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# HIGH-TECH ADHERENCE: INCORPORATING SMART PILL TECHNOLOGY INTO WELLNESS PROGRAMS

Leighanne Root\*

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### *Introduction*

Patient non-adherence to medication is not a new problem. For decades, experts have acknowledged that failure to comply with prescriptions is a costly problem that frequently results in avoidable fatalities. This well-established issue is exceedingly complex, and although steps have been taken to improve adherence rates, there is no singular solution to the crisis.

A plethora of technology has been developed to monitor and incentivize adherence, ranging from smart phone applications to sophisticated electronic medication packaging. But smart phone applications are only so smart, and electronic packaging lacks the detail and accuracy necessary to paint the comprehensive picture of patient compliance that would allow for real improvement in adherence rates.

The recent development of “smart pill” technology provides that missing detail and accuracy by retrieving real-time data about a patient’s adherence and transmitting it instantaneously to her physician, family, or other caregivers. Through a sophisticated system of ingestible sensors, a wearable patch, and a smart phone application, smart pill technology creates a system of support and accountability to encourage patients to comply with their treatment regimens.

The invention of smart pill technology is a significant move toward resolving the medication adherence crisis. However, pairing this emerging technology with developments in health insurance laws provides the opportunity to design a novel method of adherence intervention. The Patient Privacy and Affordable Care Act (PPACA) allows payors to discount the insurance premiums of beneficiaries who participate in wellness programs designed to promote health. Incorporating smart pill technology into these wellness programs incentivizes medication adherence, which is in turn associated with improved health and reduced healthcare costs. This could translate into

lower insurance premiums for employers and their employees, and ultimately reduce national healthcare expenditure.

This article advocates for the incorporation of smart pill technology into wellness programs as a means of promoting medication adherence, improving health, and reducing costs on an individual and national level. Part I addresses the causes and effects of patient non-adherence. Part II examines recent technological developments aimed at monitoring and improving adherence, including emerging smart pill technology. Part III discusses wellness programs, the legal requirements underlying them, and their impact on health outcomes and associated costs. Part IV ties the preceding parts together by advocating for the use of smart pill technology in wellness programs as a method of increasing adherence, improving health, and reducing cost, all while addressing potential concerns arising from the implementation of such programs. Part V concludes.

### *I. Medication Adherence*

#### *A. The Adherence Crisis*

Medication adherence is a well-established and costly problem. More than half of patients fail to take their medications correctly,<sup>1</sup> and twenty percent fail to even fill new prescriptions.<sup>2</sup> Considering that nearly half of Americans use at least one prescription, these numbers are alarming.<sup>3</sup>

From a technical standpoint, a patient is generally considered adherent to their prescription if they take their medication eighty percent of the time.<sup>4</sup> However, adherence is typically measured by

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<sup>1</sup> Katharine Boshinski Sparks, *Medication Adherence Technology: Medicine of the Future, Emerging Privacy Concern*, 28 J. CONTEMP. HEALTH L. & POL'Y 324, 326 (2012).

<sup>2</sup> John Tozzi, *'Take Your Pills' Reminders from Apps and Gadgets*, BLOOMBERG L.P. (March 28, 2013), <http://www.bloomberg.com/news/articles/2013-03-28/take-your-pills-reminders-from-apps-and-gadgets>.

<sup>3</sup> *Id.* Perhaps even more concerning is the fact that ten percent of Americans take five or more prescription drugs. *Id.* When considering the elderly population, these statistics are even more alarming. Ninety percent of elderly Americans take at least one prescription medication per week, and over forty percent take five or more weekly. Sparks, *supra* note 1, at 326.

<sup>4</sup> Marie T. Brown & Jennifer K. Bussell, *Medication Adherence: WHO Cares?*, 86 MAYO CLINIC PROCEEDINGS 304, 305 (2011), [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3068890/pdf/mayoclinproc\\_86\\_4\\_007.pdf](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3068890/pdf/mayoclinproc_86_4_007.pdf). See also R. Brunner et al., *Predictors of Adherence in the Women's Health Initiative Calcium and Vitamin D Trial*, 34 BEHAV. MED. 145, 145 (2009). But note, this is not necessarily an industry standard. "Some trials consider rates of greater than 80 percent to be acceptable, whereas others

dividing the number of pills absent from the prescribed amount by the total number of pills prescribed.<sup>5</sup> What is troubling about such a calculation is the failure to take into account whether the patient actually took the absent pills.<sup>6</sup> “Rationing” or “sharing” medication for financial or other reasons is a common practice patients do not often disclose to their physicians.<sup>7</sup> Consequently, even if a patient is not actually ingesting eighty percent of their pills, their physician may nevertheless deem them adherent to their prescription.

Among those most susceptible to non-adherence are patients managing chronic conditions. Troublingly, these individuals constitute nearly forty-five percent of the American population.<sup>8</sup> The National Institute of Health reported that half of patients with chronic conditions stop taking their medications after only six months.<sup>9</sup> This is especially alarming in light of the critical nature of adherence to medications prescribed for chronic conditions.<sup>10</sup> Adherence rates are particularly poor in patients managing cardiovascular disease, even among individuals who have already experienced an adverse cardiovascular event such as a stroke.<sup>11</sup> Significantly, as many as eighty percent of hypertensive patients fail to adhere to their treatment plan.<sup>12</sup> The World Health Organization (WHO) deems this the most important cause of failure to achieve blood pressure control.<sup>13</sup> This failure to regulate blood pressure significantly increases the risk of adverse

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consider rates of greater than 95 percent to be mandatory for adequate adherence. . .” Lars Osterberg & Terrence Blaschke, *Drug Therapy: Adherence to Medication*, 353 NEW ENG. J. MED. 487, 487 (2005).

<sup>5</sup> Brown & Bussell, *supra* note 4, at 305.

<sup>6</sup> *Id.*

<sup>7</sup> *Id.* at 310. Another reason this calculation is problematic is that patients often lie to their physicians about taking their pills, and then throw them out to cover up the fact that they did not take the medication. ROBERT SCOBLE AND SHEL ISRAEL, *AGE OF CONTEXT: MOBILE, SENSORS, DATA, AND THE FUTURE OF PRIVACY* 96 (Harry Miller ed., Patrick Brewster Press 2014).

<sup>8</sup> Campaign to Improve Poor Medication Adherence, 76 Fed. Reg. 12,969 (Mar. 9, 2011), <http://www.gpo.gov/fdsys/pkg/FR-2011-03-09/pdf/2011-5287.pdf>.

<sup>9</sup> Tozzi, *supra* note 2; *see also* Osterberg & Blaschke, *supra* note 4, at 487 (reporting that “persistence among patients with chronic conditions is disappointingly low, dropping most dramatically after the first six months of therapy.”).

<sup>10</sup> Brown & Bussell, *supra* note 4, at 305. Individuals with chronic conditions “are at greater risk for health complications and negative health outcomes because of medication adherence problems.” Campaign to Improve Poor Medication Adherence, 76 Fed. Reg. at 12,970.

<sup>11</sup> Brown & Bussell, *supra* note 4, at 305-06.

<sup>12</sup> *Id.* at 305.

<sup>13</sup> *Id.* at 305-06.

cardiovascular events such as myocardial infarction, stroke, and hospitalization.<sup>14</sup>

### *B. Causes and Effects of Non-Adherence*

There are a number of reasons for non-adherence. An array of medical and social issues such as intolerance, apathy, inability to pay, and poor memory may affect a patient's adherence.<sup>15</sup> Patients managing complex health issues and taking multiple medications may find it particularly difficult to keep track of which pills they have taken each day.<sup>16</sup> In fact, studies have shown that a patient's adherence decreases by ten percent with each additional daily dose he is prescribed.<sup>17</sup>

Perhaps unsurprisingly, a lack of family or social support also has a negative impact on adherence.<sup>18</sup> However, even patients with a support team may not adhere if they rely on the assistance of a caregiver who does not live with them and is unable to consistently monitor their adherence.<sup>19</sup>

Troublingly, physicians often fail to identify patients who are non-adherent to their treatment regimen.<sup>20</sup> There are many explanations for this problem, such as insufficient patient-physician communication<sup>21</sup> or the patient's inadequate medical literacy.<sup>22</sup>

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<sup>14</sup> *Id.* at 306.

<sup>15</sup> Jannet M. Carmichael & Janice A. Cichowlas, *The Changing Role of Pharmacy Practice—A Clinical Perspective*, 10 ANNALS HEALTH L. 179, 184 (2001). Ethnicity also appears to play a role. A Women's Health Initiative study indicated that African American women were forty percent less adherent than women from other ethnic backgrounds. Brunner et al., *supra* note 4, at 148.

<sup>16</sup> *Press Release, Lloydspharmacy Partners with Proteus Biomedical to Launch Innovative Digital Health Product*, PROTEUS DIG. HEALTH (Jan. 13, 2012), <http://www.proteus.com/lloydspharmacy-partners-with-proteus-biomedical-to-launch-innovative-digital-health-product/>.

<sup>17</sup> Brown & Bussell, *supra* note 4, at 310. *See also* Osterberg & Blaschke, *supra* note 4, at 490 (noting that “[s]imple dosing (one pill, once daily) helps to maximize adherence. . .”). Ease of treatment also plays a role. A study showed that swallowable (as opposed to chewable) pills benefited adherence rates. Brunner et al., *supra* note 4, at 148, 154.

<sup>18</sup> Amy Padley, Connie Perry, Claire Sharda, & Robert Turpin, *Medication Adherence Initiatives: Are There Best Practices?*, 22 J. COMPENSATION & BENEFITS 9 (2006). Conversely, strong social ties improve patient adherence. A recent study indicated that women who were married or living with a partner were twelve percent more likely to adhere to their medication. Brunner et al., *supra* note 4, at 148.

<sup>19</sup> *See Lloydspharmacy Partners with Proteus*, *supra* note 16.

<sup>20</sup> Brown & Bussell, *supra* note 4, at 307. *See also* Osterberg & Blaschke, *supra* note 4, at 487 (stating that “[t]he ability of physicians to recognize nonadherence is poor. . .”).

<sup>21</sup> Brown & Bussell, *supra* note 4, at 307. The communication problem is exacerbated by

Physicians often unwittingly contribute to patient non-compliance by prescribing complex treatment regimens, inadequately explaining the risks and benefits of the medication, or failing to consider the financial burden the prescription could place on the patient.<sup>23</sup>

Whatever the reasons for non-adherence, there is no denying that it is a costly problem.<sup>24</sup> The problem is estimated to cost the healthcare system nearly \$300 billion annually.<sup>25</sup> The American Heart Association deems the failure to follow prescriptions “the number one problem in treating illness today.”<sup>26</sup> Indeed, as many as two-thirds of medication-related hospitalizations result from poor compliance with prescriptions.<sup>27</sup> This non-adherence results in an overall ten percent increase in hospital admissions.<sup>28</sup> In 2012, non-adherence cost \$258 billion in emergency room expenses alone.<sup>29</sup>

Patients managing chronic diseases like hypertension pose a particularly serious problem when they neglect to take their medications as prescribed. Take, for example, a hypertensive patient who fails to adhere to her prescription. The short-term result of her

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the fact that patients “generally want to please their physicians and will often say what they think their doctor wants to hear.” Osterberg & Blaschke, *supra* note 4, at 490.

<sup>22</sup> Brown & Bussell, *supra* note 4, at 306. In the United States, approximately ninety million adults “have inadequate health literacy, placing them at risk for increased rates of hospitalization and poorer clinical outcomes.” The communication problem is exacerbated when patients are confused or simply lie about what medications they are taking. SCOBLE & ISRAEL, *supra* note 7, at 96.

<sup>23</sup> Brown & Bussell, *supra* note 4, at 307. See also Osterberg & Blaschke, *supra* note 4, at 490 (noting that “not giving consideration to the patient’s lifestyle” or “having poor therapeutic relationships with [] patients” are additional reasons physicians unintentionally contribute to poor adherence).

<sup>24</sup> See Sparks, *supra* note 1, at 326. Perhaps a less-explored—but equally concerning—result of failure to adhere to medication is found in clinical trials for experimental drugs. When trial participants fail to take the medication as directed, the results of the trial are skewed or rendered altogether meaningless. Employing methods to ensure visual confirmation that participants are taking the medication is extremely expensive, especially in large clinical trials with thousands of participants. Aaron Hoover & Kay Howell, *Rx for Health: Engineers Design Pill that Signals it has Been Swallowed*, UNIV. OF FLA. UF NEWS (Mar. 31, 2010), <http://news.ufl.edu/archive/2010/03/rx-for-health-engineers-design-pill-that-signals-it-has-been-swallowed.html>.

<sup>25</sup> Sparks, *supra* note 1, at 326.

<sup>26</sup> Hoover & Howell, *supra* note 24.

<sup>27</sup> Brown & Bussell, *supra* note 4, at 305. See also Osterberg & Blaschke, *supra* note 4, at 488 (noting that thirty-three to sixty-nine percent of medication-related hospital admissions in the United States are due to poor medication adherence).

<sup>28</sup> Hoover & Howell, *supra* note 24. These avoidable hospitalizations account for \$100 billion of the annual \$300 billion cost of non-adherence to the health care system. Sparks, *supra* note 1, at 326.

<sup>29</sup> SCOBLE & ISRAEL, *supra* note 7, at 96.

non-adherence is an increase in yearly treatment costs.<sup>30</sup> In fact, this patient costs the healthcare system nearly \$4,000 more per year than her counterpart who regularly adheres to his medication.<sup>31</sup> The long-term result of her non-adherence may be the patient suffering a stroke or heart attack.<sup>32</sup> Such an outcome might cost the healthcare system tens or hundreds of thousands of dollars.<sup>33</sup> Worse, it may cost the patient her life.<sup>34</sup>

Non-adherence also negatively impacts costs to employers offering health insurance to their employees. 149 million Americans obtain health insurance from their employers,<sup>35</sup> and the costs of premiums and claim payments for those employers are on the rise.<sup>36</sup> Employees who fail to adhere to their medication add to those direct costs, but there are also indirect financial consequences of their behavior.<sup>37</sup> Employee absence and on-the-job work loss can stem from patients failing to properly adhere to their prescriptions, and employers pay the price.<sup>38</sup> Indeed, the cost of these indirect consequences can constitute over half of an employer's total healthcare expenditure.<sup>39</sup>

When patients fail to follow their prescriptions, their non-adherence decreases the therapeutic effect of the medications.<sup>40</sup> Indeed, studies have shown that certain prescription drugs only have a therapeutic effect when a patient meets a certain minimal "adherence

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<sup>30</sup> *M-Health: Health and appiness*, ECONOMIST (Feb. 1, 2014), [http://www.economist.com/news/business/21595461-those-pouring-money-health-related-mobile-gadgets-and-apps-believe-they-can-work?fsrc=scn/tw\\_ec/health\\_and\\_appiness](http://www.economist.com/news/business/21595461-those-pouring-money-health-related-mobile-gadgets-and-apps-believe-they-can-work?fsrc=scn/tw_ec/health_and_appiness).

