



2012

# Health Care Reform, Wellness Programs and the Erosion of Informed Consent

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## Recommended Citation

Lamkin, Matt (2012) "Health Care Reform, Wellness Programs and the Erosion of Informed Consent," *Kentucky Law Journal*: Vol. 101 : Iss. 3 , Article 2.

Available at: <https://uknowledge.uky.edu/klj/vol101/iss3/2>

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ARTICLES

## Health Care Reform, Wellness Programs and the Erosion of Informed Consent

*Matt Lamkin*<sup>1</sup>

### INTRODUCTION

IMAGINE you are recovering from breast cancer treatment. Over the past year, you have had a mastectomy followed by five months of chemotherapy. While the nausea and memory loss caused by your therapy have receded, you continue to suffer from fatigue and headaches. Your doctor recommends you take a drug called tamoxifen for the next five years to reduce the risk of your cancer recurring. You begin taking the drug but find that it causes extremely unpleasant side effects, including hot flashes, severe joint pain, and exacerbated fatigue. These side effects erode your ability to perform at work and to engage in the lives of your children. Having just endured the tribulations of surgery and chemotherapy, you conclude you would rather assume a higher risk of recurrence than suffer these side effects for the next five years. Your doctor has a different view. While she acknowledges that tamoxifen's side effects can be unpleasant, she insists taking the drug is crucial to protecting your long-term health.

Who should decide whether you continue to take tamoxifen? As a matter of medical ethics there is no question. Competent patients have the right to determine for themselves whether a drug's risks outweigh its potential benefits—a right embodied in the general requirement that patients voluntarily consent to any course of treatment.<sup>2</sup> But your situation is complicated by the health insurance offered by your employer. Last year your employer increased the deductible in its employee health plan from \$400 for family coverage to \$4,400.<sup>3</sup> You can reduce that deductible

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<sup>2</sup> See *Schloendorff v. Soc'y of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914) (Cardozo, J.) ("Every human being of adult years and sound mind has a right to determine what shall be done with his own body . . ."), *abrogated by* *Bing v. Thunig*, 143 N.E.2d 3 (N.Y. 1957); RUTH R. FADEN & TOM L. BEAUCHAMP, *A HISTORY AND THEORY OF INFORMED CONSENT* 8 (1986).

<sup>3</sup> David S. Hilzenrath, *Wellness Incentives Could Create Health-Care Loophole*, WASH. POST, October 16, 2009, at A01 (describing a wellness program implemented by a large auto parts

to the prior, lower amount by participating in your employer's "wellness program," which requires employees to meet the company's targets for cholesterol level, blood pressure, and body mass index.<sup>4</sup> Because your condition makes it unreasonably difficult for you to reach those targets, your employer has agreed to offer you the lower deductibles as long as you follow your doctor's treatment recommendations<sup>5</sup>—which include taking tamoxifen. In order for you to obtain the lower-cost insurance, your doctor must verify to the wellness program's administrator that you have complied with her recommendations.<sup>6</sup>

If you made significantly more money you would be willing to pay the increased deductible to forgo taking tamoxifen, but at your income you struggle to afford health insurance even at the lower rate. Accordingly, if you cannot persuade your doctor to change her recommendation, you face a choice between taking tamoxifen or losing access to affordable health insurance for your family. If you agree to take tamoxifen under these circumstances, is your consent voluntary? Should the law allow employers to impose such a choice on employees?

Proponents of tying employees' insurance rates to their health behaviors emphasize that individuals' decisions can impose hardships on others. An employee's health care costs are shared by fellow employees who are insured under their employer's health plan.<sup>7</sup> When an employee experiences expensive health problems that could have been avoided by taking medications, quitting smoking, or losing weight, all employees can expect their costs to rise.<sup>8</sup> To the extent employees' health behaviors drive up the cost of coverage, their actions can help push insurance out of reach for fellow employees.<sup>9</sup> Higher health insurance costs also undermine employers' competitiveness, which can cause them to pay lower salaries, lay off employees, or hire fewer people.<sup>10</sup> In recognition of how individuals'

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company).

4 *Id.*

5 See 29 C.F.R. § 2590.702(f)(3)(exs. 3-4) (2012) (endorsing wellness programs that accommodate sick employees by providing discounts in exchange for following their doctors' recommendations).

6 See BLUE CARE NETWORK OF MICH., HEALTHY BLUE LIVING: MEMBER GUIDE 1 (2011), <http://www.mibcn.com/pdf/member/hblMemberGuideBrochure.pdf> (describing the terms of a wellness program that requires employees' doctors to verify the employees' compliance with doctors' treatment plans).

7 See *Consumer Guide to Group Health Insurance*, NAT'L ASS'N OF HEALTH UNDERWRITERS, <http://nahu.org/consumer/GroupInsurance.cfm> (last visited Jan. 31, 2013).

8 *See id.*

9 See Katherine Baicker & Amitabh Chandra, *The Labor Market Effects of Rising Health Insurance Premiums*, 24 J. LAB. ECON. 609, 609-12 (2006).

10 *Id.*; Neeraj Sood et al., *Employer-Sponsored Insurance, Health Care Cost Growth, and the Economic Performance of U.S. Industries*, 44 HEALTH SERV. RES. 1449, 1457 (2009) ("[A] 10 percent increase in 'excess' growth in health care costs . . . would have resulted in 120,803 fewer

behaviors and medical decisions affect the health care costs of an entire pool, proponents argue wellness programs can not only improve health and drive down costs, but can promote fairness by rewarding employees who make responsible choices.

While the idea of reducing costs by improving health has enormous political appeal, recent enthusiasm for wellness programs has obscured how these programs can undermine the competing value of patient autonomy—the idea that decisions about the risks and benefits of medical interventions should be made by the people who have to live with an illness and the effects of any treatment.<sup>11</sup> By conditioning employees' access to affordable health insurance on their compliance with certain prescribed behaviors, wellness programs can threaten informed consent, patient privacy and, ironically, patient health itself. Accordingly, the laws governing wellness programs should be amended to strike a better balance between patient autonomy and responsible stewardship of health care resources.

This paper proceeds in four parts. Part I examines how rapidly escalating health care expenditures in the United States drive interest in strategies to reduce costs by improving health, including a growing interest in using financial incentives to motivate employees to make specific behavioral changes. Part II describes concerns raised by wellness programs, including the widely acknowledged risk of discrimination against sick and disabled people and the largely ignored potential for these programs to erode employee autonomy. Part III casts doubt on a key rationale supporting wellness programs—the idea that incursions on employee autonomy are justified because patients will benefit as a result. This section considers how wellness programs can harm patients by threatening their privacy, health, and self-determination. Part IV argues that while existing legal protections for employees in wellness programs protect against the potential for discrimination, they are ill-suited to address qualitatively different concerns about patient autonomy. This section offers specific recommendations to limit employers' ability to condition access to affordable health insurance on employees' compliance with wellness program requirements.

### I. THE HEALTH CARE COST CRISIS AND THE IMPETUS FOR WELLNESS STRATEGIES

The United States' exploding health care expenditures, and the poor value it receives in return, may be the preeminent domestic policy challenge of our time.<sup>12</sup> The U.S. spends far more on health care per capita

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jobs, US\$28,022 million in lost gross output, and US\$14,082 million in lost value added . . . in 2005.”).

11 FADEN & BEAUCHAMP, *supra* note 2.

12 See, e.g., *Obama Taps Daschle as 'Lead Architect' of Health Care Plan*, CNN (Dec. 11, 2008), [http://articles.cnn.com/2008-12-11/politics/transition.wrap\\_1\\_office-of-health-re-](http://articles.cnn.com/2008-12-11/politics/transition.wrap_1_office-of-health-re-)

than any other country, yet positive outcomes lag far behind countries that spend much less.<sup>13</sup> For state and federal governments, health care costs consume an ever-increasing share of tax dollars,<sup>14</sup> making fewer resources available for other important purposes—including preventive measures that might do more to promote public health than treating illnesses. Rising costs also undermine the competitiveness of U.S. businesses, making companies' products and services more expensive, hurting sales, and discouraging employers from hiring workers.<sup>15</sup> Even among people whose jobs offer health benefits, rising employee contributions can render insurance unaffordable.<sup>16</sup>

This crisis has spawned enormous interest in slowing the growth of health care spending but has produced little progress toward that goal. As shown by the political firestorm over “rationing” during the health care reform debate in 2010, cutting services is profoundly unpopular among voters.<sup>17</sup> Accordingly, preventive measures that could reduce demand for expensive health care services are highly attractive. In particular, many policymakers<sup>18</sup> and health care payers<sup>19</sup> see an opportunity to bend the cost curve by encouraging people to undertake healthful behaviors that can reduce the incidence of chronic diseases and better manage these illnesses.

Nearly half of all Americans suffer from one or more chronic illnesses, like diabetes, heart disease, and obesity.<sup>20</sup> Treating chronic diseases accounts for the vast majority of U.S. health care expenditures.<sup>21</sup> To some health care reformers this bad news is also the good news, in that there are well-established ways to reduce the disease burden from chronic illnesses—if we can motivate people to change certain behaviors. For example, obese

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form—health—care—employee—health—benefits—program (quoting former Sen. Tom Daschle arguing that “fixing health care is and has been for many years our largest domestic policy challenge”).

13 See INST. OF MED. OF THE NAT'L ACAD., *THE HEALTHCARE IMPERATIVE: LOWERING COSTS AND IMPROVING OUTCOMES* 5–6 (Peirre L. Yong et al. eds., 2010).

14 See *id.* at 5.

15 Baicker & Chandra, *supra* note 9, at 610; Sood et al., *supra* note 10.

16 See Jon R. Gabel et al., *Trends in Underinsurance and the Affordability of Employer Coverage, 2004–2007*, 28 HEALTH AFF. W595, W595 (2009).

17 Edward J. Larson, *Medical Rationing, Death Panels and the Rising Cost of Health Care: Whittier Law School Health Law Symposium Paper*, 33 WHITTIER L. REV. 13, 13–15 (2011).

18 David S. Hilzenrath, *A Success Story That Isn't Shapes Health-Care Debate*, WASH. POST, Jan. 17, 2010, [http://articles.washingtonpost.com/2010-01-17/business/36834314\\_1\\_burd-health-care-costs-health-care-costs](http://articles.washingtonpost.com/2010-01-17/business/36834314_1_burd-health-care-costs-health-care-costs).

19 AON HEWITT, 2011 HEALTH CARE SURVEY, 34 (2011), available at <http://insight.aon.com/?elqPURLPage=5259>.

20 GERARD ANDERSON, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH, *CHRONIC CARE: MAKING THE CASE FOR ONGOING CARE*, 4–5 (2010), available at <http://www.rwjf.org/content/dam/web-assets/2010/01/chronic-care>.

21 *Id.* at 14.

people are at an increased risk of developing type 2 diabetes, numerous cardiovascular diseases, asthma, osteoarthritis, and many types of cancer.<sup>22</sup> Similarly, cigarette smoking increases individuals' risk of high blood pressure, heart disease, diabetes, various pulmonary diseases, and several cancers.<sup>23</sup> Since smoking and obesity are significant drivers of health care costs,<sup>24</sup> getting people to quit smoking or to lose weight could dramatically reduce health care expenditures.

As for people who already suffer from chronic illnesses, there is evidence that some simple interventions may help patients better manage these conditions and minimize the risk of expensive and debilitating complications.<sup>25</sup> Because at least half of all people with chronic illnesses fail to adhere to their doctors' prescriptions,<sup>26</sup> many policymakers see a significant opportunity to reduce health care costs by encouraging patients to take their medications as prescribed.

The potential to reduce health care costs by improving health—and the popularity of this approach among voters—has attracted the interest of Congress.<sup>27</sup> The Patient Protection and Affordable Care Act of 2010 (the “ACA”)<sup>28</sup> expands on provisions in the Health Insurance Portability

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22 Daphne P. Guh et al., *The Incidence of Co-Morbidities Related to Obesity and Overweight: A Systematic Review and Meta-Analysis*, 9 BMC PUB. HEALTH 88 (2009), at 1, available at <http://www.biomedcentral.com/1471-2458/9/88>.

23 See, e.g., *CDC Fact Sheet – Tobacco-Related Mortality – Smoking & Tobacco Use*, [http://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/health\\_effects/tobacco\\_related\\_mortality/](http://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/tobacco_related_mortality/) (last updated Mar. 21, 2011).

24 See, e.g., Kristin M. Madison et al., *The Law, Policy, and Ethics of Employers' Use of Financial Incentives to Improve Health*, 39 J.L. MED. & ETHICS 450, 450 (2011). The authors state:

By one estimate, [obesity] is responsible for almost 10 percent of medical spending in the United States, or about \$1.47 billion per year. Smoking increases the risk of heart disease, stroke, lung disease, and cancer; it accounts for nearly 20 percent of deaths each year in the United States and about \$96 billion in health care expenditures.

*Id.*

25 NAT'L CTR. FOR CHRONIC DISEASE PREVENTION & HEALTH PROMOTION, *THE POWER OF PREVENTION*, 8–9 (2009), available at [www.cdc.gov/chronicdisease/pdf/2009-Power-of-Prevention.pdf](http://www.cdc.gov/chronicdisease/pdf/2009-Power-of-Prevention.pdf).

26 EDUARDO SABATÉ, WORLD HEALTH ORG., *ADHERENCE TO LONG-TERM THERAPIES: EVIDENCE FOR ACTION 7* (2003) (finding that half of patients with chronic diseases do not take their medications as prescribed); see also Laura Landro, *The Pharmacist Is In and Nudging You to Take Your Pills*, WALL ST. J., June 26, 2012, at D1 (“Studies show only 25% to 30% of medications are taken properly, and only 15% to 20% are refilled as prescribed.”).

27 See, e.g., Jordan Rau, *Poll: Many Employees Don't Want Changes in Their Health Insurance*, PBS NEWSHOUR (August 30, 2011, 2:53 PM), <http://www.pbs.org/newshour/rundown/2011/08/poll-employees-dont-want-changes-in-their-health-insurance.html> (sixty-eight percent of surveyed employees supported wellness programs as a method of reducing health insurance costs).

28 Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (to be codified in scattered sections of 42 U.S.C.).

and Accountability Act of 1996 (“HIPAA”)<sup>29</sup> that allow companies to offer employees incentives to meet health targets, subject to certain restrictions designed to prevent discrimination against sick people. The ACA increased the size of incentives that are permitted by fifty percent, in the hope that larger incentives would better motivate employees to change health behaviors.<sup>30</sup>

A growing number of health care payers—including employers, insurers, and state Medicaid programs—are taking advantage of these provisions.<sup>31</sup> Aon Hewitt’s annual survey of more than 1000 employers offering health benefits found that in 2011 nearly eighty percent of these companies were seeking to encourage employees to take responsibility for their health “by offering tools (e.g., health risk assessment, biometric testing) to raise participants’ awareness of their health status and risks . . . .”<sup>32</sup> But many employers have found this type of “voluntary”<sup>33</sup> program ineffective at motivating employees to adopt healthier behaviors.<sup>34</sup> Accordingly, employers have shown an increasing interest in programs that use financial incentives to motivate employees to change their behavior.<sup>35</sup> In the Aon

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29 Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104–191, 110 Stat. 1936 (1996) (codified as amended in scattered U.S.C. sections).

30 Patient Protection and Affordable Care Act, Pub. L. No. 111–148, § 10408, 124 Stat. 119, 977–78 (2010) (to be codified at 42 U.S.C. § 247b–9g). The ACA also includes other provisions designed to encourage the proliferation of wellness programs, including appropriating \$200 million for grants to small businesses that implement wellness programs that include “mechanisms to encourage employee participation” and “initiatives to change unhealthy behaviors and lifestyle choices.” *Id.* In addition, the ACA instructs the CDC to provide technical assistance to help employers evaluate their wellness programs, including the effectiveness of “methods to increase participation of employees in such programs” and the effects of these programs on employees’ health status, productivity, and medical costs. *Id.* § 4303, at 582–83 (to be codified at 42 U.S.C. § 280f). The ACA also directs the Secretary of Health and Human Services to establish a demonstration project in which ten States will apply the Act’s wellness provisions to insurers offering health insurance in the individual market. *Id.* § 10504, at 1004–05 (to be codified at 42 U.S.C. § 256).

31 Notably, the Affordable Care Act bars the federal government from implementing wellness programs for federal employees. Patient Protection and Affordable Care Act, Pub. L. No. 111–148, § 4303, 124 Stat. 119, 582–84 (2010) (to be codified at 42 U.S.C. § 280l–3) (entitled “Prohibition of Federal Workplace Wellness Requirements”).

32 AON HEWITT, 2011 HEALTH CARE SURVEY, 34 (2011), available at <http://insight.aon.com/?elqPURLPage=5259>.

33 “A wellness program is ‘voluntary’ as long as an employer neither requires participation nor penalizes employees who do not participate.” EEOC, *Enforcement Guidance: Disability-Related Inquiries and Medical Examinations of Employees Under the Americans with Disabilities Act (ADA)* (July 27, 2000), <http://www.eeoc.gov/policy/docs/guidance-inquiries.html>.

