Johnson_Under_DOJ_Microscope) (reporting that federal prosecutors were considering indictment of Johnson & Johnson or its Scios unit, which could lead to exclusion of parent or subsidiary); Sue Reisinger, *In Their Long Battle with Big Pharma, The Feds Have Held Back Their Nuclear Option. Why?*, CORP. COUNS., Feb. 1, 2010, <http://www.law.com/jsp/cc/PubArticleCC.jsp?id=1202437870117> (Discretionary debarment is the OIG’s “nuclear bomb” that has never been applied to exclude a major company as it would limit patient access to drugs and “cost tens of thousands of jobs.”); see also Michael K. Loucks, *Drug Busts on the Cheap Lack Power To Deter*, BUS. WK., Mar. 8, 2010, <http://www.businessweek.com/news/2010-03-08/drug-busts-on-the-cheap-lack-power-to-deter-michael-k-loucks.html> (arguing that prosecutors need more resources to develop cases that will lead to exclusion from federal programs).

there are few opportunities to advance the law in any fair and reasonable way. Some observers are skeptical generally of the ability of the courts to properly evaluate the administrative policymaker's judgment in areas, like this, which involve "social cost accounting."<sup>85</sup> But in an area that is replete with complexity and nuance, such that even drug industry critics acknowledge significant First Amendment considerations, fair-minded observers surely must ask why federal courts have not had more opportunities to opine on these critical issues of legal policy. The lawsuit brought last year by Allergan against the HHS Secretary and the FDA Commissioner, described below, demonstrates the extraordinary lengths to which companies will go in order to reduce enforcement risk and avoid debarment.

#### *D. The Limits on Communicating Truthful Information*

The current enforcement environment is focused on conducting investigations and threatening prosecution as a means of compelling settlements. There is very little meaningful engagement with private industry. DOJ officials fail to recognize the importance of communicating truthful, non-misleading information to physicians. One might expect that regulators would be motivated to satisfy policy objectives that protect the public health while facilitating informed prescribing decisions. From a public health perspective, regulators should consider whether or not the scientific and medical information is truthful and not misleading, and whether or not physicians are prescribing the product in a medically appropriate manner. However, the government is concerned solely with whether the FDA has approved the indication in question. If it has not, and the company conveys or in some way interacts with physicians on this unapproved indication, then there will be a lengthy investigation and, in all likelihood, a costly settlement under threat of prosecution.<sup>86</sup>

DOJ officials have said that they do not believe the truthfulness of the information is relevant,<sup>87</sup> and that a manufacturer is liable under the FCA if it knowingly implements a marketing plan that foreseeably caused third parties to file claims for off-label uses that were not eligible for reimbursement.<sup>88</sup>

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85. Diver defines this term as the "sophisticated and sensitive application of common sense." Diver, *supra* note 49, at 109 (citing Jerry Mashaw, *Administrative Due Process as Social-Cost Accounting*, 9 HOFSTRA L. REV. 1423, 1441 (1981)). Courts are widely considered to lack the investigative resources, analytical tools, and technical competence to more than simply rely on the administrative record in upholding agency decisions.

86. See Loucks, *supra* note 21.

87. See *id.*

88. See *id.* A recent court decision suggests that the government may begin to see its theories

Consistent with this interpretation, the current DOJ policy perspective is evident in a court filing made in connection with a *qui tam* relator case against Pfizer.<sup>89</sup> In its filing, the DOJ rejects the view that a “false” statement under the False Claims Act need be an affirmative misrepresentation; rather, “a material omission will suffice.”<sup>90</sup> In the case of alleged off-label promotion, this omission may be established on the basis of the dissemination of information (even if truthful and non-misleading) if “the FDA has specifically concluded that the drug is not safe or effective for that use.”<sup>91</sup> The DOJ also contends that medical compendia references to a drug’s off-label use in support of reimbursement coverage is insufficient to establish the veracity of a pharmaceutical company’s communication about that off-label use for purposes of the FCA.

Similarly, the OIG equates off-label promotion by a manufacturer with the submission of a false claim for reimbursement, regardless of the inherent truthfulness of the information.<sup>92</sup> Its perspective may be gleaned from the

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challenged, as some courts have criticized the *Franklin* result, and questioned whether off-label promotion violations of the FDCA can form the basis of FCA liability. *See United States ex rel. Polansky v. Pfizer, Inc.*, No. 04-cv-0704, 2009 WL 1456582, at \*7 (E.D.N.Y. May 22, 2009). Here, the court rejected the government’s theory that drug companies effectively facilitate false claims by promoting illegally. “[T]he mere fact that Pfizer may have been violating FDA regulations does not translate into liability for causing a false claim to be filed . . . Pfizer did not file any claims for reimbursement and made no implied certifications to obtain payment.” *Id.* The case was dismissed under Federal Rule of Civil Procedure 9(b) for failing to assert with the requisite specificity facts that would establish that a physician prescribed the product and that a pharmacist filled a prescription based upon illegal off-label promotion. The court’s observations, if adopted more broadly, suggest that the reasoning of *Franklin* could be rejected or limited in subsequent rulings. This development illustrates again the problems inherent in our existing process, where a single federal district court ruling has exposed industry to billions of dollars in liability, as federal prosecutors leverage this ruling and companies’ inability to litigate to compel settlements.

89. United States’ Statement of Interest at 1, *United States ex rel. Rost v. Pfizer, Inc.*, No. 03-CV-11084 (D. Mass. 2008). The filing notes that the “United States has a keen interest in the development of the law in this area.” *Id.* The case involves the interpretation of the FCA, and the DOJ submission is focused on disputing various contentions and interpretations contained in an *amicus curiae* brief filed by the Washington Legal Foundation.

90. *Id.* at 9.

91. *Id.*

92. *See Allegations of Waste, Fraud and Abuse in Pharmaceutical Pricing: Financial Impacts on Federal Health Programs and the Federal Taxpayer: Hearing Before the H. Comm. on Oversight and Gov’t Reform*, 110th Cong. 6-7 (Feb. 9, 2007) (statement of Lewis Morris, Chief Counsel, Office of the Inspector General). Although drug manufacturers do not generally submit any claims for reimbursement, the government’s perspective is that prescription drug promotion outside the FDA-approved labeling effectively induces physicians to prescribe, which thereby causes pharmacists to fill prescriptions and (false) reimbursement claims eventually to be filed.

evolving terms of its preferred model Corporate Integrity Agreement (CIA). As a condition of avoiding discretionary exclusion from federal reimbursement programs, the government demands that drug and medical device firms that are found to have violated the FDCA, the anti-kickback statute, or other provisions of federal law, enter into a CIA prior to settlement of the case. CIAs now address matters well beyond pricing and anti-kickback law compliance, and include provisions related to the promotion of products. The CIA with Bristol-Myers Squibb, for example, requires that the company direct all inquiries related to a potential off-label use to the company's internal medical information department.<sup>93</sup> The CIA also requires that the company evaluate its proposed call plan (for example, the plan specifying which physicians will be presented with product related information by company sales representatives), specifically for those products in its portfolio "having a high potential for off-label use that could be driven by detailing an inappropriate audience" of physicians.<sup>94</sup> There is no hint that the government is concerned about the truthfulness or falsity of the message. The OIG simply intends to limit the number and scope of physicians who receive product information from company representatives.

In concert, these policy perspectives establish that the government—specifically the FDA through its approval process—is the arbiter of what information may be shared with physicians.<sup>95</sup> Moreover, law enforcement

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93. See CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND BRISTOL-MYERS SQUIBB COMPANY 29-31 (Sept. 26, 2007). The use of monitors and other provisions of this Agreement have been criticized by legal scholars in that they interject law enforcement officials into the internal workings of a company, including decisions over personal and shareholder treatment. See Richard A. Epstein, *The Deferred Prosecution Racket*, WALL ST. J., Nov. 28, 2006, at A14.

94. See CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND BRISTOL-MYERS SQUIBB COMPANY, *supra* note 93.

95. In contrast to the apparent views of the FDA, at least one federal court has seen fit to qualify its authority. "And, despite the FDA's occasional statements in its briefs to the contrary, physicians are a highly educated, professionally-trained and sophisticated audience. In making prescribing decisions, doctors want (and need) to know first and foremost if the drug is the most safe and effective means to treat the conditions suffered by the patients." Wash. Legal Found. v. Friedman, 13 F. Supp. 2d 51, 63 (D.D.C. 1998), *vacated on other grounds*, Wash. Legal Found. v. Henney, 202 F.3d 331 (D.C. Cir. 2000). "[T]he court must again note that off-label prescriptions, presently legal, do constitute the most effective treatment available for some conditions. Through the government's well-intentioned efforts to prevent misleading information from being communicated, a great deal of truthful information will also be embargoed. In this case, the truthful information may be life saving information, or information that makes a life with a debilitating

officials will punish companies without regard to whether the promotional message is truthful,<sup>96</sup> and further may choose to limit the audience as to whom a company's promotional or scientific communication may be directed. This represents a disturbing level of intrusiveness on commercial speech and on the practice of medicine.

#### V. BRINGING IT DOWN TO EARTH: SOME PRODUCT-RELATED CASE STUDIES

In considering the regulation of truthful and non-misleading off-label communication, it is useful to consider the circumstances posed by several product-based case studies. Each of these cases may seem anachronistic, but together they illustrate the unworkable tension inherent in the current American regime as it limits the free exchange of medical and clinical information.

##### *A. Gilead Sciences' Viread (tenovir disoproxil fumarate)*

In 2001, the FDA approved Viread for the treatment of HIV infection in adults based upon its review of a study of previously treated adults infected with HIV.<sup>97</sup> Two years later, the FDA added clinical data to the labeling from a second study, which examined treatment-naïve patients and their experience with the drug. Gilead has run ongoing clinical trials in order to accumulate additional patient experience data from long-term observation.<sup>98</sup> Publication of these

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condition more comfortable." *Id.* at 73.

96. For example, the 2005 settlement involving Eli Lilly and its drug Evista for osteoporosis was based exclusively on allegations of illegal, off-label promotion. In this case, the company was accused of improperly providing doctors with information about the efficacy of using Evista to treat breast cancer; this information turned out to be substantially truthful as evidenced by FDA approval in September 2007 for that very same indication. *See* Press Release, Dep't of Justice, Eli Lilly and Company To Pay U.S. \$36 Million Relating to Off-Label Promotion (Dec. 21, 2005), [http://www.usdoj.gov/opa/pr/2005/December/05\\_civ\\_685.html](http://www.usdoj.gov/opa/pr/2005/December/05_civ_685.html) (announcing the civil settlement and criminal plea agreement involving Eli Lilly and its product Evista). As another example, the government has investigated Genentech for several years concerning allegations that it improperly promoted off-label prescribing for its drug Rituxin in the treatment of certain kinds of lymphoma that subsequently were approved by the FDA. *See* Genentech, Inc., Annual Report (Form 10-K), at 24 (Feb. 25, 2008), *available at* <http://www.gene.com/gene/ir/downloadDoc.do?id=3841> (describing the ongoing investigation involving Genentech and its product Rituxan).

97. Prescribing and other background information on this product may be found at Gilead's website. *See* Gilead Sciences, Highlights of Prescribing Information (Mar. 2010), [http://www.gilead.com/pdf/viread\\_pi.pdf](http://www.gilead.com/pdf/viread_pi.pdf).

98. *See, e.g., Gilead Sciences To Present Viread Phase III Clinical Trial Data*, MED. NEWS, Nov. 2, 2009, <http://www.news-medical.net/news/20091102/Gilead-Sciences-to-present-Viread-Phase-III-clinical-trial-data.aspx>.

clinical results serves to advance the science and, more importantly, enable the medical community to better understand the safety and efficacy profile of the drug after years of patient exposure.

This is important clinical work, as those who suffer from HIV and associated health problems will likely remain on Viread for many years, at least as long as the drug continues to be effective and reasonably tolerable or until a superior treatment is developed and approved. As such, each public release of new long-term clinical data is eagerly anticipated and received at prominent medical conferences by physicians who treat patients with HIV. With each release of data, there is a pattern of information migration that runs from the company to conference attendees, to publication in peer-reviewed medical journals in the United States and abroad, to submission by the company to various regulatory authorities around the world. When the data finally is approved by the FDA and other agencies for inclusion in the product labeling, it has taken at least ten months, and usually far longer.

During the interim period, between the first presentation of the data to physicians at a medical conference and the eventual approval by regulatory authorities of modification of the product labeling, FDA regulations may not allow Gilead to have any role in disseminating this truthful, non-misleading, and extremely relevant clinical information.<sup>99</sup> At the very least, FDA regulations would not seem to permit Gilead field sales representatives or medical liaisons to discuss this data with physicians. As such, the only physicians who will become aware of the new clinical data on a timely basis would be those who were involved directly in the Gilead clinical study or those who obtain the information through their own independent efforts. Indeed, many physicians would not likely become aware of the new data, and would not take the data into consideration in their treatment of HIV patients. Although the data is at least arguably “consistent with” the existing labeling, since the clinical studies in question are of the same kinds of patients suffering from the same illness and being treated with the same drug, current FDA regulations do not make clear that these distinctions freely allow companies to disseminate information.<sup>100</sup>

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99. See *supra* text accompanying notes 26-32.

100. Viread also has been approved to treat patients with chronic hepatitis B infection (CHB). Gilead discovered this as the company reviewed data from its ongoing HIV clinical trials that included subsets of patients who were co-morbidly infected with HIV and CHB. While additional HIV patient data may be “consistent with” the existing labeling, it would not appear that data related to an entirely new prospective use, such as treating CHB, would have been covered by this broad standard prior to approval of the second indication. Press Release, Gilead Sciences, Phase III Study Evaluating Gilead’s Viread(R) for the Treatment of Chronic Hepatitis B Virus Meets

*B. Cephalon's Provigil (modafinil)*

Provigil was approved by the FDA in late 1998 for the treatment of excessive daytime sleepiness (EDS) associated with narcolepsy.<sup>101</sup> Although the precise mechanism of action is not fully understood, it appears to work by affecting an area of the brain that regulates wakefulness. The active ingredient, modafinil, is not an amphetamine but a mild stimulant, and as such most patients do not experience the jitteriness or other negative side effects associated with the use of amphetamines. Clinical data and anecdotal evidence has demonstrated that Provigil keeps patients awake and alert regardless of why they might be sleepy or tired.<sup>102</sup>

Cephalon discussed its clinical development plans with the FDA early on, including the drug's potential utility in conditions other than narcolepsy. Following these discussions, the company initiated a series of placebo-controlled clinical studies with distinct groups of patients, each group representing a recognized model of underlying sleep disorder or other medical condition. The FDA suggested that if the company demonstrated efficacy and safety in each of these patient groups, it could seek a broad label for the treatment of EDS associated with any underlying medical condition.<sup>103</sup> The company studied patients who were sleepy due to one of three conditions: narcolepsy (the first approved indication), obstructive sleep apnea, or a disturbed circadian rhythm pattern due to extended periods of shift work known as "shift work-sleep disorder." These studies demonstrated efficacy across the board and showed a limited number of relatively minor adverse events. However, after the additional data was submitted to the agency in 2003, the FDA convened an advisory committee which recommended against approving the broad label in favor of a pseudo-specific label for use in EDS associated with each condition evaluated.<sup>104</sup>

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Primary Endpoint (June 6, 2007), [http://www.gilead.com/pr\\_1012569](http://www.gilead.com/pr_1012569) (announcing positive Phase III clinical results).

101. Prescribing and other background information on this product may be found at Cephalon's Provigil website. See Cephalon, Patient Information Provigil Tablets (Mar. 2008), [http://www.provigil.com/media/PDFs/prescribing\\_info.pdf](http://www.provigil.com/media/PDFs/prescribing_info.pdf).

102. See Joel Garreau, *The Great Awakening*, WASH. POST, June 17, 2002, at C1. See also *All on the Mind*, ECONOMIST, May 22, 2008.

103. See CEPHALON, INC., PROVIGIL® (MODAFINIL) TABLETS (C-IV) SUPPLEMENTAL NDA: BRIEFING DOCUMENT FOR PERIPHERAL AND CENTRAL NERVOUS SYSTEM DRUGS ADVISORY COMMITTEE MEETING 10 (Sept. 25, 2003), [http://www.fda.gov/ohrms/dockets/ac/03/briefing/3979B2\\_01\\_Cephalon-Provigil.pdf](http://www.fda.gov/ohrms/dockets/ac/03/briefing/3979B2_01_Cephalon-Provigil.pdf).

104. Lois E. Krahn, Chair, Dep't Psychiatry and Psychology, Mayo Clinic, Remarks at the Meeting of the U.S. FDA Peripheral and Central Nervous System Drugs Advisory Committee 184 (Sept. 25, 2003) (transcript available at <http://www.fda.gov/ohrms/DOCKETS/ac/03/>

This labeling decision virtually ensured a high level of off-label prescribing for the product.

Indeed, many physicians became aware of the product and its intriguing characteristics as the additional clinical studies were conducted, as data was presented at medical meetings, and as the mainstream news media began to write about the incredible “wonder drug”<sup>105</sup> that was being prescribed to pilots, college students, and others who simply were sleepy or tired during the day without any associated medical condition.<sup>106</sup> Unaffiliated physicians and other third parties conducted additional studies, which further increased awareness. For example, the U.S. military conducted a number of clinical studies of aviator performance and pilot sustained alertness while taking Provigil.<sup>107</sup> At the advisory committee meeting, the FDA’s Dr. Robert Temple suggested that he was not necessarily troubled by off-label use of Provigil in the case of truck drivers or others who might be driving while sleepy, noting that “[i]f they’re driving next to me, I think I’d prefer they be on it.”<sup>108</sup>

transcripts/3979T2.pdf). Some committee members were concerned that a broader label would result in unwarranted prescribing for patients who did not suffer from any underlying medical disorder, but simply wished to have a “replacement for the normal amount of nighttime sleep.”

105. Wil S. Hylton, *The War. On Drugs.*, ESQUIRE, Feb. 1, 2003, at 116, 117.

106. Physicians have prescribed Provigil extensively for a number of off-label uses, but one often cited has been fatigue associated with multiple sclerosis (MS). In fact, the National Multiple Sclerosis Society characterizes the use of the drug as the standard of care (“medications commonly used in the management of MS”). See National Multiple Sclerosis Society, Medication Used in MS, <http://www.nationalmssociety.org/about-multiple-sclerosis/what-we-know-about-ms/treatments/medications/index.aspx>. The Society makes reference to two clinical studies with mixed results in its summary of the product, one study conducted over a nine-week period in 2000 by Cephalon that showed efficacy in a low dose of Provigil against placebo, and a second study conducted in 2005 by a physicians’ group in France that failed to show efficacy. However, the Society notes that the clinical experience of physicians treating patients with MS has shown “significant benefit for many patients with MS-related fatigue.” See National Multiple Sclerosis Society, *supra* note 9.

107. See, e.g., JOHN A. CALDWELL, JR. ET AL., U.S. ARMY AEROMEDICAL RESEARCH LABORATORY, THE EFFECTS OF MODAFINIL ON AVIATOR PERFORMANCE DURING 40 HOURS OF CONTINUOUS WAKEFULNESS: A UH-60 HELICOPTER SIMULATOR STUDY (1999); John A. Caldwell, Jr. et al., *A Double-Blind, Placebo-Controlled Investigation of the Efficacy of Modafinil for Sustaining the Alertness and Performance of Aviators: A Helicopter Simulator Study*, 150 PSYCHOPHARMACOLOGY 272 (2000); see also Memorandum from U.S. Dep’t of the Air Force, *supra* note 10.

108. Robert Temple, FDA, Remarks at the Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee 186 (Sept. 25, 2003) (transcript available at <http://www.fda.gov/ohrms/DOCKETS/ac/03/transcripts/3979T2.pdf>).

Two things are evident here. First, there is a host of factors outside the control and influence of the company, including government-sponsored activities that may well significantly affect the extent of off-label prescribing. Second, Provigil is a case of a company developing clinical data with studies in contemplation of a pending label expansion into related therapeutic areas in which the underlying medical cause may differ, but the condition being treated is the same or very similar. The initial, narrow indication approved by the FDA (EDS associated with narcolepsy) suggests that this additional clinical data, all related to efficacy in treating excessive daytime sleepiness, may not be “consistent with” the labeling and therefore may not lawfully be communicated by the company, and yet is truthful and relevant to physicians who might prescribe the drug.

*C. Genentech’s Avastin (bevacizumab) and Lucentis (ranibizumab injection)*

The saga of these two biological products, each a therapeutic monoclonal antibody designed to bind to and inhibit human vascular endothelial growth factor (VEGF), received substantial press coverage and generated controversy in the medical and patient community.<sup>109</sup> When VEGF is inhibited, the growth of new blood vessels, or angiogenesis, is subsequently halted. Avastin, produced by Genentech, was the first anti-angiogenesis therapy approved in the United States.<sup>110</sup> In 2004, the FDA approved it as a first-line treatment for patients with metastatic carcinoma of the colon or rectum, and in 2006 it was approved as a second-line treatment of colon or rectal cancer and a first-line treatment of non-small cell lung cancer. Lucentis, a smaller molecule, or fragment version, of the same active agent in Avastin,<sup>111</sup> was approved in 2007 for the treatment of neovascular age-related macular degeneration (AMD), a severe disorder of the retina that is a major cause of vision loss in persons over age 60.<sup>112</sup>

Prior to the approval of Lucentis, a retinal specialist in Miami was reported to have been the first to experiment with off-label use of a modified form of Avastin to treat AMD. Subsequent to this reported experimentation with Avastin

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109. See Andrew Pollack, *Drug Maker and Eye Doctors Settle Dispute Over Avastin*, N.Y. TIMES, Dec. 21, 2007, at C4; see also News Release, Am. Acad. Of Ophthalmology, Ophthalmologists Concerned About AMD Patients’ Access to Avastin (Oct. 12, 2007), <http://www.aaopt.org/newsroom/release/20071012.cfm>.

110. See Genentech, Medicines: Avastin, <http://www.gene.com/gene/products/information/oncology/avastin/> (last visited Mar. 29, 2010).

111. Morten la Cour, *Intravitreal VEGF-inhibitors: Is Avastin a Generic Substitute for Lucentis?* 85 ACTA OPHTHALMOLOGICA SCANDINAVICA 2, 3 (2007).