<sup>31</sup> *Id.*

<sup>32</sup> Fiona Graham, *The Pill that Texts Your Doctor – From Inside Your Body*, BBC NEWS TECH. OF BUS., <http://www.bbc.com/news/business-23620996> (last updated Aug. 13, 2013, 7:16 PM).

<sup>33</sup> *Id.*

<sup>34</sup> See *American Heart Association Annual Statistical Update: Heart disease and stroke continue to threaten U.S. health*, AM. HEART ASS'N (Dec. 18, 2013), <http://newsroom.heart.org/news/heart-disease-and-stroke-continue-to-threaten-u-s-health> (stating that of the approximately 720,000 Americans who have a heart attack each year, about 122,000 die. 795,000 people have a stroke each year, resulting in over 129,000 deaths annually).

<sup>35</sup> *Employer-Sponsored Coverage*, AM.'S HEALTH INS.E PLANS, <http://www.ahip.org/Issues/Employer-Sponsored-Coverage.aspx>.

<sup>36</sup> Padley et al., *supra* note 18, at 35.

<sup>37</sup> *Id.*

<sup>38</sup> *Id.* at 36.

<sup>39</sup> *Id.* at 35.

<sup>40</sup> *Press Release, NHS England and UK Trade & Investment to Bring Transformative Digital Health Technology to the UK*, PROTEUS DIG. HEALTH (March 20, 2014), <http://www.proteus.com/proteus-digital-health-nhs-england-and-uk-trade-investment-to-bring-transformative-digital-health-technology-to-the-uk/>.

threshold.”<sup>41</sup> This is clearly a costly oversight, and it is also a deadly one. On average, 130,000 people die annually from failure to adhere to the terms of their prescription medications.<sup>42</sup> This is an alarming statistic, but an avoidable one.

## *II. Technological Advances In Adherence Intervention*

Effective adherence interventions may have a much more significant impact on the health of the population than any other improvement in medical treatments.<sup>43</sup> Indeed, the WHO notes that improving medication adherence for conditions like hypertension and diabetes would yield very substantial health and economic benefits.<sup>44</sup>

But there is no fix-all solution for the adherence problem. Medication adherence is an enormously complex issue,<sup>45</sup> and an equally complex solution is required to fully resolve the problem. Nevertheless, there are strategies that can increase patient compliance. In the age of technology, it is no surprise that a plethora of devices aimed at promoting medication adherence already exist.

Pharmaceutical companies have taken initiative to improve adherence by designing packaging that reminds patients to take their medications.<sup>46</sup> Adherence packaging can range from the distribution of a calendar indicating when a medication should be taken to sophisticated electronic packaging.<sup>47</sup> Electronic packaging can include blinking pill bottles and even caps that store information about the patient’s adherence.<sup>48</sup> Some forms of electronic packaging can even transmit the adherence information directly to the patient’s physician or caregiver.<sup>49</sup> Ultimately, this may prompt the patient’s caretakers to

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<sup>41</sup> Padley et al., *supra* note 18, at 36. For example, patients taking lipid-lowering medications must take at least seventy percent of the prescribed dose to avoid greatly reducing the effectiveness of their medication. Patients on blood pressure medications need to adhere to their medications eighty percent of the time to consistently lower their blood pressure. *Id.*

<sup>42</sup> SCOBLE & ISRAEL, *supra* note 7, at 96. But even this estimate may be low. Some studies have proposed that the number of annual deaths from non-adherence exceeds 200,000. Clay Dillow, *Chip in a Pill Tells Your Doctor When You Swallow Your Medicine—and When You Don’t*, POPULAR SCI., <http://www.popsi.com/science/article/2010-03/chip-equipped-pill-tells-your-doctor-when-you-dont-take-your-medicine> (last updated March 31, 2010, 5:30 PM).

<sup>43</sup> Brown & Bussell, *supra* note 4, at 304.

<sup>44</sup> *Id.* at 306.

<sup>45</sup> *Id.* at 307.

<sup>46</sup> See Sparks, *supra* note 1, at 328.

<sup>47</sup> *Id.*

<sup>48</sup> *Id.* at 328-29.

<sup>49</sup> *Id.* at 329.

follow up with the patient when a dose is missed.

Mobile Health (mHealth) applications are another way technology helps to promote medication adherence. Patients can now easily download apps like DoseCast and MedCoach and receive reminders to take their pills.<sup>50</sup> These apps track the patient's adherence and also allow his or her caregiver to access information and manage medications.<sup>51</sup> Companies like HealthPrize and Mango Health even reward patients that follow their prescriptions by awarding them gift cards and similar prizes.<sup>52</sup> These apps engage and motivate patients by turning adherence into a game with immediate rewards.<sup>53</sup>

But just as there is always a new-and-improved smart phone emerging to better suit our needs, adherence technology is ever changing. Enter the "smart pill." Proteus Digital Health has recently developed Proteus Discover,<sup>54</sup> a system of ingestible sensor technology to help monitor and improve patient adherence.<sup>55</sup> The system includes ingestible sensor tablets, a Band-Aid-like sensor patch worn on the patient's body, and an advanced mHealth application.<sup>56</sup>

Here's how it works. The patient swallows an ingestible sensor, which is activated by stomach fluid.<sup>57</sup> The sensor sends information

<sup>50</sup> Bliss Mishler, *Forgot your Medication Again? There's an App for That*, HUNT REG'L MED. PARTNERS (Sept. 24, 2015), <http://huntregionalmedicalpartners.org/tag/mobile-health/>.

<sup>51</sup> *Id.*

<sup>52</sup> Mango Health, *Products*, <http://www.mangohealth.com/products> (last visited Feb. 1, 2016); see also Alison Bruzek, *Take Your Medicine, Tap Your Phone And Collect A Prize*, SHOTS - HEALTH NEWS FROM NPR (Oct. 17, 2014), [https://healthprize.com/wp-content/uploads/2014/12/NPR\\_Take-Your-Medicine-Tap-Your-Phone-And-Collect-A-Prize--Shots-Health-News--NPR.pdf](https://healthprize.com/wp-content/uploads/2014/12/NPR_Take-Your-Medicine-Tap-Your-Phone-And-Collect-A-Prize--Shots-Health-News--NPR.pdf).

<sup>53</sup> Health Prize, *Our Solution*, <https://www.healthprize.com/ourSolution/home.do> (last visited Feb. 1, 2016).

<sup>54</sup> At the onset of the publishing process for this article, Proteus Digital Health was marketing a product branded "Helius." During the process of publication, Proteus Digital Health ended its marketing of Helius and developed "Proteus Discover." Although Proteus could not be reached for comment, it appears to the author that the products are substantially similar, if not identical. To the extent that any sources cited herein refer to "Helius," it should be noted that such product is no longer being marketed by Proteus Digital Health, and has ostensibly been re-branded as "Proteus Discover." See *Proteus Digital Health: Proteus Discover*, <http://www.proteus.com/discover/> (last visited Sept. 11, 2016).

<sup>55</sup> *Lloydspharmacy Partners with Proteus*, *supra* note 16; see also *Proteus Digital Health Announces FDA Clearance of Ingestible Sensor*, PROTEUS DIG. HEALTH (July 30, 2012), <http://www.proteus.com/proteus-digital-health-announces-fda-clearance-of-ingestible-sensor/>. Other companies are pioneering similar technology, but Proteus is the only company that has received FDA approval for the ingestible sensor technology thus far. SCOBLE & ISRAEL, *supra* note 7, at 97.

<sup>56</sup> *Lloydspharmacy Partners with Proteus*, *supra* note 16.

<sup>57</sup> Steve Johnson, *Wireless Medical Monitors Transforming Patient Care*, SAN JOSE MERCURY NEWS BUS. (March 14, 2012),

about what medication the patient has taken and when to the sensor patch, which also collects data about the patient's heart rate, body position, temperature, and activity.<sup>58</sup> The patch then relays this information to a sophisticated mHealth application, and with the patient's consent, transmits the data to his physician and other caregivers.<sup>59</sup> Combining the most valuable features of other mHealth platforms, the Helius mHealth application can also remind patients to take their medication, prompt them to take a walk after a long period of inactivity,<sup>60</sup> and track the effects of the drug, indicating whether the prescription is the correct dosage or noting when the medication simply is not working.<sup>61</sup>

With this insight into adherence behavior, physicians can better tailor care to patient needs.<sup>62</sup> This information is especially important where the timing of a dosage is crucial, or where failing to consistently take the drug means it will not work properly.<sup>63</sup> With this data, physicians are able to make more informed treatment decisions by taking into account whether a patient is taking their medication more consistently at a certain time of day and adjusting her treatment regimen accordingly.<sup>64</sup> As a result, the patient may be more likely to stick to her medication plan, increasing the therapeutic effects of the drug.

Health developers are rapidly developing new ways to incentivize medication adherence. This technology is a giant leap in the right direction, but a larger movement to increase the effectiveness of those technological interventions is critical to improving adherence on a larger scale. With the emergence of smart pill technology like Helius and developments in healthcare laws, payors should also have the

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[http://www.mercurynews.com/business/ci\\_20174226/wireless-medical-monitors-transforming-patient-care](http://www.mercurynews.com/business/ci_20174226/wireless-medical-monitors-transforming-patient-care).

<sup>58</sup> *Proteus Digital Health*, *supra* note 54. See also Elizabeth Armstrong Moore, *Digital 'Pill' Tells Doctors When You've Swallowed It*, CNET (Aug. 1, 2012), <http://www.cnet.com/news/digital-pill-tells-doctors-when-youve-swallowed-it/>.

<sup>59</sup> *Id.*

<sup>60</sup> Esha Dey, *A Pill That Treats and Tells*, REUTERS (Aug. 27, 2012), <http://www.reuters.com/article/2012/08/27/us-proteus-ingestiblesensor-idUSBRE87Q0D520120827>.

<sup>61</sup> Graham, *supra* note 32.

<sup>62</sup> Julie Mehta, *Sensors in Your Stomach? Get Ready for the Next Wave of Medical Diagnostics*, SMARTPLANET.COM (May 30, 2014), <http://www.smartplanet.com/blog/the-report/sensors-in-your-stomach-get-ready-for-next-wave-medical-diagnostics/>.

<sup>63</sup> Graham, *supra* note 32.

<sup>64</sup> See Mehta, *supra* note 62.

opportunity to reward patient compliance. Wellness programs, as discussed in Section III below, are perhaps the best method for making use of technological developments in adherence monitoring.

### *III. Wellness Programs*

With the implementation of the Patient Protection and Affordable Care Act (PPACA) came the prohibition of discriminatory insurance premium rates.<sup>65</sup> The “premium stabilization” provision of the PPACA provides that a health insurance issuer may only vary an insured’s premium with respect to (1) who is covered, (2) the rating area, (3) age, and (4) tobacco use.<sup>66</sup> Even with respect to those factors, there are strict guidelines and ratios that must be followed.<sup>67</sup> Insurers are strictly prohibited from varying premiums on the basis of any other factors.<sup>68</sup>

But there are exceptions to the one-size-fits-all premium scheme. Effective January 1, 2014, the Department of the Treasury (DOT), Department of Labor (DOL), and the Department of Health and Human Services (HHS) issued final regulations regarding nondiscriminatory wellness programs in group health coverage.<sup>69</sup> The regulations define a wellness program as “a program of health promotion or disease prevention.”<sup>70</sup> Under the exception, a payor instituting a wellness program may offer incentives like premium discounts to beneficiaries who participate in the program.<sup>71</sup> The program and its corresponding incentive can be as simple as reimbursement for the beneficiary’s gym membership, or as complex as a premium discount for achieving a

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<sup>65</sup> 42 U.S.C.A. sec. 300gg (Westlaw through Pub. L. No. 114-114 (excluding 114-92, 114-94, 114-95, and 114-113)).

<sup>66</sup> *Id.*

<sup>67</sup> *Id.*

<sup>68</sup> *Id.*

<sup>69</sup> Incentives for Nondiscriminatory Wellness Programs in Group Health Plans, 78 Fed. Reg. 33,157-58 (June 3, 2013) (to be codified at 26 C.F.R. pt. 54, 29 C.F.R. pt. 2590, 45 C.F.R. pt. 146, and 45 C.F.R. pt. 147), <http://www.gpo.gov/fdsys/pkg/FR-2013-06-03/pdf/2013-12916.pdf>. [hereinafter *Final Rule*].

<sup>70</sup> *Id.* at 33,176.

<sup>71</sup> *Id.* at 33,158. “[S]ome employers penalize workers who fail to participate in a wellness program by imposing a surcharge on their health plan premiums.” Deborah Holland Tudor, *Is Your Wellness Program Compliant With the Law?*, 23 KY. EMP. L. LETTER 1, 1 (2013). However, very few employers have imposed these penalties, instead opting to use reward. See SOREN MATTKE ET AL., RAND CORP., WORKPLACE WELLNESS PROGRAMS STUDY: FINAL REPORT ii-iii (2013), <http://www.rand.org/pubs/periodicals/health-quarterly/issues/v3/n2/07.html> (noting that “incentives are typically framed as rewards, with 84 percent of employers reportedly using rewards rather than penalties”).

target biometric.<sup>72</sup> The regulations categorize wellness programs into two broad classes: participatory programs and health-contingent programs.<sup>73</sup> The proceeding subsections discuss each type of program in turn.

#### *A. Participatory Wellness Programs*

Most wellness programs qualify as participatory wellness programs.<sup>74</sup> Under the final rule, these are programs that either do not reward participants, or do not provide an award based on an individual satisfying a health-related standard.<sup>75</sup> For example, issuers offering a participatory wellness program might reimburse the cost of an individual's gym membership<sup>76</sup> or offer rewards to an individual who attends a monthly health education seminar.<sup>77</sup> To ensure that issuers do not discriminate against individuals on the basis of a health factor, participatory wellness programs must be made available to all similarly situated individuals, regardless of health status.<sup>78</sup> The regulations are clear, however, that a participatory program still complies with HIPAA nondiscrimination provisions if factors unrelated to health status (such as scheduling conflicts) prohibit an individual from participating in the program.<sup>79</sup>

Of the three types of wellness programs, participatory programs set the lowest threshold for both participants and issuers.<sup>80</sup> Employers offering participatory programs need not comply with the additional requirements imposed on health-contingent programs.<sup>81</sup> By their

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<sup>72</sup> *Final Rule*, *supra* note 69, at 33,165, 33,170.