34 Ann Hendrix & Joshua Buck, *Employer-Sponsored Wellness Programs: Should Your Employer Be The Boss of More Than Your Work?*, 38 Sw. L. REV. 465, 469 (2009).

35 See, e.g., Mike Colias, *Obese Police: Firms Force Workers to Slim Down*, CRAIN’S CHI. BUS. (Feb. 26, 2007), <http://www.chicagobusiness.com/article/20070226/NEWS/200023993>.

Hewitt survey, eighty-six percent of employers indicated they plan to implement incentive programs within the next three to five years.<sup>36</sup>

Employers use wellness incentives in several ways. Some offer employees a one-time cash payment in exchange for getting a health evaluation that can help them identify potential problems before they materialize.<sup>37</sup> Others eliminate co-pays for certain drugs to ensure that patients are not deterred from taking medications because of their cost.<sup>38</sup> An increasingly popular approach involves tying financial incentives to employees' compliance with specific health requirements.<sup>39</sup> For example, some companies offer health plans that tie employees' health insurance contributions (such as premiums and deductibles) to their achievement of particular health outcomes, such as reaching a certain cholesterol count or body mass index.<sup>40</sup> Some programs frame these incentives as "rewards" in the form of discounts for employees who meet the targets, while others frame them as penalties (i.e., higher contributions) imposed on those who fail to meet the targets.<sup>41</sup> In either case, the result is that employees who do not meet the targets pay more for health insurance.<sup>42</sup>

Other programs tie incentives not to health outcomes but to undertaking certain activities, such as walking a certain amount each week or attending "disease management" programs that educate employees about managing

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36 AON HEWITT, *supra* note 32, at 37.

37 Francine Knowles, *Bosses to Employees: Shape Up or Pay Up*, CHI. SUN TIMES, <http://www.suntimes.com/news/metro/6859055-418/bosses-to-employees-shape-up-or-pay-up.html> (last updated Nov. 16, 2011).

38 For additional discussion of this approach, often referred to as "Value-Based Benefit Design" (VBBD) or "Value-Based Insurance Design" (VID), see SPENCER S. JONES ET AL., RAND CORP., *POWER TO THE PEOPLE: THE ROLE OF CONSUMER-CONTROLLED PERSONAL HEALTH MANAGEMENT SYSTEMS IN THE EVOLUTION OF EMPLOYER-BASED HEALTH CARE BENEFITS*, 10–11 (2011), [http://www.rand.org/content/dam/rand/pubs/occasional\\_papers/2011/RAND\\_OP352.pdf](http://www.rand.org/content/dam/rand/pubs/occasional_papers/2011/RAND_OP352.pdf); Lucinda Jesson, *Weighing the Wellness Programs: The Legal Implications of Imposing Personal Responsibility Obligations*, 15 VA. J. SOC. POL'Y & L. 217, 226 (2008).

39 See, e.g., AON HEWITT, *supra* note 32, at 42 ("Monetary incentives used to promote participation in health improvement/wellness programs increased 22 percentage points from 37% in 2010 to 59% in 2011, and employers offering monetary incentives for disease/condition management program participation almost tripled, increasing by 37 percentage points from 2010 to 2011."); Madison et al., *supra* note 24, at 451 ("[T]he prevalence of these programs will increase rapidly; for example, about 40% of employers report an intention to implement biometric outcome incentives in 2011 or later."). States are also increasingly taking this approach, with more than half of all state Medicaid agencies considering using financial incentives to promote healthy behaviors. JESSICA GREENE, CTR. FOR HEALTH CARE STRATEGIES, INC., *STATE APPROACHES TO CONSUMER DIRECTION IN MEDICAID* (2007), [http://www.chcs.org/usr\\_doc/State\\_Approaches\\_to\\_Consumer\\_Direction.pdf](http://www.chcs.org/usr_doc/State_Approaches_to_Consumer_Direction.pdf).

40 Jesson, *supra* note 38, at 229.

41 AON HEWITT, *supra* note 32, at 37–38; Madison et al., *supra* note 24, at 458.

42 AON HEWITT, *supra* note 32, at 44 ("Virtually any targeted reward can be framed as either a penalty or an incentive.")



chronic illnesses.<sup>43</sup> One activity of particular interest is getting employees with chronic illnesses to “comply”<sup>44</sup> with their doctors’ recommendations—in particular, taking their medications as prescribed.<sup>45</sup> Medication noncompliance can cause patients with chronic diseases to experience acute complications that can be immensely expensive to treat. For example, some evidence suggests mortality rates for noncompliant patients with heart disease and diabetes are nearly double the rates for compliant patients.<sup>46</sup> By one estimate, the cumulative annual cost of medication noncompliance in the United States is \$290 billion, or approximately thirteen percent of total health care expenditures.<sup>47</sup>

Yet despite the dangers of noncompliance, about half of all patients with chronic illnesses do not take their medications as prescribed.<sup>48</sup> Accordingly, employers are showing increasing interest in using monetary incentives to motivate employees with chronic illnesses to better manage their diseases. Aon Hewitt’s survey revealed that the number of employers tying monetary incentives to participation in disease management programs roughly tripled from 2010 to 2011, rising from seventeen to fifty-four percent in a single year.<sup>49</sup> A 2009 survey found that thirteen percent of employers—more than one in eight—went further, tying incentives directly to employees’ medication compliance.<sup>50</sup>

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43 *Id.* at 42.

44 Lars Sandman et al., *Adherence, Shared Decision-Making and Patient Autonomy*, 15 MED. HEALTH CARE & PHIL. 115, 115 (2012), <http://www.springerlink.com/content/p420410823746627/> (defining “compliance” as “the extent to which a person’s behaviour . . . coincides with medical or health advice”).

45 CHUCK REYNOLDS & DANA MARTIN, NAT’L PHARM. COUNCIL, EMPLOYER MEDICATION COMPLIANCE INITIATIVES: EXECUTIVE SUMMARY I (2009), [http://www.npcnow.org/App\\_Themes/Public/pdf/Issues/pub\\_health\\_prod/CompliSurveyCover\\_Web\\_01-19-10.pdf](http://www.npcnow.org/App_Themes/Public/pdf/Issues/pub_health_prod/CompliSurveyCover_Web_01-19-10.pdf) (finding that eighty-nine percent of surveyed employers rated medication compliance as a top health management priority).

46 P. Michael Ho et al., *Adherence to Cardioprotective Medications and Mortality Among Patients with Diabetes and Ischemic Heart Disease*, 6 BMC CARDIOVASCULAR DISORDERS 48, Dec. 15, 2006, at 4. *But cf.*, The Coronary Drug Project Research Group, *Influence of Adherence to Treatment and Response of Cholesterol on Mortality in the Coronary Drug Project*, 303 NEW ENG. J. MED. 1038, 1039 (1980) (finding that compliance with placebo lowered mortality risks associated with coronary artery disease as much as compliance with lipid-influencing treatments).

47 NEW ENGLAND HEALTH INST., THINKING OUTSIDE THE PILLBOX: A SYSTEM-WIDE APPROACH TO IMPROVING PATIENT MEDICATION ADHERENCE FOR CHRONIC DISEASE (2009), [http://www.nehi.net/publications/44/thinking\\_outside\\_the\\_pillbox\\_a\\_systemwide\\_approach\\_to\\_improving\\_patient\\_medication\\_adherence\\_for\\_chronic\\_disease](http://www.nehi.net/publications/44/thinking_outside_the_pillbox_a_systemwide_approach_to_improving_patient_medication_adherence_for_chronic_disease). While NEHI’s estimate is widely cited in the press, there is some reason for skepticism. It should be noted that several of NEHI’s members are pharmaceutical companies for whom increasing patient compliance, and thereby boosting drug sales, is a top priority.

48 SABATÉ, *supra* note 26, at 7.

49 AON HEWITT, *supra* note 32, at 42 (graphing monetary incentive trends).

50 REYNOLDS & MARTIN, *supra* note 45, at 4. For examples of programs that tie incentives to medication compliance, see *infra* Part II.B.2.

Wellness advocates contend these programs support the value of fairness, arguing that it is unfair to allow people who make poor health decisions to increase insurance costs for others who have made more responsible choices. One prominent advocate of this view, Safeway CEO Steven Burd,<sup>51</sup> has analogized health care coverage to car insurance, noting that auto insurance companies charge higher premiums for drivers who have frequent accidents or speeding tickets.<sup>52</sup> Mr. Burd argues fairness similarly requires levying higher health insurance contributions on employees who make poor health choices, in order to avoid penalizing their more responsible peers.<sup>53</sup>

Wellness proponents also claim that using incentives to encourage healthful behaviors promotes responsible stewardship of scarce healthcare resources and benefits employees by improving their health. Treating illnesses that could have been prevented through behavioral changes—at substantially lower cost—wastes precious resources.<sup>54</sup> When preventable illnesses drive up the cost of insuring a pool of employees, employees may face increased health care costs and employers may reduce salaries and employ fewer workers.<sup>55</sup> Reducing the costs of insuring employees by improving their health, rather than by cutting services, is a laudable goal.<sup>56</sup>

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51 During the 2010 health care reform debate, Safeway CEO Steven Burd advanced the fairness argument so successfully in his Congressional testimony that the resulting wellness provisions in the Affordable Care Act are often referred to as the “Safeway amendment.” David S. Hilzenrath, *A Success Story That Isn't Shaping Health-Care Debate; Blood Tests and Weigh-Ins: Misleading Claims Drive 'Safeway Amendment'*, WASH. POST, Jan. 17, 2010, at G1.

52 Steven A. Burd, *How Safeway Is Cutting Health-Care Costs*, WALL ST. J, June 12, 2009, at A15.

53 *Id.*

54 *See, e.g.*, Madison et al., *supra* note 24, at 455 (citing studies indicating adult smokers incur \$1623 more in medical spending per year than non-smokers, and the medical costs of obese working-age individuals are more than thirty-five percent higher than their non-obese counterparts).

55 *See, e.g.*, Baicker & Chandra, *supra* note 9; Sood et al., *supra* note 10, at 1450; Reed Abelson, *Survey: Employers Pass on More Health Costs to Workers*, N.Y. TIMES BLOG (Sept. 2, 2010, 11:00AM), <http://prescriptions.blogs.nytimes.com/2010/09/02/survey-employers-pass-on-more-health-costs-to-workers/>.

56 However, to date there is little evidence demonstrating that the use of incentives does change employees' behavior or improve their health. *See, e.g.*, Kevin G. Volpp et al., *Redesigning Employee Health Incentives—Lessons from Behavioral Economics*, 365 NEW ENG. J. MED. 388, 388 (2011). The authors state that

[a]lthough it may seem obvious that charging higher premiums for smoking (or high body-mass index, cholesterol, or blood pressure) would encourage people to modify their habits to lower their premiums, evidence that differential premiums change health-related behavior is scant. Indeed, we're unaware of any health insurance data that have convincingly demonstrated such effects.

*Id.* Moreover, there are other possible ways of reducing costs without compromising health, including improving the efficiency of the health care system and the quality of medical care.

## II. CONCERNS

While the enthusiasm for wellness strategies is understandable, these programs also carry costs, many of which are difficult to measure. As described below, incentive-based wellness programs can undermine longstanding protections designed to promote ethical allocation and delivery of health care services.

### A. *Discrimination Against Sick and Disabled People*

The concern that has received the most attention is the potential for these programs to discriminate against sick or disabled people.<sup>57</sup> The principle of personal responsibility that underlies the fairness argument is in tension with the value of social solidarity, which “embodies goals of mutual aid and support.”<sup>58</sup> Social solidarity animates legislation such as the Americans with Disabilities Act, which prohibits discrimination on the basis of disability;<sup>59</sup> HIPAA provisions that bar group health plans from discriminating against people on the basis of their health status;<sup>60</sup> and provisions in the ACA that bar insurers from discriminating on the basis of preexisting conditions.<sup>61</sup>

Given the central importance of health in people’s lives, many people recognize a societal obligation to ensure access to adequate health care, regardless of individuals’ ability to pay.<sup>62</sup> Making health care accessible to every American was a major goal of the 2010 health care reform effort that produced the Affordable Care Act.<sup>63</sup> To the extent wellness programs

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57 See, e.g., Jesson, *supra* note 38, at 300–01; Amy Monahan & Daniel Schwarcz, *Will Employers Undermine Health Care Reform by Dumping Sick Employees?*, 97 VA. L. REV. 125 (2011); Thomas J. Parisi, *The Onus Is on You: Wellness Plans and Other Strategies Being Employed for Patients to Take Ownership of Their Health*, 13 QUINNIPIAC HEALTH L.J. 243, 263 (2010); Jennifer Dianne Thomas, *Mandatory Wellness Programs: A Plan to Reduce Health Care Costs or a Subterfuge to Discriminate Against Overweight Employees?*, 53 HOW. L.J. 513, 513–15 (2010); Harald Schmidt et al., *Carrots, Sticks, and Health Care Reform—Problems with Wellness Initiatives*, 362 NEW ENG. J. MED., at e3(1) (Jan. 14, 2010), <http://www.nejm.org/doi/pdf/10.1056/NEJMp0911552>.

58 Wendy K. Mariner, *Social Solidarity and Personal Responsibility in Health Reform*, 14 CONN. INS. L.J. 199, 205 (2008).

59 Americans with Disabilities Act of 1990, Pub. L. No. 101–336, 104 Stat. 327 (codified as amended in scattered sections of 42 U.S.C.); Mariner, *supra* note 58, at 206.

60 29 U.S.C. § 1182 (2006); Mariner, *supra* note 58, at 206. HIPAA’s wellness provisions are an exception to the general rule against this kind of discrimination. See *infra* Part IV.A.

61 Patient Protection and Affordable Care Act, Pub. L. No. 111–148, § 1101, 124 Stat. 119 (2010) (to be codified at 42 U.S.C. § 18001) (entitled “Immediate Access to Insurance for Uninsured Individuals with a Preexisting Condition”).

62 Mariner, *supra* note 58, at 202. See generally NORMAN DANIELS, JUST HEALTH CARE (1985).

63 See, e.g., Sheryl Gay Stolberg & David M. Herszenhorn, *Obama Lays Out His Health Plan*, N.Y. TIMES, Feb. 23, 2010, at A1.

increase health insurance costs for sick employees, they work against this objective.<sup>64</sup>

It is easy to see how tying incentives to employees' health behaviors or particular health outcomes could discriminate against sick employees. For example, an employer could offer two types of insurance: a standard plan with high employee contributions and basic benefits and an "enhanced" plan with low contributions and more generous benefits. Every employee would default to the standard plan but could qualify for the enhanced plan by achieving certain blood pressure and cholesterol levels. Since some employees suffering from chronic illnesses may not be able to meet these goals under any conditions—and, indeed, it may be dangerous for them to attempt to do so—this arrangement would discriminate against sick people by charging them higher insurance rates. Moreover, this arrangement could produce backdoor employment discrimination by dissuading people with chronic illnesses from seeking work at this company, particularly if the "standard" health plan were not affordable.<sup>65</sup> As described below, Congress has enacted a set of legal protections to guard against this kind of discrimination.<sup>66</sup>

### B. Patient Autonomy

While the potential for wellness programs to discriminate has been widely recognized in the literature and in the laws governing group health insurance,<sup>67</sup> these programs also raise a different kind of concern that has received scant consideration: a threat to patient autonomy. Unlike concerns about discrimination, which stress the unfairness of punishing people who cannot achieve certain health outcomes no matter how hard they try,<sup>68</sup> autonomy concerns emphasize protecting individuals' ability to make their own choices about their bodies and medical care.

1. *Medical Ethics Require Voluntary Consent to Treatment.*—Respect for patient autonomy is a core principle of modern medical ethics.<sup>69</sup> It underlies the

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64 Volpp et al., *supra* note 56, at 389 (“[e]nabling employers to vary premiums on the basis of employees’ health-related behaviors or health outcomes could undermine some of the ACA’s intended benefits,” including “spread[ing] the costs of addressing health risks across the population and . . . discourag[ing] insurers from trying to enroll only the healthiest (and lowest-cost) individuals”).

65 See Madison et al., *supra* note 24, at 456.

66 See *infra* Part IV.A.

67 See *supra* note 57 and *infra* Part IV.A, respectively.

68 Volpp et al., *supra* note 56, at 389 (noting that under a pure “personal accountability” model “many people would end up paying higher premiums for behaviors and outcomes that may not be completely under their control”).