112. See Genentech, Medicines: Lucentis, <http://www.gene.com/gene/products/information/tgr/lucentis/> (last visited Mar. 29, 2010).

and prior to the approval of Lucentis, Genentech struggled to address a number of difficult issues associated with the demand for off-label use of an approved but reformulated product, including drug access, distribution, pharmacy compounding, safety, and price. There also are interesting questions of off-label communication presented by this case.

Early on, Genentech acknowledged that the retinal physician community was acting “with noble intent, which is to help patients who are going blind as we speak . . . [but] there have been no safety and toxicity studies conducted on Avastin as an ophthalmic drug.”<sup>113</sup> However, it also emphasized that off-label use was increasing “because of advice generated by the medical community.”<sup>114</sup> What did Genentech do about communicating with physicians on the off-label use? “We make educational material available to the doctors but we don’t take a position,” said a Genentech executive.<sup>115</sup>

Although the two products were quite similar, and intravitreal use of Avastin was possible for those who purchased Avastin through a compounding pharmacy that would then dilute the potency of the formulation, it was not the preferred method of treatment. In fact, the company raised questions about the maintenance of sterility in the process of dividing the Avastin dose due to a lack of preservatives in that drug’s formulation; Genentech also cited a warning letter issued by the FDA to compounding pharmacies.<sup>116</sup> Following the approval of Lucentis, the situation was further complicated by the company’s decision to charge far more for Lucentis on a volume basis, such that some retinal physicians continued to purchase and dilute Avastin and legislators sought to pressure the company into making Avastin readily available for the off-label use.<sup>117</sup> The company responded that it continued to believe that Lucentis was “the most appropriate treatment for patients with . . . [AMD] because it was specifically

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113. *Genentech: Avastin Not Intended for AMD; Company Cautions on Off-Label Use of Cancer Drug*, RETINAL PHYSICIAN, Jan. 2006, <http://www.retinalphysician.com/article.aspx?article=100181>.

114. *Id.*

115. *Id.*

116. Genentech, Features: Open Letter (Oct. 29, 2007), <http://www.gene.com/gene/features/avastin/open-letter.html>.

117. Genentech caused a firestorm by pricing Lucentis at approximately \$2,000 per one-time monthly dose and announcing that it would no longer allow compounding pharmacies to purchase Avastin from its wholesalers. Shortly thereafter, following the announcement by U.S. Senator Herbert Kohl (D-Wisconsin) that his Senate Committee on Aging would launch an investigation into Genentech’s decision to limit Avastin availability, the company announced that it had reached agreement to continue to allow retina specialists and ophthalmologists access to Avastin under certain circumstances. *See* Pollack, *supra* note 109.

designed, formally studied, approved by the [FDA] and manufactured for intraocular delivery . . . [but it] does not interfere with physicians' prescribing choices."<sup>118</sup>

Leaving aside the apparent contradictions inherent in government officials effectively encouraging off-label use of an untested product, Genentech was at the very least in a terribly awkward position during the period 2004 to 2007 as interest in off-label use of Avastin intensified. Although the company could freely reiterate and emphasize any statements made by the FDA, it is not clear that it could lawfully communicate directly to physicians any safety information that related to the off-label use. This alternate use, unrelated to the approved cancer indications and which, by the company's own admission, raised concerns of eye infections, could not possibly be said to be "consistent with" the FDA-approved labeling. From a public policy perspective, it would be preferable to permit companies to act in an ethically responsible manner and to share fully any concerns about prevailing physician practice, rather than to limit communication to a brief press statement and the dissemination of peer-reviewed journal articles. But the current regulatory environment does not allow companies to do this.

#### *D. Allergan's Botox (botulinum toxin)*

Botox, a purified form of botulinum toxic, is a popular injectable biologic product used cosmetically to combat wrinkles and facial lines as well as a prescription therapeutic approved by the FDA to treat abnormal tone in muscles known as dystonia.<sup>119</sup> Physicians also prescribe Botox to treat spasticity, or involuntary muscle contractions. Botox has been approved in a number of countries outside the United States to treat spasticity, and Allergan recently obtained FDA approval to treat spasticity in the flexor muscles of the elbow, wrist, and fingers in adults.<sup>120</sup> However, physicians are likely to continue to use Botox for other off-label conditions, including lower limb spasticity and spasticity in juveniles suffering from cerebral palsy.

There is a risk of adverse "distant spread of toxin" associated with the injection of Botox. In connection with this risk, the FDA ordered Allergan and all other manufacturers of botulinum toxin to add a special "boxed warning" to the existing label and package insert, and to adopt a Risk Evaluation and Mitigation Strategy (REMS).<sup>121</sup> In connection with its decision, the FDA noted that its

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118. Press Statement, Genentech, Avastin Distribution Update (Dec. 20, 2007), <http://www.gene.com/gene/features/avastin/press-statement.html>.

119. See Allergan, Botox Portal, <http://www.botox.com> (last visited Mar. 29, 2010).

120. See FDA, FDA Approves Botox to Treat Spasticity in Flexor Muscles of the Elbow, Wrist and Fingers (Mar. 9, 2010), <http://www.fda.gov/newsevents/ucm203776.htm>.

121. See FDA, FDA Requires Boxed Warning for All Botulinum Toxin Products (Apr. 30,

intention was not to discourage the use of botulinum toxins for spasticity, as they remain “very effective” and “commonly used.”<sup>122</sup> The application of this order has placed Allergan and the other manufacturers of this product in an untenable position. While the FDA has approved the warning information included in the modified labeling and directed the companies to implement the terms of the REMS, the use of the product in spasticity has not yet been approved. As such, FDA regulations do not allow Allergan to speak freely with physicians about the fine points of product administration that might further reduce risk, such as dosing frequency, injection technique, and optimal patient selection.

In response to this conundrum, Allergan has brought an action against the FDA and the DOJ in federal district court in Washington.<sup>123</sup> The lawsuit asks the court to determine that a number of FDA regulations are unconstitutional, either on their face or as applied to truthful speech of drug manufacturers, and it asks for preliminary and permanent injunctions that would enjoin the government from taking any civil or criminal enforcement action against Allergan on the basis of its expression of truthful and non-misleading speech. This presents a unique opportunity for a federal court to consider the FDA framework for regulating off-label medical and scientific information. Unlike prior cases in which the First Amendment has been used as a defensive shield in circumstances where companies or their employees were accused of communicating false or misleading information, the company is asking the court to affirmatively permit it to discuss truthful information.

This case, and those others summarized above, might be seen as unusual, but they serve to illustrate the particularly anomalous results that can flow from a regulatory enforcement policy that deems all scientific and medical information not included in the FDA-approved labeling as unworthy of dissemination, and regards those who dare do so as criminals.

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2009), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149574.htm>. A Risk Evaluation and Mitigation Strategy (REMS) is required for certain drugs and biological products determined by the FDA to present safety risks. See Food & Drug Admin., FDA Issues Draft Guidance on Risk Evaluation and Mitigation Strategies (Sep. 30, 2009), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm184399.htm>.

122. Ellis Unger, Office of New Drugs, Ctr. for Drug Evaluation and Research, Food & Drug Admin., Remarks at the FDA Media Briefing on Botulinum Toxin Products (Apr. 30, 2009) (transcript available at <http://www.fda.gov/downloads/NewsEvents/Newsroom/MediaTranscripts/ucm169170>).

123. See Johnathan D. Rockoff, *Allergan Suit Seeks to Lift Botox Curbs*, WALL ST. J., Oct. 2, 2009, at B4; Natasha Singer, *Botox Maker's Suit Cites Free Speech*, N.Y. TIMES, Oct. 3, 2009, at B3.

## VI. AN ALTERNATIVE MODEL: THE BRITISH EXPERIENCE

Major drug companies operate on a global scale and are subject to oversight by authorities in various jurisdictions that act to enforce their respective laws and regulations. The broad policy objectives of regulators in Europe are identical to those in the United States: they want clear, hard rules that can be consistently enforced and which will lead to high levels of industry compliance.<sup>124</sup> However, the United Kingdom long has approached the regulation of advertising and promotion of medicines in a markedly different way. Consistent with a deep tradition of flexibility in its regulation, and more specifically of an evident fondness for private, self-regulation that began in the early twentieth century,<sup>125</sup> rulemaking and enforcement in this area are developed and led by a self-regulating body associated with the trade organization of British pharmaceutical manufacturers. Whereas the executive branch develops and enforces the rules in the United States, in Britain the responsible government agency has a more limited role, making the UK regulatory scheme even more unusual in that it is neither wholly private nor wholly public. Like the United States, the statutory language is necessarily written broadly. Unlike the United States, this statutory language is supplemented by a detailed code of practice that is adopted, interpreted, implemented, and largely enforced apart from the government. And unlike the United States, there have been virtually no prosecutions.<sup>126</sup>

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124. The observations set forth throughout this section are based, in part, on information obtained in interviews with Jeremy Mean, Group Manager, Information for Public Health, UK Medicines and Healthcare Products Regulatory Agency (MHRA), in London (Apr. 2008), and Heather Simmonds, Director, Prescription Medicines Code of Practice Authority (PMCPA), in London (Apr. & June 2008).

125. Britain “appears to be something of a haven for self-regulation.” Rob Baggott, *Regulatory Reform in Britain: The Changing Face of Self-Regulation*, 67 PUB. ADMIN. 435, 438 (1998). Another commentator observed that Britain generally is more “flexible and informal” in its regulation of society. DAVID VOGEL, NATIONAL STYLES OF REGULATION: ENVIRONMENTAL POLICY IN GREAT BRITAIN AND THE UNITED STATES 21 (1986). Consistent with these observations, there is a long history in Great Britain of private, self-regulation of advertising. See generally T.R. NEVETT, ADVERTISING IN BRITAIN (Heinemann on behalf of the History of Advertising Trust 1982). In 1919, the date often cited as the start of self-regulation of medicines advertising, an association of fifty manufacturers of patent medicines was established to control “inaccurate or misleading practices.” *Id.* at 104. Public criticism mounted, however. For example, a 1934 report by the Royal College of Surgeons found that advertising claims for medicines were “always exaggerated and are, in general, purely fraudulent,” and the medicines themselves often have “no substances of therapeutic value.” *Id.* at 164. In response to this criticism, and perhaps in a prescient effort to stave off government action, the association adopted a code of standards in 1936; in hindsight, many regard this first code as an important precedent supporting the concept of self-regulation. *Id.* at 164-65.

126. For a review of trends in effective corporate self-regulation, see CHRISTINE PARKER, THE

By definition, the self-regulating model requires the full engagement of the regulated industry members,<sup>127</sup> who must agree on the conceptual framework as well as the specific rules that delineate, refine, and clarify the language of the code over time; drug manufacturers developed and adopted the code in Great Britain and thus, have a substantial stake in its success. They also fear reprisals, which carry the stigma of peer condemnation.<sup>128</sup> Moreover, the self-regulating system is accompanied by government oversight and an implicit threat of enhanced government enforcement or statutory enactment. Ultimately, if the system is seen as ineffective by public officials and their constituents, industry risks losing a relatively sophisticated and benevolent taskmaster that, while it may threaten to withhold the carrot of association membership, does not wield a

OPEN CORPORATION: EFFECTIVE SELF-REGULATION AND DEMOCRACY (2002). As Parker suggests, the United States has a degree of self-regulation in the form of the U.S. Sentencing Commission Guidelines that were established in the late 1980s, reflecting the common use of criminal sanctions for corporate malfeasance. These guidelines encourage private firms to adopt extensive internal compliance programs, including education and self-reporting mechanisms, and provide reduced sentences for those companies that do so and yet are later found to have committed violations of the law. *Id.* at 259-60.

127. See A. Ogus, *Rethinking Self-Regulation*, 15 OXFORD J. LEGAL STUD. 97 (1995), reprinted in A READER ON REGULATION 375 (Robert Baldwin, Colin Scott & Christopher Hood eds., 1998). Noted regulatory scholar John Braithwaite also has written favorably of self-regulation, noting that it may well be more efficient, more flexible, and less costly than traditional command and control methods. See John Braithwaite, *Enforced Self-Regulation*, 80 MICH. L. REV. 1466 (1982). See also JOHN BRAITHWAITE, CORPORATE CRIME IN THE PHARMACEUTICAL INDUSTRY (1984), in which he concludes that large drug firms effectively allocate responsibility for corporate misdeeds to subordinates and external contractors.

128. All breaches of the Association of the British Pharmaceutical Industry (ABPI) Code of Practice are posted on the website of the Prescription Medicines Code of Practice Authority (PMCPA), a quasi-autonomous unit of the ABPI, with the following characterization: “[Company] has breached the ABPI Code of Practice for the Pharmaceutical Industry and brought discredit upon, and reduced confidence in, the pharmaceutical industry.” Prescription Medicines Code of Practice Authority, Advertisements, <http://www.pmcpa.org.uk/?q=advertisements> (last visited Mar. 29, 2010). As one executive based in the United Kingdom told me in a confidential interview, “we all have a huge incentive to avoid coming before the panel.” In the United States, the Pharmaceutical Research and Manufacturers of America (PhRMA) in 2002 first adopted a Code of Interactions with Healthcare Professionals, which was useful in developing an industry consensus as to appropriate marketing and promotional practices. But its public policy impact is limited in that there is no functional equivalent to the quasi-private enforcement mechanism of the British PMCPA, as discussed below. See PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AM., CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS (Jan. 2009), available at <http://www.phrma.org/files/attachments/PhRMA%20Marketing%20Code%202008.pdf>.

heavy club in the manner of the state.

This section will summarize the European and British statutory frameworks for the regulation of advertising and promotion of medicines. It will review a 2005 House of Commons Health Committee report on the undue influence of the pharmaceutical industry and consider the responses to the report from the responsible government agency, the trade group, and the industry. Next, the section will review some recent panel cases and other anecdotal and qualitative outcome data in an effort to gauge the effectiveness of the system. Finally, it will compare the British to the American system according to the normative criteria set forth above. There are significant differences in the respective reimbursement environments for off-label use of drugs, and the concomitant financial incentives to promote or otherwise encourage off-label prescribing are lower in Britain. Still, in keeping with its tradition of self-regulation, Britain has reasonably clear rules that allow for cases to be brought and resolved expeditiously in a transparent process with opportunity for appeal and with an unusually high level of engagement with industry.

#### *A. Statutory Framework*

Within the European Union there are multiple layers of law, regulation, and industry standards that govern the advertising and promotion of prescription drugs. At the highest level, the current EU directive<sup>129</sup> requires that member states adopt local legislation that broadly prohibits the unauthorized advertising and promotion of prescription medicine and requires that all advertising comply with the approved labeling. Significantly, this directive permits “voluntary control of advertising of medicinal products by self-regulating bodies.”<sup>130</sup> The European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals establishes a more detailed framework that all member state private associations may reference and further expand.<sup>131</sup>

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129. Council Directive 2004/27, art. 88, 2004 O.J. (L.136) 34, 51 (EC).

130. *Id.*

131. See EUROPEAN FED’N OF PHARM. INDUS. & ASS’NS, EFPIA CODE ON THE PROMOTION OF PRESCRIPTION-ONLY MEDICINES TO, AND INTERACTIONS WITH, HEALTHCARE PROFESSIONALS (2007), available at <http://www.efpia.eu/content/default.asp?PageID=559&DocID=3483>. The EFPIA Code provides clear, useful guidance in certain areas. For example, Article 12 proscribes service agreements that would induce the recommending, prescribing, or selling of medicine. *Id.* at 12. Article 14 goes into detail regarding consulting agreements with health care professionals, noting that “token consultancy arrangements should not be used to justify compensating healthcare professionals.” *Id.* at 13. Article 18 mandates that each national member include local enforcement

The Medicines Act of 1968 provides the basic statutory framework for the promotion and sale of prescription drugs in the United Kingdom. The Medicines and Healthcare products Regulatory Agency (MHRA) is the government agency responsible for protecting public health by ensuring the safe use of pharmaceuticals. In contrast with the FDA, the MHRA does not assume primary responsibility for routine oversight of pharmaceutical company advertising and promotion. Instead, it reserves for itself the prerogative to focus on those matters and products that present the potential for serious risk to public health. Simultaneously, it works to ensure that a quasi-autonomous unit of the Association of the British Pharmaceutical Industry (ABPI), known as the Prescription Medicines Code of Practice Authority (PMCPA), effectively controls advertising and promotion through the interpretation and enforcement of its code of practice on a day-to-day basis.<sup>132</sup>

One of the most readily apparent differences between the environment in the United States and that in the United Kingdom is the level of clarity provided to industry about the rules of engagement. The MHRA “Blue Guide”<sup>133</sup> offers reasonably clear and understandable guidance on promotion and advertising.<sup>134</sup>

provisions that are “proportionate to the nature of the infringement, have a deterrent effect and take account of repeated offences of a similar nature or patterns of different offences.” *Id.* at 18.

132. The relationship between the MHRA, the ABPI, and the PMCPA was established formally in a memorandum of understanding in 2005. *See* MEMORANDUM OF UNDERSTANDING BETWEEN THE ASSOCIATION OF THE BRITISH PHARMACEUTICAL INDUSTRY, THE PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY AND THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY (2005), *available at* [http://www.abpi.org.uk/links/assoc/PMCPA/Memo\\_understanding\\_nov3.pdf](http://www.abpi.org.uk/links/assoc/PMCPA/Memo_understanding_nov3.pdf). The memorandum characterizes the British regulatory framework as “robust” and comprised of “two complementary systems of control, self regulation by the pharmaceutical industry by means of the ABPI Code of Practice . . . administered by the PMCPA, and UK law, administered by the MHRA.” *Id.* at 1. The underlying philosophy is that “[e]fficient, stringent and transparent self regulation via the ABPI Code enables the Government to ensure that regulatory requirements are met . . . with intervention by the MHRA when there is a clear case for protection.” *Id.*

133. MEDS. AND HEALTHCARE PRODS. REGULATORY AGENCY, THE BLUE GUIDE: ADVERTISING AND PROMOTION OF MEDICINES IN THE UK (2005), *available at* [http://www.mhra.gov.uk/home/idcplg?IdcService=GET\\_FILE&dDocName=CON007552&RevisionSelectionMethod=Lates tReleased](http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON007552&RevisionSelectionMethod=Lates tReleased).

134. For example, Section 5.14 provides that company press releases “should be genuinely newsworthy rather than having the intention of promoting a product . . . [and] should provide the context in which the medicine will be used and the population for which it has been licensed.” *Id.* at 23. Section 5.15 makes clear that companies may respond to questions from health care professionals, though the answers must be balanced and fairly responsive to the question asked. *Id.*

This is not to suggest that the European and British codes are so clear that all queries are

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resolved, or that there is no room left for interpretation. A critical question in the European Union, as it is in America, lies in defining where scientific exchange ends and advertising or promotion begins. This question is at issue in the European Commission's proposal on the dissemination directly to the general public of non-promotional information on prescription medicines. As the Commission noted, the "current legal framework (Directive 2001/83/EC, as amended by Directive 2004/27/EC) does not provide for sufficient harmonised rules on the provision of information about medicines to patients." European Commission, Information to Patients, Legislative Approach, [http://ec.europa.eu/enterprise/sectors/pharmaceuticals/human-use/information-to-patient/legislative\\_en.htm](http://ec.europa.eu/enterprise/sectors/pharmaceuticals/human-use/information-to-patient/legislative_en.htm) (last visited Apr. 21, 2010). The Public Consultation provides that information to be provided to patients "should be compatible with approved summaries of product characteristics . . . and it should not go beyond the key elements specified in them." EUROPEAN COMMISSION, PUBLIC CONSULTATION: LEGAL PROPOSAL ON INFORMATION TO PATIENTS 6 (Feb. 5, 2008), available at [http://ec.europa.eu/enterprise/sectors/pharmaceuticals/files/pharmacos/docs/doc2008/2008\\_02/info\\_to\\_patients\\_consult\\_200802\\_en.pdf](http://ec.europa.eu/enterprise/sectors/pharmaceuticals/files/pharmacos/docs/doc2008/2008_02/info_to_patients_consult_200802_en.pdf). Interestingly, the United Kingdom's response to the Public Consultation on this very point notes that, in the view of the MHRA, "it is not possible to develop a clear definition, based solely on the content of the information, of what is non-promotional information about medicines in order to distinguish clearly between advertising and information." Letter from Pub. Health Meds. & Healthcare Prods. Regulatory Agency, to European Comm'n Enter. & Indus. Directorate-Gen. (Apr. 25, 2008), available at [http://www.mhra.gov.uk/home/idcplg?IdcService=GET\\_FILE&dDocName=CON014932&RevisionSelectionMethod=LatestReleased](http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON014932&RevisionSelectionMethod=LatestReleased). Following Public Consultation, the Commission adopted two proposals that, subject to affirmation by the Council of Europe and the European Parliament, would amend existing EC Directives governing the provision of information to the general public on prescription drugs. See *Commission Proposal for a Directive of the European Parliament and of the Council Amending, as Regards Information to the General Public on Medicinal Products Subject to Medical Prescription, Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use*, COM (2008) 663 final (Oct. 12, 2008), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0663:FIN:en:PDF>; *Commission Proposal for a Regulation of the European Parliament and of the Council Amending, as Regards Information to the General Public on Medicinal Products for Human Use Subject to Medical Prescription, Regulation (EC) No 726/2004 Laying Down Community Procedures for the Authorisation and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Medicines Agency*, COM (2008) 662 final (Oct. 12, 2008), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0662:FIN:en:PDF>.

Commentators are generally skeptical that the proposals will be adopted, as many are concerned that it will be difficult in practice to distinguish between the provision of medical and scientific information, and advertising itself, which will continue to be prohibited. See, e.g., Ian Schofield, *EU Pharmaceutical Package Struggles with Information Overload*, INFORMA UK (Nov. 6, 2009) ("The pharmaceutical industry and many members of the European Parliament are in favour of the patient information proposal, but most EU member state governments are not. They agree on the need to improve the provision of reliable, unbiased information on prescription drugs throughout Europe, but not by giving pharmaceutical companies a role.").