<sup>73</sup> *Id.* at 33,160-61.

<sup>74</sup> *Id.* at 33,160, 33,168.

<sup>75</sup> *Id.*

<sup>76</sup> *Final Rule*, *supra* note 69, at 33, 170. Because going to the gym involves obvious physical activity, reimbursement of gym membership fees may appear to fall on the border of participatory and activity-only health-contingent programs. *See id.* at 33,161. What qualifies this reimbursement as participatory, rather than activity-only, is the nature of the incentive. *See id.* at 33,160-61. That is, when an issuer reimburses the individual for purchasing a gym membership, the individual does not come out in the positive—they are not walking away from the program with anything greater than they entered with (aside from health benefits of using the gym). *See id.* Further, the reimbursement is not contingent on the individual's actual *use* of the gym. *See id.*

<sup>77</sup> *Final Rule*, *supra* note 69, at 33,161, 33,176.

<sup>78</sup> *Id.* at 33,158-59, 33,161.

<sup>79</sup> *Id.* at 33,161.

<sup>80</sup> *Id.* at 33, 168.

<sup>81</sup> *Id.* *See also infra* Section III.B.iii. (discussing the additional requirements imposed on health-contingent programs).

nature, participatory programs require the least commitment from participants, as individuals need not attain or maintain any specific health outcome to receive the reward or reimbursement.<sup>82</sup> Thus, the ease of instituting and participating in these programs likely contributes to their widespread use among employers with wellness programs.<sup>83</sup>

The wellness exception of PHS Act §2705(j) does not explicitly apply to the individual health insurance market.<sup>84</sup> Nevertheless, HHS is clear in its belief that participatory wellness programs in the individual market are permissible so long as they are made available to all similarly situated individuals and do not violate state law.<sup>85</sup>

### *B. Health-Contingent Wellness Programs*

At the other end of the wellness program spectrum are health-contingent programs. Employers offering these programs reward employees who satisfy a health-related standard, such as completing a health-related activity or attaining a specific health outcome.<sup>86</sup> Health-contingent programs are further divided into two subcategories: activity-only wellness programs and outcome-based wellness programs.<sup>87</sup>

#### *i. Activity-Only Wellness Programs*

Activity-only wellness programs require an individual to complete a health-related activity to obtain a reward.<sup>88</sup> For example, an issuer may offer a reward to an individual who participates in a walking, diet, or exercise program.<sup>89</sup> However, participants in these programs need not attain or maintain a specific health outcome to obtain a reward.<sup>90</sup> Thus, activity-only programs are essentially the “participatory” version of health-contingent wellness programs.<sup>91</sup>

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<sup>82</sup> *Final Rule*, *supra* note 69, at 33,168.

<sup>83</sup> *Id.* at 33,169.

<sup>84</sup> *Id.* at 33,159.

<sup>85</sup> *Id.* at 33,167. The regulations note that participatory programs could be permissible in the individual market because such programs “do not base rewards on achieving a standard related to a health factor, and thus do not discriminate based upon health status.” *Id.*

<sup>86</sup> *Final Rule*, *supra* note 69, at 33,161.

<sup>87</sup> *Id.*

<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

<sup>90</sup> *Id.*

<sup>91</sup> *See Final Rule*, *supra* note 69, at 33,161.

The final regulations recognize that some participants may experience difficulty completing the program activity due to health factors.<sup>92</sup> To ensure that such individuals are given a reasonable opportunity to qualify for a reward, activity-only programs must provide alternate requirements.<sup>93</sup> The alternative “must be provided for any individual for whom, for that period, it is either unreasonably difficult due to a medical condition to meet the otherwise applicable standard, or for whom it is medically inadvisable to attempt to satisfy the otherwise applicable standard.”<sup>94</sup> Take, for instance, a wellness program offering a reward to participants who walk a certain number of steps per day. If an individual wishing to participate in the program is unable to do so due to a health condition such as a recent surgery or severe asthma, the employer must provide a reasonable alternative for that employee. The final rule, however, does not provide an example of what a reasonable alternative for these individuals might be.<sup>95</sup> Indeed, the reasonable alternative requirement for both activity-only and outcome-based programs is a source of ambiguity in the regulations, as discussed below.

*ii. Outcome-Based Programs*

In contrast to activity-only programs, outcome-based programs require an individual to attain or maintain a specific health outcome in order to receive a reward.<sup>96</sup> For example, an issuer may reward an individual who attains a healthy body mass index (BMI) or blood pressure level, or incentivize smoking cessation by rewarding individuals who break the habit.<sup>97</sup>

Outcome-based programs typically have two stages.<sup>98</sup> First, the issuer will conduct a measurement, test, or screening as part of an initial standard.<sup>99</sup> For example, an employer might conduct a blood pressure screening for its employees who wish to participate. If a participant is deemed to fall within the target blood pressure range, he

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<sup>92</sup> *Id.*

<sup>93</sup> *Id.* at 33,163.

<sup>94</sup> *Id.* at 33,160.

<sup>95</sup> *Id.* at 33,164.

<sup>96</sup> *Final Rule*, *supra* note 69, at 33,161.

<sup>97</sup> *Id.*

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

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

is granted the reward without having to take any additional steps.<sup>100</sup> Second, the issuer will institute a broader program that targets individuals who do not meet the initial standard.<sup>101</sup> For instance, any participant who falls outside of the target blood pressure range must take additional steps (such as adhering to a health improvement plan or complying with a physician's plan of care) to obtain the reward.<sup>102</sup>

*iii. Additional Requirements for Health-Contingent Wellness Programs*

Few employers currently offer incentives based on the satisfaction of a health-related standard.<sup>103</sup> This might be due in part to the five additional requirements imposed on health-contingent programs.<sup>104</sup> First, eligible individuals must have the opportunity to qualify for the reward at least once per year.<sup>105</sup> Second, the final regulations impose limitations on the size of the reward an issuer may offer.<sup>106</sup> Currently, the maximum permissible reward in most health-contingent wellness programs is thirty percent of the total cost of coverage.<sup>107</sup> But a recent study conducted by the RAND Corporation<sup>108</sup> revealed that employers with wellness programs typically offered rewards far lower than this regulatory threshold, with incentives averaging around only ten percent of the total cost of health coverage.<sup>109</sup>

Third, and perhaps unsurprisingly, the program must be "reasonably designed to promote health or prevent disease."<sup>110</sup> The reasonableness of the design is based on four criteria: the program (1)

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

<sup>101</sup> *Id.*

<sup>102</sup> *Id.*

<sup>103</sup> MATTKE ET AL., *supra* note 71, at xxvi. The RAND report indicated that only ten percent of companies with at least fifty employees offering a wellness program used incentives tied to a health standard. *Id.*

<sup>104</sup> *Final Rule*, *supra* note 69, at 33,162.

<sup>105</sup> *Id.*

<sup>106</sup> *Id.*

<sup>107</sup> *Id.* at 33,167. This limit increased from twenty percent under the Health Insurance Portability and Accountability Act (HIPAA) when then PPACA was implemented at the beginning of 2014. Tudor, *supra* note 71, at 1. The exception to the general rule is the final rule's allowance of a reward of up to fifty percent of the cost of coverage for wellness programs aimed at preventing or reducing tobacco use. *Final Rule*, *supra* note 69, at 33,167.

<sup>108</sup> The RAND research report was published in 2013, sponsored by the U.S. Department of Labor and the U.S. Department of Health and Human Services. MATTKE ET AL., *supra* note 71, at ii-iii.

<sup>109</sup> *Id.* at xxi.

<sup>110</sup> *Final Rule*, *supra* note 69, at 33,162.

must have a reasonable chance of improving the health of, or preventing disease in, participating individuals, (2) must not be overly burdensome, (3) may not be a subterfuge for discrimination based on a health factor, and (4) must not implement a “highly suspect” method to promote health or prevent disease.<sup>111</sup> The final regulations do not elaborate on these criteria or define what is meant by “highly suspect,” instead simply stating that the determination of whether a program is “reasonably designed to promote health or prevent disease” is based on “all the relevant facts and circumstances.”<sup>112</sup>

Fourth, the full reward must be available to all similarly situated individuals.<sup>113</sup> This is one of the many sources of ambiguity in the final rule. Generally, the regulation requires that issuers provide a reasonable alternative standard to individuals who, due to a medical condition, would find it unreasonably difficult to meet the otherwise applicable standard.<sup>114</sup> However, this requirement lacks clarity. The Departments acknowledge that they received several comments in response to the proposed regulations requesting clarifications about reasonable requirements.<sup>115</sup> Part of the confusion with the requirement may stem from the generality of the requirement with few uses of examples. However, the benefit of the vagueness of the requirement is that it allows issuers maximum flexibility to design a reasonable alternative.<sup>116</sup> Regardless, the regulations are clear that the alternative is not intended to be so lax that it essentially becomes a loophole for individuals who can actually meet the otherwise applicable standard.<sup>117</sup> The reasonability of the alternative, then, should take into account factors like the required time commitment, cost, and the recommendations of the individual’s physician.<sup>118</sup> Under reasonable circumstances,<sup>119</sup> the issuer is permitted to verify that the individual’s

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<sup>111</sup> *Id.*

<sup>112</sup> *Id.*

<sup>113</sup> *Final Rule, supra* note 69, at 33,159, 33,163.

<sup>114</sup> *Id.* at 33,159, 33,163-64. Alternatively, the issuer may provide a waiver of the otherwise applicable standard for those individuals and simply provide the reward. *Id.* at 33,163.

<sup>115</sup> *Id.* at 33,163.

<sup>116</sup> *Id.* at 33,163.

<sup>117</sup> *Id.*

<sup>118</sup> *Id.* at 33,163-64.

<sup>119</sup> *Final Rule, supra* note 69, at 33,164-65. The Departments attempt to clarify the confusion brought to their attention by commenters over what circumstances qualify as “reasonable.” *Id.* While the final rule remains somewhat ambiguous on this issue, it appears that issuers may seek verification when medical judgment is required to evaluate the validity of

participation is actually limited by a health factor.<sup>120</sup>

Fifth and finally, the final regulations require all plan materials describing the terms of a health-contingent program to disclose the availability of a reasonable alternative standard to qualify for a reward.<sup>121</sup> The issuer must also disclose this information when notifying an individual that she did not satisfy an initial outcome-based standard.<sup>122</sup>

Health-contingent programs are not currently implemented in the individual market, limiting their use to employer-sponsored insurance plans.<sup>123</sup> However, this limitation is not as confining as it may seem. More than nineteen million people are individually insured,<sup>124</sup> compared to an overwhelming 149 million who are insured through their employers.<sup>125</sup> Therefore, while health-contingent programs may not reach individually insured individuals, the vast majority of Americans could still participate in wellness programs through their employers.

### *C. Impact of Wellness Programs*

Approximately half of employers currently offer wellness programs.<sup>126</sup> Fifty-six percent of those employers offer disease management programs targeting health issues like diabetes, heart disease, chronic lung disorders, and cancer.<sup>127</sup> These programs effectively serve to reduce medical costs and promote a healthier workforce.<sup>128</sup> Employers offering wellness programs are confident that

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the individual's request. *Id.*

<sup>120</sup> *Final Rule*, *supra* note 69, at 33,164-65. The final rule notes that such verification might come in the form of a statement from the individual's personal physician that it is medically inadvisable for the individual to participate. *Id.*

<sup>121</sup> *Final Rule*, *supra* note 69, at 33,166. The regulations explain that this disclosure must include contact information for obtaining the alternative, as well as a statement clarifying that the recommendations of an individual's physician will be accommodated. *Id.*

<sup>122</sup> *Final Rule*, *supra* note 69, at 33,166.

<sup>123</sup> Timothy Jost, *Implementing Health Reform: Workplace Wellness Programs*, HEALTHAFFAIRSBLOG (May 29, 2013), <http://healthaffairs.org/blog/2013/05/29/implementing-health-reform-workplace-wellness-programs/>.

<sup>124</sup> *Individual Market Health Insurance*, AM.'S HEALTH INS. PLANS, <http://www.ahip.org/Issues/Individual-Market-Health-Insurance.aspx> (last visited Feb. 1, 2016).

<sup>125</sup> *Employer-Sponsored Coverage*, AM.'S HEALTH INS. PLANS, <http://www.ahip.org/Issues/Employer-Sponsored-Coverage.aspx> (last visited Feb. 1, 2016) (this 149 million figure does not include elderly individuals).

<sup>126</sup> MATTKE ET AL., *supra* note 71, at xiv.

<sup>127</sup> *Id.* at xv-xvi.

<sup>128</sup> Tudor, *supra* note 71, at 1.

the programs reduce medical cost, absenteeism, and health-related productivity losses.<sup>129</sup> Indeed, a study conducted by the RAND Corporation suggests “participation in a wellness program over five years is associated with a trend toward lower healthcare costs and decreasing health care use.”<sup>130</sup> Johnson & Johnson, for instance, saved \$250 million over ten years by instituting wellness programs.<sup>131</sup> The RAND study also found that workplace wellness programs had positive effects on health-related behavior and health risks for individuals participating in such programs.<sup>132</sup> This confirms that workplace wellness programs “can help contain the current epidemic of lifestyle-related diseases, the main driver of premature morbidity and mortality as well as healthcare cost in the United States.”<sup>133</sup> Wellness programs targeted at improving medication adherence should become part of this movement by incorporating smart pill technology like Helius.

#### *IV. Incorporating Adherence Technology Into Wellness Programs*

Adherence technology can and should be incorporated into wellness programs to enhance the positive effects of these programs on individual health and health-related costs. Perhaps the most obvious advantage of incorporating technological adherence interventions is financial benefit. The reward offered in a wellness program is intended to incentivize the achievement of an improved health standard, which is in turn associated with lower health care costs.<sup>134</sup> As the participant’s health improves, health care costs are reduced,<sup>135</sup> saving money on a national scale. This reduction in health care costs could also translate into lower insurance premiums for employers and their

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<sup>129</sup> MATTKE ET AL., *supra* note 71, at xix.