69 See, e.g., TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* 99 (6th ed. 2009); NAT’L COMM’N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL AND

legal and ethical requirement that, with very limited exceptions, medical treatment may not be administered to competent individuals without their informed consent.<sup>70</sup> Informed consent protects the right to self-determination by ensuring that patients understand the risks and benefits of medical interventions and voluntarily consent to them or refuse them.<sup>71</sup>

Voluntariness requires that a patient's consent to a course of treatment is freely chosen rather than the product of controlling influences exerted by others.<sup>72</sup> While a patient's decision regarding a medical intervention may be influenced by many external factors, including reasoned persuasion about the treatment's benefits, the patient remains autonomous as long as he or she "freely accept[s]—as his or her own—the beliefs, attitudes, values, intentions, or actions advocated by the persuader."<sup>73</sup>

However, an individual's voluntary consent is undermined to the extent her decision is substantially *controlled* by influences exerted by others. In the extreme case, a patient can be coerced into "consenting" to a treatment if another party presents "a credible threat of unwanted and avoidable harm so severe that the person is unable to resist acting to avoid it."<sup>74</sup> "Your money or your life" is an example of an influence that would fully control an individual's decision because the influence cannot reasonably be resisted.

Other forms of influence that do not reach the level of coercion can still undermine patients' autonomy. In their seminal treatise on informed consent, Ruth Faden and Tom Beauchamp argue that an influence impairs voluntariness to the extent an individual finds the influence difficult to resist.<sup>75</sup> In this view it is not only threats of harm that can undermine voluntariness but also offers of rewards that an individual finds unwelcome but difficult to decline. Thus, in the context of conducting research on human subjects, the Council for International Organizations of Medical Sciences admonishes that "[p]ayments in money or in kind to research

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BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH 4 (1979), available at [http://www.fda.gov/ohrtms/dockets/ac/05/briefing/2005-4178b\\_09\\_02\\_Belmont%20Report.pdf](http://www.fda.gov/ohrtms/dockets/ac/05/briefing/2005-4178b_09_02_Belmont%20Report.pdf) [hereinafter THE BELMONT REPORT].

<sup>70</sup> *Schloendorff v. Soc'y of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914), Cardozo, J. ("Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages."); BEAUCHAMP & CHILDRESS, *supra* note 69, at 118 ("the primary justification advanced for requirements of informed consent has been to protect autonomous choice.").

<sup>71</sup> See, e.g., THE BELMONT REPORT, *supra* note 69, at 4.

<sup>72</sup> FADEN & BEAUCHAMP, *supra* note 2, at 256.

<sup>73</sup> *Id.* at 261–62.

<sup>74</sup> *Id.* at 339.

<sup>75</sup> *Id.* at 256–58. However, as discussed *infra* Part II.B.3, others argue that an individual's subjective ability to resist an influence is not an appropriate standard for assessing voluntariness.

subjects should not be so large as to persuade them to take undue risks or volunteer against their better judgment,” noting that “[p]ayments or rewards that undermine a person’s capacity to exercise free choice invalidate consent.”<sup>76</sup>

To illustrate the potential for unwelcome offers to undermine autonomy, Faden and Beauchamp offer the example of Mary, a financially desperate woman. Researchers offer Mary \$25 per day in exchange for her participation in research involving repeated, “painful and invasive medical procedures.”<sup>77</sup> Mary is terrified of participating in the research, but badly needs money. “Mary wishes desperately that she had never received such an offer because once it is made, she feels she must accept, whereas beforehand she would never have been faced with such a tragic ‘choice.’”<sup>78</sup> In Faden and Beauchamp’s view, Mary’s consent is no longer substantially under her control; her desperation and the researcher’s offer place her substantially under the researcher’s control.<sup>79</sup>

Thus, while it is important to protect the right of patients to make their own choices regarding medical interventions, many ethicists argue there are some choices people should not have to make. This seems to be the view motivating laws restricting the sale of human organs<sup>80</sup> and regulations governing the treatment of participants in medical research.<sup>81</sup> From a libertarian perspective, if a person values a certain amount of money more than he values his kidney, he should be free to sell it. Similarly, a laissez-faire approach to medical research would allow researchers to recruit participants for extremely risky experiments by offering very large incentives to people who badly need the money, just as employers may offer large salaries in exchange for dangerous work. When it comes to medical interventions, however, many are troubled by the prospect of treating decisions about one’s body like other market transactions.<sup>82</sup> Accordingly,

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76 COUNCIL FOR INT’L ORGS OF MED. SCIS, INTERNATIONAL ETHICAL GUIDELINES OF BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS 46 (2002), Guideline 7, available at [http://www.cioms.ch/publications/layout\\_guide2002.pdf](http://www.cioms.ch/publications/layout_guide2002.pdf). Note, however, that there are important differences between the research and clinical contexts, some of which are discussed *infra* Part II.B.3.

77 FADEN & BEAUCHAMP, note 2, at 358.

78 *Id.* at 358–59.

79 *Id.* at 359. However, as described *infra* Part II.B.3, this view is not universally accepted.

80 National Organ Transplant Act, Pub. L. No. 98–507, 98 Stat. 2339 (1984) (codified as amended at 42 U.S.C. § 273–274 (2006)).

81 See 45 C.F.R. §46 subpart A (2011).

82 See, e.g., Cynthia B. Cohen, *Selling Bits and Pieces of Humans to Make Babies: The Gift of the Magi Revisited*, 24 J. MED. PHILOS. 288, 292 (1999) (“Human beings . . . are of incomparable ethical worth and admit of no equivalent. Each has value that is beyond the contingencies of supply and demand or of any other relative estimation. They are priceless. Consequently, to sell an integral human body part is to corrupt the very meaning of human dignity.”); Margaret Jane Radin, *Market-Inalienability*, 100 HARV. L. REV. 1849, 1881 (1987) (“We feel discomfort or even insult, and we fear degradation or even loss of the value involved when bodily integrity

the federal government has enacted rules that limit the use of incentives to motivate people to undergo medical interventions.

Whether a wellness program undermines patient autonomy depends in large part on the extent to which the program threatens employees with serious harm for failing to comply or otherwise unduly influences employees to comply. As described in the next section, the use of financial incentives in wellness programs raises the prospect that employers can make penalties for noncompliance so large that many employees have little choice but to undergo prescribed treatments.

*2. How Wellness Programs Can Threaten Voluntary Consent.*—There is nothing inherently wrong with using incentives to influence behavior. Indeed the essence of a market economy is to offer incentives for others to provide us goods and services they otherwise would not provide. Moreover, the behaviors promoted by wellness programs seem benign. They tend to involve doctors' standard litany of eating less, exercising more, and quitting smoking—things we tend to think everyone wants to do, but often need some motivational help to achieve. But in the context of medical interventions, pressuring employees to undertake certain behaviors can conflict with the ethical requirement that patients voluntarily consent to treatment.

One reason the implications of wellness programs for patient autonomy have gone largely unnoticed may be because many common wellness interventions—like requirements to quit smoking or exercise more—do not sound like the kinds of medical treatments with which we typically associate the requirement of informed consent. But wellness program incentives can also extend to patients' decisions regarding whether to take prescribed medications—a paradigmatic example of the kind of medical decisions that require patients' voluntary consent.

While many people struggle to take their medications as prescribed, other noncompliant patients do not take their drugs because they do not want to. According to one study, about one third of noncompliant patients refuse to take their medications because they do not believe they need the drugs or do not like their side effects.<sup>83</sup> Other reasons patients cite for refusing to take their medications include feeling that “the medication interfered with their personal priorities [or] social life” or that the drugs made them “perceive themselves negatively.”<sup>84</sup> The purpose of tying

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is conceived of as a fungible object.”).

83 Bos. CONSULTING GRP., *THE HIDDEN EPIDEMIC: FINDING A CURE FOR UNFILLED PRESCRIPTIONS AND MISSED DOSES 1* (2003), <http://www.bcg.com/documents/file14265.pdf>.

84 Charlotte Huff, *Employers Bolster Medication Adherence Initiatives*, WORKFORCE (July 20, 2010), <http://www.workforce.com/article/20100720/NEWS02/307209995/employers-bolster-medication-adherence-initiatives>.

incentives to medication compliance is to pressure these people, who do not want to take the drugs prescribed by their doctors, to take them anyway.

The extent to which that pressure undermines patients' informed consent depends in large part on the size of the "incentives" at issue. A \$25 gift card at Starbucks seems fine, but it also seems unlikely to motivate employees to change their health behaviors in any meaningful way.<sup>85</sup> Accordingly, employers are showing an increasing appetite for using larger incentives that make access to lower-cost health insurance contingent on employees' compliance with particular requirements.<sup>86</sup> Aon Hewitt's chief medical officer, Dr. Paul Berger, explains that increasingly employers are saying, "We want you to take some responsibility, and if you don't do certain things we want you to do, you'll only be eligible for the bad [health insurance] plan with a \$3,000 deductible as opposed to the \$1,000 deductible. . . . That gets your attention."<sup>87</sup>

Blue Care Network of Michigan has taken this approach in offering employers a group health plan called "Healthy Blue Living."<sup>88</sup> Every insured employee starts out in a plan with "enhanced" (i.e., more generous) benefits and lower copayments and deductibles.<sup>89</sup> To continue to receive the enhanced benefits and lower payments beyond the first ninety days of coverage, employees and their spouses must follow their primary care physicians' treatment plans.<sup>90</sup> Blue Care Network monitors the compliance of employees and their spouses by requiring their physicians to complete a questionnaire affirming that the patients are following the doctor's plan.<sup>91</sup> If an employee's physician will not confirm her compliance with the

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85 Stephen Miller, *Wellness Programs Get a Boost in Health Care Reform Law*, SOC'Y FOR HUMAN RES. MGMT. (Mar. 25, 2010), <http://www.shrm.org/Publications/HRNews/Pages/WellnessReformBoast.aspx> (quoting Thom Mangan, CEO of health insurance consultancy Corporate Synergies, arguing that "[t]he effectiveness of financial incentives is closely tied to the amount you provide").

86 See Joseph Marlowe et al., *Complex Chronic Illness: An Essential Target in Health Cost Management*, *WORLDATWORK J.*, Third Quarter 2009 at 47, 51–52, available at [http://www.aon.com/about-aon/intellectual-capital/attachments/human-capital consulting/Client\\_Symposium\\_ChronicIllness\\_2.pdf](http://www.aon.com/about-aon/intellectual-capital/attachments/human-capital consulting/Client_Symposium_ChronicIllness_2.pdf). The authors note:

Aon Consulting has advised several clients on a new approach to incentives that is predicated on the proposition that a comprehensive, low-cost health plan should not be viewed by employees as an entitlement. Rather, employees would earn the right to enroll in a health plan with lower contributions by completing a health risk assessment, enrolling in health-behavior change programs where needed and participating in condition management to address chronic illness. The lower-value plan forced on those who are not compliant with the wellness message might have higher contributions, a large deductible and/or may lack coverage for certain services.

*Id.*

87 Knowles, *supra* note 37.

88 See BLUE CARE NETWORK OF MICH., *supra* note 6.

89 *Id.* at 1.

90 *Id.* at 2–3.

91 *Id.* at 3.



treatment plan, the employee must pay higher insurance contributions and will lose certain benefits.

A company called BeniComp Advantage sells a plan that similarly ties employees' health insurance contributions to their compliance with wellness program requirements, including medication compliance.<sup>92</sup> The first step in the Advantage plan is to raise all employees' deductibles, thereby shifting a greater share of total insurance costs from the employer to the employees.<sup>93</sup> Employees can reduce their costs by either meeting certain health targets (such as "body mass index limits, controlled blood pressure, cholesterol and non-tobacco use") or by "following the treatment regime prescribed for their condition."<sup>94</sup> BeniComp explains that employers can expect to achieve savings from this program in three ways: first, by raising employees' deductibles; second, by promoting healthier employees; and third, by motivating some employees to "choose other health care options."<sup>95</sup> While the meaning of this last item is not entirely clear, it appears to suggest employers can save money when employees who cannot afford the increased insurance contributions, and who cannot reduce the cost of their insurance by meeting specified health targets, drop their coverage.<sup>96</sup>

If wellness incentives become so large that employees' access to affordable insurance hinges on their compliance with wellness program requirements, it is reasonable to ask whether these employees' consent is voluntary. The prospect of losing access to health insurance poses a threat of serious harm to employees. The Institute of Medicine has concluded that "working-age Americans (those between 18 and 65) who do not have health insurance have poorer health and die prematurely."<sup>97</sup> The Institute's report estimates that in the year 2000, "18,000 excess deaths among adults between ages 25 and 64 could be attributed to lack of coverage"—comparable to the number of deaths annually associated with diabetes and stroke.<sup>98</sup> Uninsured infants are more likely to die prematurely, to have poorer health outcomes, and to be at risk of developmental problems.<sup>99</sup> People who lack insurance face dangers not only to their health but to

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<sup>92</sup> *Employer FAQs*, BENICOMP ADVANTAGE, [http://www.benicompadvantage.com/index.php?option=com\\_content&view=article&id=16&Itemid=20](http://www.benicompadvantage.com/index.php?option=com_content&view=article&id=16&Itemid=20) (last visited Nov. 19, 2012).

<sup>93</sup> *See id.*

<sup>94</sup> *Id.*

<sup>95</sup> *Id.* Note that this plan design could produce savings for employers without improving employee health at all—i.e., through increased employee contributions and the departure of employees who cannot afford higher deductibles.

<sup>96</sup> Schmidt et al., *supra* note 57.

<sup>97</sup> INST. OF MED. OF THE NAT'L ACADS., *INSURING AMERICA'S HEALTH: PRINCIPLES AND RECOMMENDATIONS* 44 (2004), available at <http://iom.edu/Reports/2004/Insuring-Americas-Health-Principles-and-Recommendations.aspx>.

<sup>98</sup> *Id.* at 46.

<sup>99</sup> *Id.* at 45.

their finances. A single hospitalization can saddle an uninsured family with insurmountable debt, even if the family's income is well above the Federal Poverty Level.<sup>100</sup> "Even one uninsured person in a family can put the financial stability and health of the whole family at risk."<sup>101</sup> Given the critical role of health insurance in ensuring the wellbeing of one's family, the possibility of losing coverage can constitute a threat of harm so severe that it leaves employees little choice but to accept wellness program requirements.<sup>102</sup>

3. *Counterarguments to the Voluntariness Critique.*—To date, there has been very little consideration of how wellness programs can threaten patient autonomy. The limited literature that has acknowledged this concern fails to accurately characterize the nature of this threat and is not grounded in thoughtful consideration of the kinds of harms that could result. For example, in an ethical analysis of incentive programs offered by Steven Pearson and Sarah Lieber, the authors acknowledge that "[p]enalties for medication adherence conflict with competent patients' general right to decline any treatment, and therefore they must be framed cautiously and narrowly."<sup>103</sup> However, the authors argue such penalties are justified as long as the treatment is "prescribed by an independent physician who has judged, in discussion with the employee, that the medication is likely to confer a positive net health benefit on the employee."<sup>104</sup> "If this condition can be met," the authors conclude, "then it is reasonable to consider adherence to the prescription as a voluntary action for which an employee can be held responsible."<sup>105</sup>

This argument appears untethered to any recognizable concept of voluntary consent. The fundamental idea underlying the requirement of voluntariness—which is a manifestation of the principle of respect for persons<sup>106</sup>—is that decisions about whether to follow a course of treatment are for individuals to make in accordance with their own values.<sup>107</sup>

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100 See U.S. DEPT. OF HEALTH AND HUMAN SVCS., *THE VALUE OF HEALTH INSURANCE: FEW OF THE UNINSURED HAVE ADEQUATE RESOURCES TO PAY POTENTIAL HOSPITAL BILLS* (2011), available at <http://aspe.hhs.gov/health/reports/2011/valueofinsurance/rb.pdf>.

101 INST. OF MED. OF THE NAT'L ACADS., *supra* note 97, at 2.

102 See FADEN & BEAUCHAMP, *supra* note 2, at 339 (defining coercion as "a credible threat of unwanted and avoidable harm so severe that the person is unable to resist acting to avoid it"); see also Madison et al., *supra* note 24, at 459 (defining coercion as "intentional use of a credible and severe threat of harm or force to control another or to compel him or her to do something").

103 Steven D. Pearson & Sarah R. Lieber, *Financial Penalties For The Unhealthy? Ethical Guidelines for Holding Employees Responsible for Their Health*, 28 HEALTH AFF. 845, 849 (2009).

104 *Id.*

105 *Id.*

106 THE BELMONT REPORT, *supra* note 67, at 4.

107 See, e.g., FADEN & BEAUCHAMP, *supra* note 2, at 8 ("To respect an autonomous agent is

Voluntariness simply cannot mean the right to decline a treatment unless a doctor thinks the patient would benefit from it.