There is a refreshing level of candor and engagement with industry by British government officials that extends well beyond the issuance of mere rules, to encompass meaningful, ongoing discussion about the kinds of practical challenges faced on a routine basis.<sup>135</sup> The ABPI Code of Practice for the Pharmaceutical Industry<sup>136</sup> attempts to define the line between promotion and scientific exchange by making clear that promotion does not include responding to physician inquiries, providing factual information without making a claim, or providing information related to human health or disease while omitting reference to a specific medicine. It also provides guidance concerning gifts from pharmaceutical companies to health care professionals by limiting them to inexpensive items of modest value that are relevant to their work. In recent years, the MHRA has also undertaken multiple publication initiatives that are designed to convey more clearly its policy views on industry advertising material, and in so doing, significantly improve transparency, and has undertaken significant additional pre-launch review of promotional materials, as well as certain other advertising.<sup>137</sup>

The essence of the British system is that competitors, former employees, physicians, patients, and the MHRA itself can bring complaints against ABPI members for violating the advertising and promotional rules and regulations. The complaints are frequent (more than one hundred per annum), they are decided promptly (within months if not weeks generally), they may be appealed (generally only about 20% of the initial rulings are overturned), and they allow

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135. For example, Jeremy Mean of the MHRA presented on the topic of web-based pharmaceutical company communication in Manchester in September of 2007. In his presentation, Mr. Mean acknowledged the fundamental definitional problem up front—namely, that there are clear rules covering labeling language and formal business announcements, and clear rules covering the content and use of promotional material, but, in his words, “what about everything in between?” Mr. Mean then went on to attempt to answer the question he himself raised, spelling out the conditions under which companies may communicate via the web, but noting as well that there is likely to be new legislation in this area forthcoming. Jeremy Mean, Group Manager, Info. for Pub. Health, Meds. & Healthcare Prods. Regulatory Agency, Address at British Pharmaceutical Conference: From Manchester to Malta—Communicating to Patients across Europe (Sept. 7, 2007) (on file with author).

136. ASS'N OF THE BRIT. PHARM. INDUS., CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY (2008), available at [http://www.pmcpa.org.uk/files/sitecontent/ABPI\\_Code\\_of\\_Practice\\_2008.pdf](http://www.pmcpa.org.uk/files/sitecontent/ABPI_Code_of_Practice_2008.pdf). The ABPI Code of Practice was first established in 1958, and the most recent version came into force on July 1, 2008. It is developed by the ABPI in consultation with the MHRA, the British Medical Association, the Royal Pharmaceutical Society of Great Britain, and the Royal College of Nursing, adopted by the ABPI, and administered by the PMCPA.

137. Mean, *supra* note 135.

full participation of the parties.<sup>138</sup> Perhaps the most significant aspect of this process, especially as it relates to the question of improper off-label promotion, is that panel decisions convey heightened levels of clarity and transparency to industry.

### *B. The Politics of Self-Regulation*

The British system has not been without its critics, but when faced with a scathing report issued by a Parliamentary Committee, government and industry responded expeditiously to address the perceived deficiencies. In 2004 and 2005, a select Committee on Health of the British House of Commons undertook a sweeping review of the influence of the pharmaceutical industry in the country,<sup>139</sup> encompassing among many subjects advertising, promotion, and medical education. In its review of existing circumstances related to the advertising and promotion of prescription drugs, the Committee levied criticism at each of the involved parties. It criticized the industry for inappropriate activities such as employing ghostwriters for medical journal articles and soliciting physicians excessively.<sup>140</sup> It criticized physicians themselves for lacking independence.<sup>141</sup> It

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138. See Prescription Medicines Code of Practice Authority, Constitution and Procedure, in ABPI, CODE OF PRACTICE, *supra* note 136, at 39-53. The statistics provided were compiled by the author based on the case information available at Prescription Medicines Code of Practice Authority, Completed Cases, <http://www.pmcpa.org.uk/?q=completedcases> (last visited Mar. 29, 2010).

139. HEALTH COMM., HOUSE OF COMMONS, THE INFLUENCE OF THE PHARMACEUTICAL INDUSTRY (Mar. 22, 2005), available at <http://www.parliament.the-stationery-office.co.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf> (U.K.). The Committee's perspective was fair and reasonable on its face, as it acknowledged that companies have every right to market their products and to attempt to influence the market environment, but at the same time should not rely on misleading communications or fail to disclose new safety data or potential risks associated with the product. The Committee further identified the government's role as one of using impartial judgment to detect excess and limit actions that might be adverse to the public interest, a task it acknowledged as difficult and that required productive collaboration between the private and public sectors.

140. *Id.* at 53-55. The Committee criticized the aggregate number of company promotional details and repeat visits of individual sales representatives ("drug company representatives' contact with doctors 'can almost be on a daily basis'"), the extent of free meals and other "promotional hospitality masquerading as education," and what it called the "scale of medicines advertising." *Id.* at 57-59, 64. On the latter point, the Committee expressed concern with product launch commercialization activities where "explosive marketing occurs at precisely the period in which we know least about the effects of a drug in the community." *Id.* at 58. "The intensive marketing which encourages inappropriate prescribing of drugs must be curbed." *Id.* at 105. The Committee cited, for example, benzodiazepines as a group of products that well illustrated the problems associated

criticized the MHRA for inadequate pre-vetting of advertising and marketing materials and for the length of time taken to resolve complaints presenting serious risks to public health.<sup>142</sup> It criticized the PMCPA for the duration of time taken to complete self-initiated investigations and for its failure to sufficiently coordinate its work with the MHRA.<sup>143</sup> In general, the Committee was not convinced that the private, self-regulatory system was working effectively, noting delays in investigations and in the issuance of corrective statements, and that sanctions for violations often were not serious.

With the system of private, self-regulation of medicines advertising at risk, the MHRA, the PMCPA, and the industry initiated a series of changes in direct response to the House of Commons report. The MHRA, as the responsible government agency acting under the direction of the British Parliament, faced substantial political pressure to respond to the report and reform the system. Rather than resorting to broadside attacks on drug companies, the agency reiterated the significance of the industry to Great Britain by endorsing its many contributions to public health.<sup>144</sup> The MHRA expanded its pre-vetting of all promotional material for newly approved drugs, encouraged the PMCPA to consider changes to its code of practice, and sought to better coordinate its work with the PMCPA. In addition, the MHRA completed an internal review that

with what it characterized as “over-promotion and over-prescription.” *Id.* at 65.

141. “[T]he blame for inadequate or misinformed prescribing decisions [also lies] with . . . doctors and other prescribers who do not keep abreast of medicines information and are sometimes too willing to accept hospitality from the industry and act uncritically on the information supplied by the drug companies.” *Id.* at 64.

142. “We recommend that all the promotional material for a new product be pre-vetted by the MHRA prior to publication . . .” *Id.* at 105. In addition, the Committee “recommend[ed] that there be an independent review of the MHRA.” *Id.* Such a review could “determine whether the processes now used for decision-making are adequate and reflect a patients’ health needs and society’s expectations.” *Id.* at 106.

143. “When the PMCPA has evidence that a company has breached the regulations it should inform the MHRA. . . . [C]orrective statements [should] always be required.” These statements should be “given as much prominence as the original promotional piece.” *Id.* at 106.

144. “The pharmaceutical industry is an important sector for the UK. It has an outstanding record of innovation for the benefit of patients, and of investment in the economy. It has to be recognised that to carry out its business Government and its agencies will have dealings with the industry. It has long been the Government’s policy that these dealings must be balanced and appropriate with an aim of securing beneficial outcomes for patients and the economy.” SEC’Y OF STATE FOR HEALTH, GOVERNMENT RESPONSE TO THE HEALTH COMMITTEE’S REPORT ON THE INFLUENCE OF THE PHARMACEUTICAL INDUSTRY 1 (Sept. 2005), *available at* [http://www.dh.gov.uk/dr\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_4118608.pdf](http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4118608.pdf).

resulted in changes to the complaint investigation process with enhanced transparency from publications of decisions and guidance, shorter duration in the investigation and decision making process, and increased use of corrective statements and consideration of prosecution in extreme cases.<sup>145</sup> The MHRA publicly expressed its intolerance with any future failure to comply with the law.<sup>146</sup> In 2006, the PMCPA adopted a stricter code of practice.<sup>147</sup> Companies themselves examined their business practices, limited the extent of their hospitality, and excised the influence of commercial organizations in meetings with outside scientific and medical advisers.

### *C. UK Code of Practice Panel Decisions*

In reviewing a range of PMCPA cases from the last few years that raised questions of improper advertising and promotion outside the approved labeling, some important principles are apparent. In general, the panel decisions present a fairly high level of sophistication and judgment. Moreover, the decisions serve to enhance significantly the level of clarity of guidance and transparency of thought process, which are publicly available to firms operating in the United Kingdom.

First, the PMCPA panels appear more inclined than U.S. prosecutors to give the benefit of the doubt to the company if preliminary documentation is not damning and will not launch a multi-year investigation on the basis of a single complaint.<sup>148</sup> In a case brought by an anonymous employee, the panel noted that

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145. For a summary of the MHRA internal review, see Jeremy Mean & Beryl Keeley, *Review of Advertising Procedures*, 17 INT'L J. PHARM. MED. 185 (2003).

146. As an example, the MHRA upheld complaints against two drug distribution and retail firms in the United Kingdom for excessive promotion and discounting, and went on the BBC to publicize its enforcement actions. *2-for-1 Painkiller Deals Attacked*, BBC NEWS, June 14, 2005, <http://news.bbc.co.uk/1/hi/health/4091184.stm>.

147. The 2006 code of practice enhanced its provisions related to patient safety warning requirements, better defined and restricted promotional gifts and hospitality, better defined permissible relationships with patient groups, banned promotional competitions and placed a cap on advertising pages, accelerated the pace of complaint resolutions, and strengthened various penalties for code violations. See ASS'N OF THE BRIT. PHARM. INDUS., CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY (2006), available at <http://www.pmcpa.org.uk/files/sitecontent/code06use.pdf>. Sanctions meted out by the PMCPA have become more severe. Although there has still only been one prosecution for promotional impropriety in British history, there have been suspensions from ABPI membership of several leading multinational drug companies, including Abbott Laboratories, Roche, and Merck's affiliate, MS&D.

148. See, e.g., Prescription Medicines Code of Practice Auth., *CASE AUTH/2043/9/07, Anonymous Employee v Sanofi-Aventis*, CODE PRAC. REV., Nov. 2007, at 139, available at <http://www.pmcpa.org.uk/files/2007%20November%20Review.pdf>. This case stands in contrast to the American practice, where "whistleblower" complaints are kept confidential under the *qui tam*

although it had some concerns about the company using its cardiovascular scientific advisors to initiate promotional discussions using unlicensed data with “difficult to access customers,” there was no direct evidence of impropriety and no way to obtain additional information since the complainant was anonymous.<sup>149</sup> Second, there is an ongoing effort to clarify ambiguous areas of the law. In a case brought by a physician, the panel’s decision focused on website linkage questions in finding that the company breached the code by referring health professionals from a patient group website to another website that itself contained references on the use of its product for a then-unapproved condition.<sup>150</sup> Third, the panels are willing to consider the most difficult definitional and contextual issues in the area, including subtle distinctions between scientific exchange and promotion. In a case brought by a competing company, the panel engaged in a detailed analysis of the specific circumstances related to sponsorship of an independent abstract with an unrestricted medical grant.<sup>151</sup> Here, although the company expected that the published abstract would contain some favorable reference to its then unapproved protease inhibitor, the panel found that this did not constitute illegal off-label promotion since there was no direct contact with the editor and no substantive influence on the publication.<sup>152</sup> Fourth, in reaching judgments, the panels are sensitive to prevailing clinical and medical practice issues. For example, a panel found that a company’s promotion of combination therapy in the treatment of breast cancer was permissible in that the approved labeling did not specifically limit the product’s use to monotherapy, and that combination therapy was an integral part of accepted medical practice.<sup>153</sup>

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statute, and the DOJ is required to investigate the allegations.

149. *See id.* at 140.

150. *See* Prescription Medicines Code of Practice Auth., *CASE AUTH/1801/2/06, General Practitioner v GlaxoSmithKline*, CODE PRAC. REV., Aug. 2006, at 20, 24, available at [http://www.pmcpa.org.uk/files/August\\_2006.pdf](http://www.pmcpa.org.uk/files/August_2006.pdf). Although GSK strongly refuted the allegation since the advertisement containing the referral was published by a patient support group and did not disclose proprietary product names or make product claims, this ruling was upheld on appeal. The panel regarded the website linkage as inappropriate, noting that otherwise “companies would be able to refer to independent websites as a means of avoiding the restrictions in the Code.” *Id.*

151. *See* Prescription Medicines Code of Practice Auth., *CASE AUTH/1696/3/05, Bristol Myers-Squibb v Boehringer Ingelheim*, CODE PRAC. REV., Aug. 2005, at 125, 127, available at [http://www.pmcpa.org.uk/files/2005\\_August\\_Review.pdf](http://www.pmcpa.org.uk/files/2005_August_Review.pdf). Boehringer subsequently distributed the abstract on an unsolicited basis to physicians, though other HIV treatment products also were referenced in the publication. This was found to constitute scientific exchange, and not promotion.

152. *See id.* at 127.

153. *See* Prescription Medicines Code of Practice Auth., *CASE AUTH/1674/1/05, Sanofi-Aventis v Pierre Fabre*, CODE PRAC. REV., Aug. 2005, at 58, 60-61, available at

These cases illustrate several important features of the self-regulatory system in the United Kingdom. The MHRA process is expeditious, as it does not involve extensive discovery and investigatory burden. It also is transparent, as it moves from broad EU guidelines to slightly refined UK law, to more detailed ABPI codification, to yet more detail in the interpretation of rules in the context of actual business practice. The opinions themselves are clear in expressing both results and reasoning. The panel process is equitable and adheres to widely accepted due process principles, as it addresses complaints from all interested parties, including competitor companies, and allows for appeals. Although the UK system is focused on ensuring compliance with the law and applicable regulation, it appears to be congruous with the prevailing realities of medical practice and the consideration of relevant clinical data.

#### VII. EQUITY, EFFICIENCY, AND EFFECTIVENESS: TOWARD AN ETHICALLY RESPONSIBLE MODEL?

The House of Commons Health Committee Report and the associated reforms and policy changes adopted by the MHRA, together with the ongoing enhancement by the PMCPA to its code of practice, have had a reformative impact on the behavior of drug companies operating in Britain, though it is difficult to assess precisely the aggregate impact on industry promotion and marketing practices. The British regulatory environment appears less confrontational than the prevailing system in the United States. This may reflect differences in the underlying political dynamic, in which government officials in Britain are more readily willing to engage with industry and more apt to recognize the contributions that the pharmaceutical industry has made to the economic prosperity and public health of the citizenry.<sup>154</sup>

A number of UK industry executives conveyed in informal discussions that their companies have significantly restricted policies related to sales, marketing, and medical education policies since 2005 in response to the changed

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[http://www.pmcpa.org.uk/files/2005\\_August\\_Review.pdf](http://www.pmcpa.org.uk/files/2005_August_Review.pdf). The applicable regulatory submission included clinical data from a range of combination treatments, though the panel expressed concerns about Pierre Fabre's effective promotion of an oncology treatment developed by Roche since the approved labeling of the Roche product specified combination use only with two other named products. *Id.* at 59, 61.

154. At one point, British Prime Minister Tony Blair described the pharmaceutical industry as "a prime example of what is needed in a successful knowledge economy" along with praising the industry for its "very substantial contribution to our economy and welfare of our citizens." Corporate Watch, The Association of the British Pharmaceutical Industry (ABPI), <http://www.corporatewatch.org/?lid=332> (last visited Apr. 21, 2010). It is difficult to conceive of a senior American official or member of Congress uttering similar sentiments.

environment.<sup>155</sup> More specifically, companies recently have modified policies and practices in response to PMCPA panel decisions in areas such as the provision of bonus payments, the awarding of unconditional medical grants, and the need to distinctly separate promotional activities from the provision of medical and educational goods and services.<sup>156</sup>

Not surprisingly, American drug and device firms also have changed their practices in the face of an *ad hoc* hostile enforcement environment. For example, companies have limited the range of physicians to whom they detail their products, they have curtailed or limited strictly the discretion held by individual sales representatives to engage physicians in broader discussions about their patients and treatment options, and they have changed compensation schemes to reduce or eliminate incentive pay stemming from off-label prescribing.

In the short run, this environment does not seem likely to change. There will continue to be regular announcements of civil settlements with staggering financial penalties and criminal plea agreements with individual charges for

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155. Interviews conducted with pharmaceutical company executives from various firms in the United Kingdom between April and June, 2008, including those at GlaxoSmithKline, AstraZeneca, and Merck Serono. More than one executive working in Great Britain for a multi-national pharmaceutical company emphasized that self-regulation is effective largely because the APBI has been willing to suspend company membership in the case of flagrant abuse. *See supra* note 128. APBI membership is important for firms since the Association negotiates with the government of the United Kingdom to obtain price approvals for new products and modifications for existing ones.

156. *See, e.g.*, Prescription Medicines Code of Practice Auth., *CASE AUTH/1186/5/01, Anonymous v Pfizer*, CODE PRAC. REV., Feb. 2002, at 10, 29, available at [http://www.pmcpa.org.uk/files/2002\\_February\\_review.pdf#page=10](http://www.pmcpa.org.uk/files/2002_February_review.pdf#page=10) (holding that so-called medical liaison executives were too closely linked to the sales force, and should not be communicating with physicians during pre-license approval time period); Prescription Medicines Code of Practice Auth., *CASES AUTH/1807/3/06 and AUTH/1810/3/06, The Sunday Times/Director and a General Practitioner v Pfizer*, CODE PRAC. REV., Nov. 2006, at 3, available at [http://www.pmcpa.org.uk/files/1807\\_and\\_1810\\_November.pdf#page=1](http://www.pmcpa.org.uk/files/1807_and_1810_November.pdf#page=1) (describing allegations that payment to sponsored service providers cannot be linked to specific level of product sales or receive bonuses based on product sales); Prescription Medicines Code of Practice Auth., *Case AUTH/1859/6/06, Anonymous Employees v Merck Sharp & Dohme*, CODE PRAC. REV., Feb. 2007, at 15, 16, available at [http://www.pmcpa.org.uk/files/1859\\_Feb\\_2007.pdf#page=1](http://www.pmcpa.org.uk/files/1859_Feb_2007.pdf#page=1) (company return on investment calculations were alleged inconsistent with the concept of unrestricted grants, need to have procedures to ensure funds spent for valid purposes); Prescription Medicines Code of Practice Auth., *CASES AUTH/1902/10/06 and AUTH/1903/10/06, Employee v Sanofi-Aventis and Procter & Gamble*, CODE PRAC. REV., Nov. 2007, at 3, 34, available at <http://www.pmcpa.org.uk/files/2007%20November%20Review.pdf> (challenging company-funded nurse audit program as too closely linked to promotion of the underlying product to treat osteoporosis).

executives likely. However, perpetuating this trend is untenable over the long term, particularly when the rules are not clear, there are significant individual and institutional political biases at work, and the outcomes are inconsistent. While the promotional and financial excesses of pharmaceutical companies in recent years cannot be excused, it is especially troubling that companies seeking to act in an ethically responsible manner cannot find substantial clarity in existing law and regulations. In turn, this lack of clarity raises an important constitutional dimension when measuring the law's requirements for specificity against the potential for criminal judgments under the strict liability framework of the FDCA.<sup>157</sup>

The critical question is how best to motivate companies to behave ethically in adopting sound policies, exercising self-restraint in their business practices, and engaging in self-policing under an effective compliance program. Based upon field research interviews with government and private sector officials, as well as a review of the pattern of panel cases brought in the past few years, the British system appears to be working effectively to allow for the dissemination of truthful, non-misleading information under appropriate circumstances while significantly enhancing clarity and transparency.<sup>158</sup> Admittedly, empirical analysis would be useful in refining our understanding of the British model and its role in encouraging compliant policies and practices in the United Kingdom.

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157. See George Terwilliger, former U.S. Deputy Att'y Gen., Address at the American Enterprise Institute for Public Policy Research: Off-Label Uses of Approved Drugs: Medicine, Law, and Policy (May 21, 2008) (criticizing the application of the exclusionary rule and current DOJ policy and practice). An illustrative case involves three former executives of Purdue Pharma, under which they were compelled to plead guilty to personal misdemeanors under a strict vicarious liability theory in which their service as "responsible corporate officers" made them individually liable for the alleged misdeeds of the corporation in making false claims related to its OxyContin opioid painkiller medicine. See Barry Meier, *3 Officials Are Sentenced In Case Involving OxyContin*, N.Y. TIMES, July 21, 2007, at C4; Barry Meier, *Narcotic Maker Guilty of Deceit over Marketing*, N.Y. TIMES, May 11, 2007, at A1.

158. As suggested above, these cases typically arise in the context of whether or not the conveyance of truthful scientific and medical information constitutes promotion. See, e.g., Prescription Medicines Code of Practice Auth., *CASE AUTH/1100/11/00, Abbott v Roche*, CODE PRAC. REV., May 2001, at 22, available at [http://72.47.199.56/files/2001\\_May\\_review.pdf](http://72.47.199.56/files/2001_May_review.pdf); Prescription Medicines Code of Practice Auth., Completed Cases, *CASE AUTH/2234/5/09–Lilly v Novo Nordisk*, Interim Case Report, <http://www.pmcpa.org.uk/?q=node/750> (last visited Apr. 21, 2010) (company may provide truthful scientific information about an unapproved drug to current and potential clinical investigators, especially if grant of marketing authorization is not imminent).

## VIII. POLICY RECOMMENDATIONS

There is much to absorb from the regulatory approach of our colleagues in Britain. Beginning with the development and adoption of reforms in 2005, there has been evident substantial collaboration between the government and the private sector. The embrace of regulatory strictures by British executives has precipitated changes in company policies and business practices and a concomitant rise in reputation, thereby further reinforcing industry's commitment to the process. This is not a panacea; PMCPA proceedings make clear that some companies in Britain continue to break the rules, and their employees and those of rivals continue to complain about improper promotional practices. However, in such cases these complaints are presented, confronted, investigated, and resolved efficiently, transparently, and effectively without criminal exposure and excessive cost.

It is unrealistic politically to imagine the wholesale importation of the British approach to regulating off-label promotion. Among other things, America lacks the tradition and experience of decades of private, self-regulation of advertising and promotion. However, the United States would do well to consider modifying its approach such that it better achieves the efficiency and transparency now prevailing in the United Kingdom. Our public policy should support the sound practice of medicine without restricting the prerogative of physicians to make decisions. Granted, government oversight is necessary on some level to ensure that firms provide consistently accurate and balanced information about their products when profits and sales commissions are at issue. But our current system, which is based on the precept that a paternalistic FDA is uniquely situated to shield consumers and doctors from the vulgar commercial motivations of industry, is grossly unbalanced. We must trust academic physicians and practicing doctors to digest and evaluate medical and scientific information as it becomes available.