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

<sup>131</sup> Veda Collmer, Chase Millea, & Nick Wearne, *Guidelines For Improving Workplace Wellness*, 25 HEALTH LAW. 44, 46 (2013). Certainly, companies with significantly less than Johnson & Johnson’s 128,100 employees should not expect to save hundreds of millions. See *Company Profile: Johnson & Johnson*, FORBES (May 2014), <http://www.forbes.com/companies/johnson-johnson/>. Still, when broken down to per-participant costs, the savings are still significant. Johnson & Johnson saved \$1,400 per participant in medical claims costs and decreased lost work days by eighty percent, earning the company \$2.71 per dollar invested. Collmer et al. at 46.

<sup>132</sup> MATTKE ET AL., *supra* note 71, at xviii. The RAND Corporation’s research showed improvements in smoking cessation, physical activity, weight reduction, cholesterol levels, and blood pressure.

<sup>133</sup> *Id.* at xxvi.

<sup>134</sup> *Final Rule*, *supra* note 69, at 33,172.

<sup>135</sup> *Id.*

employees.<sup>136</sup>

By focusing on preventative treatment like medication adherence, rather than providing reactive care after an adverse health event occurs, both insurers and patients can save money in the long-term. When that patient is focused on preventive measures, such as adhering to her medication plan, she is less likely to undergo expensive procedures for her condition in the future.<sup>137</sup> Take, for instance, the same hypertensive patient considered above. If money is spent to ensure that she adheres to her blood pressure medication—say, fifty dollars monthly for the prescription,<sup>138</sup> plus the cost (if any) of the adherence technology—her chances of later having to have a defibrillator placed in her failing heart (to the tune of approximately \$100,000) are decreased, saving both the patient and her insurer money.<sup>139</sup>

Employers who develop adherence-focused wellness programs incorporating technology can decrease the costs they face as a consequence of employee non-adherence. This is particularly true when the employee suffers from a chronic health condition. Evidence shows that chronic patients who properly adhere to their medication may “recover and return to productive work more quickly, and reduce the subsequent need for more expensive care” such as emergency and inpatient services.<sup>140</sup> Payors who create adherence-focused wellness programs utilizing technology, then, can reduce costs stemming from employee sick time, disability time, and lost productivity.<sup>141</sup>

According to the Center for Disease Control (CDC), the treatment of chronic illness accounts for over seventy-five percent of national

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<sup>136</sup> *Id.*

<sup>137</sup> See Padley et al.

<sup>138</sup> *Consumer Summary: Choosing Medicines for High Blood Pressure: A Review of the Research on ACEIs, ARBs, and DRIs*, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (October 24, 2011), <http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?productid=758&pageaction=displayproduct>.

<sup>139</sup> Aditi Pai, *Digital health execs: Focus should be on consumer not technology*, MOBIHEALTHNEWS (October 24, 2013), <http://mobihealthnews.com/26680/digital-health-execs-focus-should-be-on-consumer-not-technology/>.

<sup>140</sup> Padley et al., *supra* note 18, at 9.

<sup>141</sup> But employers should not expect an immediate return on their investment. Indeed, it may take years for employers to see a sustained downward trend on costs. However, the investment can save the employer from incurring higher health care costs in the long term, as “the cost of complications from unhealthy lifestyle behaviors and less-than-optimal management of chronic illnesses can be catastrophic to the health plan and take an enormous toll personally and professionally.” Melissa Tobler, *Maximizing the Effectiveness of Your Wellness Program*, 25 J. COMPENSATION & BENEFITS 5, 29 (2009).

healthcare expenditures.<sup>142</sup> This is particularly troubling in light of the fact that the number of working-age adults with a chronic condition has grown by twenty-five percent in the last decade.<sup>143</sup> As a result, healthcare expenditures on the management of these chronic conditions will continue to grow. But just as employers and employees will save from improving medication adherence among chronic patients, national expenditures will necessarily see a downward trend if these patients are properly complying with their treatment regimens.<sup>144</sup> Incorporating adherence technology like smart pills into wellness programs will help achieve that goal.

*A. Why Smart Pills, Specifically?*

Certainly, the incorporation of any of the aforementioned adherence technology into wellness programs has the potential to improve patient compliance. However, this article advocates for the use of smart pill technology specifically for several reasons. First, smart pills provide a level of accuracy and detail unparalleled by other adherence technology. Second, technology like Proteus Discover builds a system of support that is crucial to improving adherence. Smart pill technology also simplifies the much-touted team approach to medication adherence by reducing the number of healthcare staff necessary to ensure proper patient adherence. Subsections i through iii discuss these benefits in detail. Sections B and C then proceed to address the logistics of incorporating smart pills into wellness programs, as well as the potential concerns arising from the implementation of such programs.

*i. Accuracy and Detail*

Many mHealth applications rely on the patient to enter information about their adherence.<sup>145</sup> This leaves abundant room for

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<sup>142</sup> MATTKE ET AL., *supra* note 71, at 1.

<sup>143</sup> *Id.*

<sup>144</sup> See Padley et al., *supra* note 18, at 36 (noting that chronic patients who properly adhere to their medication may “reduce the need for more expensive care” such as emergency and inpatient services.)

<sup>145</sup> See *About Dosecast*, MONTUNO SOFTWARE, <http://www.montunosoftware.com/products/dosecast/about/> (last visited Aug. 4, 2016); see also Fard, Maggie Fazeli, *Mobile health apps to manage health; Why we like it when others fall, or fail.*, THE WASHINGTON POST (Aug. 12, 2013), <https://www.washingtonpost.com/national/health-science/mobile-health-apps-to-manage-health->

error, whether through neglect or intention of the patient. Even more advanced adherence packaging fails to provide the level of accuracy and detail needed to paint a comprehensive picture of patient adherence.<sup>146</sup> For instance, the blinking light of electronic packaging may remind a patient to take her medication. The patient may open the packaging, transmitting a signal to their physician or caregiver that she is taking the medication. But the information trail ends there, without any indication as to what time the patient actually ingested the medication, or whether they in fact took the medication at all.<sup>147</sup>

Smart pill technology like Proteus Discover provides the level of accuracy and detail necessary to fully understand and improve adherence behavior. For example, by documenting the time a pill is ingested, Proteus Discover ultimately creates a long-term picture of when the patient is most likely to take their medication. If a pattern emerges suggesting that the patient is most likely to take their medication in the morning, the physician may use that information to prescribe a treatment regimen that is most likely to result in patient adherence.<sup>148</sup> Proteus Discover also collects data about the patient's heart rate, body position, temperature, and activity.<sup>149</sup> This information paints a detailed picture of how the patient is reacting to the medication, allowing the physician to make informed treatment decisions and alter patient care accordingly.<sup>150</sup>

Further, Proteus Discover provides the patient herself with a visual representation of her adherence. Visual access to this unequivocal data gives the patient a clear look at her adherence (or lack

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[why-we-like-it-when-others-fall-or-fail/2013/08/12/94897f40-fb88-11e2-8752-b41d7ed1f685\\_story.html](http://why-we-like-it-when-others-fall-or-fail/2013/08/12/94897f40-fb88-11e2-8752-b41d7ed1f685_story.html).

<sup>146</sup> See Osterberg & Blaschke, *supra* note 4, at 489.

<sup>147</sup> *Id.* Further, "patients may open a container and not take the medication, take the wrong amount of medication, or invalidate the data by placing the medication into another container or taking multiple doses out of the container at the same time." *Id.*

<sup>148</sup> See Mehta, *supra* note 62.

<sup>149</sup> *Proteus Digital Health*, *supra* note 54.

<sup>150</sup> Proteus Discover may also help inform treatment decisions by enhancing the medication reconciliation process. Medication reconciliation is the process by which an accurate list of all patient medications is created, including the name, dosage, and frequency of the prescription. Brown & Bussell, *supra* note 4, at 312. After a hospitalization, the chance that a patient's primary care physician will receive a discharge summary prior to his next interaction with that patient is only around thirty-three percent. *Id.* As a result, the primary care physician must rely on the ability of the patient to provide an accurate list of any new medications she was prescribed during her hospitalization. Situations such as this make medication reconciliation nearly impossible and may result in medication duplication and errors. *Id.* But a patient who is enrolled in a wellness program utilizing Proteus Discover avoids these problems by keeping an accurate, ever-developing list of medications without the use of hospital documentation.

thereof), leaving no room for denial about how closely she is following her prescription. Such a clear visual representation may empower the patient to take control of her medication compliance.

*ii. Creating a Support System for Patients*

Lack of family or social support has a negative impact on patient compliance.<sup>151</sup> Using smart pill technology builds a support system by connecting patients to caregivers, family, and physicians, creating a team of encouragement and accountability.<sup>152</sup> With the consent of the patient, Proteus Discover provides physicians and family with real-time data about the patient's physiological and behavioral patterns,<sup>153</sup> which the caregivers can then evaluate and discuss with the patient. This direct communication allows family, caregivers, and physicians to interact with the patient and provide support without being physically present at all times.

When an employer sponsors a wellness program incorporating smart pill technology, an extra layer of support and accountability is added. A participant who lacks family support will be held accountable for their adherence not only by their physician, but by their employer issuer as well. A support system may also develop between the individual and other employees participating in the wellness program, providing a sense of unity.

*iii. A Team Approach to Adherence*

A common suggestion for increasing adherence is to develop a team-based approach. This approach involves recruiting a multitude of people into the patient's adherence regimen, including office staff to assess non-adherence, pharmacists to educate the patient, clerical staff to call patients and remind them to take their medication, and case managers to follow up on the patient's compliance.<sup>154</sup>

Doctors Lars Osterberg and Terrence Blaschke studied the multi-faceted team approach with respect to psychiatric patients.<sup>155</sup> They

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<sup>151</sup> Brown & Bussell, *supra* note 4, at 307.

<sup>152</sup> *Proteus Digital Health*, *supra* note 54.

<sup>153</sup> *Id.*

<sup>154</sup> Brown & Bussell, *supra* note 4, at 311. *See also* Osterberg & Blaschke, *supra* note 4, at 491 (noting that “[i]nterventions that enlist ancillary health care providers such as pharmacists, behavioral specialists, and nursing staff can improve adherence.”).

<sup>155</sup> Osterberg & Blaschke, *supra* note 4, at 493.

found that the most successful approaches to improving adherence include a combination of educational and cognitive-support interventions, as well as reinforcement techniques such as “monetary rewards or vouchers, frequent contact with the patient, and other types of personalized reminders.”<sup>156</sup> As the doctors note, the unfortunate aspect of such a comprehensive intervention is that it requires “trained personnel and repeated sessions” in order to maintain increased adherence.<sup>157</sup>

While recruiting a team of providers is likely to improve compliance, it is also an additional strain on already over-burdened healthcare staff.<sup>158</sup> The use of smart pill technology in wellness programs significantly improves the ability to institute this well established but difficult-to-implement approach. Using smart pill technology such as Proteus Discover can cut down on the number of resources depleted to achieve the same results that a team-based approach provides. Smart pill technology effectively negates the need for “trained personnel” and “repeated sessions.” With monitoring and reminders built-in, this technology relieves healthcare staff of these additional duties, allowing them to focus their attention on more pressing issues. Incorporating smart pills into wellness programs satisfies the “reinforcement” aspect of the approach by providing a monetary award for adherence. Thus, using smart pill technology in wellness programs effectively achieves the team-based approach touted in the medical community to enhance adherence—without depleting the resources of the team.

#### *B. How to Incorporate Smart Pills Into Wellness Programs*

The final rule leaves some questions about its application to individual wellness programs unanswered. Indeed, the regulations acknowledge that due to the unique nature of each wellness program, the rule may not provide thorough guidance for the application of its requirements.<sup>159</sup> The Departments note that they anticipate “issuing

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<sup>156</sup> *Id.*

<sup>157</sup> *Id.*

<sup>158</sup> See generally, Darrel G. Kirch, *A Word From the President: Facing the Facts About the Physician Shortage*, AM. ACADEMY MED. CS. (2013), <https://www.aamc.org/newsroom/reporter/december2013/363844/word.html> (discussing the problem of physician shortage, even in light of the increasing prevalence of health care teams including nurse practitioners and physician assistants).

<sup>159</sup> *Final Rule*, *supra* note 69, at 33,159.

future subregulatory guidance to provide additional clarity and potentially proposing modifications to [the] final rule as necessary.”<sup>160</sup> As a result, it is unclear under which category of wellness program adherence technology is best incorporated. This section proceeds to analyze how smart pill technology might fit under the requirements of the different types of wellness programs.

*i. Smart Pill Technology in Participatory Wellness Programs*

A discussion of an example in the final rule helps to guide an analysis of how smart pill technology may be used in a participatory program. The regulations suggest that an employer may offer a participatory program that rewards or reimburses an employee for his participation in a smoking cessation program, without regard to whether he actually quits smoking.<sup>161</sup> The ostensible benefit from this type of program is that it brings the option of quitting to the forefront of the smoker’s mind, and perhaps educates him about methods for quitting should he choose to do so.

It appears, then, that an employer could offer a wellness program that rewards or reimburses participants for agreeing to use Proteus Discover, without regard to whether they use it consistently or actually adhere to their medication.<sup>162</sup> This sets a very low bar for participants, as they need not do much of anything to obtain a reward or reimbursement. Just as with the smoking cessation program, though, perhaps merely acknowledging the adherence problem by establishing such a program could encourage individuals to comply with their treatment regimen. However, it seems unlikely that providing an actual reward for a mere agreement to use the technology, without regard to whether the individual actually adheres to their medication, would provide any substantial return on the employer’s investment. Even if the employer provides only reimbursement for the cost of the Proteus Discover system, a worthwhile return may not result. Because

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<sup>160</sup> *Id.*

<sup>161</sup> *Id.* at 33,161, 33,176 (Examples of participatory wellness programs include “A program that reimburses employees for the costs of participating, or that otherwise provides a reward for participating, in a smoking cessation program without regard to whether the employee quits smoking.”).

<sup>162</sup> The employer would, however, have to ensure that the program is made available to all similarly-situated individuals. *Id.* at 33,161. While “similarly-situated” is not clearly defined in the regulations, the smoking cessation example suggests that specific groups can be targeted (i.e., smokers). Thus, it seems that employers could institute an adherence-based participatory program so long as the program is made available to all individuals who take medication.

of the incredibly low bar set by a participatory program, it seems this example is not the most valuable use of an employer's resources in designing a wellness program.