However there are other, more plausible objections to the claim that wellness programs threaten voluntariness. For example, one might argue that, at least in the context of treatment compliance, we need not worry about voluntariness because doctors would shield their patients from unwanted treatments by conforming their prescriptions to patients' preferences. More broadly, authors Madison, Volpp, and Halpern contend that since employees are not entitled to health insurance in the first place, they cannot be harmed by any conditions employers may attach to the provision of insurance.<sup>108</sup> Because wellness programs do not threaten noncompliant employees with a cognizable harm, the authors argue, these programs cannot be considered coercive. These authors also argue that because the purpose of wellness incentives is to get patients to make choices that are in their own best interests, no amount of incentives could be deemed to constitute an "undue influence" on employees' consent. On inspection, however, these arguments fail to allay concerns about patient autonomy.

#### a. Will Doctors Act as Buffers?

In the context of using incentives to compel patients to take their prescribed medications, one might object that in practice physicians would protect patients by conforming their treatment recommendations to their patients' preferences. Typically treatment plans are produced through a process of negotiation between patients and their physicians.<sup>109</sup> Those plans are renegotiated in light of subsequent events, including changes in the patient's health status and difficulties patients may experience with the initial course of treatment.<sup>110</sup> It seems reasonable to assume that, in general, doctors want to assist their patients in promoting their health, not to force them to use unwanted treatments.

However, the assumption that doctors will follow patients' wishes in setting treatment plans is not as safe as it first appears. Doctors and patients may disagree about the kinds of side effects that are worth tolerating in order to achieve a particular health goal, or how to deal with those side effects—e.g., by discontinuing the drug or "managing" the side effects with other drugs. Patient noncompliance is a significant source of frustration for

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to recognize with due appreciation that person's capacities and perspective, including his or her right to hold certain views, to make certain choices, and to take certain actions based on personal values and beliefs.").

<sup>108</sup> See Madison et al., *supra* note 24, at 459–61.

<sup>109</sup> Gene Bishop & Amy C. Brodkey, *Personal Responsibility and Physician Responsibility — West Virginia's Medicaid Plan*, 355 NEW ENG. J. MED. 756, 757 (2006).

<sup>110</sup> See *id.*

doctors.<sup>111</sup> Many doctors' current deference to patients may be a function of the fact that there is little they can do to motivate patients to comply. These doctors may welcome the additional leverage incentive programs can provide in getting patients to follow their advice.<sup>112</sup>

Moreover, doctors can have secondary interests that may conflict with their interest in respecting patient autonomy. Some doctors have financial incentives to resist letting patients make their own treatment decisions. For example, doctors who operate their own pharmacies can earn tens of thousands of dollars a year from filling the prescriptions they write for patients, creating a direct relationship between patient compliance and physician profits.<sup>113</sup> In addition, patients are not the only stakeholders in the health care system whose behavior payers are seeking to modify with incentives. Increasingly health plans and hospitals are using “pay-for-performance” systems that reward or penalize doctors based on their adherence to certain medical best practices. Some of these systems work by creating treatment rules for various conditions, and then financially rewarding or penalizing doctors based on the extent to which they adhere to those care rules.<sup>114</sup> Thus, if the “best practice” for treating type 2 diabetes calls for keeping patients' blood glucose levels below seven percent, physicians in this type of system would have an incentive to aggressively treat diabetic patients to maintain those levels, regardless of whether that treatment conflicts with the patient's priorities<sup>115</sup> or even if it is not in the patient's best medical interests.<sup>116</sup> A patient who experiences unpleasant

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111 See, e.g., *What Doctors Wish Their Patients Knew*, CONSUMER REPS. (Feb. 2011), <http://www.consumerreports.org/health/doctors-hospitals/doctors/physician-survey/index.htm> (reporting survey results showing that “[n]oncompliance with advice or treatment recommendations was the top complaint doctors had about their patients”).

112 See, e.g., Cynthia S. Rand & Mary Ann Sevick, *Ethics in Adherence Promotion and Monitoring*, 21 CONTROLLED CLINICAL TRIALS S241, S243 (2000) (“Clinicians who believe that adherence with therapy is in the patient's best interest may violate a patient's autonomy by pressing, coercing, or in some subtle or explicit manner forcing adherence.”).

113 Barry Meier & Katie Thomas, *Insurers Pay Big Markups as Doctors Dispense Drugs*, N.Y. TIMES, July 11, 2012, <http://www.nytimes.com/2012/07/12/business/some-physicians-making-millions-selling-drugs.html>.

114 Michael F. Cannon, *Pay-for-Performance: Is Medicare a Good Candidate?*, 7 YALE J. HEALTH POL'Y L. & ETHICS 1, 3 (2007); *Symmetry EBM Connect Product Sheet*, INGENIX 1, 1 (2009), <http://www.optuminsight.com/~media/Ingenix/Resources/Downloads/Product%20Sheets/SymmetryEBMConnectproductsheet.pdf>.

115 Lois Snyder & Richard L. Neubauer, *Pay-for-Performance Principles That Promote Patient-Centered Care: An Ethics Manifesto*, 147 ANNALS INTERNAL MED. 792, 793 (2007) (“Pay-for-performance and other programs that create strong incentives for high-quality care set up a potential conflict between this duty [to care for patients] and the competing interest of trying to comply with a performance measure—whether the measure is a priority for that patient or not”); Cannon, *supra* note 114, at 13 (under certain pay-for-performance systems that tie payments to following clinical guidelines, “a provider would be penalized for treating patients according to their preferences”).

116 Cannon, *supra* note 114 at 10 (“[pay for performance] schemes that encourage pro-

side effects from this course of treatment, who has different treatment goals, or who otherwise believes the risks of this approach outweigh its benefits, might ask his doctor to modify his treatment plan. A doctor in a pay-for-performance system may have a substantial incentive to deny that request, since departing from the best practice may incur a penalty.<sup>117</sup> In sum, patients in wellness programs that tie incentives to compliance with doctors' recommendations may not be able to rely on their doctors to defer to their wishes regarding treatment.

In most cases, however, if a patient complains of unpleasant, let alone dangerous, side effects, presumably most doctors would be willing to change the patient's treatment plan. Nevertheless, there remains something deeply troubling about effectively requiring patients to seek their doctors' permission to discontinue use of a drug. This scenario turns the concept of informed consent on its head. Rather than respect patients as autonomous agents entitled to make medical choices on the basis of their own values, this arrangement insults patients' dignity in precisely the way that the requirement of voluntariness is intended to prevent.

#### b. Can Financial Incentives Be Coercive?

Madison, Volpp, and Halpern contend incentive programs should not be deemed coercive because tying employees' insurance contributions to their health behaviors would not "worsen the situation or violate the rights of individuals who are unable to engage in healthy behaviors."<sup>118</sup> In support of this argument, the authors examine hypothetical incentive programs in which smokers face up to a \$100 penalty for failing to quit.<sup>119</sup> They argue that although smokers may pay more for insurance in these scenarios, the programs cannot be considered coercive for two reasons. First, the imposition of an annual \$100 surcharge on smokers does not constitute a threat of harm so severe that it leaves smokers with no reasonable alternative but to comply.<sup>120</sup> Second, the authors argue that even if smokers end up paying more for insurance, they cannot have been "harmed" because employees are not entitled to health insurance in the first place.<sup>121</sup>

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viders to treat outliers like the average patient can . . . create perverse incentives that encourage low-quality care"); Daniel G. Larriviere & James L. Bernat, *Threats to physician autonomy in a performance-based reimbursement system*, 70 *NEUROLOGY* 2338, 2339 (2008) ("physicians across all specialties share a concern that a system created to make medical decisions more rational will become . . . one which places a premium on rigid adherence to guidelines at the expense of individual physician judgment and patient preferences.").

117 See Cannon, *supra* note 114, at 10; Larriviere & Bernat, *supra* note 116, at 2341; Snyder & Neubauer, *supra* note 115, at 793.

118 Madison et al., *supra* note 24, at 459.

119 *Id.* at 459-61.

120 *Id.* at 460.

121 *Id.*

Since an employer that implements this kind of program has not violated any employee right to health insurance, the employees cannot be made worse off by any conditions an employer may attach to the provision of insurance.<sup>122</sup> Neither of these arguments is convincing.

First, while the authors' hypothetical \$100 annual surcharge may not be a sufficient threat of harm to constitute coercion, employers can and do charge considerably more. Consider the wellness program implemented by Valeo, an auto parts supplier with more than 73,000 employees.<sup>123</sup> The company began by increasing the deductibles in its employee health plan dramatically—from \$200 for individual coverage to \$2,200, and from \$400 for family coverage to \$4,400.<sup>124</sup> Valeo's employees could reduce their deductibles to the prior, lower amounts by ceasing to smoke and meeting the company's goals for cholesterol, blood pressure, and body mass.<sup>125</sup> Unlike a \$100 charge, these increased deductibles are so large that some employees may not be able to afford them, leaving them with a choice between complying with the wellness program requirements or losing health insurance.

Madison et al. appear to argue that even this scenario cannot be deemed coercive because employees are not entitled to health insurance on any particular terms. In this view, because employer-subsidized health insurance is a privilege, any increase in the employee's cost for that privilege cannot be considered a "harm," but is more properly considered a smaller benefit. This argument is based on a "rights-violating" definition of coercion, under which A can only be said to coerce B if "A proposes or threatens to violate B's rights or not fulfill an obligation" unless B complies, and if "B has no reasonable alternative but to accept A's proposal."<sup>126</sup> For example, a prosecutor who offers a criminal defendant a lenient sentence if he pleads guilty does not "coerce" the defendant to accept by threatening to take the case to trial if he refuses the plea agreement.<sup>127</sup> Since the defendant has no right either to avoid trial or to obtain a lenient sentence, the defendant is not harmed by the prosecutor's offer even if he has no

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<sup>122</sup> *Id.*

<sup>123</sup> Hilzenrath, *supra* note 3. As of the writing of this article, Valeo claims to employ approximately 73,800 people worldwide. *Global presence*, VALEO, <http://www.valeo.com/en/home/the-group/global-presence.html> (last visited Jan. 31, 2013).

<sup>124</sup> *Id.*

<sup>125</sup> *Id.* Valeo's human resources director acknowledged that the ostensible "rewards" the company offers for meeting wellness targets are in fact penalties imposed on noncompliant employees, stating "[i]f they don't comply, they end up being penalized, if you will, but we refer to it as a Healthy Rewards program."

<sup>126</sup> Madison et al., *supra* note 24, at 459 (quoting Alan Wertheimer & Frank G. Miller, *Payment for Research Participation: A Coercive Offer?*, 34 J. MED. ETHICS 389, 390 (2008)).

<sup>127</sup> Alan Wertheimer & Frank G. Miller, *Payment for Research Participation: A Coercive Offer?*, 34 J. MED. ETHICS 389, 390 (2008).

reasonable alternative but to accept.<sup>128</sup> By contrast, if a doctor is obligated to treat patients free of charge (e.g., in a single-payer health system), the doctor may coerce a patient by refusing to provide important health services unless the patient pays a fee.<sup>129</sup> Because the patient is legally entitled to receive free medical services and the doctor is obligated to provide them, the doctor's actions may be considered coercive.<sup>130</sup>

Drawing on this rights-violating framework, Madison et al. note that “[h]istorically . . . employers have not been obligated to offer insurance, and moreover . . . they are expressly permitted to offer wellness programs that include incentives.”<sup>131</sup> Since “[e]mployers do not as a general matter threaten employee *rights* by setting premiums based on health behaviors,”<sup>132</sup> the authors argue they cannot harm employees by penalizing noncompliance.

The problem with applying this “rights-violating” framework to incentive programs is that it begs the question of what rights employees *ought* to have with respect to the terms of their health insurance. For example, despite the fact that employers are not obligated to offer health insurance, employers who choose to do so are barred from discriminating against disabled people by charging them higher rates.<sup>133</sup> The law has created a set of rights according to which people are entitled not to be discriminated against on the basis of disability. Congress could similarly pass legislation requiring that when employers make health insurance available, they may not condition employees' insurance contributions on their compliance with wellness program dictates. If Congress passed that kind of law, then incentive programs could indeed be considered coercive under the rights-violating view. Thus, if our inquiry is not what the law currently allows, but what the law should allow, the rights-based analysis simply is not helpful.<sup>134</sup> Instead, we must grapple with how to weigh competing values

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<sup>128</sup> *Id.*

<sup>129</sup> *Id.*

<sup>130</sup> *Id.*

<sup>131</sup> Madison et al., *supra* note 24, at 460.

<sup>132</sup> *Id.* (emphasis added).

<sup>133</sup> Health Insurance Portability and Accountability Act of 1996, 29 U.S.C. § 1182(b) (2012).

<sup>134</sup> Indeed, Madison et al. seem inclined to create some rights for employees that would render certain incentives coercive under the rights-violating framework. They argue, for example, that “firms should not require employees to participate in [wellness programs] as a condition of employment.” Madison et al., *supra* note 24, at 458. But just as employers are under no obligation to offer employees health insurance, they also are not obligated to offer employment to any particular individual. Since employees generally are not entitled to their jobs, it is not clear how they can be “harmed,” in the view of Madison et al., by an employer requiring compliance as a term of employment. If this constitutes a cognizable harm, it is difficult to understand why the choice between compliance or unemployment should be considered coercive, while the choice between compliance and losing health insurance should not.

of fairness, responsible stewardship, and individual autonomy, informed by a thoughtful and thorough assessment of not only the economic benefits of incentive programs but the personal costs to individuals.

c. Can Financial Incentives Unduly Induce Employees to Place Themselves at Risk?

Coercion is not the only way voluntariness can be undermined. Ethicists have also recognized that some offers may be so attractive that they undermine individuals' ability to act as autonomous agents, which is often characterized as a concern about "undue inducement."<sup>135</sup> Traditionally, bioethicists have defined undue inducement by reference to an individual's subjective perception of a reward or penalty—specifically, how easily the person can resist the offer.<sup>136</sup> In this view, even if an incentive program that imposed substantial penalties for noncompliance were not "coercive," it could be ethically objectionable on the grounds that it would unduly influence employees' decision-making regarding health decisions. To the extent employees found the wellness proposition—the offer of lower insurance costs, or avoiding higher insurance costs, in exchange for their compliance—unwelcome but difficult to resist, under the traditional view their decisions would not be deemed free of substantially controlling influences.

More recently, however, critics have questioned this view of undue influence. Most notably, in the context of human subjects research, Ezekiel Emanuel has argued that concerns about undue inducement must be grounded not in how difficult an individual finds an offer to resist, but in an offer's potential to induce people to engage in activities that may harm them.<sup>137</sup> Emanuel argues persuasively that most concerns about undue inducement are really concerns about the nature of the underlying activity being induced. He notes, for example, that no one claims that movie stars and professional athletes are "unduly induced" to perform when they are offered millions in salary.<sup>138</sup> While these individuals may find fame and fortune difficult to resist, because these activities are ethical, reasonable, and legal, it does not make sense to say these people have been treated unethically.<sup>139</sup> Rather, Emanuel argues that "[i]nducements prompt ethical concern when they distort people's judgment, encouraging them to engage in activities that contravene their interests because they are harmful."<sup>140</sup>

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<sup>135</sup> Ezekiel J. Emanuel, *Ending Concerns About Undue Inducement*, 32 J. L. MED. & ETHICS 100, 100 (2004).

<sup>136</sup> See *supra* Part II.B.1.

<sup>137</sup> Emanuel, *supra* note 135, at 100–01.

<sup>138</sup> *Id.* at 101–02.

<sup>139</sup> *Id.*

<sup>140</sup> *Id.* at 100.



He further argues that because medical research on humans is subject to ethical rules and oversight designed to protect people from risky research,<sup>141</sup> undue inducement cannot be a valid concern in research that otherwise meets ethical standards.<sup>142</sup>

Madison et al. extend this reasoning to wellness incentive programs, arguing that such programs “are unlikely to constitute undue inducements, because they promote healthy behaviors . . . .”<sup>143</sup> They argue that because “[t]he risks or drawbacks of participating in wellness programs seem much less of a concern than risks in human subjects research. . . . a wellness incentive cannot be deemed an undue inducement, regardless of its magnitude.”<sup>144</sup>

However, Emanuel’s reasoning from the human research context cannot be so easily imported into an analysis of wellness programs. Although Madison et al. assume that participation in wellness programs presents “much less” risk than human subjects research, in reality that is far from clear. Deciding whether to participate in research typically involves determining whether to accept payment in exchange for assuming minimal risks over a fixed period of time. This calculus is qualitatively different from deciding whether to indefinitely comply with certain behavioral changes and medical interventions in exchange for access to health insurance. Moreover, wellness programs are not subject to ethics reviews or the other machinery designed to protect human research subjects from harm. While wellness programs are supposed to be designed to improve employee health, from the employer’s perspective that improvement is not the ultimate goal but a means of achieving a different end: saving money. Within that context there is little reason to assume these programs cannot subject employees to serious risks.