What should be done to address this imbalance? First and foremost, the FDA should adopt new regulations that eliminate ambiguity and provide clear guidance as to company behavior in each of the areas in which pharmaceutical companies interact with physicians and payers: consulting agreements, continuing medical education, internet and electronic media postings, reimbursement information, sales representative promotional messages, and the permissible activities of medical liaison and medical affairs. These areas can and should be addressed just as the FDA did early in 2009 when it adopted its final rule on the dissemination of peer-reviewed journal articles.<sup>159</sup> Moreover, the

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159. See Good Reprint Practices for the Distribution of Medical Journal Articles and Medical

pharmaceutical industry could work with the agency to develop jointly a code of conduct that embraces these principles.<sup>160</sup> While there likely will be disagreement as to the restrictions on speech associated with these commercial activities, many companies are so anxious for clarity that they would be willing to accept a Faustian bargain that embraces certainty in lieu of autonomy. Second, HHS should reassert its prerogative and wrest control from the DOJ of off-label enforcement actions. As described in this article, the DOJ has the authority and responsibility to prosecute and threaten the prosecution for criminal matters, and the FDCA includes criminal sanctions for violating its statutory provisions. I am suggesting a subtle shift in the government's perspective, such that HHS and the FDA have the authority to address cases as they develop, and referral to the DOJ for criminal investigation is reserved for those egregious cases that, based upon the FDA's understanding of the drug and company in question, present significant malfeasance. Regulatory enforcement must minimize the likelihood of disseminating untruthful and misleading information, but unless companies are found to have intentionally misled physicians or the public and caused injury or damage to health, violations should be treated as civil regulatory infractions and not criminal offenses. Accordingly, one alternative to the present criminal enforcement approach would be to establish significant, statutory civil penalties for the dissemination of false or misleading information. This scheme could establish a legal presumption in favor of liability based upon some showing by the government or private plaintiffs that could then be rebutted by the accused company. One might consider as well an enforcement panel operated by the OIG, with medical, legal, and policy input from the FDA, that metes out civil liability penalties in a streamlined process reminiscent of that used by Britain's PMCPA. Third, as others have suggested,<sup>161</sup> the FDA could provide incentives or mandates to compel companies to conduct clinical studies and submit data to the agency for review prior to speaking about it. Fourth, Congress should increase its appropriations for the FDA to allow the agency to more effectively and efficiently review supplemental New Drug Applications for expanded indications. In turn, the FDA should consider developing an expedited process that would allow new indications to be approved without the same extent of clinical testing currently required for NDAs. Fifth, while I recognize that many support using the federal False Claims Act to provide an incentive for

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or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices; Availability, 74 Fed. Reg. 1,694.

160. See PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AM., CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS, *supra* note 128.

161. See Rebecca Dresser & Joel Frader, *Off-Label Prescribing: A Call for Heightened Professional and Government Oversight*, 37 J.L. MED. & ETHICS 476 (2009).

whistleblowers in the health care arena, my experience leads me to believe that Congress should evaluate the wisdom of applying this statute to off-label promotion cases, as it has created a vehicle for current and former employees to ignore the in-house compliance process and go directly to the government in pursuit of extraordinary wealth.

## IX. CONCLUSION

In the end, public policy should create incentives for self-reform and ethical corporate behavior. Rather than destroying our research-based drug companies by applying the “death penalty”<sup>162</sup> of debarment, a far better outcome for society would follow if the companies that are responsible for much of the innovation that drives our future health and well-being are allowed to “reform themselves.”<sup>163</sup> Companies must adopt and enforce rigorous compliance policies and programs, and more than that, must act in a meticulous, ethical manner when speaking about products for human health. Pharmaceutical company executives must be brutally honest with themselves, their various stakeholders, and other third parties as they evaluate clinical and medical data. In many cases, this may require extensive consultation with medical experts in the field, and the timely publication of comprehensive summaries of all relevant product information. Above all, they must act with the highest levels of integrity in their relationships with physicians and patients so as to avoid even the appearance of impropriety. This kind of responsible behavior will be reinforced by the fair application of clear rules.

Each of the stakeholders in this area should reflect on their respective interests and values. Industry leaders must develop a greater degree of genuine respect for government regulators and policymakers and must operate their firms with integrity. At the same time, government policy makers should recognize that if we transform the research-based pharmaceutical and biomedical device industries into the functional equivalent of public utilities, we will have cheaper medicine and technology in the short run but not much in the way of new medicine or technology in the long run. Physicians need to consider whether they value the products, medical education, and information provided by drug companies, and if they do, break their lengthy silence on this issue. Patients, whether suffering from rare diseases or otherwise, should serve as advocates for the products that they believe are vital to their health, even if the use happens to

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162. *See supra* note 84.

163. John Simons, *Why Do Drug Companies Fear This Man?*, FORTUNE, Oct. 27, 2003, at 167 (quoting Michael Sullivan, then-United States Attorney for the District of Massachusetts).

be off-label.

These developments will not transform the present environment in the near term. There are substantial political forces at work and there is substantial momentum in favor of continued regulation by threat of prosecution as companies scramble to reform their practices in light of evolving government policy. Perhaps the Supreme Court ultimately will hear the *Allergan* case and will rule that those FDA regulations prohibiting companies from speaking about truthful scientific and medical information are unconstitutional. Absent this, policy makers and regulators might regard favorably the British model of private, self-regulation combined with meaningful, effective government regulatory oversight. While empirical work undertaken over a longer time frame would be useful to validate this conclusion, substantial anecdotal evidence suggests that the UK approach has succeeded in curtailing many of the very same troubling promotional and marketing practices by many of the very same companies in a fair and expeditious manner. It is time for America to learn something from the old country.

**Transferring Behavioral Interventions for Global Health:  
Intellectual Property Barriers, Information Constraints,  
and Possible Solutions**

**Kristen Underhill\***

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## TRANSFERRING BEHAVIORAL INTERVENTIONS

### INTRODUCTION

Diseases are “biosocial realities”<sup>1</sup>: health problems arise not only from biological vulnerability to disease but also from complex systems of environmental risk factors. Such factors range from individual risks, such as behavior and exposure, to mid-level risks, such as neighborhood and culture, to large-scale structural risks, such as war and intellectual property regimes.<sup>2</sup> Each layer of risk presents an opportunity to intervene and to modify not only individual biological and behavioral processes but also the social and structural contexts that threaten health.

Practitioners and researchers in the global health field have for decades emphasized effective biomedical interventions for improving health,<sup>3</sup> often focusing on technology that addresses physiological causes and cures: pharmaceuticals, medical devices, and clinical protocols designed to address the biomedical components of disease. More recently, health researchers have focused on international- and national-level determinants of health, such as international intellectual property interests,<sup>4</sup> poverty and marginalization,<sup>5</sup>

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1. PAUL FARMER, *INFECTIONS AND INEQUALITIES: THE MODERN PLAGUES* 5 (1999) (emphasis removed).

2. The multi-level description of risk factors originated in Urie Bronfenbrenner’s ecological theory. See URIE BRONFENBRENNER, *THE ECOLOGY OF HUMAN DEVELOPMENT: EXPERIMENTS BY NATURE AND DESIGN* (1979). Bronfenbrenner’s work has heavily informed more recent models of risk for disease, as in K.E. Poundstone, S.A. Strathdee & D.D. Celentano, *The Social Epidemiology of Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome*, 26 *EPIDEMIOLOGIC REVIEWS* 22 (2004); Craig R. Waldo & Thomas J. Coates, *Multiple Levels of Analysis and Intervention in HIV Prevention Science: Exemplars and Directions for New Research*, 14 *AIDS S18* (Supp. 2 2000).

3. See, e.g., Gareth Jones et al., *How Many Child Deaths Can We Prevent This Year?*, 362 *LANCET* 65 (2003) (quantifying the preventive effects of various technological interventions for averting child mortality); H. Varmus et al., *Grand Challenges in Global Health*, 302 *SCIENCE* 398, 399 (2003) (denoting fourteen research priorities in global health for the scientific community). The effectiveness of technological interventions is a key component of efforts to increase access to technological treatments.

4. See, e.g., Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 *JAMA* 1886 (2001); Michael Westerhaus & Arachu Castro, *How Do Intellectual Property Law and International Trade Agreements Affect Access to Antiretroviral Therapy?*, 3 *PUB. LIBR. SCI. MED.* e332 (Aug. 2006), available at <http://www.plosmedicine.org/article/fetchObjectAttachment.action?uri=info%3Adoi%2F10.1371%2Fjournal.pmed.0030332&representation=PDF>.

5. See, e.g., WORLD HEALTH ORG., THE WORLD BANK & VOICES OF THE POOR, *DYING FOR CHANGE: POOR PEOPLE’S EXPERIENCE OF HEALTH AND ILL-HEALTH* (2002), available at [http://www.who.int/hdp/publications/dying\\_change.pdf](http://www.who.int/hdp/publications/dying_change.pdf) (describing the health-related consequences of severe poverty in various countries); Thomas Pogge, *Severe Poverty as a Human Rights Violation*, in *FREEDOM FROM POVERTY AS A HUMAN RIGHT: WHO OWES WHAT TO THE VERY POOR?*

conflict,<sup>6</sup> climate change,<sup>7</sup> human rights abuses,<sup>8</sup> market forces,<sup>9</sup> brain drain,<sup>10</sup> and other social factors.<sup>11</sup> Improving access to highly effective technological interventions is undoubtedly a critical priority in global health.

While there has been longstanding discussion regarding access to effective biomedical interventions, scientists have only recently begun to study facets of health shaped by the behaviors of individuals and communities. Scientists in this emerging field consistently point out that behavioral choices are shaped by larger-level social factors, such as poverty and discrimination.<sup>12</sup> However, individuals can often find opportunities to make healthier decisions even within these contexts.<sup>13</sup> Health behaviors are particularly important in the context of the

12-13 (Thomas Pogge ed., 2007) (stating that “[r]oughly one third of all human deaths, 18 million annually or 50,000 each day, are due to poverty-related causes”).

6. See, e.g., Catherine A. Hankins et al., *Transmission and Prevention of HIV and Sexually Transmitted Infections in War Settings: Implications for Current and Future Armed Conflicts*, 16 AIDS 2245 (2002).

7. See, e.g., WORLD HEALTH ORG., CLIMATE CHANGE AND HUMAN HEALTH: RISKS AND RESPONSES (2003), available at <http://www.who.int/globalchange/publications/climchange.pdf>.

8. For illustrations of the intersection between human rights and HIV, see, e.g., STEPHEN LEWIS, RACE AGAINST TIME (2005); STEPHANIE NOLEN, 28 STORIES OF AIDS IN AFRICA (2007); UNAIDS, COURTING RIGHTS: CASE STUDIES IN LITIGATING THE HUMAN RIGHTS OF PEOPLE LIVING WITH HIV (2006), available at [http://data.unaids.org/Publications/IRC-pub07/JC1189-CourtingRights\\_en.pdf](http://data.unaids.org/Publications/IRC-pub07/JC1189-CourtingRights_en.pdf); UNAIDS, Human Rights and HIV, <http://www.unaids.org/en/PolicyAndPractice/HumanRights/default.asp> (last visited Mar. 31, 2010).

9. See, e.g., Sean Flynn, Aidan Hollis & Mike Palmedo, *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries*, 37 J.L. MED. & ETHICS 184 (2009) (describing market forces at work in the patenting of pharmaceutical interventions).

10. See Barry R. Bloom, *Public Health in Transition*, SCI. AM., Sept. 2005, at 92, 98.

11. For an explanation of some of these factors, see SOCIAL DETERMINANTS OF HEALTH: THE SOLID FACTS (Richard Wilkinson & Michael Marmot eds., 2d ed. 2003), available at <http://www.euro.who.int/DOCUMENT/E81384.pdf>. The WHO recently established the Commission on Social Determinants of Health to identify social causes of disease and possible remedies. See Michael Marmot, *Social Determinants of Health Inequalities*, 365 LANCET 1099 (2005); WHO, Social Determinants of Health, [http://www.who.int/social\\_determinants/en/](http://www.who.int/social_determinants/en/) (last visited Mar. 31, 2010).

12. Paul Farmer has referred to institutionalized discrimination and marginalization as “structural violence.” FARMER, *supra* note 1, at 79 (“[S]ickness is a result of structural violence: neither culture nor pure individual will is at fault; rather, historically given (and often economically driven) processes and forces conspire to constrain individual agency.”). Specific social and biological risk factors may vary by illness. This interplay of risk has been elegantly summarized for HIV by Poundstone, Strathdee & Celentano, *supra* note 2.

13. It is important to be realistic and sensitive to real constraints when addressing health behaviors. For example, it would be unrealistic and unfair to expect people who live in unsafe areas to exercise outside their homes or to fault individuals who live in areas of famine or “food deserts” for not eating an optimum balance of vegetables, fruits, and whole grains. However, sensitively

“double burden” of disease, where developing countries now experience not only the “unfinished agenda” of infectious disease but also the growing prevalence of chronic health conditions, such as diabetes and various types of cancer.<sup>14</sup> Health behaviors contribute to both sides of this double burden: some behaviors can make individuals more vulnerable to infections (for example, unprotected sex and HIV), while other behaviors can make individuals more susceptible to chronic conditions (for example, diet and obesity, lack of exercise and heart disease, smoking and lung cancer, and alcohol use and cirrhosis). Efforts to improve individual health behaviors have gained recognition as necessary components of global and national health strategies.<sup>15</sup>

Just as pharmaceuticals and medical devices are designed to address the biological elements of disease, a growing number of behavioral interventions are specifically designed to address the *behavioral* risks that make individuals more vulnerable to certain types of illness. Some of these interventions are already well-known globally; for example, Alcoholics Anonymous, Weight Watchers, Drug Abuse Resistance Education (“DARE”), and a variety of smoking cessation programs are household names. The terminology used to refer to such programs varies,<sup>16</sup> but for consistency this Note will refer to them as “behavioral interventions.” Health researchers have noted that, although some programs have no effect on behavior,<sup>17</sup> many others are not only *effective* (in other words, they have protective effects on different health behaviors) but also *transferable* (in other words, they work in multiple settings or for multiple populations).<sup>18</sup>

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designed behavioral interventions recognize these real constraints and attempt to help people maximize health-promoting behaviors among the options available.

14. See Julio Frenk, *Bridging the Divide: Global Lessons from Evidence-Based Health Policy in Mexico*, 368 LANCET 954, 954 (2006).

15. As one example, the behavioral prevention movement has been particularly galvanized by the AIDS epidemic, as non-governmental organizations throughout high-prevalence countries have received funding to deliver preventive interventions. The U.S. President’s Emergency Plan for AIDS Relief is one example of funding for such prevention. See United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria, 22 U.S.C.A. § 7601 (West 2008).

16. These programs are variously referred to as behavior change programs, health promotion interventions, psychosocial interventions, social interventions, social marketing programs, multimodal or multi-component interventions, and complex social interventions. These programs vary widely in their approaches.

17. For instance, D.A.R.E., although popular in U.S. communities, is among programs that have been identified as ineffective. See CHRISTOPHER L. RINGWALT ET AL., PAST AND FUTURE DIRECTIONS OF THE D.A.R.E. PROGRAM: AN EVALUATION REVIEW (1994). There may also be little empirical evidence to support the use of Alcoholics Anonymous and other twelve-step programs; however, current studies have many limitations, and more research may be required. See M.M.F. Ferri, L. Amato & M. Davoli, *Alcoholics Anonymous and Other 12-Step Programmes for Alcohol Dependence*, 3 COCHRANE DATABASE SYSTEMATIC REVIEWS Art. No.: CD005032, 13 (2006).

18. For example, the Diffusion of Effective Behavioral Interventions (“DEBI”) project was

Adaptation is often necessary to transport effective behavioral interventions to new settings, such as language translation and modification of cultural references.<sup>19</sup> Not every program will work in every setting. Many programs, however, have beneficial effects in a variety of settings when they are implemented with their essential components intact.

The promising, generalizable effects of many behavioral interventions prompt new questions about how to broaden access to such programs, particularly among people living in low-income countries. Patents are the most salient intellectual property barriers discussed in global health because of the lifesaving effect of many pharmaceuticals and the fact that monopoly pricing often makes drugs inaccessible to those who need them.<sup>20</sup> Very little literature, however, seeks to identify the legal barriers, if any, to the broad dissemination of behavioral interventions. This Note will examine the particular problem of information barriers and intellectual property interests in behavioral interventions—the programs that attempt to modify the way people behave with regard to their health. This Note is exploratory in nature, in part because this area is undertheorized and in part because it would be impossible to both characterize and solve these problems at once.

The exploration proceeds in five Parts. Part I briefly sketches the role that health behaviors play in global health, focusing particularly on the double burden of infectious and chronic disease. Part II describes behavioral interventions and notes that in practice, effective interventions are often not transferred to new settings. To investigate some reasons for these failings, Part III questions the formal and informal barriers to information-sharing that limit the transfer of effective behavioral interventions. In an attempt to diminish these barriers, Part IV contemplates solutions that might foster information-sharing, implicating the roles of researchers, funders, governments, institutional review boards, and the World Health Organization. Finally, Part V responds to potential arguments against broader information-sharing and the project of transferring effective behavioral intervention. The central argument of this Note is that expanding

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founded in 1999 to promote the dissemination of empirically supported behavioral interventions, and the DEBI project provides training and materials free of charge to applicant organizations. Diffusion of Effective Behavioral Interventions Project, Fact Sheet, [http://effectiveinterventions.org/files/09-0817\\_DEBI\\_overview\\_factsheet.pdf](http://effectiveinterventions.org/files/09-0817_DEBI_overview_factsheet.pdf) (last visited Mar. 31, 2010). See also CDC, 2009 Compendium of Evidence-Based HIV Prevention Interventions, <http://www.cdc.gov/hiv/topics/research/prs/evidence-based-interventions.htm> (last visited Mar. 31, 2010) (listing sixty-nine evidence-based behavioral interventions for HIV prevention that may be used in a variety of populations).

19. See Vel S. McKleroy et al., *Adapting Evidence-Based Behavioral Interventions for New Settings and Target Populations*, 18 AIDS EDUC. & PREVENTION 59 (Supp. 2006).

20. See, e.g., Richard D. Smith, Carlos Correa & Cecilia Oh, *Trade, TRIPS and Pharmaceuticals*, 373 LANCET 684, 685-86 (2009).

global access to effective behavioral interventions can reduce both infectious and chronic disease, and that reducing the barriers to disseminating these interventions can play a key role in improving global health.

### I. HEALTH BEHAVIORS AND THE DOUBLE BURDEN OF DISEASE

Disease in developing countries is characterized by a double burden, both halves of which are affected by health behaviors.<sup>21</sup> Julio Frenk has characterized this pattern of disease as a convergence of “the unfinished agenda of infections, malnutrition, and reproductive health problems” and “the emerging challenges represented by non-communicable diseases (along with their associated risk factors such as smoking and obesity), by mental disorders, and by the growing scourge of injury and violence.”<sup>22</sup> Frenk has also noted that, paradoxically, recent success in reducing infectious disease and child mortality may contribute to the chronic disease burden in later years:

In health we are victims of our own success. The improvement in basic health conditions . . . enhance[s] the survival of children to reach ages at which non-communicable diseases are more prevalent . . . . [P]roblems only of the poor, like many common infections and malnutrition, are no longer the only problems of the poor, who also have the highest rates of many non-communicable diseases, mental disorders, injury, violence, smoking, obesity, and other risk factors.<sup>23</sup>

Barry Bloom has echoed this description, noting that chronic diseases are now “the greatest contributor to the global burden of disease,” even as infectious diseases remain destructive.<sup>24</sup> Bloom argues convincingly for increased attention to behavioral prevention efforts, highlighting the need to decrease tobacco use, vitamin deficiencies, and weight gain.<sup>25</sup> Other estimates of disease are similarly alarming. Katsuri Sen and Ruth Bonita found in 2000 that variation in rates of premature death among populations aged 15 to 60 years is primarily the result of non-communicable diseases and injury.<sup>26</sup> An estimate published by the *Lancet* in

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21. See, e.g., JoAnne Epping-Jordan et al., *Preventing Chronic Diseases: Taking Stepwise Action*, 366 LANCET 1667, 1667 (2005); Frenk, *supra* note 14, at 954; Derek Yach et al., *The Global Burden of Chronic Diseases: Overcoming Impediments to Prevention and Control*, 291 JAMA 2616, 2617 (2004).

22. See Frenk, *supra* note 14, at 954.

23. *Id.* at 955.

24. Bloom, *supra* note 10.

25. *Id.*

26. Katsuri Sen & Ruth Bonita, *Global Health Status: Two Steps Forward, One Step Back*, 356 LANCET 577, 577 (2000); see also Abdesslam Boutayeb, *The Double Burden of Communicable and Non-Communicable Diseases in Developing Countries*, 100 TRANSACTIONS OF THE ROYAL SOC'Y OF TROPICAL MED. & HYGIENE 191 (2006); Yach et al., *supra* note 21, at 2616.

2005 found that four out of five deaths from chronic disease occur in low-income and middle-income countries.<sup>27</sup> There has been inadequate attention to deaths from chronic disease in these settings,<sup>28</sup> which are characterized by inadequate access to treatment and a lack of effective prevention programs.<sup>29</sup> World Health Organization (“WHO”) personnel such as Frenk and Lee Jong-wook have called on the WHO and national health systems to guide the response to the double burden,<sup>30</sup> and the WHO has labeled the prevention of chronic diseases “a vital investment.”<sup>31</sup>

The consequences of this double burden, particularly the impact of chronic disease, are financially and socially devastating. Chronic disease impoverishes individuals and nations, whether by low-level disability over a long period of time<sup>32</sup> or by impoverishment caused by out-of-pocket medical expenses where access to subsidized health care is poor.<sup>33</sup> The WHO has estimated, for example, that China alone will lose \$558 billion in national income between 2005 and 2015 due to premature deaths caused by heart disease, stroke, and diabetes.<sup>34</sup> Poverty, in turn, drives further illness, disability, and premature death caused by infectious and chronic disease, exacerbating global inequalities in health and wealth.