*ii. Smart Pill Technology in Activity-Only Health-Contingent Wellness Programs*

Activity-only programs require participants to perform or complete an activity related to a health factor, but do not mandate that the individual attain or maintain a specific health outcome.<sup>163</sup> Here is where the lack of guidance in the final rule blurs the lines between programs. What remains most unclear is what constitutes an “activity related to a health factor.” For instance, the regulations provide that walking and exercise programs involve activities related to a health factor—these are considered activity-only wellness programs.<sup>164</sup> But participating in a smoking cessation program is not considered an activity related to a health factor—such a program qualifies as participatory.<sup>165</sup> However, the smoking status of an individual is unequivocally a factor related to health.<sup>166</sup> Perhaps the distinction the regulations make, then, is not based so much on the relation of the activity to the health factor, but rather the mere level of activity involved. For instance, participating in the smoking cessation program, in and of itself, does not qualify as an actual “activity” under the regulations, while physically walking does.

This leaves the application of the regulations to many wellness programs quite unclear. Indeed, the same example program provided above as a participatory program could potentially qualify as an activity-only program. In that scenario, the individual's reward is not based on the outcome of his use of the technology (such as whether he meets a target biometric or adherence rate). Rather, he is rewarded for merely using smart pill technology, whether he uses it ten percent of the time or ninety-nine percent of the time. The distinction between classifying this as a participatory or activity-only program, then, seems

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<sup>163</sup> *Id.* at 33,161.

<sup>164</sup> *Id.*

<sup>165</sup> *Id.* at 33,176.

<sup>166</sup> As the DOL notes, “[m]edical evidence suggests that smoking may be related to a health factor. *The Diagnostic and Statistical Manual of Mental Disorders*, which states that nicotine addiction is a medical condition, supports that position.” *Frequently Asked Questions: The HIPAA Nondiscrimination Requirements*, U.S. DEP'T OF LABOR, EMP. BENEFITS SEC. ADMIN., [http://www.dol.gov/ebsa/faqs/faq\\_hipaa\\_ND.html](http://www.dol.gov/ebsa/faqs/faq_hipaa_ND.html) (last visited Feb. 1, 2016).

to be the definition of “activity”—that is, is ingesting a sensor and wearing a patch more akin to attending a smoking cessation program, or to taking a walk around the block?

Given this ambiguity, it appears that an issuer could implement such a program and claim that it qualifies as either participatory or activity-only. Because of the significantly less stringent requirements of participatory programs, it seems that qualifying this type of program as such would be in the best interest of the employer. Additionally, because participatory programs are permissible in the individual market,<sup>167</sup> classifying this program as such would allow more individuals to participate.<sup>168</sup>

Nevertheless, because this program does not require the participant to achieve a target adherence outcome, the benefits of its implementation are not guaranteed. As such, it appears that outcome-based programs set the highest bar for participants and thus guarantee the best results. Fortunately, as described in section iii below, these programs are the most clear-cut in the final rule.

### *iii. Smart Pill Technology in Outcome-Based Health-Contingent Wellness Programs*

This article proposes two alternative methods of incorporating smart pill technology into outcome-based wellness programs, utilizing an example of the same hypothetical hypertensive patient as previously discussed.

Say, for instance, a payor establishes a wellness program targeted at individuals with high blood pressure,<sup>169</sup> incentivizing participation with a fifteen percent premium discount. The payor could set up this program in one of two ways.<sup>170</sup> First, the hypertensive patient could

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<sup>167</sup> As addressed in Section III.A, *supra*, HHS has stated that such programs are likely to be deemed permissible in the individual market if they are made available to all similarly-situated individuals and do not violate state law.

<sup>168</sup> *Final Rule*, *supra* note 69, at 33,167.

<sup>169</sup> Recall that outcome-based programs may target specific groups of individuals. The regulations provide that, “[f]or example, plans and issuers are able to target only individuals with high cholesterol for participation in cholesterol reduction programs, or individuals who use tobacco for participation in tobacco cessation programs, rather than the entire population of participants and beneficiaries, with the reward based on health outcomes or participation in reasonable alternatives.” *Id.* at 33,165.

<sup>170</sup> Note that both examples assume that the individual has participated the screening stage of the outcome-based program and was deemed not to fall within the target range, therefore requiring her to take additional steps to obtain a reward. *See id.* at 33,161.

participate in this wellness program by (1) agreeing to use Proteus Discover, (2) adhering to her medication and documenting that adherence through Proteus Discover, and (3) achieving a target adherence rate—by, say, taking her medication ninety percent of the time. This clearly qualifies as an outcome-based program, as the participant must attain a specific health outcome (ninety percent adherence to her medication) to obtain a reward.<sup>171</sup>

There are benefits to this first example of an outcome-based program incorporating smart pill technology. Recall, first, that from a technical standpoint, a patient taking her medication greater than eighty percent of the time is considered adherent.<sup>172</sup> Partial adherence to a medication can have a significant impact on the effectiveness of certain prescription drugs.<sup>173</sup> For example, patients taking lipid-lowering medications can avoid a great reduction in therapeutic impact by taking their medication at least seventy percent of the time.<sup>174</sup> Similarly, an individual such as our hypertensive patient can consistently lower her blood pressure by adhering to her medication at least eighty percent of the time.<sup>175</sup> While less than perfect adherence rates may not be ideal, there is certainly benefit to creating a program encouraging individuals to meet these minimal adherence thresholds.

Alternatively, the payor could set up a program wherein, to receive the premium discount, the hypertensive patient must (1) agree to use Proteus Discover, (2) adhere to her medication and document it through Proteus Discover, and (3) attain or maintain a target blood pressure. Again, this clearly qualifies as an outcome-based program because the individual must achieve a specific health outcome (a target blood pressure) to obtain a reward. Requiring this additional level of achievement could also encourage the patient to attain a perfect adherence rate in an attempt to achieve the target blood pressure. Beyond that, it may encourage the patient to take additional steps to lower her blood pressure that she would not have otherwise taken, such as exercising or eating healthier. This second example of an outcome-based program incorporating smart pill technology sets the highest threshold, but is likely to yield the best outcomes.

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<sup>171</sup> *Final Rule*, *supra* note 69, at 33,161.

<sup>172</sup> Brown & Bussell, *supra* note 4, at 305.

<sup>173</sup> Padley et al., *supra* note 18, at 9.

<sup>174</sup> *Id.*

<sup>175</sup> *Id.*

Implementing an outcome-based wellness program incorporating smart pill technology like either of the examples above is the best option for several reasons. First, between the three types of programs, there is no difference in the financial investment of the issuer—the employer will spend the same amount of money reimbursing or rewarding participants regardless of what standard the participants must meet. In fact, the employer will likely spend less on investing in one of the outcome-based examples because unfortunately, fewer employees may agree to the more stringent standard they impose. In the long-term, the financial benefits to the individual, the issuer, and the nation are far greater when the issuer implements an outcome-based program. This is necessarily true by virtue of the standard the participant must meet. Under these programs, the participant has the most incentive to actually achieve target adherence rates or biometrics, which will in turn be associated with improved health outcomes. The ultimate results are lower premiums for the employer and employee and reduced healthcare expenditure on a national level.

### *C. Concerns*

Though the incorporation of smart pills in wellness programs promises many benefits, a number of concerns arise in the implementation of such programs.

This subsection analyzes a few of these concerns.

#### *i. Privacy*

In a world where our data are constantly bought, sold, and monitored by the government, the privacy implications of technology that stores and transmits intimate health information may make some patients uncomfortable.<sup>176</sup> With stories about data breaches making headlines daily, these fears are not unfounded. Certainly, any system using wireless communication can be subject to data interception.<sup>177</sup> Some individuals may fear that hackers could use health data to steal patient identities, while others are concerned that their data may be

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<sup>176</sup> Alexis Madrigal, *Someday Soon You May Swallow A Computer With Your Pill*, NPR SHOTS (June 18, 2014), <http://www.npr.org/blogs/health/2014/06/18/323243085/someday-soon-you-may-swallow-a-computer-with-your-pill>.

<sup>177</sup> Johnson, *supra* note 57.

remotely altered to conceal its seriousness or issue false alarms.<sup>178</sup>

Notwithstanding these reasonable concerns, Americans generally seem comfortable with the electronic sharing of their health data.<sup>179</sup> In an age where younger generations are exceedingly comfortable divulging personal information on social media platforms, it seems unlikely that those individuals would fear that someone may hack into their mHealth applications to see how many steps they have taken or how much they weigh.<sup>180</sup> Additionally, the abundant use of wristbands based on accelerometer technology, such as FitBit and Jawbone Up, indicate that Americans are becoming increasingly comfortable wearing devices that sense their body and behavior and transmit that information onto their smartphones.<sup>181</sup> The implication is that Americans are warming to the idea of using medical technology to analyze and improve their health.

Proteus emphasizes the patient's right to privacy in its advertising and informational materials, stressing that the patient is in "complete control" of his information and assuring users that the company follows strict security protocols to protect the data.<sup>182</sup> Fitbit offers a similar guarantee of individual privacy and control over information, claiming it will "always take the security of [the individual's] data seriously," only sharing what it deems "personally identifiable data" when the individual instructs it to.<sup>183</sup> The DoseCast privacy policy states that no personally identifiable information is collected, but information may be released when the company believes doing so is appropriate to "comply with the law, enforce [its] site policies, or protect . . . rights, property, or safety."<sup>184</sup> The MedCoach Frequently

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<sup>178</sup> *Id.*

<sup>179</sup> *Id.* "Of 2,000 consumers surveyed by PricewaterhouseCoopers in 2010, 40 percent said they would willingly buy a device and pay a monthly fee to automatically send their heart rate, blood pressure, blood sugar and weight data to their doctors."

<sup>180</sup> Pai, *supra* note 139.

<sup>181</sup> *Id.*

<sup>182</sup> *Privacy Policy*, PROTEUS DIGITAL HEALTH (Sept. 21, 2015), <http://www.proteus.com/privacy/>.

<sup>183</sup> *Privacy Policy*, FITBIT <https://www.fitbit.com/fi/legal/privacy> (last visited May 1, 2016). Fitbit's privacy policy further details circumstances in which it may share personally identifiable information, such as when the company believes "after due consideration, that doing so is reasonably necessary to comply with a law," or when doing so "is necessary to prevent imminent and serious bodily harm to a person."

<sup>184</sup> *Dosecast: Android Terms of Service*, MONTUNO SOFTWARE, <http://www.montunosoftware.com/products/dosecast/android-terms-of-service/> (last visited Feb. 1, 2016). The company also notes that it "undertakes reasonable steps to protect data from unauthorized or accidental access, disclosure, misuse or processing, or from alteration,

Asked Questions website states that the company is “committed to protecting health information about [the individual],” but offers no specifics on its protocols for doing so.<sup>185</sup>

But whatever the fears may be in sharing our health data, the importance of using healthcare technology cannot be overlooked.<sup>186</sup> David O’Reilly, Chief Product Officer at Proteus, addressed privacy concerns at a symposium in 2013, suggesting, “. . .like every other industry you have to embrace [the technology]. You’re going to make mistakes and there are going to be companies and efforts that violate trust and pay for it, but you have to embrace it because it’s too important. The healthcare applications of connected mobile technologies are so fundamental and so important that we have to embrace these questions and figure out the answers.”<sup>187</sup> Indeed, technology like Proteus Discover must be embraced in order to achieve the potentially vast benefit of its incorporation into the way we provide health insurance.

#### *ii. Cost*

Another concern about the use of groundbreaking technology like Proteus Discover is its cost, and who will foot the bill for use of the product. Proteus has been vague about the cost of the system, suggesting that the price will be dependent on “the context in which [it] is being used.”<sup>188</sup> As of August 2014, Proteus was in early discussions with insurers about reimbursement.<sup>189</sup> While there is no indication of when and how insurers might cover the cost of this budding

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destruction, or loss. Data that we collect resides on servers operated by [the company] and is accessible only to personnel who, by virtue of their duties, are required to have access and have been trained in, and tasked with, the observance of the principles embodied in this Privacy Policy.”

<sup>185</sup> *MedCoach: Frequently Asked Questions*, GREATCALL, <http://www.greatcall.com/support#faq> (last visited Feb. 1, 2016).

<sup>186</sup> See ECONOMIST, *supra* note 30 (suggesting that mHealth makes it easier for patients and doctors to track what is happening with the patient, alerting them to the need for action before the patient’s condition deteriorates); see also Sindya Bhanoo, *When Wearable Tech Saves Your Life You Won’t Take it Off*, FAST CO. (July 23, 2014), <http://www.fastcompany.com/3033417/when-wearable-tech-saves-your-life-you-wont-take-it-off#1> (noting that research has shown that sensor devices can help lower the rate of ER visits, reduce trips to the doctor, and keep people healthier).

<sup>187</sup> Pai, *supra* note 139.

<sup>188</sup> Moore, *supra* note 58.

<sup>189</sup> Elizabeth Cairns, *Interview – Proteus aims to change the shape of healthcare delivery*, EP VANTAGE (August 18, 2014), <http://www.epvantage.com/Universal/View.aspx?type=Story&id=524666&isEPVantage=yes>.

technology, Andrew Thompson, the president and CEO of Proteus, is confident that the payer openness and interest is “very high.”<sup>190</sup>

Despite the clear financial benefit from preventative care like adherence monitoring, the potential cost of Proteus Discover—especially without the possibility of reimbursement—may deter issuers and individuals from instituting or participating in wellness programs utilizing the technology. Still, research shows that some Americans are willing to pay the price to send their physicians real-time information about their health. A recent study revealed that forty percent of consumers are willing to purchase a device and pay a monthly fee to have their health data automatically transmitted to their physician.<sup>191</sup> As we embrace the privacy risk of this emerging technology, we must also embrace the cost associated with it. Indeed, successful adherence interventions are not just substantially complex—they are costly.<sup>192</sup> Nevertheless, to the extent that smart pill technology is cost-prohibitive, less expensive technological developments such as those discussed in Section III would still improve medication adherence when incorporated into wellness programs.

#### *V. Conclusion*

There is no singular solution for the adherence crisis the United States is facing. Medication compliance is an extremely complex problem that requires an equally complex solution. Incorporating smart pill technology into wellness programs will not solve the nation’s healthcare expenditure problems, nor will it eliminate the prevalence of chronic conditions like hypertension—but it would be a giant leap in the right direction. Despite reasonable concerns about privacy and the potential cost of this emerging technology, the conceivable benefits stemming from its use in wellness programs could be tremendous.

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<sup>190</sup> *Id.*

<sup>191</sup> Johnson, *supra* note 57. “Of 2,000 consumers surveyed by PricewaterhouseCoopers in 2010, 40 percent said they would willingly buy a device and pay a monthly fee to automatically send their heart rate, blood pressure, blood sugar and weight data to their doctors.