This is the key problem not only with Madison et al.’s argument, but with many justifications of incentive programs: the assumption that wellness programs are ethical because they benefit employees by making them healthier.<sup>145</sup> As described in Part III below, even programs that are designed to promote the health of a pool of employees may not further

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<sup>141</sup> For example, federal regulations commonly referred to as the “Common Rule” require all research conducted or funded by the federal government to be approved by institutional review boards (“IRBs”). 45 C.F.R. § 46.109(a) (2011). IRBs are responsible for ensuring that research minimizes risks to participants, and that the risks of such research are reasonable in relation to anticipated benefits. 45 C.F.R. § 46.111(a) (2011).

<sup>142</sup> Emanuel, *supra* note 135, at 100.

<sup>143</sup> Madison et al., *supra* note 24, at 461.

<sup>144</sup> *Id.*

<sup>145</sup> See, e.g., David M. Cutler & Wendy Everett, *Thinking Outside the Pillbox — Medication Adherence as a Priority for Health Care Reform*, 362 NEW ENG. J. MED. 1553, 1554 (2010); Scott D. Halpern et al., *Patients as Mercenaries? The Ethics of Using Financial Incentives in the War on Unhealthy Behaviors*, 2 CIRC. CARDIOVASC. QUAL. OUTCOMES 514, 515–16 (2009); Volpp et al., *supra* note 56.

individual employees' best interests and can actually subject them to risks. For these individuals, excessive inducements to comply with wellness program requirements—and to abdicate their prerogative to determine their own courses of treatment—can cause real harm.

### III. THE HARMS OF COMPELLED COMPLIANCE

The key justification for wellness programs is that employees will benefit, since the purpose of these programs is to reduce costs by promoting employee health.<sup>146</sup> While the possible systemic, economic benefits of these programs are clear (though by no means guaranteed), there has been little consideration of the costs they might impose on individuals.<sup>147</sup> The ethical principle of autonomy is intended to express respect for the right of competent individuals (i.e., people who have “the ability to make decisions based on [their] own preferences and beliefs”) to conform their choices about medical interventions to their own values.<sup>148</sup> Tying substantial penalties to employees' failure to adopt behaviors that reduce costs for an insurance pool directly harms patients by undermining their right to self-determination. In addition, while the condition of voluntariness is important in its own right as a reflection of respect for individual autonomy, it is also a safeguard for other important values. Preserving patients' rights to refuse treatment is a bulwark against invasions of patient privacy and threats to their health.<sup>149</sup> These potential harms should not be overlooked simply because they are harder to quantify than the possible economic gains.

#### A. *Loss of Privacy*

Employees in many incentive-based wellness programs must decide not only whether to comply with particular health requirements, but also whether to consent to having their behaviors monitored.<sup>150</sup> While

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146 See, e.g., Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1201, 124 Stat. 119, 158 (2010) (codified at 42 U.S.C. § 300gg-4(j)(3)(B) (2006 & Supp. V 2011)) (requiring that wellness programs must “be reasonably designed to promote health or prevent disease”).

147 See *supra* text accompanying note 56.

148 Sandman et al., *supra* note 44, at 119 (“To be decision competent, the person needs to have some idea about what he or she wants, some ability to contemplate options and what they would result in, and an ability to judge the value of these results.”).

149 See generally BEAUCHAMP & CHILDRESS, *supra* note 69, at 74 (noting that informed consent not only protects patients' autonomy, but also protects patients against harm and encourages physicians to act responsibly toward patients).

150 Madison et al. acknowledge that these are valid concerns, arguing that “[e]mployees concerned that sharing health-related information with an employer might violate their privacy, unacceptably mix their work and personal lives, or subject them to employment dis-

surrendering some measure of personal privacy is a necessary part of receiving health insurance and services, incentive-based wellness programs can take privacy intrusions to a new level of invasiveness. Offering incentives in exchange for meeting certain health targets or undertaking certain behaviors requires program administrators to verify that employees have met these goals. When incentives are connected to achieving particular outcomes, verification can take the form of periodic weight measurement, blood pressure and glucose level tests, and other tests. While employees may object to this type of episodic monitoring, these measures pale in comparison to the kinds of monitoring required to determine whether an employee is adhering to a diet, exercising regularly, or taking her medications as prescribed.

One approach to monitoring employees' behaviors is to enlist employees' physicians to verify patients' compliance with their treatment plans. West Virginia has pioneered this approach in its state Medicaid plan, which offers a two-tiered insurance plan in which patients can obtain enhanced benefits<sup>151</sup> by participating in health care screenings, "adher[ing] to health improvement programs as directed by their health care providers," and taking their prescribed medications.<sup>152</sup> The plan charges physicians with monitoring their patients' compliance with their treatment plans and reporting patients' compliance (or lack thereof) to the state.<sup>153</sup> Some private health plans have implemented this strategy as well. For example, in the Healthy Blue Living program,<sup>154</sup> employees can only obtain the lower-cost insurance plan by getting their physicians to complete a questionnaire to confirm that the employee and her spouse have reached or are continuing to actively work toward their health goals.<sup>155</sup>

Using physicians to monitor patients' compliance raises troubling issues. It intrudes on the doctor-patient relationship and creates conflicts of interest for doctors, both of which may undermine patients' trust in their physicians. Obligating doctors to report patients' health behaviors to their employers' wellness plan administrators can conflict with doctors' ethical and professional obligation to protect patients' health. A doctor faced with a noncompliant patient would face a choice between falsely verifying her

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crimination, should be able to decline to participate in such programs without risk of being fired." Madison et al., *supra* note 24, at 458.

151 The enhanced plan offers additional access to prescription drugs, diabetes care, and mental health services that are not provided in the state's standard Medicaid plan. *E.g.*, HENRY J. KAISER FAMILY FOUND., WEST VIRGINIA MEDICAID STATE PLAN AMENDMENT: KEY PROGRAM CHANGES AND QUESTIONS (2006), available at <http://www.kff.org/medicaid/upload/7529.pdf>.

152 Gene Bishop & Amy C. Brodkey, *Personal Responsibility and Physician Responsibility—West Virginia's Medicaid Plan*, 355 NEW ENG. J. MED. 756, 756 (2006).

153 *E.g.*, HENRY J. KAISER FAMILY FOUND., *supra* note 151.

154 *See supra* Part II.B.2.

155 BLUE CARE NETWORK OF MICH., *supra* note 6, at 1.

patient's compliance or accurately reporting the patient's noncompliance and risk adversely affecting her patient's health (e.g., by reducing the benefits for which the employee qualifies or raising the cost of the employee's health coverage).<sup>156</sup> Moreover, when patients (rightly) perceive their doctors as agents of their employers, they may be less inclined to disclose important health information to their physicians.<sup>157</sup>

Increasingly, however, new technologies are eliminating the need for employers to rely on physicians to monitor employee compliance, as the development of smaller and cheaper sensors has spawned a dizzying array of technologies capable of measuring and reporting biometric data.<sup>158</sup> For example, Corventis, a healthcare technology company, has developed an adhesive patch "designed to support patient compliance."<sup>159</sup> When stuck to a patient's chest or back, the patch continuously monitors and wirelessly transmits information about the patient's temperature, heart rate, respiratory rate, fluid status, body angle, activity trends, and other variables.<sup>160</sup> Proteus Biomedical uses a similar patch in combination with "smart pills" outfitted with tiny, digestible microchips.<sup>161</sup> When a patient swallows the smart pill, her stomach acid activates the microchip, which sends a signal to the patch indicating the pill has been ingested.<sup>162</sup> The patch then transmits that information to Proteus through the patient's cell phone.<sup>163</sup>

As a recent report by the Rand Corporation explains, monitoring technologies "enable consumers and employers (through a third party) to accurately track behaviors (such as walking) and biometrics (such as weight or blood pressure). This capacity might promote sustained engagement and behavioral change, as well as steady progress toward health goals, thus providing employers more 'bang' per incentive dollar."<sup>164</sup> Indeed, employers are showing increasing interest in using remote biometric monitoring in this way. According to a 2010 survey conducted by Towers Perrin, twenty

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156 See Bishop & Brodkey, *supra* note 152, at 757.

157 *Id.*

158 See, e.g., Rand & Sevick, *supra* note 112, at S245. Rand & Sevick write:

The development of new electronic medication monitoring devices has also created the possibility of detailed monitoring of each patient's medication adherence. New assays, devices, tests, and biochemical measures have also expanded our ability to identify patients who are failing to comply with behavioral recommendations related to smoking, exercise, dietary changes, and alcohol and other substance abuse.

*Id.*

159 *AVIVO Mobile Patient Management (MPM) System*, CORVENTIS, <http://www.corventis.com/us/avivo.asp> (last visited Jan. 31, 2013).

160 *Id.*

161 See *Pills Get Smart: Potential Encapsulated*, THE ECONOMIST, Jan. 14, 2010, <http://www.economist.com/node/15276730>.

162 *Id.*

163 *Id.*

164 JONES ET AL., *supra* note 38, at 25.

percent of “high performing” companies (i.e., companies that have been most effective at keeping health costs low) indicated they intended to implement remote biometric monitoring of employees by 2012.<sup>165</sup> Large employers like International Paper and Welch Allyn are employing the services of RedBrick Health, which provides health insurance plans that tie employees’ premiums to their health behaviors.<sup>166</sup> RedBrick offers employers the option of using wireless devices to monitor, for example, the amount employees are walking.<sup>167</sup>

Even employees who may be quite willing to comply with the health behaviors required by wellness programs may object strongly to their employer (or their employer’s designee) monitoring their exercise habits, medication compliance, and other health behaviors. For example, a patient with coronary artery disease “may choose not to take diuretic medicines prior to a long day of travel, or he or she may choose not to limit dietary sodium on the occasion of a celebratory meal, despite having agreed to the treatment plan.”<sup>168</sup> Even if this patient generally wishes to follow his treatment plan and typically does so, he may object to having to explain the highly personal reasons for his noncompliance to the administrator of his wellness program. But if he participates in a coercive incentive program, he may have little choice but to agree to be monitored in this way.

As monitoring technologies proliferate, it will become feasible for wellness programs to track an expanding range of employee behaviors that affect health. To the extent employees object to this kind of monitoring but feel they have little choice but to consent, wellness programs can inflict substantial harm on employees.

### *B. Threats to Health*

Some studies have found that people who adopt certain healthy behaviors ultimately incur greater health care costs because they tend to live longer and end up making more health care claims. A 2008 study determined that lifetime health expenditures were highest for “healthy-living people” (i.e., non-obese non-smokers), lower for obese individuals, and lowest for smokers.<sup>169</sup> In light of these findings, perhaps proponents of the fairness

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<sup>165</sup> TOWERS PERRIN, TOWERS PERRIN 2010 HEALTH CARE COST SURVEY Exhibit 9 (2010), available at [www.towersperrin.com/hcg/hcc/HCCS\\_9.pdf](http://www.towersperrin.com/hcg/hcc/HCCS_9.pdf).

<sup>166</sup> *Select RedBrick Clients*, REDBRICK HEALTH, <http://www.redbrickhealth.com/clients> (last visited Jan. 31, 2013).

<sup>167</sup> See Camille Ricketts, *Redbrick Gets a \$15M Boost for Incentive-Based Health Insurance*, VENTUREBEAT, (Apr. 2, 2009), <http://venturebeat.com/2009/04/02/redbrick-gets-a-15m-boost-for-incentive-based-health-insurance>.

<sup>168</sup> Sandman et al., *supra* note 44, at 116 (“Similar examples can be found in many other cases, such as diabetes, vascular problems, etc.”).

<sup>169</sup> Pieter H. M. van Baal et al., *Lifetime Medical Costs of Obesity: Prevention No Cure for Increasing Health Expenditure*, 5 PLOS MED. 242, 245 (2008), [HTTP://WWW.PLOSMEDICINE.ORG/AR-](http://www.plosmedicine.org/AR-)

argument—the idea that people whose behaviors drive up health care costs should pay more—should support charging higher insurance rates to non-smokers and employees with healthy body weights. Modifying the Valeo example accordingly, smokers and obese employees would qualify for the insurance plan with the \$400 deductible, while employees who refused to take up smoking or gain weight would pay \$4,400, in recognition of the extra costs their choices impose on fellow employees.

Clearly such a program would be unethical, and the ACA expressly prohibits it—the Act’s exception to the general prohibition against discriminating based on health factors applies only to programs that are “reasonably designed to promote health or prevent disease.”<sup>170</sup> The ethical and political justifications for wellness programs rest critically on the premise that using incentives will improve employee health, constituting a win-win for employers and employees alike. In this view, substantial incursions on employee autonomy may be justified because patients will be better off.

But some employees may not benefit from complying with wellness program dictates, and in fact may be harmed by them. Looking specifically at treatment compliance, requiring an employee to follow her physician’s recommendations can actually endanger her health in ways the requirement of voluntary consent is intended to avoid.<sup>171</sup>

1. *The Frailty of Medical Standards.*—The key targets of wellness programs are employees with chronic illnesses, like diabetes, hypertension, and coronary artery disease.<sup>172</sup> For these illnesses there are well-known and widely-prescribed treatments that comprise the “best practices” doctors employ in treating these conditions. These are the treatments most likely to be prescribed to employees suffering from chronic illnesses—and the treatments employees in some incentive-based programs will have to agree to undergo in order to be eligible for cheaper health insurance.

Unfortunately there is substantial reason to doubt the efficacy of many accepted medical practices.<sup>173</sup> The evidence supporting the benefits of

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TITLE/INFO:DOI/10.1371/JOURNAL.PMED.0050029. It is important to note that reducing smoking and obesity could still produce short-term savings for employers, since healthier employees are likely to incur their higher medical expenses during their retirement years.

170 The Patient Protection and Affordable Care Act, Pub. L. No. 111–148, § 1201, 124 Stat. 119, 162 (2010) (to be codified at 42 U.S.C. § 300gg-4(j)(3)(B)).

171 See *supra* note 148.

172 AON HEWITT, *supra* note 32, at 51.

173 Cannon, *supra* note 114, at 9–10 (“One expert notes that [clinical practice guidelines] ‘have been reported to be variably flawed in terms of conflict of interest, specialty turf battles, endorsement of new or relatively unproven pharmaceutical agents, and focus on a single condition compared with a broader clinical focus.’”) (quoting Patrick J. O’Connor, *Adding Value to Evidence-Based Clinical Guidelines*, 294 JAMA 741, 741 (2005)).

many interventions is often extremely limited.<sup>174</sup> When medical standards are subjected to rigorous research, they are reversed with alarming frequency. One analysis of highly-cited articles published in medical journals between 1990 and 2003 revealed that nearly a third of the articles that made claims about the efficacy of an intervention were either contradicted by subsequent clinical studies or found to have weaker effects than claimed in the initial articles.<sup>175</sup> Notably, these numbers reflect only the highly cited trials with respect to which researchers sought to replicate the results. Many other highly cited trials are never challenged.<sup>176</sup>

Reversals of medical standards are worrisome because every medical intervention carries risks. Physicians prescribe treatments on the grounds that their benefits exceed these risks. To the extent medical science overestimates the benefits of an intervention, patients may be exposed to risks that are not justified by the treatment's true benefits.<sup>177</sup>

One of the key ways in which existing medical standards harm patients is through pervasive over-treatment.<sup>178</sup> Consider diabetes—the top target of employers who push participation in disease management programs.<sup>179</sup> The American Diabetes Association, American Heart Association, and American College of Cardiology all recommend that most adults with type 2 diabetes achieve a glycated hemoglobin (HbA1c) level below seven percent to reduce the risk of vascular complications.<sup>180</sup> While accepted practice involves aggressively lowering HbA1c levels by prescribing higher levels of therapy, meta-analyses of recent trials found this approach

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174 John P. A. Ioannidis, *Contradicted and Initially Stronger Effects in Highly Cited Clinical Research*, 294 JAMA 218, 224 (2005) (“[F]or most clinical questions of interest, no large trials are ever conducted and evidence is based only on small trials or nonrandomized studies.”).

175 *Id.* at 223 (“16% of the top-cited clinical research articles on postulated effective medical interventions that have been published within the last 15 years have been contradicted by subsequent clinical studies and another 16% have been found to have initially stronger effects than subsequent research.”); see also Vinay Prasad et al., *The Frequency of Medical Reversal*, 171 ARCH INTERN MED. 1675, 1676 (2011) (“The reversal of medical practice is not uncommon in high-impact literature: 13% of articles that make a claim about a medical practice constituted reversal in our review of 1 year of the *New England Journal of Medicine*. The range of reversals we encountered is broad and encompasses many arenas of medical practice including screening tests and all types of therapeutics.”).

176 Ioannidis, *supra* note 174, at 225.

177 Prasad et al., *supra* note 175, at 1675.

178 See, e.g., Dario Giugliano & Katherine Esposito, *Clinical Inertia as a Clinical Safeguard*, 305 JAMA 1591, 1591–92 (2011) (“[The] failure of [some] health care providers to initiate or intensify therapy when indicated . . . may be a clinical safeguard for the drug-intensive style of medicine fueled by the current medical literature. . . . One study found that 58% of medications could be discontinued in elderly patients and that quality of life improved with drug discontinuation.”) (footnote omitted).