Health behaviors contribute to both the infectious and the chronic disease halves of this double burden, particularly as “ideas and lifestyles” travel among countries.<sup>35</sup> As identified by a variety of research groups and the WHO, behaviors adding most to the global health burden include unprotected sex,

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27. Epping-Jordan et al., *supra* note 21, at 1668; *see also* WORLD HEALTH ORG., PREVENTING CHRONIC DISEASES: A VITAL INVESTMENT 3 (2005), *available at* [http://www.who.int/chp/chronic\\_disease\\_report/full\\_report.pdf](http://www.who.int/chp/chronic_disease_report/full_report.pdf) (estimating that 60% of deaths worldwide were due to chronic disease).

28. Yach et al., *supra* note 21, at 2617.

29. Epping-Jordan et al., *supra* note 21, at 1667.

30. *See* Julio Frenk & Octavio Gómez-Dantés, *Globalization and the Challenges to Health Systems*, HEALTH AFF., May/June 2002, at 160, 161; Lee Jong-wook, *Global Health Improvement and WHO: Shaping the Future*, 362 LANCET 2083, 2083 (2003).

31. WORLD HEALTH ORG., *supra* note 27, at 1.

32. *See, e.g.*, Charles H. King & Madeline Dangerfield-Cha, *The Unacknowledged Impact of Chronic Schistosomiasis*, 4 CHRONIC ILLNESS 65, 72 (2008); *see also* WORLD HEALTH ORG., *supra* note 27, at viii.

33. *See, e.g.*, Diane McIntyre, *What Are the Economic Consequences for Households of Illness and of Paying for Health Care in Low- and Middle-Income Country Contexts?*, 62 SOC. SCI. & MED. 858 (2006); Eddy van Doorslaer et al., *Effect of Payments for Health Care on Poverty Estimates in 11 Countries in Asia: An Analysis of Household Survey Data*, 368 LANCET 1357 (2006) (concluding that measures of poverty should not count out-of-pocket medical spending as household consumption and that, if properly measured, poverty rates would rise).

34. WORLD HEALTH ORG., *supra* note 27, at 5.

35. Frenk & Gómez-Dantés, *supra* note 30, at 161.

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alcohol use, indoor air pollution, occupational health risks, tobacco use, and physical inactivity.<sup>36</sup> Interventions to address these behaviors are an important part of the response to both chronic and infectious diseases.

### II. A QUICK PRIMER ON BEHAVIORAL INTERVENTIONS: DEFINITIONS, ORIGINS, AND ACCESS

Addressing disease, whether chronic or infectious, requires an integrated approach consisting of both treatment and prevention,<sup>37</sup> including efforts to promote healthy behaviors through behavioral interventions. It is possible to blur the boundary between “behavioral” and “biomedical” interventions, illustrated by hard-to-classify examples such as breastfeeding, vitamin supplementation, condom use, or growth monitoring. However, the basic contours of this argument remain the same: behavioral interventions targeting health choices, such as smoking, diet, physical activity, sexual activity, and hygiene have the potential to make an impact on global disease burden. National health reforms and global health funding streams have acknowledged this in recent years. Consider, for example, Mexico’s *Oportunidades*, a federally funded program that transfers cash incentives directly to families who take enumerated preventive health care actions such as prenatal care, regular checkups for children, cervical cancer screening for women, and diabetes control for adults;<sup>38</sup> the growing U.S. National Institutes of Health (“NIH”) prevention research budget,<sup>39</sup> and the funding earmarked for behavioral prevention in initiatives such as the President’s Emergency Plan for AIDS Relief.<sup>40</sup> Effective programs designed specifically to

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36. WORLD HEALTH ORG., *supra* note 27, at 6 (estimating at least 2.6 million deaths worldwide each year due to obesity or excess weight; 7.1 million due to raised blood pressure; 4.4 million due to raised cholesterol; and 4.9 million due to tobacco use); Jürgen Rehm et al., *Global Burden of Disease and Injury and Economic Cost Attributable to Alcohol Use and Alcohol-Use Disorders*, 373 LANCET 2223, 2223 (2009); Sen & Bonita, *supra* note 26, at 580; Yach et al., *supra* note 21, at 2616.

37. Of course, the relationship between treatment and prevention is not always dichotomous. As Paul Farmer has noted, treatment *is* prevention in some contexts, such as antiretroviral treatment for HIV infection, which leads to a decrease in viral load and a corresponding decrease in infectiousness. FARMER, *supra* note 1; *see also* Jesús Castilla et al., *Effectiveness of Highly Active Antiretroviral Therapy in Reducing Heterosexual Transmission of HIV*, 40 J. ACQUIRED IMMUNE DEFICIENCY SYNDROMES 96, 100 (2005).

38. *See* Lia C.H. Fernald, Paul J. Gertler & Lynnette M. Neufeld, *Role of Cash in Conditional Cash Transfer Programmes for Child Health, Growth, and Development: An Analysis of Mexico’s Oportunidades*, 371 LANCET 828, 829-30 (2008) (noting that the program had a \$3.7 billion budget in 2007, covering over five million families); Frenk, *supra* note 14, at 957.

39. NIH Office of Disease Prevention, NIH Prevention Research Budget, <http://prevention.nih.gov/budget.aspx> (last visited Mar. 31, 2010).

40. United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria, 22 U.S.C.A. §

encourage behavior change can be powerful tools in lessening the double burden of disease. The remainder of this section will provide a rough definition of behavioral interventions and identify the main groups that create them: researchers, non-governmental organizations (“NGOs”) and other community groups (for example, schools or community centers), and governments.

### *A. Behavioral Interventions: Definitions and Origins*

A behavioral intervention—“any intervention that has as its expressed purpose changing a person’s health-related attitudes, beliefs, intentions, and behavior so as to enhance his or her health”<sup>41</sup>—generally includes some kind of education about health risks and protective behaviors. Studies in social science and psychology, however, have demonstrated that knowledge alone is insufficient to change most health behaviors.<sup>42</sup> For this reason, behavioral interventions generally include multiple components, such as education sessions, media components, skills training and practice, counseling, group activities, and exercises involving family members, peers, or other social systems. Interventions can target behavior change at a variety of levels, including the individual,<sup>43</sup> the family,<sup>44</sup> social groups such as peer networks or schools,<sup>45</sup> entire communities,<sup>46</sup> or even broader levels.<sup>47</sup>

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7601 (West 2008).

41. Ralph J. DiClemente, Laura F. Salazar & Richard A. Crosby, *Designing Randomized Controlled Trials in Health Promotion Research*, in RESEARCH METHODS IN HEALTH PROMOTION 129, 129 (Richard A. Crosby, Ralph J. DiClemente & Laura F. Salazar eds., 2006) (defining the term “health promotion program”).

42. See, e.g., ALBERT BANDURA, PRINCIPLES OF BEHAVIOR MODIFICATION (1969).

43. For a discussion of an individual-level intervention, see The EXPLORE Study Team, *Effects of a Behavioural Intervention To Reduce Acquisition of HIV Infection Among Men Who Have Sex with Men: The EXPLORE Randomised Controlled Study*, 364 LANCET 41 (2004).

44. For a discussion of a family-level intervention, see Bonita Stanton et al., *Randomized Trial of a Parent Intervention: Parents Can Make a Difference in Long-Term Adolescent Risk Behaviors, Perceptions, and Knowledge*, 158 ARCHIVES PEDIATRICS & ADOLESCENT MED. 947 (2004).

45. For discussions of social-level interventions, see Karin K. Coyle et al., *Draw the Line/Respect the Line: A Randomized Trial of a Middle School Intervention To Reduce Sexual Risk Behaviors*, 94 AM. J. PUB. HEALTH 843 (2004); and Susan M. Kegeles, Robert B. Hays & Thomas J. Coates, *The Mpowerment Project: A Community-Level HIV Prevention Intervention for Young Gay Men*, 86 AM. J. PUB. HEALTH 1129 (1996).

46. For a discussion of a community-level intervention, see Zunyou Wu et al., *Community-Based Trial To Prevent Drug Use Among Youths in Yunnan, China*, 92 AM. J. PUB. HEALTH 1952 (2002).

47. See, e.g., Gerry V. Stimson, *AIDS and Injecting Drug Use in the United Kingdom, 1987-1993: The Policy Response and the Prevention of the Epidemic*, 41 SOC. SCI. & MED. 699 (1995). For a brief description of community-level, group-level, and structural interventions, see CDC, *Diffusion of Effective Behavioral Interventions*, <http://www.effectiveinterventions.org/go/>

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A useful four-part framework for considering behavioral interventions is to consider 1) the program's design, 2) its actual delivery to participants by program staff, 3) the uptake of program by participants, and 4) the context in which the program takes place.<sup>48</sup> A behavioral intervention generally takes the form of a written program manual, which can be accompanied by media components such as workbooks or videos. Program manuals specify the curriculum, interactive activities or exercises, and the accompanying media or other components. Interventions are generally delivered by program staff, often including social workers, counselors, teachers, volunteers, NGO staff, students, nurses, doctors, dietitians, community workers, and parents. The extent of training and skills necessary to achieve program effects varies; program staff may need intervention-specific training and access to a program manual or protocol. The effects of behavioral interventions also depend on active uptake and participation levels by the people receiving the program. These participants can be individuals, families, schools, communities, or other groups. In order to change behaviors, participants must actually receive the necessary information and skills training, understand what they receive, and then enact and sustain new behaviors in their own lives.<sup>49</sup> Contextual factors such as resource availability, program setting, language, and the intervention's cultural fit can also influence design and delivery; successful programs are tailored to the physical, cultural, legal, and social environment.

One example of an effective behavioral intervention is the Focus on Youth program (also called Focus on Kids), which aims to reduce the risk of HIV infection among adolescents. The initial trial of this program, which was developed by a research team at the University of Maryland, took place in low-income African American communities in Baltimore.<sup>50</sup> The initial intervention consisted of seven weekly meetings at a community center and a full one-day session and celebration at a nearby camping site.<sup>51</sup> The curriculum was based on social cognitive theory and protection motivation theory, and it was delivered by pairs of adults to adolescents aggregated in small single-sex groups. Activities

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interventions (last visited Mar. 31, 2010).

48. The design and application of this four-part framework was part of the author's doctoral thesis.

49. See Albert J. Bellg et al., *Enhancing Treatment Fidelity in Health Behavior Change Studies: Best Practices and Recommendations from the NIH Behavior Change Consortium*, 23 HEALTH PSYCHOL. 443, 444 (2004).

50. CDC, A Focus on Kids Intervention: Focus on Youth with ImPACT: Fact Sheet, [http://www.effectiveinterventions.org/files/foy\\_with\\_impact\\_fact\\_sheet.final\\_08-1027.pdf](http://www.effectiveinterventions.org/files/foy_with_impact_fact_sheet.final_08-1027.pdf) (last visited Mar. 31, 2010).

51. Bonita Stanton et al., *A Randomized, Controlled Effectiveness Trial of an AIDS Prevention Program for Low-Income African-American Youths*, 150 ARCHIVES PEDIATRICS & ADOLESCENT MED. 363 (1996).

included small group discussions, lectures, videos, games, roleplaying, arts and crafts, and community projects, and the culturally sensitive curriculum focused on decision-making, condom use, communication, family trees, and negotiation skills. Compared to youth who simply viewed videos about AIDS and received condoms, youth enrolled in the Focus on Youth intervention were significantly more likely to report using condoms at six-month follow-up.<sup>52</sup> Subsequent trials of this program modified it to include booster sessions and a parent-child communication component; this combined program had protective effects at long-term follow-up on risky sexual behavior, alcohol use, marijuana use, crack/cocaine use, and drug selling.<sup>53</sup> An adapted version of the program was recently shown to reduce sexual risk behavior among a youth population in the Bahamas.<sup>54</sup> Interestingly, however, an adapted intervention had no effect on risk behaviors in schools in a rural area of West Virginia. The difference in effectiveness between programs might have been due to school-mandated modifications that eliminated condom practice exercises.<sup>55</sup> The Centers for Disease Control and Prevention (“CDC”) has classified Focus on Youth as an effective behavioral intervention, encouraging its adoption through the Diffusion of Effective Behavioral Interventions (“DEBI”) project,<sup>56</sup> which entails training sessions and ongoing technical assistance. A recent survey of organizations implementing the Focus on Youth program found that it has also been implemented in eleven U.S. states and the District of Columbia, Mexico, Trinidad and Tobago, and Vietnam, and it has been translated into five languages.<sup>57</sup> Groups in China and Namibia have also implemented adapted

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52. *Id.* at 363 (reporting that rates of self-reported condom use were 85% and 61% among intervention and control youths, respectively, at a follow-up six months post-intervention).

53. See Ying Wu et al., *Sustaining and Broadening Intervention Impact: A Longitudinal Randomized Trial of 3 Adolescent Risk Reduction Approaches*, 111 PEDIATRICS e32 (2003) (evaluating the intervention with parental monitoring and booster sessions); see also Bonita F. Stanton et al., *Parental Underestimates of Adolescent Risk Behavior: A Randomized, Controlled Trial of a Parental Monitoring Intervention*, 26 J. ADOLESCENT HEALTH 18 (2000) (evaluating the parental monitoring and communication component only).

54. See Jie Gong et al., *Effects Through 24 Months of an HIV/AIDS Prevention Intervention Program Based on Protection Motivation Theory Among Preadolescents in the Bahamas*, 123 PEDIATRICS e917 (2009).

55. See Bonita F. Stanton et al., *Trial of an Urban Adolescent Sexual Risk-Reduction Intervention for Rural Youth: A Promising but Imperfect Fit*, 38 J. ADOLESCENT HEALTH 55.e25, 55.e35 (2006).

56. CDC, *Diffusion of Effective Behavioral Interventions: Focus on Youth with Informed Parents and Children Together*, <http://www.effectiveinterventions.org/go/interventions/focus-on-youth--impact> (last visited Mar. 31, 2010).

57. Jennifer S. Galbraith et al., *Exploring Implementation and Fidelity of Evidence-Based Behavioral Interventions for HIV Prevention: Lessons Learned from the Focus on Kids Diffusion Case Study*, 36 HEALTH EDUC. BEHAV. 532, 538-39 (2009).

versions of the curriculum.<sup>58</sup>

Behavioral interventions like Focus on Youth are under development in many places, although very few are actually evaluated for effectiveness.<sup>59</sup> They are generated, broadly, by three groups of people with overlapping incentives. Often, programs are developed directly by academics—public health researchers, medical professors, social and behavioral scientists, and psychologists. Most academics do not seek to make a profit on the interventions that they produce, and many intervention packages are sold by nonprofits after their development.<sup>60</sup> Because researchers are constrained by the need to continually apply for grants and publish new research findings, they generally have limited time to put into publicizing and disseminating effective programs after evaluating them.

NGOs are another source of health behavior interventions, which are implemented by community-based groups, private health insurers, clinics, hospitals, schools, and professional associations. Incentives for community groups also include a desire to improve the health of target populations, the need for continued funding, positive media attention, and the increased need to provide external funders with measurable outcome data. These program creators are often overburdened and may lack the time and incentives to disseminate interventions, to generate program manuals or other replicable materials, or to publicize programs that appear to be effective.

Finally, local and national governments also generate behavioral interventions, which can be delivered through government-run schools, clinics, mass media, and departments of health and welfare. Governmental incentives can include accountability to citizens, a desire to lessen disease burden and increase national productivity, financial considerations, and international or external pressures; however, these incentives do not generally align with disseminating interventions outside the jurisdiction.

### *B. Access to Behavioral Interventions: The Ideal and Reality of Intervention Transfer*

Intervention transfer refers to the process of identifying a program with

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58. *See id.* at 538.

59. *See, e.g.,* Manuel Nebot, *Health Promotion Evaluation and the Principle of Prevention*, 60 J. EPIDEMIOLOGY & COMMUNITY HEALTH 5, 5 (2006) (“While the ‘scientific community’ holds to the principle that all public health must be evidence based, in practice the effectiveness of many health promotion interventions and programmes is not properly assessed.”); *cf.* ROSS C. BROWNSON ET AL., EVIDENCE-BASED PUBLIC HEALTH 7 (2003), available at [http://prc.slu.edu/Documents/Chapter\\_1.pdf](http://prc.slu.edu/Documents/Chapter_1.pdf) (describing that public health interventions have fewer studies for effectiveness than medical studies for pharmaceutical products).

60. *See, e.g.,* ETR Associates, <http://www.etr.org> (last visited Mar. 31, 2010) (describing the work of ETR Associates, a nonprofit organization that evaluates and markets sexual risk reduction programs for young people).

proven effects in one setting, and then modifying that program and implementing it somewhere else. Creators of such programs rarely initiate transfers themselves; decision-makers in new settings often must seek them out independently. At the heart of the transfer process is the ideal of evidence-based practice (“EBP”).<sup>61</sup> Briefly, EBP in public health is a process in which decision-makers formulate a research question, search for responsive and methodologically rigorous evidence, appraise the quality of the evidence, integrate the evidence with the situation at hand, adopt an intervention, and monitor the actual intervention effect.<sup>62</sup> Relevant considerations for adopting an intervention include appraisal of a program’s acceptability to participants, ease of implementation by practitioners, resource requirements, and cost-effectiveness. Evidence-based practice also *produces* important knowledge about the effectiveness of a given behavioral intervention in a new setting, thereby contributing to the body of evidence. To replicate the protective effects of a behavioral intervention, it is also necessary to balance two competing concerns: *fidelity* (implementing the same program that was used before, or at least the core components responsible for behavior change)<sup>63</sup> and *adaptation* (implementing the program in a way that will work in the new setting).<sup>64</sup> Randomized controlled trials and systematic reviews have shown

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61. Introductions to evidence-based practice include BROWNSON ET AL., *supra* note 59; J.A. MUIR-GRAY, *EVIDENCE-BASED HEALTHCARE* (2001); and DAVID L. SACKETT ET AL., *EVIDENCE-BASED MEDICINE: HOW TO PRACTICE AND TEACH EBM* (2000). For a primer on the hierarchy of evidence, see Gordon H. Guyatt et al., *Users’ Guides to the Medical Literature: A Method for Grading Health Care Recommendations*, 274 *JAMA* 1800 (1995); Centre for Evidence Based Medicine, *Levels of Evidence*, <http://www.cebm.net/index.aspx?o=1025> (last visited Mar. 31, 2010).

62. See sources cited *supra* note 61 for variations on these steps.

63. Theoretical work in implementation fidelity for behavioral interventions is extensive, including the following highlights: Felipe González Castro, Manuel Barrera, Jr. & Charles R. Martinez, *The Cultural Adaptation of Prevention Interventions: Resolving Tensions Between Fidelity and Fit*, 5 *PREVENTION SCI.* 41 (2004); Andrew V. Dane & Barry H. Schneider, *Program Integrity in Primary and Early Secondary Prevention: Are Implementation Effects Out of Control?*, 18 *CLINICAL PSYCHOL. REV.* 23 (1998); Linda Dusenbury et al., *A Review of Research on Fidelity of Implementation: Implications for Drug Abuse in School Settings*, 18 *HEALTH EDUC. RES.* 237 (2003); Frank J. Moncher & Ronald J. Prinz, *Treatment Fidelity in Outcome Studies*, 11 *CLINICAL PSYCHOL. REV.* 247 (1991); Barbara Resnick et al., *Examples of Implementation and Evaluation of Treatment Fidelity in the BCC Studies: Where We Are and Where We Need To Go*, 29 *ANNALS BEHAV. MED.* 46 (2005); William H. Yeaton & Lee Sechrest, *Critical Dimensions in the Choice and Maintenance of Successful Treatments: Strength, Integrity, and Effectiveness*, 49 *J. CONSULTING & CLINICAL PSYCHOL.* 156 (1981). Opinions differ on how much fidelity is necessary when scaling up effective interventions. See Dane & Schneider, *supra*.

64. See, e.g., Jeffrey A. Kelly et al., *Transfer of Research-Based HIV Prevention Interventions to Community Service Providers: Fidelity and Adaptation*, 12 *AIDS EDUC. & PREVENTION* 87 (Supp. A 2000).

many behavioral interventions to be effective for modifying health behaviors,<sup>65</sup> and transferring these interventions to new settings could have a significant impact on global disease.

Despite the ideal of evidence-based practice, many effective interventions are neglected, and it has been estimated that “penetration of even the most successful interventions rarely surpasses 1% of any target population.”<sup>66</sup> Reasons for the limited reach of effective behavioral interventions are manifold.

One key limitation of evidence-based practice is the need for training, both to apply the EBP process and to negotiate the public health literature. A large part of the workforce in public health may lack this training.<sup>67</sup> The public health and social services sectors are largely unregulated in many places, and even trained professionals may not have been exposed to EBP. Governmental officials, community organizers, school personnel, and other practitioners may not know about electronic databases that index published evaluations of programs—which usually do not contain full text reports of published evaluations—and those who successfully search databases may find an overwhelming amount of

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65. See, e.g., Laurie M. Anderson et al., *The Effectiveness of Worksite Nutrition and Physical Activity Interventions for Controlling Employee Overweight and Obesity: A Systematic Review*, 37 AM. J. PREVENTIVE MED. 340, 355 (2009) (summarizing trial findings across a range of worksites to show that worksite nutrition and exercise programs can reduce employee weight); Eileen F. Kaner et al., *The Effectiveness of Brief Alcohol Interventions in Primary Care Settings: A Systematic Review*, 28 DRUG & ALCOHOL REV. 301 (2009) (finding that brief interventions delivered in a variety of primary care settings led to significant reductions in alcohol consumption among men); Seth M. Noar, Hulda G. Black & Larson B. Pierce, *Efficacy of Computer Technology-Based HIV Prevention Interventions: A Meta-Analysis*, 23 AIDS 107 (2009) (synthesizing evidence from a variety of populations showing that computer-based HIV prevention programs can have significant impacts on behavior); L.F. Stead & T. Lancaster, *Group Behaviour Therapy Programs for Smoking Cessation*, COCHRANE DATABASE SYSTEMATIC REVIEWS Art. No.: CD001007, 11 (2005) (summarizing evidence from 53 separate trials to show that group therapy is effective for smoking cessation).