<sup>192</sup> Osterberg & Blaschke, *supra* note 4, at 487-88.



# MEDIATION AND END-OF-LIFE FUTILITY DECISIONS FOR NEWBORNS

Oren Faircloth\*

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## *I. Introduction*

*A wise man once said: “It isn’t enough to do the right thing; the right thing must be done in the right way and at the right time, too.” There are few cases where this truth is more vividly exemplified than in the neonatal/pediatric futility context.”- Peter A. DePergola II*

The healthcare industry is currently undergoing rapid change, and debates over cost containment and the future of quality healthcare have raised interesting legal and ethical concerns regarding end-of-life (“EOL”) futility decisions. All futility decisions, specifically the

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decision to withdraw life-sustaining medical treatment (“LSMT”), challenge the moral competency of everyone involved, especially when the decision will result in the death of a newborn baby. The tragedy of withdrawing LSMT from a newborn seems more acute than cases involving an elderly parent or grandparent. Just thinking about a newborn child overcome by feeding tubes and monitoring wires elicits an emotional and empathetic response; our hearts go out to the grieving parents. Against this backdrop, however, healthcare providers must exercise enduring moral agency and defend their ability to act as moral agents, even when that means withdrawing LSMT from a newborn child.

Futility disputes emerge when a provider and parents disagree about the medical or ethical appropriateness of withdrawing LSMT. Parents in futility disputes often insist, “everything be done,” but providers have different interests at play and might believe that continued treatment is cruel and inhumane. The potential for conflict in EOL decision-making has led providers to adopt various techniques to approaching futility disputes, like mediation and facilitation. While mediation can be useful in certain cases, the effectiveness of the technique is limited to negotiable issues with the possibility of more than one outcome; when providers have final authority over the decision to withdraw LSMT, futility disputes become “un-mediabile” issues.

So, when futility disputes between providers and parents emerge, who has the final say, the parent or the provider? At the federal level, several congressional acts seem to place the power to withdraw LSMT in the hands of the provider, but the Fourth Circuit, in the case of *Baby K*,<sup>1</sup> still found in favor of the mother. At the state level, legislatures have taken varying approaches to answering the question of who has the final say by enacting either “red,” “yellow,” or “green light” futility statutes.<sup>2</sup> In states with “red light” futility statutes, like New York and New Jersey, providers cannot withdraw LSMT without parental or surrogate<sup>3</sup> consent.<sup>4</sup> In “yellow light” states like Connecticut, the

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<sup>1</sup> In the Matter of BABY “K”, 16 F.3d 590 (4th Cir. 1994).

<sup>2</sup> The “red,” “yellow,” and “green light” categories of futility statute are attributed to Professor Thaddeus M. Pope, M.D., THADDEUSPOPE.COM. See Pope, *Medical Futility Statutes*, *infra* note 18.

<sup>3</sup> “Surrogates” and “parents” will be used interchangeably; although there are many instances in which the surrogate is not the parent (e.g. a grandparent or guardian), and there are even more complex disputes that can emerge in those types of situations. See Thaddeus M.

outcome is less certain as providers who decide to withdraw LSMT without parental consent must satisfy a substantive standard in court.<sup>5</sup> In “green light” states like Texas, providers can withdraw treatment without parental consent under statutory safe harbors. As long as providers in “green light” states follow the statutory procedure, they are permitted to withdraw LSMT within ten days of deeming a patient’s case futile.<sup>6</sup>

This paper supports the “green light” approach to futility disputes for a number of reasons. First, providers in the neonatal field are the most qualified individuals to determine when a newborn’s case is futile. Second, providers have taken an oath and have a professional responsibility to “first do no harm;”<sup>7</sup> once a newborn’s case is deemed futile, further administering of LSMT cruel and inhumane because it prolongs only suffering and death for a potentially indefinite amount of time. Granting parents in futility disputes the power to force providers to administer treatment that conflicts with their oath and professional responsibility to “first do no harm” is problematic. Finally, providers have broader considerations, and a fiduciary duty to allocate the resources available in a just, caring, and reasonable way. Making the right decision means doing the right thing, in the right way, and *at the right time*. If more states adopted “green light” futility statutes, then providers in futility disputes would not be forced to administer treatment in violation of their oath to first do no harm, and they could appropriately allocate the resources available.

If, however, more states adopted the “green light” approach, then mediation would no longer be an appropriate approach to futility disputes involving newborns because the decision to withdraw LSMT in “green light” states is non-negotiable, as there is only one possible outcome. If the provider has final authority over the decision to withdraw LSMT, and believes the patient’s case is futile, there can only be one possible outcome to the dispute: that LSMT be withdrawn as soon as possible. In effect, “green light” futility statutes transform futility disputes from mediable issues to non-negotiable discussion topics. As a result, providers in “green light” states should institute

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Pope, *Surrogate Selection: An Increasingly Viable, but Limited, Solution to Intractable Futility Disputes*, 3 St. LOUIS U.J. HEALTH L. & POL’Y 183, 185 (2010).

<sup>4</sup> See State Law – Part II, *infra*.

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> Kasman, *infra* note 126.

traditionally facilitative, process-based approaches to futility disputes instead of trying to mediate the issue.

Thus, this paper makes two primary assertions. First, more states should adopt “green light” futility statutes. Second, providers in “green light” states should not attempt to mediate between parents and providers in futility disputes; instead, providers should institute standardized, traditionally facilitative, process-based techniques that will contribute to greater understanding and communication.

Part II of this paper will provide background on futility disputes between parents and providers and discuss various techniques to approaching futility disputes including mediation and facilitation. Part II will also discuss existing federal and state law in the area. Part III will analyze how the “traffic light” futility statutes influence the bargaining positions of parents and providers and recommend that more states adopt the “green light” approach. Part III will also advance the notion that futility disputes in “green light” states are non-negotiable issues, so instead of trying to mediate, providers should institute a standardized, traditionally facilitative, process-based approach to futility disputes between parents and providers. Part IV will conclude and make recommendations.

## *II. Background*

### *A. Futility Disputes: Parents vs. Providers*

Baby Michael was born to unmarried teenage parents without health insurance. He was born with necrotic small bowel syndrome. Surgery at birth determined that he would not be able to process food in the normal way. Hence, he would have to remain in an intensive care unit, fed via total parenteral nutrition. After six months the hospital administrator approached the attending physician and pointed out that Michael was responsible for \$250,000 in uncompensated care costs. Michael could live another six to eighteen months, which would mean potential uncompensated care costs of one million dollars. The administrator reminded the physician that this was the only hospital in town that provided charity care to the poor, and that if Michael remained in the hospital then the emergency room would have to be closed to all the poor, except those with true life-threatening medical problems. The state was willing to care for Michael and place him in a nursing home, but it would not provide the treatment for nutrition,

which would mean Michael would die of infection and/or starvation within two weeks.<sup>8</sup>

Futility disputes like Michael's present acute ethical challenges for providers<sup>9</sup> who must make difficult decisions while exercising care, justice, and fairness in allocating resources. As Professor Leonard Fleck asks, how should a good provider respond to Michael's parents who want him to live as long as possible when the provider is tasked with balancing a plethora of legitimate healthcare needs while containing costs?<sup>10</sup> What happens when providers conclude that further administering of LSMT is medically inappropriate and that treatment should be withdrawn immediately, but the parents insist on continued treatment for the newborn?

A medical futility dispute emerges when the parties involved disagree over the medical and ethical appropriateness of further medical intervention.<sup>11</sup> In the case of "futile" newborns, parents might insist on aggressive treatment for their child, while the provider might believe that continued treatment would be "medically or ethically inappropriate."<sup>12</sup> Newborns that require LSMT and are deemed "futile" will never attain any level of consciousness, and will require constant mechanical and artificial support to sustain their vital functions.<sup>13</sup> These newborns will never possess decision-making capacity, and as a result, their parents usually have the authority to communicate healthcare decisions on their behalf.<sup>14</sup> When parents fundamentally disagree with a provider over the decision to withdraw LSMT from their newborn child, futility disputes in the neonatal context emerge.

Unsurprisingly, parents want providers to "do whatever it takes" for their child. Parents in these circumstances are often in shock and are still mourning the perfect baby they never had.<sup>15</sup> Many parents feel

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<sup>8</sup> Lawrence B. McCullough, *Moral Dilemmas and Economic Realities*, HOSP. & HEALTH SERVICES ADMIN., Sept.- Oct. 1985, at 63, 68-69. Leonard M. Fleck, *Just Health Care Rationing: A Democratic Decisionmaking Approach*, 140 U. PA. L. REV. 1597, 1597 (1992).

<sup>9</sup> Again, recognizing many distinctions between individual physicians and healthcare providers in a more institutional sense, "physician" and "provider" will be used interchangeably throughout.

<sup>10</sup> See Fleck, *supra* note 8.

<sup>11</sup> Thaddeus M. Pope, *Dispute Resolution Mechanisms for Intractable Medical Futility Disputes*, 58 N.Y.L. SCH. L. REV. 347, 351 (2014) [hereinafter Pope, *Mechanisms*].

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> See *id.*

<sup>15</sup> E-mail correspondence with Dr. John O' Reilly, M.D. (Baystate Cardiology and Ethics

guilty about their infants prematurity or illness, and worry that the glass of wine or cigarette they had before they knew they were pregnant caused their baby's condition.<sup>16</sup> Nurturing, protecting, and feeding your child is an essential part of being a parent, so being asked to withdraw treatment from that child goes against the natural order and usually adds to parents' angst.<sup>17</sup> Sometimes, parents hope that perhaps the provider's prognosis is wrong or mistakenly believe that providers can cure, reverse, or ameliorate the symptoms of the disease or condition.<sup>18</sup> Parents can also experience "therapeutic illusions" whereby they believe that "particular treatment or research protocol will improve the patient's condition despite the likelihood that such treatment will have no beneficial effect."<sup>19</sup> In other instances, parents might be driven by their religious beliefs.<sup>20</sup> They might believe that human life is holy and should therefore be cherished, saved, and protected; or that despite all the odds, God will perform a miracle. Finally, parents might suspect providers of being driven by cost-considerations.<sup>21</sup> Providers seeking to end LSMT, however, have differing views and may believe that "doing everything possible" is actually causing more unnecessary harm.

Providers locked in futility disputes with parents must make value judgments about what constitutes a life worth living, which can be an even more difficult determination in the case of a newborn struggling to survive. Newborns and young babies are capable of some pretty remarkable turnarounds,<sup>22</sup> so providers in these situations monitor the patients closely and work to establish realistic timeframes early in the process.<sup>23</sup> Providers might view parents' goals as impossible or inappropriate under the circumstances. At a certain point, providers

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Committee member) (Apr. 5, 2015).

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> Thaddeus Mason Pope, *Medical Futility Statutes: No Safe Harbor to Unilaterally Refuse Life-Sustaining Treatment*, 75 TENN. L. REV. 1, 11 (2007) [hereinafter Pope, *Medical Futility Statutes*].

<sup>19</sup> Stacey A. Tovino, J.D., & William J. Winslade, Ph.D., J.D., *A Primer on the Law and Ethics of Treatment, Research, and Public Policy in the Context of Severe Traumatic Brain Injury*, 14 ANNALS HEALTH L. 1, 26 (2005).

<sup>20</sup> See Pope, *Medical Futility Statutes*, *supra* note 18, n. 45.

<sup>21</sup> See generally *Views on End-of-Life Medical Treatments*, PEWRESEARCHCENTER (Nov. 21, 2013), <http://www.pewforum.org/2013/11/21/views-on-end-of-life-medical-treatments/>.

<sup>22</sup> E-mail correspondence with Peter A. DePergola II, Ph.D., MTS (Clinical Ethicist & Chair, Baystate Health) (Mar. 31, 2015).

<sup>23</sup> *Id.*

may believe that “continued intervention [is] inhumane, invasive, pointless, cruel, [and] burdensome.”<sup>24</sup> Additionally, providers might not be interested in continuing LSMT out of a concern that treatment is providing “false hope” to the parents. Providers that are mindful of their obligation to maximize the utility of scarce resources could also be reluctant to continue LSMT.<sup>25</sup> While many are uncomfortable with the notion of life and death decisions being made based on the funds available, the current environment of healthcare requires that providers consider cost-containment when approaching EOL decision-making.<sup>26</sup> While not newborns, the Schiavo and Cruzan cases<sup>27</sup> demonstrated that futility disputes that drag on for years can cost millions of taxpayer dollars.<sup>28</sup> The emotionally charged nature of EOL futility decisions involving newborns can, unsurprisingly, lead to conflict. Over the years, providers have developed standard protocols for dealing with conflict in futility disputes.<sup>29</sup>

While the majority of futility disputes are resolved between parents and medical professionals internally,<sup>30</sup> a great deal of conflict can be traced one of three sources: that of intrapersonal matters, conflicts which are a result of a faulty communication process, and those which are based upon dissimilar interpersonal views and opinions that result in overt disagreement.<sup>31</sup> In the first stage of futility disputes, there can be frequent miscommunications between the providers and the parents, for example a treating physician may explain to a parent that her child is brain-dead, but what the provider is really trying to communicate is “your child is no longer ‘your child’ in any sense of the word.” Instead, the grief stricken parent interprets this to mean,

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<sup>24</sup> Tovino & Winslade, *supra* note 19, at 16.

<sup>25</sup> *Id.* at 198.

<sup>26</sup> See Pope, *Medical Futility Statutes*, *supra* note 18, n. 73.

<sup>27</sup> In the case of Nancy Cruzan, a young woman who was diagnosed as being in a persistent vegetative state after suffering a car accident, the state of Missouri spent nearly \$1,000,000 over an eight-year period to keep her alive. See Leonard M. Fleck, *Just Health Care Rationing: A Democratic Decisionmaking Approach*, 140 U. PA. L. REV. 1597, 1611 (1992). Similarly, estimates for Schiavo’s care were roughly \$80,000 annually. See Jonathon Weisman & Ceci Connolly, *Schiavo Case Puts Face on Rising Medical Costs* (Mar. 23, 2005) WASH. POST, <http://www.washingtonpost.com/wp-dyn/articles/A58069-2005Mar22.html>.

<sup>28</sup> See Pope, *Medical Futility Statutes*, *supra* note 18, n. 73.

<sup>29</sup> Pope, *Medical Futility Statutes*, *supra* note 18, at 22-27.

<sup>30</sup> *Id.* at 21.

<sup>31</sup> See Kimberlee K. Kovach, *Neonatology Life and Death Decisions: Can Mediation Help?*, 28 CAP. U. L. REV. 251, 272 (2000).