179 AON HEWITT, *supra* note 32, at 51; REYNOLDS & MARTIN, *supra* note 45, at 4 (“Diabetes is—by far—the condition employers are most likely to target with their medication compliance initiatives.”).

180 Giugliano & Esposito, *supra* note 178, at 1591.

produced only minor benefits.<sup>181</sup> On the other hand, the risks of the intensive–therapy approach were significant. In a massive clinical trial funded by the National Heart, Lung, and Blood Institute, the all–cause death rate in the group of patients whose target was a 6% HbA1c level was 22% higher than in the group whose target was between 7–7.9% – that is, above the recommended 7% level.<sup>182</sup> Members of the therapy–intensive group were also more likely to experience weight gain and hypoglycemia requiring assistance.<sup>183</sup> The same trial cast doubt on nearly two decades of guidelines that recommended lower blood pressure goals for patients with diabetes.<sup>184</sup>

Standard medical practice for preventing heart disease, which often involves using statins to lower cholesterol levels, tells a similar story: “From 1988–1994 to 2003–2006, the use of statin drugs by adults 45 years and older increased almost 10–fold, from 2% to 22%.”<sup>185</sup> Although statins appear to be effective in treating cardiovascular disease, today many doctors prescribe these drugs for primary prevention—that is, to lower the risks of heart attacks and strokes among patients who do not have cardiovascular disease.<sup>186</sup> However, meta–analyses of the use of statins for primary prevention show no benefit in preventing heart attacks or death.<sup>187</sup> Yet the use of statins poses serious risks to patients. Recent studies suggest statins cause diabetes (itself a major cause of heart disease) in one out of every 200 patients, or about 100,000 of the twenty million Americans taking statins.<sup>188</sup> Another recent study found that among post–menopausal women the diabetes risk was dramatically higher.<sup>189</sup>

Concerns about diabetes management and heart disease prevention are just two prominent examples among many other reversals regarding some of the most commonly prescribed interventions, including hormone

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181 *Id.*

182 *Id.*

183 *Id.* See also Victor M. Montori and Merce Fernandez–Balsells, *Glycemic Control in Type 2 Diabetes: Time for an Evidence–Based About–Face?*, 150 ANN. INT. MED. 803, 803–08 (2009).

184 Giugliano & Esposito, *supra* note 178, at 1591.

185 *Id.* at 1592.

186 *Id.*

187 *Id.* (“Today, many patients are prescribed statins for primary prevention, although the short–term benefits, if any, are very small for primary prevention.”); Fiona Taylor et al., *Statins for the primary prevention of cardiovascular disease*, THE COCHRANE COLLABORATION 2 (Sept. 7, 2011), <http://www.update–software.com/BCP/WileyPDF/EN/CD004816.pdf>.

188 Eric J. Topol, *The Diabetes Dilemma for Statin*, N.Y. TIMES, March 4, 2012, <http://www.nytimes.com/2012/03/05/opinion/the–diabetes–dilemma–for–statin–users.html>.

189 Annie L. Culver et al., *Statin Use and Risk of Diabetes Mellitus in Postmenopausal Women in the Women’s Health Initiative*, 172 ARCH. INTERN. MED. 144, 144 (2012); see also Kirsten L. Johansen, *Increased Diabetes Mellitus Risk With Statin Use – Tipping the Balance*, 172 ARCH. INTERN. MED. 152, 152 (2012) (“These data confirm and extend associations previously demonstrated among participants in randomized trials.”).



replacement therapy,<sup>190</sup> routine mammograms,<sup>191</sup> and prostate cancer screenings,<sup>192</sup> to name just a few. In each of these cases the story is the same: an intervention endorsed by the medical establishment, widely prescribed by doctors, and undergone by millions of people is later found to pose little prospect of benefit and serious risks of harm. To the extent patients are compelled to comply with their doctors' recommendations even if they would prefer less aggressive therapy, the absence of true consent can threaten their health.

2. *Medical Corruption.*—In addition to unavoidable gaps in medical knowledge, patients face risks from coerced treatments as a result of corruption in the medical industry. The clinical trials that test drugs' safety and efficacy are conducted and interpreted primarily by the companies that hope to profit from these drugs.<sup>193</sup> These studies can be designed in ways that overstate drugs' benefits and downplay risks.<sup>194</sup> Studies performed by drug companies are more likely to produce favorable results than independent studies, and these favorable studies are more likely to be published in medical journals.<sup>195</sup> Pharmaceutical companies often lend credibility to these articles by enlisting well-credentialed academic researchers to claim authorship for articles that were actually ghostwritten by writers hired by the drug companies.<sup>196</sup>

In some cases, drug companies have withheld data that revealed their drugs posed serious health risks to patients. For example, in 1999 the top

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190 Richard Knox, *Hormone Replacement Therapy Raises Risk Of Death From Breast Cancer*, NAT'L PUB. RADIO (October 20, 2010), <http://www.npr.org/blogs/health/2010/10/20/130693401/hormone-replacement-therapy-raises-risk-of-death-from-breast-cancer>.

191 Gina Kolata, *Panel Urges Mammograms at 50, Not 40*, N.Y. TIMES, November 16, 2009, <http://www.nytimes.com/2009/11/17/health/17cancer.html>.

192 Gardiner Harris, *U.S. Panel Says No to Prostate Screening for Healthy Men*, N.Y. TIMES, October 6, 2011, <http://www.nytimes.com/2011/10/07/health/07prostate.html>.

193 Richard Smith, *Medical Journals Are an Extension of the Marketing Arm of Pharmaceutical Companies*, 2 PLOS MED. 364, 364–65 (2005) (noting that between two-thirds and three-quarters of drug trials published in major medical journals are funded by the pharmaceutical industry).

194 *Id.*; see also Bodil Als-Nielsen et al., *Association of Funding and Conclusions in Randomized Drug Trials: A Reflection of Treatment Effect or Adverse Events?*, 290 JAMA 921, 924 (2003) (“[C]onclusions were significantly more likely to recommend the experimental drug as treatment of choice in trials funded by for-profit organizations.”); Vinay Prasad et al., *Reversals of Established Medical Practices: Evidence to Abandon Ship*, 307 JAMA. 37, 38 (2012) (“Asking corporate sponsors to conduct pivotal trials on their own products is like asking a painter to judge his or her own painting so as to receive an award.”).

195 Als-Nielsen et al., *supra* note 194; Smith, *supra* note 193, at 138.

196 Peter C. Gøtzsche et al., *What Should Be Done To Tackle Ghostwriting in the Medical Literature?*, 6 PLOS MED. 122, 124 (2009) (“Information from questionnaire studies suggest that authorship in up to 10% of published papers could be attributed to ghostwriters, although the fraction in industry-sponsored clinical trials in one study was considerably higher.”); Simon Stern & Trudo Lemmens, *Legal Remedies for Medical Ghostwriting: Imposing Fraud*

antidiabetic drug in the United States was Avandia. Although the drug's maker, GlaxoSmithKline, conducted its own study in 1999 that linked Avandia to increased cardiovascular risks, "instead of publishing the results, the company spent the next 11 years trying to cover them up."<sup>197</sup> In one internal email, a SmithKline executive wrote that "Per Sr. Mgmt request, these data should not see the light of day to anyone outside of GSK."<sup>198</sup> In the ensuing years, GSK continued to promote the drug and doctors continued to prescribe it heavily to diabetics, writing as many as one million prescriptions per month in 2007.<sup>199</sup> That same year the *New England Journal of Medicine* published an independently conducted meta-analysis indicating Avandia increased patients' risk of heart attack by forty-three percent and increased the risk of death from cardiovascular causes by sixty-four percent.<sup>200</sup> According to a subsequent independent study, between 1999 and 2009 "more than 47,000 people taking Avandia needlessly suffered a heart attack, stroke or heart failure, or died."<sup>201</sup> Finally in 2010 European regulators pulled the drug off the market, and the FDA dramatically restricted its availability.<sup>202</sup>

Recent years have also seen a parade of scandals in which pharmaceutical companies have illegally promoted their drugs for "off-label" uses—i.e., uses for which a drug has not been approved by the FDA. There is nothing inherently improper about doctors prescribing drugs for off-label uses. Doctors can prescribe drugs more or less as they see fit,<sup>203</sup> and they do not hesitate to do so: by one estimate, off-label uses account for about a fifth of all prescriptions.<sup>204</sup> However, often there is little, if any, evidence to support certain off-label uses of drugs.<sup>205</sup> And although it is illegal for

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*Liability on Guest Authors of Ghostwritten Articles*, 8 PLoS MED. 1, 1 (2011); Stephanie Saul, *Merck Wrote Drug Studies for Doctors*, N.Y. TIMES, Apr. 16, 2008, <http://www.nytimes.com/2008/04/16/business/16vioxx.html>; Duff Wilson, *Drug Maker Said to Pay Ghostwriters for Journal Articles*, N.Y. TIMES, Dec. 12, 2008, <http://www.nytimes.com/2008/12/12/business/13wyeth.html>.

<sup>197</sup> Gardiner Harris, *Diabetes Drug Maker Hid Test Data, Files Indicate*, N.Y. TIMES, July 13, 2010, <http://www.nytimes.com/2010/07/13/health/policy/13avandia.html>.

<sup>198</sup> *Id.*

<sup>199</sup> Rita Rubin, *Avandia Prescriptions Decline After Study*, USA TODAY, June 18, 2007, [http://www.usatoday.com/news/health/2007-06-18-avandia\\_N.htm](http://www.usatoday.com/news/health/2007-06-18-avandia_N.htm).

<sup>200</sup> Steven E. Nissen & Kathy Wolski, *Effect of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes*, 356 NEW ENG. J. MED. 2457, 2457 (2007).

<sup>201</sup> Gardiner Harris, *F.D.A. to Restrict Avandia, Citing Heart Risk*, N.Y. TIMES, Sept. 23, 2010, [http://www.nytimes.com/2010/09/24/health/policy/24avandia.html?pagewanted=print&\\_r=0](http://www.nytimes.com/2010/09/24/health/policy/24avandia.html?pagewanted=print&_r=0).

<sup>202</sup> *Id.*

<sup>203</sup> Michael Wilkes & Margaret Johns, *Informed Consent and Shared Decision-Making: A Requirement to Disclose to Patients Off-Label Prescriptions*, 5 PLoS MED. 1553, 1553 (2008).

<sup>204</sup> David C. Radley et al., *Off-label Prescribing Among Office-Based Physicians*, 166 ARCHIVES INTERNAL MED. 1021, 1023 (2006).

<sup>205</sup> Wilkes & Johns, *supra* note 203, at 1553.

drug companies to promote their drugs for unapproved uses, the practice is remarkably common in the industry.<sup>206</sup>

For example, drug-maker AstraZeneca recently paid more than half a billion dollars to settle federal investigations into illegal marketing of its drug, Seroquel.<sup>207</sup> Although the FDA approved Seroquel only as a short-term treatment for schizophrenia and bipolar disorders, the company allegedly paid kickbacks to doctors<sup>208</sup> as part of an effort to market the drug “for a variety of illnesses for which it had never been tested, including aggression, Alzheimer’s, anger management, anxiety, attention-deficit hyperactivity disorder, dementia, depression, mood disorder, post-traumatic stress disorder and sleeplessness.”<sup>209</sup> Internal AstraZeneca emails revealed that the company had “buried” unfavorable studies about the drug and praised the company’s Seroquel project physician for performing a “great smoke-and-mirrors job” on negative studies.<sup>210</sup> In the year prior to the settlement Seroquel was the fifth-best-selling drug in the U.S.<sup>211</sup>

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206 Prominent recent examples of drugs for which pharmaceutical companies have been prosecuted for illegally marketing off-label include: *Paxil*, see Katie Thomas & Michael S. Schmidt, *Glaxo Agrees to Pay \$3 Billion in Fraud Settlement*, N.Y. TIMES, July 2, 2012, <http://www.nytimes.com/2012/07/03/business/glaxosmithkline-agrees-to-pay-3-billion-in-fraud-settlement.html>; *Welbutrin*, *id.*; *Depakote*, see Michael S. Schmidt & Katie Thomas, *Abbott Settles Marketing Lawsuit*, N.Y. TIMES, May 7, 2012, <http://www.nytimes.com/2012/05/08/business/abbott-to-pay-1-6-billion-over-illegal-marketing.html>; *Risperdal*, see Katie Thomas, *J.&J. Fined \$1.2 Billion in Drug Case*, N.Y. TIMES, Apr. 11, 2012, <http://www.nytimes.com/2012/04/12/business/drug-giant-is-fined-1-2-billion-in-arkansas.html>; *Detrol*, see Margaret Cronin Fisk, *Pfizer Settles Whistle-Blower Suit Over Detrol Marketing*, BLOOMBERG BUS. WK., Oct. 20, 2011, <http://www.businessweek.com/news/2011-10-20/pfizer-settles-whistle-blower-suit-over-detrol-marketing.html>; *Seroquel*, see Duff Wilson, *For \$520 Million, AstraZeneca Settles Case Over Marketing of a Drug*, N.Y. TIMES, Apr. 27, 2010, <http://www.nytimes.com/2010/04/28/business/28drug.html>; *Bextra*, see Rita Rubin, *Pfizer Fined \$2.3 Billion for Illegal Marketing in Off-Label Drug Case*, USA TODAY, Sept. 2, 2009, [http://www.usatoday.com/money/industries/health/2009-09-02-pfizer-fine\\_N.htm](http://www.usatoday.com/money/industries/health/2009-09-02-pfizer-fine_N.htm); *Zyprexa*, see Press Release, U.S. Dep’t of Justice, *Pharmaceutical Company Eli Lilly to Pay Record \$1.415 Billion for Off-Label Drug Marketing*, Jan. 15, 2009, <http://www.justice.gov/usaop/pae/News/Pt/2009/jan/lillyrelease.pdf>; *Abilify*, see Denise Lavoie, *Bristol-Myers Squibb to Pay \$515M Settlement*, ABC NEWS, Oct. 30, 2007, <http://abcnews.go.com/Business/story?id=3670595>; and *Genotropin*, see *Pfizer to Pay \$35 Mln in Genotropin Settlements*, REUTERS, Apr. 2, 2007, <http://www.reuters.com/article/2007/04/02/idUSWNAS544720070402>.

207 As is common in these settlements, AstraZeneca denied all wrongdoing. Wilson, *supra* note 206.

208 Huma Khan & Pierre Thomas, *Drug Giant AstraZeneca to Pay \$520 Million to Settle Fraud Case*, ABC NEWS (Apr. 27, 2010), <http://abcnews.go.com/Politics/Health/astrazeneca-pay-520-million-illegally-marketing-seroquel-schizophrenia/story?id=10488647>.

209 *Id.*

210 Wilson, *supra* note 206; see also Carl Elliott, *Making a Killing*, MOTHER JONES, Sept.–Oct. 2010 at 59 (noting internal AstraZeneca emails in which a company official states “Thus far, we have buried trials 15, 31, 56. . . . The larger issue is how do we face the outside world when they begin to criticize us for suppressing data.”).

211 Wilson, *supra* note 206.

Common side effects of Seroquel include chills, cold sweats, confusion and dizziness. The drug also carries several dozen “less common” (though not “rare”) side effects that include drooling, slurred speech, unusual facial expressions and spasms, rapid or worm-like movements of the tongue, inability to move the eyes, trembling hands, ulcers around the mouth, and trouble with breathing, speaking, or swallowing.<sup>212</sup> Patients who are prescribed Seroquel to treat conditions for which its benefits have not been established are subjected to risks of these and many other side effects, with highly questionable prospects of experiencing any benefit.

For most patients prescribed Avandia or Seroquel,<sup>213</sup> the requirement of voluntary consent offers a layer of protection against the dangers of these drugs: patients who disagree with their doctors’ assessment of the drugs’ risk/benefit profiles can unilaterally discontinue use of the drugs. For example, researchers began raising well-publicized, serious concerns about Avandia’s risks in 2007<sup>214</sup> and at least one FDA safety official called for the drug to be taken off the market that same year<sup>215</sup>—more than three years before the FDA finally restricted access to the drug.<sup>216</sup> Yet doctors still wrote 2.6 million Avandia prescriptions in 2009 alone.<sup>217</sup> During this period, patients who were concerned about the drug’s risks could protect themselves by discontinuing use of the drug, even if their doctors continued to recommend taking it—but only if their voluntary consent was intact. Undermining patients’ autonomy in making treatment decisions compounds the dangers of unethical drug company practices by eroding patients’ ability to protect themselves.

Notwithstanding serious doubts about some of the most commonly accepted and prescribed interventions, it may be that in most cases overriding patients’ treatment preferences would promote their health. But even if this were always the case, there are other important reasons to respect

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212 *Quetiapine (Oral Route): Side effects*, MAYO CLINIC, <http://www.mayoclinic.com/health/drug-information/DR601493/DSECTION=side-effects> (last visited Jan. 31, 2013).