66. Peter S. Jensen, *Commentary: The Next Generation Is Overdue*, 42 J. AM. ACAD. CHILD & ADOLESCENT PSYCHIATRY 527, 527 (2003) (cited in Mary Jane Rotheram-Borus, Dallas Swendeman & Gary Chovnick, *The Past, Present, and Future of HIV Prevention: Integrating Behavioral, Biomedical, and Structural Intervention Strategies for the Next Generation of HIV Prevention*, 5 ANN. REV. CLINICAL PSYCHOL. 143, 146 (2009)). Research into the actual dissemination of most social interventions is also lacking. See, e.g., Russell E. Glasgow & Karen M. Emmons, *How Can We Increase Translation of Research into Practice? Types of Evidence Needed*, 28 ANN. REV. PUB. HEALTH 413 (2007).

67. See, e.g., BROWNSON ET AL., *supra* note 59, at 7 (“[P]ublic health relies on a variety of disciplines, and there is not a single (or even small number of) academic credential(s) that ‘certifies’ a public health practitioner. In the United States, for example, fewer than half of the 500,000 individuals in the public health workforce have had formal training in a public health discipline such as epidemiology or health promotion.”).

information.<sup>68</sup> Next, even if an effective program in an analogous setting is discovered and transferred with perfect fidelity, it may not work the same way in the new setting. For example, the “Be Proud! Be Responsible!” sexual risk reduction intervention has repeatedly been shown to have protective effects in urban settings such as Trenton and Philadelphia;<sup>69</sup> however, a recent implementation of this intervention in a suburban setting has shown no effect on behavior.<sup>70</sup> Adaptation of programs may be necessary for transfer, but it is difficult to know what to change.<sup>71</sup> Interventions may require trained staff or materials that are unavailable, particularly in low-income settings.<sup>72</sup> Some programs may be further hampered by cultural or legal constraints; for example, stringent drug paraphernalia laws may limit the effectiveness of needle exchange

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68. See, e.g., Cynthia D. Mulrow, *Rationale for Systematic Reviews*, 309 BRIT. MED. J. 597, 597 (1994) (“Over two million articles are published annually in the biomedical literature in over 20,000 journals . . . . Clearly, systematic literature review is needed to refine these unmanageable amounts of information.”). To illustrate this problem, when I set out to summarize the evidence for abstinence-based HIV prevention programs, I worked with a team to screen over 20,000 abstracts to find the 52 program evaluations that were responsive to our research question. Kristen Underhill, Paul Montgomery & Don Operario, *Sexual Abstinence Only Programmes To Prevent HIV Infection in High-Income Countries: Systematic Review*, 335 BRIT. MED. J. 248 (2007); Kristen Underhill, Don Operario & Paul Montgomery, *Systematic Review of Abstinence-Plus HIV Prevention Programs in High-Income Countries*, 4 PUB. LIBR. SCI. MED. e275 (Sept. 2007), available at <http://www.plosmedicine.org/article/fetchObjectAttachment.action?uri=info%3Adoi%2F10.1371%2Fjournal.pmed.0040275&representation=PDF>. Locating full-text copies of these evaluations, appraising study methodology, and aggregating the results took months. Ideally, the systematic reviews we produced should make this evidence available to others in a fraction of that time, but this will depend on whether our reviews are easily accessible.

69. See Centers for Disease Control and Prevention, *Be Proud! Be Responsible!*, [http://www.cdc.gov/hiv/topics/research/prs/resources/factsheets/Be\\_Proud.htm](http://www.cdc.gov/hiv/topics/research/prs/resources/factsheets/Be_Proud.htm) (last visited Mar. 31, 2010) (reviewing primary studies by John and Loretta Sweet Jemmott, the program developers); see also John B. Jemmott, III, et al., *Reducing HIV Risk-Associated Sexual Behavior Among African American Adolescents: Testing the Generality of Intervention Effects*, 27 AM. J. COMMUNITY PSYCHOL. 161 (1999).

70. See Elaine A. Borawski et al., *Taking Be Proud! Be Responsible! to the Suburbs: A Replication Study*, 41 PERSPECTIVES SEXUAL REPROD. HEALTH 12 (2009).

71. See, e.g., Stephanie G. Bell et al., *Challenges in Replicating Interventions*, 40 J. ADOLESCENT HEALTH 514 (2007); Dane & Schneider, *supra* note 63; Kelly et al., *supra* note 64; Rotheram-Borus et al., *supra* note 66, at 146, 153 (“There is no consensus on the level at which to define core elements and the causal mechanisms implied. There are not typically data on the [evidence-based intervention] to identify that specified core elements are indeed the causal mechanisms necessary for behavior change . . .”).

72. See Rotheram-Borus et al., *supra* note 66, at 153 (“Staff persons in agencies who wish to implement [evidence-based interventions] often do not have the skills or capacities to pull a manualized [intervention] off the shelf and implement it effectively.”) (internal references removed).

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programs, or criminalization of same-sex sexual activity may limit the effectiveness of programs that aim to build community among men who have sex with men. Finally, even when the EBP process works perfectly and transferred interventions do lead to safer behaviors in the new context, the resources required to make these programs sustainable may be lacking.

Beyond these practical challenges to broadening the access to effective behavior change programs, formal and informal barriers to information-sharing might also inhibit transfer. This Note will now turn to these obstacles.

### III. INTELLECTUAL PROPERTY AND BEHAVIORAL INTERVENTIONS: BARRIERS TO TRANSFER

Although behavioral interventions resemble patented medical technologies in some ways, a broader view of the international intellectual property regime will be necessary to identify relevant information-sharing constraints. While there may also be contract restrictions, applicable trade regulations, or potentially even antitrust barriers to the transfer of effective behavioral interventions, this Note focuses only on intellectual property and information-sharing barriers. This Part will outline both formal barriers and informal limitations to the information-sharing necessary to disseminate behavioral interventions. This investigation suggests that although patents, trademarks, and trade secret protections pose few barriers to transfer, copyrights and informal information constraints can be important obstacles to intervention dissemination.

#### *A. Formal Intellectual Property Barriers to the Dissemination of Effective Behavioral Interventions*

In domestic law, the broad categories of intellectual property protection are fourfold: 1) copyrights,<sup>73</sup> 2) patents,<sup>74</sup> 3) trademark or trade dress,<sup>75</sup> and 4) trade secrets, which are protected through a patchwork of state laws and tort doctrines.<sup>76</sup> These four categories map onto the types of intellectual property

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73. See 17 U.S.C. § 102(a)-(b) (2006). Copyrights are awarded for “original works of authorship fixed in any tangible medium of expression” but not for “any idea, procedure, process, system, method of operation, concept, principle, or discovery . . . .”

74. See 35 U.S.C. § 101 (2006). Patents are awarded in the United States for “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof . . . .”

75. Protected marks include “corporate and product names, symbols, logos, slogans, pictures and designs, product configurations, colors and even smells.” INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 30 (Robert P. Merges, Peter S. Menell & Mark A. Lemley eds., 2007) [hereinafter INTELLECTUAL PROPERTY]. Domestic trademark regulations in the United States are set forth in the Lanham Act, 15 U.S.C. §§ 1051-1141n (2006).

76. See, e.g., UNIF. TRADE SECRETS ACT § 1(4) (1985). Trade secrets consist of “information,

protected by international agreements. On the international stage, with which this Note is primarily concerned, the most significant agreement on intellectual property rights is the World Trade Organization's ("WTO's") Trade-Related Aspects of Intellectual Property agreement, or TRIPS. Signing nations must comply with or "harmonize" their own law with respect to the entire TRIPS agreement by 2016,<sup>77</sup> including the enforcement of pharmaceutical patents. Under TRIPS, the categories of intellectual property are sevenfold: patents, copyrights, trademarks, trade secrets or other undisclosed information, geographical indications, industrial designs, and layout designs of integrated circuits.<sup>78</sup> This Note will deal with only the first four broad categories, which are most relevant to behavior change programs and mirrored by domestic law in TRIPS signing nations. Enforcement of intellectual property rights is not automatic; the owners of intellectual property must instigate private actions to protect those rights using national court systems, and the TRIPS agreement requires nations to provide enforcement mechanisms and penalties sufficient to deter infringement.<sup>79</sup> In some instances, such as trade secrets, intellectual property cannot formally exist if the owners do not make reasonable prior efforts to maintain secrecy. Penalties for infringement vary by jurisdiction and type of protection, but can include injunctions and monetary damages.

The owners of formal intellectual property rights to behavioral interventions, if such rights exist, could range from private owners like individual investors and institutions to public owners like governments.<sup>80</sup> Identifying the owners of both interventions and evaluations is important, because if formal intellectual property constraints diminish the dissemination of effective behavioral interventions, non-enforcement by owners may be one way to sidestep such barriers.

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including a formula, pattern, compilation, program, device, method, technique, or process" that "derives independent economic value" and "is the subject of efforts that are reasonable under the circumstances to maintain its secrecy."

77. See WTO, *Understanding the WTO – Intellectual Property: Protection and Enforcement*, [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/agrm7\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm) (last visited Mar. 31, 2010).

78. *Id.*

79. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 1197 [hereinafter TRIPS], available at [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips.doc](http://www.wto.org/english/docs_e/legal_e/27-trips.doc).

80. Notably, government-created works cannot receive formal intellectual property protection in some jurisdictions. U.S. federal law explicitly bans copyright protection for any work "prepared by an officer or employee of the United States Government as part of that person's official duties." 17 U.S.C. § 101 (2006). There may be discretion, however, in awarding copyright to "works prepared under Government contract or grant." H.R. REP. NO. 94-1476 (1976) (quoted in INTELLECTUAL PROPERTY, *supra* note 75, at 432). This may be the case for many behavioral interventions and evaluations thereof, which are often produced using governmental funding like NIH grants.

### 1. Copyrights

Copyrights may be the most significant formal barriers to the process of transferring effective behavioral interventions. Copyrights are automatically awarded to most literary and artistic work, without the need for application, and are not contingent on expensive prosecution processes. Under the Berne Convention, the term of copyright is limited to fifty years after the death of the author.<sup>81</sup> Because all written program manuals and program evaluations are “literary work,” copyrights are pervasive in the field of behavioral interventions. As upheld under the TRIPS agreement, copyrights can impede the transfer of behavioral interventions in two important ways.

First, copyrights on published evaluations of program effectiveness prevent others from identifying evidence-based interventions that might work in a given setting. Although the open-access movement among academic publications is a beneficial trend, many full-text papers remain inaccessible to non-subscribers.

Second, copyrights inhibit access to program manuals and materials. Barriers to accessing program materials affect the processes of *deciding* which intervention to use and of *implementing* the intervention that is selected. As the previous Part noted, effective replication requires fidelity—something that is impossible without access to the correct program materials and instructions, even if those original materials require adaptation. The costs of acquiring copyrighted program manuals and materials can make interventions inaccessible to nonprofit organizations seeking to implement evidence-based programs.<sup>82</sup> Costs of

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81. Berne Convention for the Protection of Literary and Artistic Works, art. 7(1), Sept. 9, 1886, revised July 24, 1971, 25 U.S.T. 1341, 1161 U.N.T.S. 3, available at [http://www.wipo.int/treaties/en/ip/berne/trtdocs\\_wo001.html](http://www.wipo.int/treaties/en/ip/berne/trtdocs_wo001.html).

82. See, e.g., Rosemary C. Veniegas et al., *HIV Prevention Technology Transfer: Challenges and Strategies in the Real World*, 99 AM. J. PUB. HEALTH S124, S126, S128 tbl.3, S129 (2009) (finding based on a survey of community-based organizations that inaccessibility of manuals and intervention information can inhibit intervention transfer; also noting that a lack of intervention materials during the selection phase led organizations to choose and acquire programs that they were “underprepared to carry out”); see also Alice A. Gandelman, Linda M. DeSantis & Cornelis A. Rietmeijer, *Assessing Community Needs and Agency Capacity—An Integral Part of Implementing Effective Evidence-Based Interventions*, 18 AIDS EDUC. & PREVENTION 32, 38 (Supp. A 2006) (noting that the average prevention budget of AIDS organizations is “typically not enough to implement one, much less more than one EBI [evidence-based intervention]”); Robin Lin Miller, *Innovation in HIV Prevention: Organizational and Intervention Characteristics Affecting Program Adoption*, 29 AM. J. COMMUNITY PSYCHOL. 621, 639 (2001) (reporting a survey of community-based organizations, which found that money “dictated whether programs were deemed feasible”; also noting that many organizational representatives “talked about programs they hoped to adopt, if they could secure the financial support to do so”). Program materials form only part of the costs of implementing an evidence-based intervention. Debra P. Ritzwoller et al., *Costing Behavioral Interventions: A Practical Guide to Enhance Translation*, 37 ANNALS BEHAV.

implementation may be higher when materials are branded and licensed for a profit.<sup>83</sup> Depending on the format of the intervention, entire programs may be copyrighted. For example, some behavioral interventions are in the form of self-help booklets, videos, theater productions, or computer software.<sup>84</sup> Passing costs onto consumers is often unrealistic for interventions addressing ill health, which is largely shaped by poverty and a scarcity of prevention resources.

The remedies for copyright enforcement depend on the place of enforcement, but they can include actual damages, statutory damages, lost royalties or licensing fees, attorneys' fees, and injunctions, with some prosecution possible under the criminal law. The costs of legal actions to monitor infringement and enforce copyrights offset this barrier to some extent; it may well be prohibitively expensive for most owners of copyrights to protect their intervention materials. However, the *de facto* consequences of copyrights—namely that most published evaluations and intervention materials are not freely accessible to the public—may be the most significant barrier faced in intervention transfer.

## 2. Patent Protection

Some behavioral interventions could arguably be described as “processes,” which are eligible for twenty-year patent protection under TRIPS if they “are new, involve an inventive step and are capable of industrial application.”<sup>85</sup> The requirement of industrial application<sup>86</sup> would present little obstacle to patenting behavioral interventions. Provisions denying patents on the grounds of public policy are also likely inapplicable; while public policy concerns limit the patentability of inventions whose commercial exploitation could prove dangerous

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MED. 218 (2009) (enumerating different costs involved in delivering a behavioral intervention). However, broadening access to program materials can improve feasibility and help organizations select programs that match their actual capacity.

83. For example, the costs of licensing multisystemic therapy and receiving mandatory supervision have been well documented by a Canadian study team. See A.W. LESCHIED & ALISON CUNNINGHAM, SEEKING EFFECTIVE INTERVENTIONS FOR SERIOUS YOUNG OFFENDERS: INTERIM RESULTS OF A FOUR-YEAR RANDOMIZED STUDY OF MULTISYSTEMIC THERAPY IN ONTARIO, CANADA 118-125 (2002), available at <http://www.lfcc.on.ca/seeking.html> (documenting licensing fees, site fees, continued supervision fees, and high per-client costs).

84. Computer programs are copyrightable as “literary works” in the United States. See 17 U.S.C. §§ 101, 117 (2006). Copyrightability and ease of enforcing copyrights for computer programs in other jurisdictions vary.

85. TRIPS, *supra* note 79, § 5, art. 27(1).

86. The “industrial application” requirement in TRIPS is defined to be synonymous with the term “useful.” TRIPS, *supra* note 79, § 5, art. 27(1), n.5. This aligns with the U.S. patent requirement of utility, and it would almost certainly be satisfied by a program that produces public health improvements.

to human life,<sup>87</sup> this exception does not enable governments to deny patent protection on the grounds that inventions are *helpful* to public health.<sup>88</sup> Despite the lack of formal barriers to patents on the grounds of utility and public policy, intervention developers are unlikely to seek and obtain patents due to patentability of subject matter and practical obstacles to obtaining and enforcing patents.

First, even if they are described as processes, behavioral interventions likely would not qualify as patentable processes in most jurisdictions. The text of TRIPS suggests that processes that qualify for patents should lead directly to physical, commercial products, because process patents confer the right “to prevent third parties not having the owner’s consent from . . . using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.”<sup>89</sup> The lack of a physical product may well be a terminal deficiency for patenting behavioral interventions. Under U.S. patent law, for example, a behavioral intervention would likely not qualify for a process patent.<sup>90</sup>

Next, even if behavioral interventions were readily classifiable as patentable processes, there remain practical reasons why program developers might not seek or receive patents. First, obtaining and enforcing a patent requires time and resources that may be unavailable or counter to the incentives of many, though not all program developers.<sup>91</sup> Second, as Milby et al. identify, evaluations of

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87. TRIPS, *supra* note 79, § 5, art. 27(2).

88. See INTELLECTUAL PROPERTY, *supra* note 75, at 347. TRIPS also permits governments to deny patent protection for “diagnostic, therapeutic, and surgical methods for the treatment of humans.” TRIPS, *supra* note 79, § 5, art. 27(3)(a). Behavioral interventions may be denied patents on these grounds if they are classified as therapeutic; however, the patenting of drugs suggests that this rationale alone is often insufficient to prevent patenting. In the United States, patents may be awarded for medical treatment processes; however, these patents do not confer the right to seek monetary or injunctive relief from any licensed medical practitioner for infringement. See 35 U.S.C. § 287(c) (2006). If behavioral interventions fell under this type of designation, patents would present no bar to dissemination.

89. TRIPS, *supra* note 79, § 5, art. 28(1)(b).

90. The standard definition of a patentable process is “an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.” *Cochrane v. Deener*, 19 U.S. 780, 788 (1877). Behavioral interventions would not pass the “machine-or-transformation” test as articulated in *In re Bilski*, 545 F.3d 943, 960 (Fed. Cir. 2008), *cert. granted*, 129 S. Ct. 2735 (2009). They would also have failed the older *State Street Bank* test, which requires that patent-eligible processes produce “a useful, concrete, and tangible result.” *State St. Bank v. Signature Fin. Group*, 149 F.3d 1368, 1375 (Fed. Cir. 1998). At a stretch, some behavioral interventions might be classified as methods of carrying out business, which are indeed patentable in some jurisdictions, including the United States. *Id.* However, the *Bilski* opinion appears to hold these processes to the same standard of eligibility, which would likely present an insurmountable barrier. *In re Bilski*, 545 F.3d at 960.

91. As discussed in Part II.A, program developers are generally academic researchers,

behavioral interventions are usually published;<sup>92</sup> in many jurisdictions, such publication is a bar to the receipt of a patent, because it undermines the requirement that the invention be “new.”<sup>93</sup> Finally, the delivery of a behavioral intervention to human participants would constitute a “public use” of the invention, which would also undermine the novelty requirement for patent eligibility. It would be impossible to pilot or to evaluate a behavioral intervention without such use, thereby erecting statutory barriers to patenting an intervention in the United States.<sup>94</sup> Fourth, processes invented using governmental funding may not be patentable due to statutory bars in various jurisdictions; this could disqualify a large number of behavioral interventions. Fifth, it may be difficult for behavioral interventions to fulfill the “inventive step” requirement in TRIPS, which is synonymous with the “non-obviousness” requirement that is a lynchpin of patent law in the United States and elsewhere.<sup>95</sup> “Prior art” for these

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governmental institutions, and nonprofit organizations; when they create new programs, these groups tend to be motivated respectively by publications and career advancement, accountability to constituents and funders, and community concerns—none of which align exactly with patenting. Patenting an intervention would require secrecy during program development, which does not comport with the incentive for publications and career advancement among researchers. There may be public policy barriers to patenting interventions created by governmental institutions, whose accountability to constituents may prevent profiting from the sales of a patented intervention. NGOs may simply lack the resources necessary for a lengthy patent prosecution process, and in some fields of behavioral intervention (for example, HIV prevention), NGOs that develop new programs may be familiar enough with the detrimental health effects of pharmaceutical patents that they may choose not to patent or enforce patents for their own work. For all program developers, the expected return for patenting a behavioral intervention may be small in comparison to the cost of patent prosecution, given that program purchasers tend to be nonprofit institutions with limited budgets for new program materials.

92. Jesse B. Milby et al., *A Progressive Process for Technology Transfer of a Complex, Effective Psychosocial Intervention: Methods and Preliminary Results*, 6 *ADDICTIVE DISORDERS & THEIR TREATMENT* 187, 187 (2007) (“In behavioral science, especially research supported by the US government, [transferring behavioral interventions to practice settings] rarely involves intellectual property protection, because most science and technology findings are published in journal literature.”).

93. TRIPS, *supra* note 79, § 5, art. 27(1). Under U.S. law, for example, if a printed publication occurs more than one year before an attempt to patent a process, that publication can be a bar to patenting. *See, e.g.*, 35 U.S.C. § 102(b) (2006); *In re Hall*, 781 F.2d 897 (Fed. Cir. 1986) (holding that publication in a doctoral thesis in Germany was a bar to patenting an invention in the United States).

94. *See, e.g.*, *Egbert v. Lippman*, 104 U.S. 333, 333 (1881). The “experimental use” exception to the public use bar, however, might help someone seeking to patent a behavioral intervention despite its prior use in an effectiveness trial. *See, e.g.*, *City of Elizabeth v. Pavement Co.*, 97 U.S. 126 (1877).

95. TRIPS, *supra* note 79, § 5, art. 27(1), n.5 (describing the inventive step requirement); *see also* *INTELLECTUAL PROPERTY*, *supra* note 75, at 347.

interventions—which would consist of prior programs aimed at behavior change—may render most types of program activities obvious. Sixth, although the improvement of health behaviors is undoubtedly “useful,” the *demonstration* of utility may be a difficult requirement for a behavioral intervention. Evaluations of behavioral interventions are expensive, lengthy, and usually published. The effects of a behavioral intervention, unlike the results of most patented processes, are likely to vary widely and may not be entirely reliable. Finally, even if an intervention *did* receive a process patent and *were* enforced, compulsory license exceptions to the TRIPS agreement may apply for particularly effective interventions, although power dynamics among states could make compulsory licensing politically or economically costly.<sup>96</sup> TRIPS also contains a provision enabling case-by-case review of “Other Use Without Authorization of the Right Holder,” conditional on “adequate remuneration” for the patentee.<sup>97</sup>

Importantly, interventions that integrate a technological component, such as a software program or electronic reminder device, may involve patented *pieces*. For example, patents have been awarded to a hand-held computer device that prompts users to exercise and provides meal suggestions,<sup>98</sup> to Weight Watchers software and hardware that help users follow program guidelines,<sup>99</sup> to a Weight Watchers calculator,<sup>100</sup> and to software that enables users to see what they might look like in clothing if they lose weight according to a specified regimen.<sup>101</sup> Patents may be a bar to transferring these types of interventions, if the technological piece is a core component responsible for intervention effects.