“my child’s *brain* is dead, but *she* is still alive!”<sup>32</sup> So, during the first stage of EOL decisions involving newborns and young babies, providers conduct “family meetings” with the parents to discuss a prognosis and present the medical data in a comprehensible way.<sup>33</sup> Again, a great deal of disputes are avoided or resolved at this stage,<sup>34</sup> but when conflict persists providers tend to introduce third parties.

During the third stage of futility disputes, a hospital’s ethics committee frequently gets involved.<sup>35</sup> Ethics committees (“ECs”) became increasingly popular in healthcare institutions following the case of Karen Ann Quinlan,<sup>36</sup> and are responsible for addressing ethical concerns in patient care as well as assisting in the resolution of a variety of conflicts.<sup>37</sup> ECs are often comprised of individuals with multidisciplinary educational backgrounds (including philosophy, medicine, law, theology, nursing, social sciences, social work, public health, and health administration),<sup>38</sup> and while the committee may not always agree on the best way to achieve the goal, their decisions are unanimous<sup>39</sup> and usually reflect the treating physician’s recommendation.<sup>40</sup> During this stage, the provider and ECs often attempt to resolve the dispute by employing techniques like mediation or facilitation.<sup>41</sup>

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<sup>32</sup> Interview with Dr. John O’Reilly M.D., Peter DePergola II, Ph.Dc, MTS and Thomas Derr, Ph.D, Baystate Medical Center, in Springfield Mass. (Mar. 24, 2015) [hereinafter Interview].

<sup>33</sup> *Id.*

<sup>34</sup> Pope, *Medical Futility Statutes*, *supra* note 18, at 22.

<sup>35</sup> *Id.* at 23.

<sup>36</sup> “Quinlan was a young woman in a persistent vegetative state whose father requested removal of a respirator that was assisting her breathing in the belief that his daughter would not have wanted to be kept alive by that technology if there were no hope of her recovery to a cognitive state. A devout Catholic, the father had sought to confirm the moral rightness of his request by consulting Catholic clergy. At trial, his request was also supported by a formal statement from the Roman Catholic Church, which did not require the continuation of his daughter’s unconscious life by this extraordinary means. Her treating physicians, however, declined to withdraw the respirator because it conflicted with their professional judgment under then-prevailing medical standards, practice, and ethics.” See Charity Scott, *Ethics Consultations and Conflict Engagement in Health Care*, 15 CARDOZO J. CONFLICT RESOL. 363, 364 (2013-2014).

<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

<sup>39</sup> Interview, *supra* note 32.

<sup>40</sup> Pope, *Medical Futility Statutes*, *supra* note 18, at 23.

<sup>41</sup> See Pope, *Medical Futility Statutes*, *supra* note 18, at 21-26.

*B. Various Techniques to Approaching Futility Disputes*

Given the inherently stressful and sensitive nature of futility decisions involving newborns, dispute resolution techniques like mediation and facilitation have a large role to play.<sup>42</sup> Of the various techniques available to providers, mediation has been widely endorsed in legal scholarship for its capacity to provide “a process in which all of the involved and affected parties are able to participate in decision making.”<sup>43</sup> There are, however, a number of forms or models of mediation.<sup>44</sup> The American Arbitration Association<sup>45</sup> defines mediation as “a voluntary. . . process in which a mutually-selected, impartial [third party] helps people involved in controversy reach an outcome of their own making. . .”<sup>46</sup> As Michael Alberstein points out, mediation under the pragmatic model is used to help parties exercise “integrative bargaining” so that the parties’ goals are no longer mutually exclusive and both sides can achieve their objectives and maximize their mutual gain.<sup>47</sup> Evaluative mediation, one form of mediation under the pragmatic approach, creates a process whereby the third party neutral pressures the parties to reach an outcome by “assessing the strengths and weaknesses of each side, predicting the outcomes, proposing agreement, or urging or pushing the parties to accept settlement.”<sup>48</sup> While this form of mediation can be particularly effective at resolving disputes, there is a strong emphasis placed on the outcome as opposed to the process, but other models emphasize process over outcome.

The transformative model of mediation places a much greater emphasis on the process to resolution, as opposed to resolution itself. Parties that participate in mediation under the transformative model can “experience moral growth and improve their communication skills. . . regardless of the outcomes of the process and without necessarily

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<sup>42</sup> Kovach, *supra* note 31, at 253.

<sup>43</sup> *Id.* at 283.

<sup>44</sup> Michael Alberstein, *Forms of Mediation and Law: Cultures of Dispute Resolution*, 22 OHIO ST. J. ON DISP. RESOL. 321, 328 (2006-2007).

<sup>45</sup> *Learn About Mediation*, AM. ARB. ASS'N, [https://www.mediation.org/mediation/faces/what\\_is\\_mediation?](https://www.mediation.org/mediation/faces/what_is_mediation?) (last visited Aug. 13, 2016).

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

<sup>47</sup> Alberstein, *supra* note 44, at 329.

<sup>48</sup> Armand H. Matheny Antommara, *Alternative Dispute Resolution and Pediatric Clinical Ethics Consultation: Why the Limits of Ethical Expertise and the Indeterminacy of the Best Interests Standard Favor Mediation*, 23 OHIO ST. J. ON DISP. RESOL. 17, 28 (2007).

satisfying their actual needs.”<sup>49</sup> According to Bush and Folger, “parties are helped to transform their conflict interaction – from destructive to constructive.”<sup>50</sup> Indeed, the mediator’s role, in transformative mediation, is to help the parties make “positive interactional shifts by supporting the exercise of their capacities for strength and responsiveness.”<sup>51</sup> To that extent, mediation “has a relational dimension that should be emphasized and promoted.”<sup>52</sup> Similar to transformative mediation is facilitation, which can help parties engage with one another to generate more understanding and acceptance as oppose to mutual agreement.

While facilitation can take many forms, it often involves a third party who assists in guiding the direction of discussion to help the parties build consensus.<sup>53</sup> Traditional facilitation involves “an impartial facilitator guid[ing] the parties. . . using a variety of collaborative techniques.”<sup>54</sup> The facilitative approach “identifies and analyzes. . . the range of morally acceptable options. . . [which] in some circumstances [requires the facilitator] to make decisions for the parties as an arbitrator would.”<sup>55</sup> In that sense, traditional facilitation offers a more efficient alternative to traditional mediation as “deciding not to reach a resolution is not an option.”<sup>56</sup> Similarly, the “ethics facilitation approach” employed in EOL futility cases, seeks to identify and analyze “the nature of the value uncertainty” and “facilitate the building of a principled ethical resolution.”<sup>57</sup> Under this approach, the facilitator can work to “delimit the range of acceptable outcomes,”<sup>58</sup> but should avoid “unduly influencing the ultimate decision-maker by recommending a single best course of action or imposing her own values on other.”<sup>59</sup> Nevertheless, through ethics facilitation, ECs can

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<sup>49</sup> Alberstein, *supra* note 44, at 330.

<sup>50</sup> *Id.* at 330; see also ROBERT A. BARUCH BUSH & JOSEPH P. FOLGER, *THE PROMISE OF MEDIATION: RESPONDING TO CONFLICT THROUGH EMPOWERMENT AND RECOGNITION* 53 (1994).

<sup>51</sup> Robert A. Baruch Bush & Sally Ganong Pope, *Changing the Quality of Conflict Interaction: The Principles and Practice of Transformative Mediation*, 3 PEPP. J. DISP. RESOL. 67, 83 (2002).

<sup>52</sup> Alberstein, *supra* note 44, at 330.

<sup>53</sup> Antommara, *supra* note 48, at 41.

<sup>54</sup> *Id.* at 42.

<sup>55</sup> *Id.* at 41.

<sup>56</sup> *Id.* at 46.

<sup>57</sup> See Scott, *supra* note 36, at 377.

<sup>58</sup> Antommara, *supra* note 48, at 47.

<sup>59</sup> Scott, *supra* note 36, at 378.

work to open the lines of communication between the parties while limiting the available options in order to efficiently reach a consensus. Thus, the facilitative approach conflicts with, to some extent, the notion of varying potential outcomes, which is a prerequisite for negotiations and the basis upon which mediation rests.

There are some issues that are simply “un-mediabile” because the underlying needs or interests of the parties are non-negotiable. As Frenkel and Stark assert, “mediation is a time-limited process, with participants who seek tangible results;”<sup>60</sup> consequently, mediation is only applicable in situations involving negotiable issues. For an issue to be negotiable it must have three essential characteristics:<sup>61</sup>

(1) The issue must have more than one possible outcome or solution; (2) the issue must be concrete and tangible enough to be adjusted through a bargaining process of give and take; and (3) the issue must be within the parties’ ability to resolve given their authority and the resources under their control.<sup>62</sup>

Issues that fail to satisfy these requisites might “be a fruitful area for detailed exploration,”<sup>63</sup> but they are not issues that are mediable because they are non-negotiable. If, however, the issue does satisfy these elements, then mediation can be an economical and effective way of addressing controversy while maintaining control over the process and outcome.<sup>64</sup> In the context of futility disputes, the negotiability of EOL decisions depends heavily on the bargaining power and positions of the parents and the providers, which are often contrived from the parties’ legal rights.<sup>65</sup> So, the question becomes, what legal authority do parents and providers have in deciding whether to withdraw LSMT from a newborn?

### *C. Federal Law on the Right to Withdraw LSMT*

Generally, federal law seems to imply that providers have the authority over whether to withdraw LSMT from newborns. Under the

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<sup>60</sup> DOUGLAS N. FRENKEL & JAMES H. STARK, *THE PRACTICE OF MEDIATION: A VIDEO INTEGRATED TEXT* 209 (2<sup>nd</sup> ed. 2012).

<sup>61</sup> *Id.*

<sup>62</sup> *Id.* at 209-10.

<sup>63</sup> *Id.*

<sup>64</sup> *Learn About Mediation*, *supra* note 45.

<sup>65</sup> *See generally* Thaddeus M. Pope & Ellen A. Waldman, *Mediation at the End of Life: Getting Beyond the Limits of the Talking Cure*, 23 OHIO ST. J. ON DISP. RESOL. 143, *passim* (2007), <http://open.mitchellhamline.edu/cgi/viewcontent.cgi?article=1285&context=facsch>.

Emergency Medical Treatment and Labor Act (“EMTALA”),<sup>66</sup> a hospital must treat “any individual [that] comes to a hospital. . . [with] an emergency medical condition”<sup>67</sup> by providing stabilizing medical treatment, after which the patient can be transferred to another medical facility.<sup>68</sup> The Child Abuse Prevention and Treatment Act (“CAPTA”)<sup>69</sup> is another federal act stipulating that infants with life-threatening conditions be provided with “medically indicated treatment.”<sup>70</sup> Under CAPTA, providers are required to provide “aggressive treatment [to] almost all defective newborns,” however, the statute “spells out three circumstances under which treatment is not considered ‘medically indicated.’”<sup>71</sup>

- (1) When the infant is “chronically and irreversibly comatose;” (2) when treatment would merely prolong dying and not be effective in ameliorating or correcting the infant’s life threatening condition, or otherwise would be futile in terms of survival of the infant; or (3) when treatment would be virtually futile in terms of survival of the infant and the treatment itself under such circumstances would be inhumane.<sup>72</sup>

CAPTA, however, does not empower providers because CAPTA only authorizes child protective service agencies to bring suit in cases where providers are accused of medical neglect of infants without guardians.<sup>73</sup>

The Uniform Health-Care Decisions Act (“UHCDA”)<sup>74</sup> also demands that providers satisfy a subjective standard for futility as outlined in CAPTA. The UHCDA states that a “health-care provider or institution may decline to comply with an individual instruction or health-care decision that requires *medically ineffective health care* or health care contrary to generally accepted health-care standards

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<sup>66</sup> Emergency Medical Treatment and Labor Act (EMTALA), 42 U.S.C.A. §1395dd (2011).

<sup>67</sup> EMTALA, 42 U.S.C.A. §1395dd(b)(1).

<sup>68</sup> *Id.*

<sup>69</sup> Child Abuse Prevention And Treatment Act of 1973 (CAPTA) (2010), 42 U.S.C.A. §§ 5106-5119.

<sup>70</sup> 42 U.S.C.A. § 5106(g).

<sup>71</sup> *Id.*

<sup>72</sup> *Id.*

<sup>73</sup> In the Matter of BABY K, 832 F. Supp. 1022, 1029 (E.D. Va. 1993).

<sup>74</sup> UNIFORM HEALTH-CARE DECISIONS ACT (UHCDA), NAT’L CONF. OF COMM’R ON UNIF. STATE LAWS (1993), [http://www.uniformlaws.org/shared/docs/health%20care%20decisions/uhcda\\_final\\_93.pdf](http://www.uniformlaws.org/shared/docs/health%20care%20decisions/uhcda_final_93.pdf).

applicable to the health-care provider or institution.”<sup>75</sup> Commentary in the UHCDA defines “medically ineffective health care” as treatment that would not offer the patient any *significant benefit*.<sup>76</sup> Ostensibly, federal law gives deference to providers in futility disputes, but some courts have nevertheless ruled in favor of the parents, as demonstrated in the case of *Baby K*.<sup>77</sup>

Perhaps, the most famous example of a court ruling in favor of a mother in a futility dispute with providers over the life of her daughter was in the case of *Baby K*.<sup>78</sup> There, the Fourth Circuit Court of Appeals affirmed a district court ruling in favor of Mrs. K, Baby K’s mother.<sup>79</sup> Stephanie Keene (“Baby K”) was born with anencephaly, a congenital malformation in which a major portion of the brain, skull, and scalp are missing.<sup>80</sup> She was permanently unconscious, had no cognitive abilities or awareness, and could not see, hear, or otherwise interact with her environment.<sup>81</sup> Baby K had difficulty breathing immediately and required a ventilator.<sup>82</sup> Treating physicians explained to Mrs. K that the ventilator was medically unnecessary and inappropriate because Baby K’s case was futile, but Mrs. K insisted on ventilator treatment for her daughter.<sup>83</sup> After Mrs. K rejected a three-person Ethics Committee’s conclusion that ventilator care was futile, the hospital transferred Baby K to a nursing home.<sup>84</sup> Shortly after being released, Baby K was brought back to the hospital, twice, for respiratory distress and provided with breathing assistance both times.<sup>85</sup> Following the second visit, the hospital, along with Baby K’s father, filed an action to resolve whether the hospital was obligated to administer “respiratory support or other aggressive treatments.”<sup>86</sup> Mrs. K contested and the district court denied the hospital’s request for declaratory relief.<sup>87</sup>

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<sup>75</sup> *Id.* at 29. (UHCDA §7(f)).