213 Or both. AstraZeneca also allegedly failed to disclose studies showing Seroquel increases the risk of diabetes. Wilson, *supra* note 206.

214 Nissen & Wolski, *supra* note 200, at 2467 (finding that treatment with Avandia was “associated with a significant increase in the risk of myocardial infarction”); Gardiner Harris, *More Studies Cast Doubt on Safety of Diabetes Drug*, N.Y. TIMES, Sept. 12, 2007, <http://www.nytimes.com/2007/09/12/health/12drug.html>; Stephanie Saul, *Another Study Finds Heart Risks in a Diabetes Drug*, N.Y. TIMES, Dec. 12, 2007, <http://www.nytimes.com/2007/12/12/business/12drug.html>; Stephanie Saul, *Heart Attack Risk Seen in Drug for Diabetes*, N.Y. TIMES, May 22, 2007, <http://www.nytimes.com/2007/05/22/business/22drug.html>.

215 Gardiner Harris, *U.S. Drug Safety Official Recommends Avandia Be Withdrawn*, N.Y. TIMES, July 30, 2007, <http://www.nytimes.com/2007/07/30/business/worldbusiness/30iht-drug.4.6902082.html>.

216 Gardiner Harris, *F.D.A. to Restrict Avandia, Citing Heart Risk*, N.Y. TIMES, Sept. 23, 2010, <http://www.nytimes.com/2010/09/24/health/policy/24avandia.html>.

217 Duff Wilson, *Avandia’s Sales Drop Far Behind Actos*, N.Y. TIMES, July 12, 2010, <http://prescriptions.blogs.nytimes.com/2010/07/12/avandias-sales-drop-far-behind-actos/>.

patients' treatment decisions—e.g., because patients value things other than health, and have a compelling interest in controlling their own bodies. The shortcomings of medical knowledge and the corruption of medical practice simply lend additional urgency to protecting patients' autonomy. If a physician recommends a treatment based on the best available evidence and an informed patient voluntarily consents to it, the patient has not been “wronged” even if the treatment harms her health. If, however, a patient is injured by an intervention she was effectively compelled to undergo, the harm to her health compounds the injury to her autonomy.

### C. *Personal Values and Self-Determination*

Even when a treatment promotes a patient's health, it still may not be in the patient's best interest.<sup>218</sup> People value things other than maximum health, and even the idea of “maximum health” is itself subjective. Some people are more risk-averse than others. Some place a higher value on living longer, others on better quality of life. As Cynthia Rand and Mary Sevick have argued:

The best medical outcome may not be the patients' primary goals nor in the patients' overall best interests. Patients generally balance medical goals against the costs associated with treatment. When patients experience unforeseen adverse events or side effects as a result of the treatment, they may determine that it is in their best interest to reduce or discontinue treatment. . . . Finally, treatment may not address the symptoms that are most bothersome to the patients. When patients are urged to comply to achieve medical treatment goals and to do so at the expense of something that they value more, the clinician has not behaved in the best interest of the patients.<sup>219</sup>

Consider tamoxifen. In a world in which there are few interventions known to be highly effective in lowering cancer risks, tamoxifen is a wonder drug.<sup>220</sup> For women who have an elevated risk of contracting breast cancer, tamoxifen cuts their risk in half.<sup>221</sup> If you were interested in promoting the health of women in a population and minimizing health care costs,

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218 Rand & Sevick, *supra* note 112, at S242 (“[C]linicians and patients may differ in their understanding of the problem being treated and the goals of treatment. While clinicians and researchers are interested in cure rates, improvements in biophysiologic measures, and reductions in health service use, patients are likely to be more interested in the impact of treatment on their quality of life.”); Sandman et al., *supra* note 44, at 117 (noting the traditional model of compliance has been criticized for “its emphasis on biomedical goals and its lack of emphasis on the short and longer-term life-goals of the patient.”).

219 Rand & Sevick, *supra* note 112, at S242.

220 Gina Kolata, *Medicines to Deter Some Cancers Are Not Taken*, N.Y. TIMES, Nov. 13, 2009, <http://www.nytimes.com/2009/11/13/health/research/13prevent.html?pagewanted=all&gwh=ADD8EF9A76BC73A1837CC44A981CoC89>.

221 *Id.*

tamoxifen seems like a no-brainer for at-risk women. Doctors know which patients are most likely to benefit, the benefits are substantial, and the most common side effects often are not considered serious. As *The New York Times*' Tara Parker-Pope asked, "If someone invented a pill to cut a cancer risk in half, would you take it? Who wouldn't?"<sup>222</sup>

The answer, Ms. Pope noted, is "millions of women."<sup>223</sup> Even when women are informed that their lifetime risk of breast cancer is twenty percent—double the average risk—about half turn down tamoxifen.<sup>224</sup> And among those who begin treatment, many abandon it before completing the five-year treatment course.<sup>225</sup> The most common reason women refuse to take tamoxifen is concern about its side-effects.<sup>226</sup> Tamoxifen can cause hot flashes, urinary problems, fatigue, weight gain, severe joint pain, and numerous other unpleasant effects.<sup>227</sup> It also raises the risk of endometrial cancer, blood clots, cataracts, and other health problems.<sup>228</sup> From the perspective of doctors whose objective is to help patients avoid tumors, these risks pale compared to the benefits of taking tamoxifen. Yet when researchers at the University of Michigan clearly spelled out the benefits and risks of the drug to a group of research participants, only six percent said they would consider taking it.<sup>229</sup>

From a public health perspective, refusing tamoxifen looks like the kind of irrational health decision that might be remedied by using financial incentives to alter women's risk/benefit assessments. Indeed, health researchers refer to this kind of choice as an example of common "decision errors that contribute to poor health-related behaviors."<sup>230</sup> Drawing on behavioral economics, some researchers describe patients' refusal to take an effective intervention as a form of "omission bias": overemphasizing low risks of harm that might result from taking action (such as taking tamoxifen) and deemphasizing higher risks of harm from failing to act.<sup>231</sup> Others argue people err by placing too much weight on the present rather than the future, which leads us to avoid the immediate costs of taking medications

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222 Tara Parker-Pope, *When Lowering the Odds of Cancer Isn't Enough*, N.Y. TIMES, Dec. 14, 2009, <http://well.blogs.nytimes.com/2009/12/14/when-lowering-the-odds-of-cancer-isnt-enough/?gwh=7AB29D46511E05439AAD8A3160F369A1>.

223 *Id.*

224 Kolata, *supra* note 220.

225 Christian Nordqvist, *Breast Cancer Drug Abandoned by 36% of Patients Due to Side Effects*, MEDICAL NEWS TODAY (Dec. 12, 2011), <http://www.medicalnewstoday.com/articles/239020.php>.

226 See Elizabeth A. Grunfeld et al., *Adherence Beliefs Among Breast Cancer Patients Taking Tamoxifen*, 59 PATIENT EDUC. & COUNSELING 97, 101 (2005); Parker-Pope, *supra* note 222.

227 Grunfeld et al., *supra* note 226, at 97, 99; Nordqvist, *supra* note 225.

228 Parker-Pope, *supra* note 222.

229 *Id.*

230 Volpp et al., *supra* note 56, at 389.

231 Parker-Pope, *supra* note 222.

that offer “delayed and often uncertain benefits of better health years later.”<sup>232</sup> As behavioral economist Dan Ariely puts it, “[t]he problem is that it’s all about trading off the long-term future with the short-term consequences . . . . It turns out that when we are faced with this tradeoff, we often make the wrong choice.”<sup>233</sup>

Cecilia Anderson may be the poster child for this short-term-oriented “wrong choice.” Although the fifty-seven-year-old has a one-in-five lifetime risk of breast cancer, she declined tamoxifen because she found it incompatible with her active lifestyle.<sup>234</sup> “I felt like my quality of life was in question . . . . I am busy, I am out there. I totally love my life and don’t want it to be compromised,” Ms. Anderson explained.<sup>235</sup> The behavioral economics view suggests Ms. Anderson has placed too much emphasis on her present quality of life—a decision she may come to regret if she develops breast cancer. But then there is Kay Wissmann, who was prescribed tamoxifen to prevent a recurrence of breast cancer. She stopped taking the drug “because it made her feel terrible and exhausted.”<sup>236</sup> Even when her breast cancer did recur, Ms. Wissman continued to believe she had made the right decision in discontinuing the drug.<sup>237</sup>

What looks to economists like an irrational decision can also be explained as a difference in values. Patients are not interested in maximizing societal utility but in living a life. The decision of whether and to what extent to sacrifice one’s current quality of life in exchange for potential future benefits is a deeply personal decision that includes costs that are not captured in economic analysis. For example, in one study of tamoxifen noncompliance two patients cited religious fasting as their reason for failing to comply with their prescriptions.<sup>238</sup> Noncompliance with tamoxifen is also higher among women who have undergone chemotherapy.<sup>239</sup> For women who are just starting to emerge from the physical and emotional trauma of chemotherapy and experience crippling side effects from tamoxifen, the certainty of spending the next five years in misery in the hopes of avoiding a future event that may never occur—or that may occur despite the drug—may be too much to bear.<sup>240</sup> Declining to take tamoxifen under

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232 Volpp et al., *supra* note 56, at 389.

233 Huff, *supra* note 84.

234 Kolata, *supra* note 220.

235 *Id.*

236 Andrew Pollack, *Take Your Pills, All Your Pills*, N.Y. TIMES, March 11, 2006, at C1.

237 *Id.*

238 Vedang Murthy et al., *Tamoxifen Non-Compliance: Does it Matter?*, 3 THE LANCET ONCOLOGY 654 (2002).

239 See Nordqvist, *supra* note 225.

240 See *id.* (“If they had a rough time with chemo, if they’re feeling beaten up by treatment and medications, or if they’re the type of person who has difficulty tolerating side effects, then they’re much more likely to quit the drugs early.”).

these circumstances may end up increasing health care costs, but it cannot be fairly characterized as a “decision error.”

Using incentives to compel patients to conform to economists’ assessments of their best interests is a radical departure from current standards of medical ethics. Until advocates of this approach establish that its benefits outweigh the costs to patients’ autonomy, wellness programs should be required to conform to existing ethical standards. As described below, however, the laws that regulate these programs do little to ensure that result.

#### IV. THE NEED FOR ENHANCED LEGAL PROTECTIONS

##### *A. Legal Protections Against Discrimination Do Not Protect Patient Autonomy*

1. *Legal Protections Against Discrimination.*—Several ACA and HIPAA provisions are designed to protect against discrimination in the provision of employer–sponsored health insurance while enabling employers to promote employee health.<sup>241</sup> The ACA, which incorporates HIPAA’s anti-discrimination provisions and related regulations,<sup>242</sup> bars group health plans from establishing rules for eligibility<sup>243</sup> or charging higher premiums<sup>244</sup>

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<sup>241</sup> Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111–148, § 1201, 124 Stat. 119, 156 (2010) (codified as amended at 42 U.S.C. § 300gg–4 (2011)) (entitled “Prohibiting Discrimination against Individual Participants and Beneficiaries Based on Health Status”); Health Insurance Portability and Accountability Act (HIPAA), 29 U.S.C. § 1182 (*same*). In addition to the ACA and HIPAA, several other federal and state laws can regulate wellness programs. The Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110–233, 122 Stat. 881 (2008), limits employers’ ability to collect employees’ genetic information. Anita K. Chancey, *Getting Healthy: Issues to Consider Before Implementing a Wellness Program*, J. HEALTH LIFE SCI. LAW, Apr. 2009, at 73, 73. Many states have laws that prohibit employers from discriminating based on certain aspects of an employee’s “lifestyle,” including off–duty smoking. Jesson, *supra* note 38, at 265–67. However, in the context of wellness programs that are part of group health benefit plans offered by self–insured employers, these state laws are generally preempted by the Employee Retirement Investment Security Act. *Id.* at 265 & n.212. Most notably, the Americans with Disabilities Act (ADA), Title I, 42 U.S.C. § 12102 (2006), limits employers’ ability to discriminate against disabled individuals—i.e., “individuals with a mental or physical impairment that substantially limits a major life activity.” Jesson, *supra* note 38, at 256. The ADA also prohibits employers from discriminating against any employee for declining to submit to medical examinations. 42 U.S.C. § 12112(d)(4)(A) (2011). The Equal Employment Opportunity Commission has issued no formal guidance regarding the extent to which the ADA may constrain wellness programs that comply with ACA and HIPAA requirements. Chancey at 73.

<sup>242</sup> Compare Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111–148, § 1201, 124 Stat. 119, 156–60 (2010) (codified as amended at 42 U.S.C. § 300gg–4 (2011)), with 29 C.F.R. § 2590.702(f) (2012).

<sup>243</sup> § 1201, 124 Stat. at 156 (2010) (codified as amended at 42 U.S.C. § 300gg–4(a) (2011)).

<sup>244</sup> *Id.* at 154–55 (2010) (codified as amended at 42 U.S.C. § 300gg–4(b) (2011)).



based on any individual's or dependent's health status or medical history.<sup>245</sup> However, the statute carves out an exception that expressly authorizes offering lower premiums or deductibles "in return for adherence to programs of health promotion and disease prevention."<sup>246</sup>

Wellness programs that do not tie rewards to satisfying a particular health standard are not subject to the Act's anti-discrimination provisions.<sup>247</sup> Examples of exempt programs include rewarding employees who attend a monthly health education seminar or participate in a diagnostic testing program, without regard to employees' health outcomes.<sup>248</sup> Because these kinds of programs do not tie employees' insurance contributions to meeting particular health standards that sick people may not be able to achieve or to activities sick people cannot undertake, they seem to present little danger of discrimination and are therefore exempt from the anti-discrimination provisions.

By contrast, wellness programs that tie rewards or penalties<sup>249</sup> to achieving a health status must meet several requirements designed to mitigate the potential for these programs to punish employees for health factors beyond their control.<sup>250</sup> First, a program's reward must not exceed thirty percent of the total cost of coverage, including both the employees' and the employers' contributions.<sup>251</sup> In other words, if the employer's total per capita cost of insuring its employees is \$15,000, it may charge up to \$4,500 more to employees who do not meet the wellness program's standards. The ACA empowers the Secretaries of Labor, HHS, and the Treasury to increase this cap to up to fifty percent of the cost of coverage if they deem it appropriate.<sup>252</sup>

Second, the ACA requires that wellness programs "be reasonably designed to promote health or prevent disease."<sup>253</sup> To meet this broad standard the program must have "a reasonable chance of improving the health of or preventing disease in participating individuals," must not be

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245 *Id.* at 156 (2010) (codified as amended at 42 U.S.C. § 300gg-4(a) (2011)).

246 *Id.* at 154-55 (2010) (codified as amended at 42 U.S.C. § 300gg-4(b)(2)(B) (2011)).

247 *Id.* at 157 (2010) (codified as amended at 42 U.S.C. § 300gg-4(j)(1)(B) (2011)).

248 *Id.* at 157 (2010) (codified as amended at 42 U.S.C. § 300gg-4(j)(2) (2011)).

249 "A reward may be in the form of a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or co-insurance), the absence of a surcharge, or the value of a benefit that would otherwise not be provided under the plan." *Id.* at 158 (2010) (codified as amended at 42 U.S.C. § 300gg-4(j)(3) (A) (2011)).

250 *Id.* at 157 (2010) (codified at 42 U.S.C. § 300gg-4(j)(1)(C) (2011)).

251 *Id.* at 157-58 (2010) (codified as amended at 42 U.S.C. § 300gg-4(j)(3)(A) (2011)). HIPAA previously imposed a cap of twenty percent. 29 C.F.R. 2590.702(f)(2)(i) (2012). The ACA's key amendment with respect to wellness programs was to raise this cap.

252 § 1201, 124 Stat. at 158 (2010) (codified at 42 U.S.C. § 300gg-4(j)(3)(A) (2011)).

253 *Id.* (codified as amended at 42 U.S.C. § 300gg-4(j)(3)(B) (2011)).

overly burdensome, and must not be “a subterfuge for discriminating based on a health status factor.”<sup>254</sup>

Third, “[t]he full reward under the wellness program shall be made available to all similarly situated individuals.”<sup>255</sup> To meet this requirement, the program must accommodate individuals for whom it is either medically inadvisable or unreasonably difficult due to a medical condition to satisfy the generally applicable standard for obtaining the reward.<sup>256</sup> For these individuals, the wellness program must either provide a reasonable alternative standard for obtaining the reward or waive the standard altogether for that individual.<sup>257</sup> A plan may seek verification, such as a statement from an employee’s physician, that a health factor makes it unreasonably difficult or medically inadvisable for the individual to satisfy or attempt to satisfy the otherwise applicable standard.<sup>258</sup>

These provisions seek to strike a balance between the potential for wellness programs to improve health and cut costs and the need to protect sick people from discrimination. Thus, for example, the Act permits charging higher rates to people who cannot meet a wellness program’s targeted health outcomes but limits the impact to thirty percent of the total cost of insurance. The Act also seeks to ensure that wellness programs genuinely seek to improve health, rather than simply charge more to unhealthy people, and requires accommodating people whose illnesses prevent them from achieving targeted health outcomes or undertaking certain activities.