### 3. Trademarks

Trademark protection, which TRIPS permits for “any sign, or any combination of signs, capable of distinguishing the goods or services of one

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96. See, e.g., Robert C. Bird, *Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines While Minimizing Investment Side Effects*, 32 J.L. MED. & ETHICS 209, 210 (2009) (summarizing some of the economic and political “secondary effects” of issuing a compulsory license, including loss of investment, litigation by pharmaceutical corporations, and possible trade sanctions).

97. TRIPS, *supra* note 79, § 5, art. 31, 31(h).

98. Apparatus To Control Diet and Weight Using Human Behavior Modification Techniques, U.S. Patent No. 5,673,691 (filed Jan. 2, 1996) (issued Oct. 7, 1997).

99. Weight Control System Having Varying Meal Plans and Meal Planning Schemes, U.S. Patent No. 7,361,143 (filed Mar. 10, 2004) (issued Apr. 22, 2008).

100. Process for Controlling Body Weight, U.S. Patent No. 6,878,885 (filed Oct. 14, 2003) (issued Apr. 12, 2005).

101. Diet and Exercise Planning and Motivation Including Apparel Purchases Based on Future Appearance, U.S. Patent No. 7,328,119 (filed May 2, 2005) (issued Feb. 5, 2008).

undertaking from those of other undertakings,”<sup>102</sup> largely originated from the impulse to protect consumers by identifying the source of the goods and services they purchased. This form of intellectual property protection has now evolved to protect the companies who have registered their trademarks, and trademarks themselves are increasingly bought, sold, and licensed as goods in their own right. The term of trademark protection is potentially unlimited, and TRIPS permits indefinite renewals of trademark registrations for terms of at least seven years each.<sup>103</sup>

Trademark protection applies less readily to most behavioral interventions. Although some commercially marketed behavioral interventions, such as Weight Watchers, have registered marks, trademark protection is unlikely to bar most intervention dissemination. Generally the name or logo of a behavioral intervention is unlikely to be an “essential component” for program effectiveness, and therefore marks need not be transferred with other key components of the intervention.<sup>104</sup> If the original program materials were used, the trademarks would refer correctly to the source of the goods, and so their use would not be infringing. People who purchase trademarked goods may use them as they choose, and organizations who deliver behavioral interventions often do so without making a profit. Likelihood of confusion is the touchstone for trademark infringement,<sup>105</sup> which is unlikely for the vast majority of behavioral interventions that are limited in fame and geographical scope.

Given these caveats, it is *possible*, but not probable, that developers of behavioral interventions may seek to avoid the dilution of their own program names, logos, or identities by others seeking to duplicate and package them elsewhere. These types of claims, however, would be offset by the same factors mentioned above. Policing trademark infringement is expensive and may be counter to the incentives or financial capacity of program developers, given that initial trademark registration costs time and money, and trademarks can lapse if they are not defended rigorously by filing new legal actions against infringers.<sup>106</sup> There can also be “exceptions” to trademark rights in the interests of third parties,<sup>107</sup> and prosecution would be legally difficult given the need to prove a

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102. TRIPS, *supra* note 79, § 2, art. 15.

103. TRIPS, *supra* note 79, § 2, art. 18.

104. For example, a recent study of 34 organizations implementing the Focus on Youth program found that 11 (32%) changed the program name. Galbraith et al., *supra* note 57, at 539. If an intervention’s trademark is protected, implementation of the exact same program under a different mark may qualify as reverse passing off, however, which could rise to claims of false designation of origin by any person “who believes that he or she is likely to be damaged by such act.” 15 U.S.C. § 1125(a) (2006).

105. TRIPS, *supra* note 79, § 2, art. 16.

106. For a fuller discussion of this point, see *supra* note 91.

107. TRIPS, *supra* note 79, § 2, art. 17.

likelihood of confusion between the original and the copycat. Finally, even if trademarks were vigorously enforced, the penalties would be limited to rebranding and discontinuing of the trademark, trade dress, or service mark; no delivery of interventions could be enjoined. For these reasons, it appears that trademarks are not a major barrier to the transfer of behavioral interventions.

#### 4. Trade Secret Protection

Trade secrecy is often discussed apart from the other three forms of intellectual property law, in part because it is difficult to define. The nature of a trade secret—called “Undisclosed Information” in TRIPS—can be any information that fulfills three conditions: 1) it must be “secret in the sense that it is not . . . generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question”; 2) it must “ha[ve] commercial value because it is secret”; and 3) it must “ha[ve] been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.”<sup>108</sup> State parties to TRIPS agree to “protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”<sup>109</sup> Although patents and copyrights are finite and require disclosure of the innovation, trade secret protection depends on non-disclosure and is limited only by the duration of reasonable efforts to maintain secrecy. These efforts can include non-disclosure agreements, implied secrecy, and contracts. Remedies for disclosing trade secrets may vary, but can include injunctions, damages, and attorney’s fees.<sup>110</sup> In some ways, it is tempting to suggest that information barriers in the transfer of behavioral interventions are most akin to trade secrecy. Much of the information about actual implementation is only known to program developers and staff, especially if there are deviations from a written manual. Trade secrecy is available to processes and other information that escapes easy classification among the patent, copyright, and trademark domains, which may make this type of protection more appropriate for complex interventions. Contracts to protect the dissemination of implementation information are possible, and many behavioral interventions have commercial value.

Practically, however, trade secret protection will not formally apply to most

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108. TRIPS, *supra* note 79, § 7, art. 39(2)(a)-(c).

109. TRIPS, *supra* note 79, § 7, art. 39(3).

110. UNIF. TRADE SECRETS ACT §§ 2-4 (1985). The Uniform Trade Secrets Act has been adopted by 45 states, the District of Columbia, and the U.S. Virgin Islands. *See* Uniform Law Commissioners, A Few Facts About the Uniform Trade Secrets Act, [http://www.nccusl.org/Update/uniformact\\_factsheets/uniformacts-fs-utsa.asp](http://www.nccusl.org/Update/uniformact_factsheets/uniformacts-fs-utsa.asp) (last visited Mar. 31, 2010).

behavioral interventions because secrecy will be impossible to maintain. Most obviously, interventions must involve participants that observe the workings of the program and could potentially disclose or replicate it outside the intervention setting, making a claim of secrecy difficult to uphold.<sup>111</sup> The availability or sale of intervention manuals or protocols, the inclusion of intervention details in published evaluations, or the presentation of intervention plans to academic conferences or funding bodies are also barriers to proving secrecy. Reverse engineering of programs based on publicly accessible information would be permissible, and misappropriation or dishonest commercial practices may be difficult to prove given the exposure of program participants. Finally, so many different strategies have been tested for behavioral interventions that, although each program on its own is unique, it would likely be very difficult to show that any specific intervention component were not “readily accessible to persons within the circles that normally deal with the kind of information in question . . . .”<sup>112</sup>

On the balance, therefore, it is very unlikely that formal trade secrecy protections will inhibit the transfer of behavioral interventions, although we can draw similarities between trade secrets and the types of de facto information barriers already existing in this field. This Note will now sketch the outlines of these informal barriers.

### *B. Informal Constraints on the Availability of Information*

Information about behavioral intervention programs is rarely widely available. Many behavioral intervention programs are not tested, while completed evaluations may go unpublished. Studies showing evidence of harm or no effect could help program adopters weed out ineffective or detrimental interventions; however, evaluations with such findings are even less likely to be written or published. This is due in part to the biases of journals in selecting pieces for publication,<sup>113</sup> and in part because program developers or funders may be reluctant to release findings suggesting that their programs are ineffective.

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111. Programs could potentially ask participants to sign nondisclosure contracts as a condition of participation, but this is unlikely to be acceptable in practice.

112. TRIPS, *supra* note 79, § 7, art. 39(2)(a). One exception to the general lack of trade secret protection may be interventions that involve the provision of food according to specific recipes, which may be likely only for behavioral interventions that involve weight loss. Weight Watchers recipes have been deemed trade secrets. *See* *Weight Watchers Int’l, Inc. v. Stouffer Corp.*, 744 F. Supp. 1259, 1280 (S.D.N.Y. 1990).

113. This is the problem of publication bias, which refers to the tendency of journals to be more accepting of papers reporting statistically significant findings. The seminal article on this topic is Kay Dickersin, *The Existence of Publication Bias and Risk Factors for Its Occurrence*, 263 *JAMA* 1385 (1990); *see also* Kay Dickersin, *How Important Is Publication Bias? A Synthesis of Available Data*, 9 *AIDS EDUC. & PREVENTION* 15 (Supp. A 1997).

Another information barrier is the lack of data about how programs are actually implemented. Although methods for monitoring program implementation are improving, much of the information about participant attendance, program staff activity, use of program materials, and relevant contextual details is not gathered. Poor metrics exist for this type of data.<sup>114</sup> Journals do not have space to publish all of this information, and funders are unlikely to demand it along with other metrics of program accomplishment. This lack of reporting results in a de facto monopoly on relevant information, much of which may be eventually lost due to turnovers in program staff or management.

Program developers and researchers rarely have the time, resources, or expertise to devote to disseminating their intervention. Program manuals and materials are not made available for free, and cost-free distribution of materials is particularly unthinkable when programs are branded, sold, and licensed. Technical assistance to help others adopt an intervention can be expensive, time-consuming, and hard to provide. There are also few good guides available to help program adopters adapt an intervention to fit a new setting. Although some procedures to adapt interventions for transfer are under study,<sup>115</sup> it is still very difficult to determine which intervention components can and cannot be modified while retaining the program's effectiveness.

Even with all of these constraints on information availability, the information that *is* available is disorganized and overwhelming. Databases like PubMed<sup>116</sup> and PsycINFO,<sup>117</sup> where articles are abstracted, can be daunting. The type of systematic literature search and evidence assessment that EBP requires is time-consuming and skills-based. As discussed above, potential program adopters may lack the time and skills necessary to find, evaluate, and use the information already available. There is no centralized database for behavioral intervention evaluations or program materials; there is also no mandatory prospective registration database for trials of behavioral interventions, which contributes to the potential for bias in conducting and reporting evaluations. CENTRAL<sup>118</sup> and Clinicaltrials.gov<sup>119</sup> have made a start in this area, but registration is either optional or tied to specific funding requirements. Similarly,

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114. Dane & Schneider, *supra* note 63.

115. See Bell et al., *supra* note 71; Russell E. Glasgow et al., *Evaluating the Public Health Impact of Health Promotion Interventions: The RE-AIM Framework*, 89 AM. J. PUB. HEALTH 1322 (1999).

116. See NCBI, PubMed, <http://www.ncbi.nlm.nih.gov/pubmed> (last visited Mar. 31, 2010).

117. See APA Databases, PsycINFO, <http://www.apa.org/psycinfo> (last visited Mar. 31, 2010).

118. The Cochrane Library, The Cochrane Central Register of Controlled Trials, [http://www.mrw.interscience.wiley.com/cochrane/cochrane\\_clcentral\\_articles\\_fs.html](http://www.mrw.interscience.wiley.com/cochrane/cochrane_clcentral_articles_fs.html) (last visited Mar. 31, 2010).

119. Clinicaltrials.gov, Home, <http://clinicaltrials.gov> (last visited Mar. 31, 2010).

there is no single organization tasked with identifying effective behavior change programs for different types of settings and participants. Individual organizations such as the CDC Prevention Research Synthesis Project, NICE, or the Cochrane Library have made a start towards gathering program evidence; however, these research institutions are more dedicated to comparing research findings across groups of programs than matching individual interventions to settings and participant groups. Few of these research institutions have the type of global recognition necessary to reach most communities in the developing world, and none has made program evaluations available alongside the materials necessary to deliver the interventions in practice.

#### IV. SYSTEMIC SOLUTIONS

The previous section identified many needs. Among these, we need incentives for researchers, funders, and program developers to provide open access to program materials and evaluations to people who implement behavior change programs: community organizers, schools, local and national departments of health, hospitals, and other groups. We need incentives for transferability trials, for the publication of non-significant or iatrogenic effects, and for methods that enable more systematic adaptation of effective programs, all of which have been neglected by academic journals and institutional research funders. We need ways to distill the evaluations and materials that are already available, so that groups can identify and make use of this information. And we need to centralize some of these functions in a way that can be publicized and that conveys legitimacy on a global scale.

How can we fulfill these needs in a way that is systemic—that is, in a way that does not place the obligation entirely on program developers and program adopters?<sup>120</sup> This section will outline some suggestions for changing the incentive structure at several levels of global health governance.

##### *A. The World Health Organization*

The World Health Organization (WHO) has been consistently cast as the central figure and repository for hope in the systems of global health governance envisioned by leading global health experts.<sup>121</sup> The WHO possesses the

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120. Program developers and adopters play critical roles in disseminating interventions; however, this section specifically addresses actors who can influence broader incentive structures for program development and dissemination.

121. See Bloom, *supra* note 10; Lawrence O. Gostin, *Meeting Basic Survival Needs of the World's Least Healthy People: A Proposed Model for Global Health Governance*, 298 JAMA 225 (2007); Lawrence O. Gostin, *Meeting Basic Survival Needs of the World's Least Healthy People: Toward a Framework Convention on Global Health*, 96 GEORGETOWN L.J. 331 (2008); Dean T. Jamison, Julio Frenk & Felicia Knaul, *International Collective Action in Health: Objectives,*

## TRANSFERRING BEHAVIORAL INTERVENTIONS

worldwide recognition, expertise, and humanitarian legitimacy necessary to encourage changes in the incentives listed above, and it has the capacity to make information available to communities worldwide. The WHO receives a relatively stable funding stream<sup>122</sup> and has the technical capacity to host large quantities of information online; it also has the linguistic capacity to translate much of that material into the most widely understood languages. Furthermore, the WHO is perceived to have scientific and political authority to distinguish among effective and ineffective interventions without bias, and the WHO has the technical expertise needed to appraise the evaluation evidence and contextual factors that might help match programs to settings where they would be effective.

It seems that the WHO could help facilitate the transfer of effective behavioral interventions in several ways, all of which would fall under Frenk's conception of the WHO's "core functions"<sup>123</sup> and the need for information-sharing among states.<sup>124</sup> First, the WHO could host an online registry of evaluations of behavior change programs; at first, the registry could be limited to randomized controlled trials, but it may also be desirable to include other study methods. Ideally, registration would be prospective and would include contact information for the study personnel; after an evaluation concluded, the registry could be updated with study outcomes, published and unpublished evaluation reports, process evaluations, and other relevant information about the implementation of the program, including costs and acceptability. The registry could be searchable based on a variety of criteria, such as target health behaviors, the type of participant, the location of the evaluation, other evaluations of the same or similar programs, and characteristics of the intervention. The initial formation of the database should include past evaluations, both published and unpublished, which would require some pressure on the international copyright regime and individual researchers or institutions. To encourage registration, the WHO could work with national governments, academic journals, and research funders to require registration and sharing as a condition of funding projects or impact evaluations.

Second, the WHO could link the database of *evaluations* with a searchable database of *intervention materials*. These materials could include program manuals, worksheets or workbooks, intervention videos, and otherwise copyrightable materials that are necessary to select and adopt interventions for use. The two databases should work in tandem, such that groups trying to select a

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*Function, and Rationale*, 351 LANCET 514 (1998).

122. The WHO is funded primarily by assessed contributions from member states, although a growing proportion of funds are voluntary contributions by other donors. See WORLD HEALTH ORG., MEDIUM-TERM STRATEGIC PLAN 11-13 (2009), available at [http://apps.who.int/gb/ebwha/pdf\\_files/AMTSP-PPB/a-mtsp\\_2en.pdf](http://apps.who.int/gb/ebwha/pdf_files/AMTSP-PPB/a-mtsp_2en.pdf).

123. Jamison et al., *supra* note 121, at 514.

124. Frenk & Gómez-Dantés, *supra* note 30.

program can move easily from program evaluations (seeing which ones have worked, and where they worked before) to program materials (seeing which ones are feasible, and then getting the materials for implementation). Although this would likely take up a great deal of space, programming time, and IT resources, this would be the most direct way to get program materials into the hands of people who can use them. This information should be universally accessible (not just accessible to organizations that develop or deliver interventions), because open access may also enable potential program participants to identify and suggest effective programs.

Third, regardless of whether it is possible to host full-text evaluations and materials, the WHO can be instrumental in identifying behavioral interventions that are known to be effective, along with the contexts in which those programs were shown to have protective effects. This process would mitigate the problems of insufficient time and expertise by people who develop, evaluate, or seek to adopt the programs, and it would create a centralized repository of information and recommendations that would be perceived as scientifically authoritative. Creating a publicly accessible repository of strategies that have been evaluated with evidence of *ineffectiveness or harm* may be equally valuable, since this could help avoid the financial and opportunity costs associated with the delivery of ineffective programs.

Fourth, the WHO could also pressure journals, program developers, and researchers to release copyright on past evaluations and program materials so that they could be included in the trial registry and the database. The WHO could apply this pressure by issuing position statements, sending open letters to journal editors and research institutions, encouraging researchers to submit articles to journals that have favorable open-access policies, discussing the availability of behavioral intervention materials at international scientific meetings, encouraging research funders to require open access to program materials, and ensuring that its own scientists make published evaluations and program materials available online.

Fifth, the WHO could suggest a systematic approach for adapting behavioral interventions for use in new settings, particularly given its expertise in advising a variety of state and local governments in similar questions. Any kind of adaptation guidance would need to be framed at a very high level of generality to be useful for a majority of interventions, but this would help fill the guidance gap in program adaptation strategies.

Sixth, to the extent that copyrights prevent the sharing of behavioral intervention materials and published evaluations, the WHO might be instrumental in developing an open-access license permitting the sharing of such materials, similar to the Creative Commons licensing scheme.<sup>125</sup> The availability

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125. See, e.g., Creative Commons, About Licenses, <http://creativecommons.org/>

and potential popularity of an open-access license for behavioral intervention materials may help to change norms of information-sharing among researchers and program developers, and providing legal language to insist on appropriate attribution could also help to align information-sharing with program creators' career goals.

### *B. Scholarly Journals and Academic Institutions*

Because academic institutions and scholarly journals provide powerful incentives for researchers who develop and evaluate behavioral interventions, and because they have widespread reputations for scientific legitimacy, these groups can significantly encourage the release of program evaluations and materials. For example, journals can make published evaluations of behavioral interventions available for free through publishing on PubMed Central, making the material available on their websites at no cost, or permitting authors to release reports to a central registry like the WHO database proposed above. This could be complicated, however, without some protection for royalties in place. If journals must forego some royalties or other profits to make evaluations accessible immediately, a lag time may be necessary to prevent a chilling effect on the publication of program evaluations. To foster the sharing of intervention manuals and other materials, journals could request that manuals of evaluated programs be made available for free or a discounted cost online as a condition of publication, providing links to the materials in published reports. Journals could also revise reporting requirements for primary studies, requiring researchers to include more information about implementation in original program reports.<sup>126</sup> Finally, journals could announce and fulfill a commitment to publishing more transferability trials and adaptation research on effective programs.

Like journals, academic institutions could also require their researchers to

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about/licenses (last visited Mar. 31, 2010) (providing standard licenses that enable copyright owners to customize the level of copyright protection applied to their copyrighted materials). Several open-access journals, including the PLoS (Public Library of Science) collection, already use Creative Commons licensing to permit free distribution and sharing of published program evaluations. See Creative Commons, About: Who Uses CC?, <http://creativecommons.org/about/who-uses-cc> (last visited Mar. 31, 2010). Crafting a license that specifically applies to health promotion programs might seek to encompass many different types of copyrighted materials (for example, intervention booklets, videos, and posters), and it could tailor privileges to their health-related justifications.

126. See Don C. Des Jarlais et al., *Improving the Reporting Quality of Nonrandomized Evaluations of Behavioral and Public Health Interventions: The TREND Statement*, 94 AM. J. PUB. HEALTH 361 (2004); David Moher et al., *The CONSORT Statement: Revised Recommendations for Improving the Quality of Reports of Parallel-Group Randomised Trials*, 357 LANCET 1191 (2001); David Moher et al., *Improving the Quality of Reports of Meta-Analyses of Randomised Controlled Trials: the QUOROM Statement*, 354 LANCET 1896 (1999).

make program information available online, and they could host intervention content on their institutional website (or at least allow it to be made available to a centralized database). Academic institutions generally contain the Institutional Review Boards (“IRBs”) that approve most institution-based research, and those IRBs could also play a role in requiring public release of evaluation results and program materials as a condition of approving research. The fact that most programs are un-patented (despite copyright protection) may help in encouraging universities to adopt pro-transfer policies. Journals and academic institutions might choose to refrain from enforcing copyrights that might be violated by groups that make behavioral intervention materials available for free elsewhere. They could also reach out to service providers to diminish some of the demand-side barriers to identify effective programs, such as by running workshops to teach providers skills for locating and appraising evidence of program effectiveness.

### *C. Funders of Research and Programs*

Research and program funders wield some of the same sticks and carrots as academic institutions and journals; reaching out through funders also has the capacity to incentivize both academic *and* non-academic researchers. To improve *supply*-side information shortages, funders of research and intervention trials can require NGOs and researchers to make program materials and evaluations available online free of charge, either on their own websites or through central databases. They can also encourage the conduct and publication of methodologically rigorous and well-reported program evaluations. Funders of groups seeking to adopt behavioral interventions can also nurture the *demand* side of intervention transfer by fostering evidence-based practice. For example, funders could provide training in evidence-based practice, require grantees to show an evidence base for intervention programming, and suggest promising interventions for implementation.

Research funders could also contribute to the production of knowledge about how interventions are transferred to new settings, including ways to support organizations in delivering new programs. As an example, the National Institute of Mental Health has funded a study of a technology exchange system that aims to help community-based organizations implement the MPowerment Project, an HIV prevention program for young men who have sex with men.<sup>127</sup> Research

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127. See Gregory M. Rebchook et al., *Translating Research into Practice: The Dissemination and Initial Implementation of an Evidence-Based HIV Prevention Program*, 18 AIDS EDUC. & PREVENTION 119, 121 (Supp. A 2006). This article provides an excellent overview of the intervention dissemination process, from initial program development to widespread implementation. See also U.S. Department of Health and Human Services, Project Information, Project Number 5R01MH065196-08, [http://projectreporter.nih.gov/project\\_info\\_description.cfm](http://projectreporter.nih.gov/project_info_description.cfm)

fundes could also require the evaluators of behavioral interventions to collect and maintain field notes related to program implementation, which may require the collection of additional data beyond the usual evaluation protocol.<sup>128</sup>

#### *D. Governments and Regulators of Research*

National governments can be involved in the process of disseminating behavioral interventions in at least four ways: as actors in the international and national legal process, as providers of behavioral interventions, as fundes of research and locally delivered programs, and as regulators of federally funded research.