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<sup>254</sup> *Id.*

<sup>255</sup> *Id.*

<sup>256</sup> *Id.* (codified as amended at 42 U.S.C. § 300gg-4(j)(3)(D)(i)(I)–(II) (2011)).

<sup>257</sup> *Id.*

<sup>258</sup> *Id.* In addition to these three requirements, the ACA requires that “[t]he plan shall give individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year,” *id.* (codified as amended at 42 U.S.C. § 300gg-4(j)(3)(C) (2011)), and that the health plan “shall disclose in all plan materials describing the terms of the wellness program the availability of a reasonable alternative standard (or the possibility of waiver of the otherwise applicable standard).” *Id.* (codified as amended at 42 U.S.C. § 300gg-4(j)(3)(E) (2011)).

2. *Anti-Discrimination Provisions Do Not Protect Autonomy.*—While these rules limit discrimination based on health factors, they are decidedly less well-suited to protecting employee autonomy.<sup>259</sup> As an initial matter, it is not clear whether the ACA's anti-discrimination protections apply to programs that tie rewards to certain health *behaviors*, such as medication compliance, as opposed to achieving particular health outcomes.<sup>260</sup> The Act's restrictions on wellness programs apply only to programs in which "any of the conditions for obtaining a . . . reward . . . is based on an individual *satisfying a standard* that is related to a health status factor."<sup>261</sup> The restrictions do not apply to programs that tie rewards to employees' "participation" in the program rather than to the achievement of certain outcomes.

It is not clear whether a program that ties rewards to employees' compliance with their physicians' recommendations, but does not base rewards on the achievement of particular health outcomes, is subject to the ACA's restrictions. Would regulators view this arrangement as rewarding "participation" in a program to manage chronic illness, like exempt programs that tie incentives to attending health education classes? Or would this more closely resemble a program that ties rewards to meeting a particular cholesterol level? Note that the purpose of the ACA's restrictions is to mitigate the potential for discrimination against people who cannot achieve certain health outcomes, or cannot undertake certain activities, because of a sickness or disability.<sup>262</sup> That concern does not seem to apply to incentives for an employee to take the actions a doctor has determined will best promote her health. Accordingly, regulators might determine this kind of program is exempt from the Act's wellness provisions.

Even if the ACA's anti-discrimination provisions do apply to this kind of program, they are still inadequate to protect employee autonomy. First, the Act's caps on the size of permissible incentives are set far too high to protect voluntary consent. According to a report by the Kaiser Family Foundation, in 2011 the average annual health insurance premium for employer-sponsored coverage was more than \$15,000 for family coverage.<sup>263</sup> Under

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259 See, e.g., Madison et al., *supra* note 24, at 462–63 (noting that the ACA's cap on the size of wellness incentives could offer some protection for patient voluntariness, "but the ceiling is not particularly well suited for this task").

260 See Schmidt et al., *supra* note 57, at e3(1) (interpreting HIPAA regulations, subsequently codified in the ACA, as distinguishing between "participation incentives," in which incentives are tied to "participation" in a health-promotion program, and "attainment incentives" "which provide reimbursements for only meeting targets—for example, a particular body-mass index or cholesterol level").

261 Patient Protection and Affordable Care Act § 1201 (codified as amended at 42 U.S.C. § 300gg-4(j)(1)(C) (2011)) (emphasis added).

262 *Id.* (codified as amended at 42 U.S.C. § 300gg-4 (2011)) (entitled "Prohibiting discrimination against individual participants and beneficiaries based on health status").

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the ACA's thirty percent cap on incentives, employers with average health insurance costs could increase noncompliant employees' contributions by up to \$4,500 per year. For an employee with a household income of \$50,000—the median household income in the United States<sup>264</sup>—\$4,500 is nearly ten percent of that employee's annual pre-tax income. Moreover, the ACA gives the federal government authority to raise the incentive cap to as high as fifty percent of the total cost of coverage, or \$7,500 under an average-cost employer-sponsored plan.<sup>265</sup> Under these caps, any employee who cannot pay an additional \$4,500 to \$7,500 in deductibles or an additional \$375 to \$625 in monthly premiums may have to choose between complying with the wellness program or going without coverage.

Other anti-discrimination provisions likewise do little to protect patient autonomy. While the Act requires that wellness programs must not be “overly burdensome,”<sup>266</sup> this requirement refers to the program's overall design—not the burdens a particular individual may experience in achieving the targeted standard. This requirement is one component of the rules that require a wellness program to be “reasonably designed to promote health or prevent disease” and not “a subterfuge for discriminating based on a health status factor.”<sup>267</sup> A program that ties incentives to following doctors' recommendations presumably would not, as a matter of program design, constitute a “highly suspect . . . method . . . to promote health,” which this portion of the statute prohibits<sup>268</sup>—regardless of whether such a program would impose significant burdens on some employees.<sup>269</sup>

The ACA's requirements that wellness programs accommodate people who cannot meet certain health targets appear closer to the mark, insofar as they relate to the burdens individuals may experience in seeking to comply with wellness program requirements. On closer inspection, however, these provisions do not protect employees' right to decline a course of treatment recommended by their physicians. The Act requires employers to accommodate individuals for whom it is inadvisable or unreasonably difficult to comply with wellness program requirements—but only if doing so is *medically* inadvisable or unreasonably difficult *due*

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BENEFITS 2011 ANNUAL SURVEY I (2011), available at <http://ehbs.kff.org/pdf/2011/8225.pdf>.

264 U.S. CENSUS BUREAU, STATISTICAL ABSTRACT OF THE UNITED STATES: 2012 § 13, at 452 tbl.690 (2012), available at <http://www.census.gov/compendia/statab/2012/tables/12s0691.pdf>.

265 Patient Protection and Affordable Care Act § 1201 (codified as amended at 42 U.S.C. § 300gg-4(j)(3)(A) (2011)).

266 *Id.* (codified as amended at 42 U.S.C. § 300gg-4(j)(3)(B) (2011)).

267 *Id.*

268 *Id.*

269 *See, e.g.,* Madison et al., *supra* note 24, at 457 (arguing that “[d]ifferences in program participants' abilities to respond to incentives . . . do not necessarily imply that incentive programs impermissibly discriminate,” in part because “[t]he individuals facing the most significant barriers may have the most to gain from incentive programs”).

to a medical condition.<sup>270</sup> That is not a determination a patient can make on her own. Rather, employers are entitled to “seek verification, such as a statement from the individual’s physician” attesting to the fact that a health factor makes it unreasonably difficult or inadvisable for the employee to comply.<sup>271</sup> If a wellness program merely requires an employee to obey his doctors’ recommendations, clearly a physician is not going to certify that her own prescriptions are unreasonably difficult or medically inadvisable for the patient to follow. These provisions offer no protection to patients who would prefer to decline treatments recommended by their doctors.

In sum, the ACA does not require employers to accommodate individuals who object to treatments prescribed by their doctors. On the contrary, in the examples recited in the applicable regulations, following a doctor’s recommendations *is* the accommodation offered to employees who cannot meet the health standard required of other employees.<sup>272</sup> One example considers a wellness program in which employees who achieve a cholesterol count under 200 receive an annual premium discount of twenty percent of the cost of their coverage.<sup>273</sup> The plan provides that it will accommodate any participant for whom it is unreasonably difficult to achieve a count under 200:

Individual *D* begins a diet and exercise program but is unable to achieve a cholesterol count under 200 within the prescribed period. *D*’s doctor determines *D* requires prescription medication to achieve a medically advisable cholesterol count. In addition, the doctor determines that *D* must be monitored through periodic blood tests to continually reevaluate *D*’s health status. The plan accommodates *D* by making the discount available to *D*, but only if *D* follows the advice of *D*’s doctor’s regarding medication and blood tests.<sup>274</sup>

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<sup>270</sup> Patient Protection and Affordable Care Act § 1201 (codified at 42 U.S.C. § 300gg-4(j)(3)(D)(i)(I)-(II) (2011)).

<sup>271</sup> *Id.* (codified as amended at 42 U.S.C. § 300gg-4(j)(3)(D)(ii) (2011)).

<sup>272</sup> 29 C.F.R. § 2590.702(f)(3) exs. 3 & 4 (2012). While these examples are found in regulations implementing HIPAA, they apply with equal force to the ACA’s wellness provisions. The ACA adopted and codified HIPAA regulations of wellness programs, while modifying the size of incentives permitted under these regulations. *Compare* Patient Protection and Affordable Care Act § 1201 (codified as amended at 42 U.S.C. § 300gg-4) (2011), *with* 29 C.F.R. § 2590.702(f) (2012).

<sup>273</sup> 29 C.F.R. § 2590.702(f)(3) ex. 3 (2012). This example uses the twenty percent cap provided for in the HIPAA regulations. 29 C.F.R. § 2590.702(f)(2)(i) (2012). The ACA raised that limit to thirty percent of the total cost of coverage. Patient Protection and Affordable Care Act § 1201 (codified at 42 U.S.C. § 300gg-4(j)(3)(A) (2011)).

<sup>274</sup> 29 C.F.R. § 2590.702(f)(3) ex. 3 (2012).

The regulations conclude that this program is permissible and that it adequately accommodates *D* by providing a reasonable alternative standard for obtaining the discount.<sup>275</sup>

Thus, the regulations protect *D* against discrimination based on his health status by ensuring that he is not penalized for failing to meet targets that his health prevents him from achieving. But it does not protect *D*'s right to choose his course of treatment, free from substantially controlling influences. If *D* faces a \$4,500 increase in his health insurance costs for refusing his prescription medications—and particularly if he cannot afford health insurance for his family after imposition of that penalty—the voluntariness of *D*'s consent is seriously undermined.

As described above, there are many valid reasons a patient may wish to refuse a treatment that a physician believes would promote the patient's health.<sup>276</sup> But the ACA's anti-discrimination provisions offer no protection for employees who do not wish to undergo the treatments recommended by their physicians.

### *B. Recommended Enhancements*

In light of the ethical imperative to reduce health care costs and the attractiveness of doing so by promoting health, it may be appropriate to make limited use of incentives to encourage people to improve their health. But any such use should be subject to clearly defined limits, which currently do not exist. Just as the ACA seeks to encourage programs that promote health while protecting against discrimination, the laws and regulations governing wellness programs should also protect against undue infringements on patients' autonomy.

The ACA provides an opportunity to raise these issues. The Act requires the Secretary of HHS to submit a report to Congress evaluating "the effectiveness of wellness programs . . . in promoting health and preventing disease," "the impact of such wellness programs on the access to care and affordability of coverage for participants and non-participants of such programs," "the impact of premium-based and cost-sharing incentives on participant behavior and the role of such programs in changing behavior," and "the effectiveness of different types of rewards."<sup>277</sup> The Secretary should use this report to highlight the potential for wellness programs to

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<sup>275</sup> See also 29 C.F.R. § 2590.702(f)(3) ex. 4 (2012) (endorsing a wellness program in which a participant for whom it is medically inadvisable or unreasonably difficult due to a medical condition to achieve the targeted health standard can still receive the applicable reward as long as he follows his physician's recommendations).

<sup>276</sup> See *supra* Part III.

<sup>277</sup> Patient Protection and Affordable Care Act § 1201 (codified as amended at 42 U.S.C. § 300gg-4(m) (2011)).

undermine employee autonomy and to recommend modifications to the ACA to curtail problematic uses of incentives.

As an initial matter, the report should include a frank, thorough, and nuanced acknowledgement of the threats wellness programs can pose to voluntariness and the potential harms that can result. Since these concerns have received scant attention in political debates and academic literature, the HHS report represents an opportunity to alert policymakers and stakeholders to hidden costs of the Act's wellness provisions.

The Secretary should also use the report to offer three specific recommendations to protect employee autonomy. First, the ACA's wellness provisions should be amended to make explicit that the Act's anti-discrimination provisions apply not only to programs that tie incentives to particular health targets but also to those that reward compliance with particular health behaviors. In the Act's current form, the line between rewarding achievement of particular health outcomes and incentivizing employee "participation" in particular activities is not at all clear.<sup>278</sup> If the ACA does not apply to programs that tie incentives to employees undertaking particular behaviors, there are few limits on employers' ability to penalize non-disabled employees for failing to diet, adopt a particular exercise regime, or take prescribed medications.<sup>279</sup>

Second, even if the ACA's anti-discrimination provisions apply to behavior-based programs, they are inadequate to protect patient autonomy. The Secretary should recommend sharply reducing the size of incentives employers may use to promote employee compliance with wellness programs. Many employees could not afford health insurance if required to pay the maximum penalties permitted by the ACA. Employees' access to affordable health insurance should not depend on their willingness to comply with wellness program requirements.

The ACA's approach to limiting incentives is particularly problematic for lower income workers. The Act ties the size of permissible penalties to the employer's total per capita cost of insuring its employees, which has no relation to employees' ability to afford these penalties.<sup>280</sup> Unlike their lower-earning peers, higher income workers who can afford increased health insurance contributions can refuse to comply with wellness program requirements without threatening the welfare of their families. Under these circumstances, voluntary consent is transformed from a core, universal ethical requirement to a commodity that can be purchased by individuals who can afford to pay more for health insurance. In order to protect the autonomy of all employees, the Secretary should recommend modifying

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<sup>278</sup> See *supra* Part IV.A.2.

<sup>279</sup> The Americans with Disabilities Act provides additional protections for disabled employees. See *supra* note 241.

<sup>280</sup> Patient Protection and Affordable Care Act § 1201 (codified at 42 U.S.C. § 300gg-4(j)(3)(A) (2011)).

the ACA's incentive caps so that either they are so small that they cannot coerce even low income employees, or they are tied not to an employer's insurance costs but to individual employees' ability to pay.

Finally, although limiting the size of incentives is the simplest and most effective way to protect employee autonomy, if Congress will not make those changes HHS should recommend amendments that bar employers from penalizing workers for failing to follow their doctors' recommendations. Decisions regarding whether to take medications must be made voluntarily by patients, without threat of penalty.

Constraining the use of incentives in these ways might (or might not) reduce the effectiveness of certain wellness approaches in lowering health care costs. But it is critical to assess the total costs of any given approach, including non-monetary costs such as diminished privacy and autonomy. If protections that are essential to ensuring a basic level of patient autonomy make some wellness approaches less effective, so be it. That may be a compelling reason to favor a different mix of strategies. This is particularly true in light of the current paucity of evidence that incentive programs actually improve health or reduce costs.<sup>281</sup> Rather than worrying that limiting the use of incentives will undermine the effectiveness of wellness programs, we ought to worry about eroding patient autonomy based on hope in, and hype about, an unproven theory. A more sensible approach would be to implement limited pilot projects to study the efficacy of different incentive program designs in promoting health and reducing costs and to determine how those programs are experienced by patients. Only when we know what society stands to gain from incentive programs can we determine how much we should be willing to sacrifice for them.

## CONCLUSION

Patient autonomy is not a moral absolute that can never be compromised. Any assessment of the propriety of using incentives to modify patient behaviors must take into account competing demands of fairness and responsible stewardship of scarce health care resources. No one is well served by policies that foreclose improvements to public health or unduly hamper the ability of employers—who provide health benefits to most of the nation's insured individuals<sup>282</sup>—to reduce health care costs. Given the attractiveness of achieving these objectives by improving employees' health, there may be some role for using financial incentives to nudge people to take better care of themselves.

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281 See *supra* note 56.

282 See STATE HEALTH ACCESS DATA ASSISTANCE CTR., STATE-LEVEL TRENDS IN EMPLOYER-SPONSORED HEALTH INSURANCE 1 (2011), available at [http://www.shadac.org/files/shadac/publications/ESI\\_Trends\\_Jun2011.pdf](http://www.shadac.org/files/shadac/publications/ESI_Trends_Jun2011.pdf) (stating sixty-one percent of nonelderly Americans received health insurance through employers in 2008–2009).



That said, when employees must choose between complying with wellness program requirements or losing access to affordable health insurance, this approach looks less like a nudge than a shove. Allowing employers to threaten noncompliant employees with such a serious harm is a radical departure from existing ethical standards requiring that patients' consent to treatment be free from substantially controlling influences. Only an individual patient can determine whether the benefits of a treatment outweigh its risks, based on her own values, circumstances, and personal experience with a treatment. Voluntary consent should not be a privilege available only to those who can afford higher premiums.

We should think carefully before contravening the fundamental requirement that competent, adult patients retain control over decisions regarding their own bodies. Yet to date advocates of using financial incentives to shape patient behavior have failed to even acknowledge how this strategy can undermine informed consent, let alone supply evidence that wellness programs' benefits justify these incursions. Until we have had a thorough airing of the risks and potential benefits of this strategy, Congress should amend the laws governing wellness programs to conform to current ethical standards.