As actors in the international legal process, state governments can press for the WHO to take on the functions outlined above. They can also collectively pursue modifications to the international legal regime to ensure that effective behavioral interventions can be identified and disseminated, although this may be politically difficult. At a national level, lawmakers may also seek modifications or exceptions to national copyright laws, or even simply call attention to the ways that behavior change interventions could be used contribute to health improvements in local communities.

As organizations that adopt, modify, fund, and deliver behavioral interventions, governments can take on a direct role in publicizing program materials and evaluations, as well as ensuring that the interventions they finance are empirically supported. The Diffusion of Effective Behavioral Interventions (“DEBI”) project, which began in 1999 and is run by the CDC,<sup>129</sup> could provide a model for this process. The DEBI initiative identifies effective programs for HIV prevention based on pre-specified criteria, including the methodological rigor of the program evaluation and a clear description of the intervention’s key components.<sup>130</sup> The DEBI initiative then provides applicants, usually community-

?aid=7667249&icde=2795168 (last visited Mar. 31, 2010) (outlining the study description).

128. For a discussion of the types of program implementation data that are most useful for dissemination, see Agatha N. Eke et al., *Preparing Effective Behavioral Interventions To Be Used by Prevention Providers: The Role of Researchers During HIV Prevention Research Trials*, 18 AIDS EDUC. & PREVENTION 44, 50 tbl.2 (2006).

129. Centers for Disease Control and Prevention, About DEBI, <http://www.effectiveinterventions.org/go/about-debi> (last visited Mar. 31, 2010). The DEBI program works with the Replicating Effective Programs initiative (which packages program materials for dissemination), and the Prevention Research Synthesis initiative (which identifies evidence-based programs and reviews evidence of program effectiveness). See Eke et al., *supra* note 128, at 45-46; Centers for Disease Control and Prevention, Replicating Effective Programs Plus, [http://www.cdc.gov/hiv/topics/prev\\_prog/rep](http://www.cdc.gov/hiv/topics/prev_prog/rep) (last visited Mar. 31, 2010).

130. See Cynthia M. Lyles et al., *Evidence-Based HIV Behavioral Prevention From the Perspective of the CDC’s HIV/AIDS Prevention Research Synthesis Team*, 18 AIDS EDUC. & PREVENTION 21, 24 (Supp. A 2006) (listing criteria for a best-evidence behavioral intervention).

based organizations, with training sessions and program materials without charge.<sup>131</sup> Various city health departments and other funders now require their grantees to implement interventions selected from the DEBI project or the CDC's list of effective behavioral interventions.<sup>132</sup> To date, over 10,000 people and 5,000 agencies have received DEBI training to deliver evidence-based HIV prevention programs.<sup>133</sup> Despite the successes of the DEBI project, there are drawbacks as well; for example, although the list of DEBI-supported interventions is growing, there remain population groups for whom no intervention has yet been identified. Organizations and researchers who work with these groups must adapt DEBI-supported interventions to the new population, rather than developing a new program that may be more appropriate.<sup>134</sup> However, overall the DEBI project is a successful demonstration of how governments can take a more active role in minimizing barriers to the identification and dissemination of effective programs. Scaling up the DEBI project to address health risks other than HIV may be a promising new trajectory, and the initiative could serve as a model for efforts by other governments, funders, and possibly the WHO.

As funders and regulators of research, governments could also require the disclosure of intervention materials and evaluations as a condition of funding. For example, governmental review of applications for NIH funding already requires a rigorous evidence base, and the NIH Public Access policy requires that the public gain access to evaluations of NIH-funded programs.<sup>135</sup> If this policy were extended to intervention manuals and materials, this would facilitate the dissemination of effective programs. Regulations governing the conduct of research on human subjects in the United States do not address the accessibility of program evaluations and materials;<sup>136</sup> however, it may be useful for IRBs who approve research efforts to consider researchers' commitments to make intervention materials and evaluations accessible after the evaluation is complete.<sup>137</sup>

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131. See Diffusion of Effective Behavioral Interventions (DEBI) Project, Frequently Asked Questions (FAQs) – General, <http://www.effectiveinterventions.org/go/general-faqs> (last visited Mar. 31, 2010).

132. McKleroy et al., *supra* note 19, at 60.

133. See Diffusion of Effective Behavioral Interventions (DEBI) Project, Welcome, <http://effectiveinterventions.org/> (last visited Mar. 31, 2010).

134. See, e.g., *Adapting CDC DEBI List for Target Audiences Is a Major Issue Among CBOs. Translation Changes Can Affect Funding*, 20 AIDS ALERT 75 (2005) (outlining difficulties in the translation process).

135. See U.S. Department of Health and Human Services, Public Access Policy, <http://publicaccess.nih.gov/> (last visited Mar. 31, 2010).

136. Protection of Human Subjects, 45 C.F.R. § 46 (2009).

137. Other national and international ethics groups, such as the World Medical Association, could apply similar pressure by making subsequent dissemination a priority in their ethical

V. COUNTERING OBJECTIONS TO THE PROJECT OF BROADENING ACCESS TO BEHAVIORAL INTERVENTIONS

The solutions this Note proposed in the previous section are vulnerable to a wide variety of criticisms. This section will acknowledge and attempt to counter at least the most significant objections to the proposals above. These objections include logistical problems in broadening access to behavioral intervention materials, the possibility that later implementers may change programs in ways that diminish their effects, difficulties with the larger project of transferring interventions to new settings, the problem of preserving incentives for innovation, and the possibility that increased focus on behavioral interventions may distract from underlying causes of ill health and health inequalities.

*A. Logistic Problems in Information-Sharing*

There are clear logistical challenges involved in broadening access to program evaluations and materials, most particularly in the suggested WHO database effort, but also more broadly in the process of transferring behavioral interventions at all. The information required to deliver a behavior change program—including program evaluations, program manuals, program materials, and information about actual implementation and context during evaluations—is vast, complex, and sometimes difficult to collect. Not all programs have manuals. Most researchers do not collect or report data on participant attendance or contextual factors affecting implementation. We lack good instruments for monitoring program delivery or uptake during trials. Process evaluations, which assess how programs are implemented, are becoming more prevalent, but still do not complement the majority of effectiveness studies. The groups that implement behavior change programs might be reluctant to release some implementation details. (For example, consider an NGO that delivers an effective anti-smoking program in schools but must creatively persuade school administrators to give them access. These persuasion techniques might be useful to other groups, but there are good reasons why the NGO may be reluctant to release them). Detractors from this Note’s proposal may well argue that there is simply too much information, and that even if the information could be gathered into a single database, the sheer quantity of detail would overwhelm the technological capacity of the database and the ability of users to find what they need. It is time-consuming to identify effective behavior change programs, and setting up and publicizing a database will take time and resources. People in developing countries who are in a position to adopt evidence-based behavior change programs may lack access to the Internet or may have connections that have

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guidance to researchers. Professional associations such as the American Public Health Association could also contribute to this effort.

insufficient power to download large files (for example, program manuals and videos). It may also be conceptually challenging to identify what behavioral interventions should qualify for the database, given that all behaviors are related to health in some way (for example, consider the earlier example of efforts to encourage recycling—is this a health behavior change program?). And many of the people who are in a position to adopt effective behavior change programs are new to the idea of evidence-based practice in the first place, suggesting that the database might fall short of its full potential at first.

Many of these criticisms are viable. However, the database approach is not meant to be a total solution—indeed, simply making program materials available will not ensure that they are used. The WHO could mitigate some of these problems by making the database user-friendly and by taking the lead in identifying interventions that were effective. Although not all programs are manual-based, many are, particularly those that have been evaluated and shown to be effective. Even if we cannot make *all* of the relevant information available, we can certainly improve on what is available now. Our metrics for evaluating program implementation and translating research to practice are improving all the time, and the Internet and open-access movement are opening up unprecedented possibilities to make more of that information available to others. Internet access is increasing, and many improvements can be made in the communities that already have access to the web; the involvement of governments in encouraging evidence-based practice could be one way to mitigate the technological barriers to accessing information. It is true that the WHO efforts and other suggestions advanced here would be expensive; however, the economic burdens of chronic disease are also weighty, and prevention is cheaper than treatment.<sup>138</sup> If improving access to behavior change programs can improve health behaviors and minimize the disease burden to even a small extent, this could very well be worth the expense.

### *B. Risks of Adapting Interventions: The Dilution of Program Effects*

Dilution refers to the possibility that modifications to an effective program will diminish effects on behaviors. For example, participants may look at program materials online, then decide that they do not need to attend in-person program sessions, despite in-person sessions actually being more effective. Program creators may also worry that publicly accessible materials will be used to implement their interventions incompletely or badly, thereby diluting program effects or giving the program a bad reputation. Communities where programs are implemented poorly may believe they are receiving an effective intervention,

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138. See, e.g., Robert Beaglehole et al., *Prevention of Chronic Diseases: A Call to Action*, 370 LANCET 2152 (2007) (outlining the economic imperative for improving preventive services in global health).

when in fact they are not. These fears invoke intellectual property doctrines such as dilution of trademark<sup>139</sup> and the “moral rights” element of copyright.<sup>140</sup> Similar concerns may well be harnessed by licensing systems that limit who can deliver certain interventions.

These risks, however, seem worth running. Not all programs will work everywhere, but it seems unjust to deny new groups the opportunity to identify, duplicate, and experiment with programs that have been effective in the past. This is especially true when the actions that would be necessary to give them that opportunity (for example, making evaluations and materials available online) are minimal. The original rationales for trademarks, copyrights, and patents—where fears of imitation and dilution are acute—were either to protect the consumer (trademarks) or to encourage innovation because it is in the interest of the greater good (copyrights and patents). Here, those with most at stake are not program developers and researchers, but the individuals who could benefit from behavioral interventions and should be given that opportunity. Programs should evolve over time to remain effective in a changing social context, and open access to behavioral intervention materials will enable that change.

### *C. Drawbacks to the General Goal of Intervention Transfer*

Because health behaviors and interventions that target them are influenced by context, there are ways to criticize the entire project of transferring effective programs, particularly when that transfer requires crossing borders. Adaptation is difficult, and it raises concerns about community “ownership” of imported programs, as well as about imperialism when behavior change programs are transported from high-income to low-income settings. Spending our time, energy, and resources to facilitate the transfer of interventions may be misguided from the first, some may argue.

However, these counterarguments may be answered in a few ways. First, there is empirical evidence that some programs work in a variety of settings. Consider, for example, the Focus on Kids intervention described earlier, which has had protective effects in communities as diverse as inner-city Baltimore and the Bahamas.<sup>141</sup> Another good example is the Becoming a Responsible Teen intervention, which has shown protective effects for sexual risk behavior among

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139. Under U.S. law, trademark dilution refers to the use of a famous mark (a mark “widely recognized by the general consuming public”) that, despite the absence of competition and likelihood of confusion, “impairs the distinctiveness” or “harms the reputation” of the famous mark. 15 U.S.C. § 1125 (2)(A)-(C) (2006).

140. For an overview discussion of moral rights in copyright law, see Cyril P. Rigamonti, *Deconstructing Moral Rights*, 47 HARV. INT’L L.J. 353 (2006).

141. See sources cited *supra*, notes 51-55.

African-American adolescents in urban areas,<sup>142</sup> ethnically diverse young males in juvenile detention facilities,<sup>143</sup> and primarily white youth in residential substance abuse treatment centers.<sup>144</sup> The Incredible Years<sup>145</sup> and Triple P<sup>146</sup> parenting programs for antisocial behavior in young children have shown effects among diverse communities in the United States, Germany, Canada, Australia, Switzerland, Jamaica, New Zealand, Norway, Portugal, Wales, Scotland, and Sweden. Weight Watchers, a familiar commercial program, has had a significant effect on weight loss in randomized controlled trials in the United States and the United Kingdom.<sup>147</sup> Adaptations of the Project RESPECT intervention for HIV prevention have shown promise among female sex workers in China,<sup>148</sup> adult heterosexual men and women in a variety of U.S. cities,<sup>149</sup> African American and Latina adolescents,<sup>150</sup> and men who have sex with men.<sup>151</sup>

Second, we might consider the migration of “lifestyles.” If unhealthy

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142. See Janet S. St. Lawrence et al., *Cognitive-Behavioral Intervention To Reduce African American Adolescents' Risk for HIV Infection*, 63 J. CONSULTING & CLINICAL PSYCHOL. 221 (1995).

143. See Janet S. St. Lawrence et al., *Sexual Risk Reduction and Anger Management Interventions for Incarcerated Male Adolescents: A Randomized Controlled Trial of Two Interventions*, 24 J. SEX EDUC. & THERAPY 9 (1999).

144. See Janet S. St. Lawrence et al., *Reducing STD and HIV Risk Behavior of Substance-Dependent Adolescents: A Randomized Controlled Trial*, 70 J. CONSULTING & CLINICAL PSYCHOL. 1010 (2002).

145. See The Incredible Years, Library: Incredible Years Research Outside the USA, [http://www.incredibleyears.com/library/show\\_countries.asp](http://www.incredibleyears.com/library/show_countries.asp) (last visited Mar. 31, 2010) (providing links to effectiveness studies in various program locations).

146. See Ireen de Graaf et al., *Effectiveness of the Triple P Positive Parenting Program for Behavioral Problems in Children: A Meta-Analysis*, 32 BEHAVIOR MODIFICATION 714 (2008).

147. See, e.g., Michael L. Dansinger et al., *Comparison of the Atkins, Ornish, Weight Watchers, and Zone Diets for Weight Loss and Heart Disease Risk Reduction: A Randomized Trial*, 293 JAMA 43 (2005); Stanley Heshka et al., *Weight Loss with Self-Help Compared with a Structured Commercial Program*, 289 JAMA 1792 (2003); Helen Truby et al., *Randomised Controlled Trial of Four Commercial Weight Loss Programmes in the UK: Initial Findings from the BBC “Diet Trials,”* 332 BRIT. MED. J. 1309 (2006).

148. See Xiaoming Li et al., *Short-Term Effect of a Cultural Adaptation of Voluntary Counseling and Testing Among Female Sex Workers in China: A Quasi-Experimental Trial*, 18 AIDS EDUC. & PREVENTION 406 (2006).

149. See Mary L. Kamb et al., *Efficacy of Risk-Reduction Counseling To Prevent Human Immunodeficiency Virus and Sexually Transmitted Diseases*, 280 JAMA 1161 (1998).

150. See Carol Roye, Paula Perlmutter Silverman & Beatrice Krauss, *A Brief, Low-Cost, Theory-Based Intervention To Promote Dual Method Use by Black and Latina Female Adolescents: A Randomized Clinical Trial*, 34 HEALTH EDUC. & BEHAV. 608 (2007).

151. See Beryl A. Koblin et al., *Effects of a Behavioural Intervention To Reduce Acquisition of HIV Infection Among Men Who Have Sex with Men: The EXPLORE Randomised Controlled Study*, 364 LANCET 41 (2004).

behaviors are in fact traveling from place to place (and from high-income to low-income settings), it may be a very good starting point to see if the same types of things that “work” in one area work in another. Third, this Note has already outlined how barriers to intervention transfer also *limit our knowledge* about program effectiveness in different settings. If we cannot try interventions in different places, we cannot speak definitively about whether they retain their effectiveness. Increasing the availability of program evaluations and materials will enable interventions to be evaluated in other settings, and if the criticism does indeed hold true—that is, if a program is non-transferable—then that will be valuable knowledge as well.

Finally, even if the wholesale transportation of programs to other settings is not viable, simply having a repository of behavior change strategies could well be valuable. The database may spur program adopters to use parts of other interventions, to adapt or evaluate their own, or to gauge how close their own interventions are to programs in other settings. If the database included a listing of program settings or a networking component that enabled different groups to contact one another, it could be even more useful for this purpose.

#### *D. Preserving Incentives for Innovation in Behavioral Interventions*

It is possible that making program materials available at a lower cost will diminish the incentives to create new or more precisely tailored programs. Potential program developers may worry about the loss of reputation or profits, while others might use program materials that are inappropriate for their setting without making adaptations or developing a more appropriate intervention.

Neither of these arguments is fully persuasive. To answer the first objection, many incentives remain for program developers beyond program reputation and profits. These include publication, career advancement, research funding, program funding in one’s own setting, and the renown that comes from developing a program that is recognized as effective. Those who develop effective behavior-change interventions are also motivated by genuine regard for health, and many of these developers would welcome broader dissemination of their interventions. Those who do want to sell their own programs for a profit might be more concerned; however, programs that are already sold for profit could opt out of databases of program materials. Total coverage is not necessary for this initiative to be valuable—even making *some* effective programs available for free would be a good start. To answer the second objection, it also seems unlikely that making existing programs available will hinder creative efforts entirely. Those who consider using a program in a new setting will almost always want to change *some* details, either to make the program a better fit for the new setting, or to foster community ownership of the intervention. Groups who wish to create programs out of whole cloth could also benefit from access to strategies that have proven effective in the past—a database of program materials may in

fact inspire creativity, enabling combinations of program components that would not have been identified otherwise.

*E. Concern that an Increased Focus on Behavioral Interventions May Distract Attention from Underlying Causes of Health Inequalities*

It is possible to challenge the entire premise of behavioral interventions, holding that behavior is socially constituted and depends on resources, education, environment, laws, and other factors that are often beyond individuals' control. Even perfectly healthy behaviors cannot guarantee disease prevention. It might be argued that emphasizing behavior change is therefore unrealistic, as it unduly "blames people" for their circumstances, and diverts attention and resources from efforts to change the social determinants of behavior and illness.

To be sure, some behavioral interventions may take an unfairly individualistic view of health behaviors or expect too much of participants. But this criticism does not apply to all interventions. We should not conflate the effects of interventions with access to effective interventions. When programs prove to be ineffective, then they should be discontinued. When programs are unrealistic, they should not be used. But some interventions do help people make better choices, and we should to maximize accessibility to those programs. Many interventions are specifically developed in light of the contextual determinants of health behaviors, and as we gain knowledge about the ways that context affects the choices we make, interventions may improve further.

It is also unpersuasive to argue that focusing on health behaviors is a distraction from the broader determinants of health inequalities. This argument has arisen before—for example, to argue that providing antiretroviral medication to people in low-income countries is inefficient or detracts from the larger project of reducing the inequalities that contribute to HIV risk.<sup>152</sup> It would be unethical to deny people downstream interventions simply because we want to focus on the upstream determinants of their problems. The provision of health behavior services is already widespread, and we have a duty to make those interventions as effective as possible.

Finally, we should be wary of undermining the agency of people in low-income settings. Behavioral choices are indeed influenced by social factors, but people choose among the options they have. Even among people who are constrained to engage in activities that are detrimental to health, it may be

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152. Dr. Paul Wise and Dr. James Orbinski have separately outlined the flaws of this argument in lectures at Yale. James J. Orbinski, Assoc. Professor of Med. & Political Sci., Univ. of Toronto, Guest Lecture in the Yale University Global Health Ethics, Politics, and Economics Course (Apr. 16, 2009); Paul H. Wise, Richard E. Behrman Professor of Child Health and Soc'y, Professor of Pediatrics, Stanford Univ., Guest Lecture in the Yale University Global Health Ethics, Politics, and Economics Course (Feb. 12, 2009).

## TRANSFERRING BEHAVIORAL INTERVENTIONS

possible to engage in these behaviors in ways that minimize those detrimental effects. Interventions that take this approach often fall under the category of harm-minimization, a concept common in HIV prevention programs. For example, interventions that encourage injection drug users to avoid using non-sterile injection equipment can minimize the health risks of injecting, even if intervention participants do not reduce drug use.<sup>153</sup> When we say that health behavior interventions are unrealistic and distracting, we walk a fine line between recognizing the real ways that context influences behavior, and denying outright the agency and capability of individuals in low-income settings.

## CONCLUSION

Health behaviors matter in global health, and they can exacerbate risk for both infectious and chronic diseases. Obesity, heart disease, diabetes, some cancers, sexually-transmitted infections, and many other conditions are in part related to modifiable behaviors. Although behavioral choices are constrained by contextual factors and constitute only one component of disease risk, improving health behaviors can have a beneficial effect on health outcomes.

Behavioral interventions, complex programs that can involve media and interpersonal components, are designed to help participants engage in healthier behaviors. Through the work of community groups, social and public health researchers, governments, and NGOs, we now know that although some of these programs are ineffective, many behavioral interventions can improve health behaviors and outcomes and retain their effectiveness in a variety of settings. Given the prevalence of health risk behaviors and increases in unhealthy lifestyles,<sup>154</sup> the transfer of effective behavioral interventions can improve global health. But there are information barriers, both formal and informal, that stop us from getting those interventions to people who could benefit from them. Although patents, trademarks, and trade secrecy protection are not particularly significant barriers to dissemination, copyrights and informal barriers are formidable. Transferring interventions requires access to information about program effects and program implementation, and much of that information is either copyrighted or inaccessible.

To lower these barriers, this Note proposes an initiative by the WHO to identify effective programs, to make evaluations accessible, and to make the actual program materials and manuals available online at no cost. This initiative should be supplemented by efforts to incentivize information-sharing among program developers, program adopters, and researchers—and these efforts would benefit from the participation of academic institutions, scholarly journals,

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153. See Alex Wodak & Leah McLeod, *The Role of Harm Reduction in Controlling HIV Among Injecting Drug Users*, 22 AIDS S81 (2009).

154. See, e.g., Frenk and Gómez-Dantés, *supra* note 30.

research and program funders, IRBs, national and local governments, and researchers and program developers themselves. If we can improve the dissemination of effective behavioral interventions, we may make a start toward reducing behavioral risks and the role they play in the global disease burden.

This argument and its proposed resolution have flaws. However, the central goal of this Note is to identify and respond to a gap in theory and knowledge. Given the salience of health behaviors in many global health problems, the formal and informal barriers inhibiting the dissemination of effective behavioral interventions should not go unquestioned. This Note aims to make a start towards that goal.