<sup>76</sup> *Id.* at 29 (Commentary to UHCDA §7).

<sup>77</sup> In the Matter of BABY “K”, 16 F.3d 590 (4th Cir. 1994).

<sup>78</sup> *Id.*

<sup>79</sup> *Id.* at 598.

<sup>80</sup> *Id.* at 592.

<sup>81</sup> *Id.*

<sup>82</sup> *Id.*

<sup>83</sup> In the Matter of BABY K, 832 F. Supp. 1022, 1025 (E.D. Va. 1993).

<sup>84</sup> *Id.*

<sup>85</sup> *Id.*

<sup>86</sup> *Id.* at 1026.

<sup>87</sup> *Id.* at 1027.

The Fourth Circuit affirmed the district court's decision, and held that the hospital was not authorized to deny providing "stabilizing treatment, which it [the hospital] considered morally and ethically inappropriate."<sup>88</sup> Under EMTALA, the court found that the hospital was obliged to provide "treatment as may be required to stabilize the medical condition."<sup>89</sup> At the trial level, the district court found that Mrs. K had a "constitutionally protected right to 'bring up children' grounded in the . . . due process clause,"<sup>90</sup> and that "where the choice essentially devolves to a subjective determination as to the quality of Baby's K's life, it cannot be said that the continuation of Baby K's life is so unreasonably harmful as to constitute child abuse or neglect."<sup>91</sup> The district court's presumption in favor of life was also based on Mrs. K's religious Free Exercise rights.<sup>92</sup> Despite the hospital's pleas to the Fourth Circuit to recognize an exception to EMTALA for treatment that is cruel, inhumane, and outside the prevailing standard of medical care, the court affirmed the district court's ruling.<sup>93</sup>

The Fourth Circuit's ruling was contentious. The dissenting judge argued that Baby K was "not the kind of emergency patient contemplated by the statute."<sup>94</sup> Justice Sprouse wrote,

[Baby K] will suffer repeated medical emergencies during her day-to-day maintenance care. The hospital argues that anencephaly, not the subsidiary respiratory failure, is the condition that should be reviewed in order to judge the applicability *vel non* of EMTALA. I agree. I would consider anencephaly as the relevant condition and the respiratory difficulty as one of many subsidiary conditions found in a patient with the disease. EMTALA was not designed to reach such circumstances.<sup>95</sup>

Others expressed sharper criticisms. Linda Greenhouse for the New York Times wrote, "for a judge to insist on a treatment that is contrary to all established standards of care is to destroy medicine as a profession and turn physicians into servants of the fantasies of

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<sup>88</sup> In the Matter of BABY "K", 16 F.3d 590, 590 (4<sup>th</sup> Cir. 1994).

<sup>89</sup> EMTALA, *supra* note 66.

<sup>90</sup> In the Matter of BABY K, 832 F. Supp. 1022, 1029 (E.D. Va. 1993).

<sup>91</sup> *Id.*

<sup>92</sup> *Id.* at 1030.

<sup>93</sup> In the Matter of Baby re Baby "K", 16 F.3d 590, 598 (4<sup>th</sup> Cir. 1994).

<sup>94</sup> *Id.* (Sprouse, J., dissenting).

<sup>95</sup> *Id.*

families.”<sup>96</sup> Another problem with the Fourth Circuit’s ruling is that it established that a parent’s religious beliefs take precedence over the doctor’s often more qualified and objective health-related ethical responsibilities.<sup>97</sup> The case of *Baby K* sheds light on the notion that courts may still rule in favor of the parents even if treatment is, in the provider’s reasonable medical judgment, only prolonging death and inhumane. By contrast, authority over the decision to withdraw LSMT at the state level can range from being completely in the parents’ control, at one end of the spectrum, to completely in the providers’, at the other.

*D. State Law: “Traffic Light” Futility Statutes*

At the state level, varying distributions of power between parents and providers in futility disputes are manifested in three characteristic statutes: “red,” “yellow,” and “green light” futility statutes.<sup>98</sup> If power over the decision to withdraw LSMT were a spectrum, at one end of the spectrum parental consent would be required before providers could withdraw LSMT; these states are referred to as “red light” states because the provider cannot go ahead with the decision to withdraw LSMT without parental consent.<sup>99</sup> At the other end of the spectrum are states in which providers can withdraw LSMT without any consent or permission from the parents; these types of states are called “green light” states.<sup>100</sup> “Yellow light” states “neither clearly forbid nor clearly permit” providers from unilaterally withdrawing LSMT,<sup>101</sup> and although “yellow light” statutes purport to immunize providers that do decide to withdraw LSMT unilaterally, actually securing immunity “depends upon the satisfaction of standards and conditions that clinicians cannot be sure are really satisfied.”<sup>102</sup> A closer look at some

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<sup>96</sup> Linda Greenhouse, *Hospital Appeals Ruling on Treating Baby Born with most of Brain Gone*, N.Y. TIMES (Sept. 24, 1994), <http://www.nytimes.com/1993/09/24/us/hospital-appeals-ruling-on-treating-baby-born-with-most-of-brain-gone.html>; Robert Cantwell, *Anencephalic Child Kept Alive Through the Fourth Circuit’s Interpretation of the Emergency Medical Treatment and Labor Act: A Medical Miracle or a Living Corpse*, 14 ST. LOUIS U. PUB. L. REV. 323, 343 (1994-1995).

<sup>97</sup> Cantwell, *supra* note 96, at 344.

<sup>98</sup> *Medical Futility Statutes*, THADDEUSPOPE.COM, <http://thaddeuspope.com/futilitystatutes.html> (last visited Apr. 16, 2015).

<sup>99</sup> Pope, *Mechanisms*, *supra* note 11, at 359-61.

<sup>100</sup> *Id.* at 361-63.

<sup>101</sup> *Id.* at 363-65.

<sup>102</sup> *Id.* at 363.

of these statutes will reveal their impact on the bargaining positions of providers locked in futility disputes with parents.

### III. Analysis

#### A. “Traffic Light” Futility Statutes and a Provider’s Power to Negotiate: Why More States Should Adopt the “Green Light” Approach

Providers in “red light” states, like New York, have very little power vis-à-vis parents when it comes to withdrawing LSMT from a newborn child because the legal authority over the decision to withdraw LSMT rests wholly with the parents.<sup>103</sup> Under New York’s Family Healthcare Decisions Act (“FHCDA”),<sup>104</sup> the “parent or guardian of a minor patient shall have the authority to make decisions about life-sustaining treatment, including decisions to withhold or withdraw such treatment.”<sup>105</sup> As the court found in the case of *In re AB*, the decision to end the dying process of a minor child is “a personal decision for the parents. . . as they bear the legal, moral and ethical responsibility for their child.”<sup>106</sup> By enacting a “red light” futility statute, the New York legislature has implicitly endorsed the notion that, in certain circumstances, a parent must have the right to set the standard of care for their child, despite recommendations from the provider. If a provider recommends that LSMT be withdrawn because it is only prolonging suffering and death, and a parent refuses, the parent’s standard of care that “everything be done” effectively trumps the provider’s professional responsibility to “first do no harm.”<sup>107</sup> Other states, however, trust providers to make such determinations.

“Yellow light” states like Connecticut and California, do not require providers obtain parental consent before withdrawing LSMT, but providers are inherently risk-averse and, as a result, will not withdraw LSMT without first obtaining parental consent.<sup>108</sup> Connecticut’s futility statute outlines that a licensed physician is not

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<sup>103</sup> *Id.* at 359-60.

<sup>104</sup> Chapter 8, 2010 Laws of New York, A.7729-D & S. 3164-B., <http://www.nysba.org/WorkArea/DownloadAsset.aspx?id=26473>. Section 2 of Chapter 8 amends N.Y. Public Health Law to create “Article 29-CC Family Health Care Decisions Act.”

<sup>105</sup> New York FHCDA, Sec. 2994-e.

<sup>106</sup> *In re AB*, 768 N.Y.S.2d 256, 271 (Sup. Ct. 2003).

<sup>107</sup> See generally Kasman, *infra* note 126, *passim*.

<sup>108</sup> See generally Pope, *Mechanisms*, *supra* note 11.

liable for damages for “withholding, removing or causing the removal of a life support system,”<sup>109</sup> if “in the treating physician’s (or physicians’) reasonable medical judgment” any of the CAPTA circumstances apply (ie. chronically and irreversibly comatose, prolong dying, treatment is futile).<sup>110</sup> While physicians in “yellow light” states are permitted to withdraw LSMT, the uncertain outcome of any subsequent litigation is enough to prevent risk-averse providers from withdrawing LSMT unilaterally, without parental consent.<sup>111</sup> As courts tend to favor the parents in futility disputes,<sup>112</sup> providers are usually unwilling to test the courts in the hopes that they *might* rule in favor of the provider. Consequently, parents in “yellow light” states have a disproportionate amount of bargaining power vis-à-vis providers in futility disputes. So, providers in “yellow light” states continue administering treatment even when they believe treatment is cruel and inhumane. “Green light” futility statutes, however, eliminate the paralyzing risk that providers face in “yellow light” states by creating safe harbors for providers seeking to unilaterally withdraw LSMT.<sup>113</sup>

In contrast to the vague substantive standards used in “yellow” light states, “green light” futility statutes like the Texas Advance Directives Act (“TADA”)<sup>114</sup> remove the risk of uncertainty by explicitly outlining the procedure providers must follow to ensure legal immunity when unilaterally withdrawing LSMT.<sup>115</sup> Under TADA, if an attending physician refuses to honor a parent’s decision regarding treatment, “and the review process [the EC] has affirmed” that treatment is “inappropriate,” then the provider can withdraw treatment 10 days later.<sup>116</sup> The procedure outlined in TADA is as follows: first, the treating physician must inform the parents of his or her decision to withdraw treatment.<sup>117</sup> Next, the case goes to an EC or similar body for review;<sup>118</sup> if the EC supports the physician’s decision then the

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<sup>109</sup> Conn. Gen. Stat. § 19a-571 (2012).

<sup>110</sup> *Id.*

<sup>111</sup> Pope, *Mechanisms*, *supra* note 11, at 365.

<sup>112</sup> *In re AB*, 768 N.Y.S.2d at 263.

<sup>113</sup> *See generally* Advanced Directives Act, Tex. Health & Safety Code §§ 166.001 – 166.165 (1999).

<sup>114</sup> *Id.*

<sup>115</sup> *See generally id.*

<sup>116</sup> TEX. HEALTH & SAFETY CODE §166.046 (LexisNexis, Lexis Advance through the 2015 regular session, 84th Legislature).

<sup>117</sup> *Id.*

<sup>118</sup> *Id.*

parents have 10 days to transfer their child to another facility or the provider can withdraw LSMT with legal immunity on the 11<sup>th</sup> day.<sup>119</sup> The assurance of immunity under “green light” futility statutes effectively empowers providers to stand up to parents’ demands.<sup>120</sup> Granting providers the power over the authority to withdraw LSMT, however, transforms the nature of a futility dispute from a negotiable and potentially mediable dispute into a non-negotiable discussion topic with only one possible outcome (i.e. that life support will be withdrawn, with or without consent).<sup>121</sup>

This paper supports the notion that more states adopt “green light” futility statutes because providers ought to have the final authority to withdraw LSMT from newborns, not parents. Providers in the neonatal field are the most qualified individuals to determine when a newborn’s case is futile; they have experience, training, and education the average person does not, and they are capable of determining the point at which a newborn is no longer receiving any medically beneficial care.<sup>122</sup> Providers draw on their training and expertise to analyze quantitative and qualitative aspects of a newborn’s status to determine whether the patient is capable of experiencing or appreciating any of the care being administered.<sup>123</sup> Once a provider determines, based on qualitative and quantitative futility,<sup>124</sup> that a patient is no longer receiving any medically beneficial care, the provider deems the case futile; at that point, the provider has a professional responsibility to advise that LSMT be withdrawn because prolonging the vital operations of a newborn, for a potentially indefinite amount of time, is cruel, inhumane and violates the provider’s responsibility to “first do no harm.”<sup>125</sup>

Another reason more states should adopt “green light” futility statutes is because providers in “red” and “yellow light” states locked in futility disputes with parents must comply with a standard of care

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<sup>119</sup> Pope, *Mechanisms*, *supra* note 11, at 365.

<sup>120</sup> See Pope & Waldman, *supra* note 65, at 194.

<sup>121</sup> See generally Pope, *Mechanisms*, *supra* note 11, at 361.

<sup>122</sup> See generally Lawrence Schneiderman & Michael De Ridder, *Medical Futility*, 118 HANDBOOK OF CLINICAL NEUROLOGY 167, 171-74 (2013).

<sup>123</sup> See *id.*

<sup>124</sup> Quantitative futility refers to the statistical chance of the patient making a full recovery, which is usually based on the question: how many times, out of the last 100 cases, have patients with similar ailments recovered? The qualitative aspect is usually measured by the degree to which the patient can experience any treatments being administered. Futile patients are those who experience no perceivable benefit. See *id.*

<sup>125</sup> See *id.*

that can directly conflict with their professional oath and responsibility to “first do no harm.” As Dr. Deborah Kasman asserts, “physicians are not obligated to provide treatments they believe are ineffective or harmful to patients” because physicians have taken a professional oath to “first do no harm.”<sup>126</sup> She points out that while withdrawing treatment should be done in a respectful and considerate way,<sup>127</sup> once a patient’s case has been deemed futile, “it is important that physicians are not forced into practicing medicine which conflicts with their moral or fiduciary responsibilities.”<sup>128</sup> While every parent has a “fundamental right to rear his or her own child” in the way they see fit,<sup>129</sup> providers also have an obligation to deny providing treatment they find cruel and inhumane.<sup>130</sup> Healthcare professionals are responsible for administering medically beneficial care, they are not responsible for catering to the wishes of the public.<sup>131</sup> So, even when parents insist providers “do everything possible” for their newborn child, providers must exercise clear moral judgment because they have a professional responsibility to “first do no harm.” In cases in which a provider’s responsibility conflicts with the wishes of parents, the provider’s professional responsibility should trump the parent’s wishes. When parents have final decision-making authority over whether to withdraw LSMT, patients and the team administering treatment continue to suffer, and “scarce healthcare resources are wasted.”<sup>132</sup>

Finally, more states should adopt “green light” futility statutes because these statutes enable providers to make quick efficient decisions.<sup>133</sup> Indeed, providers have financial constraints and fiduciary duties to allocate the resources available in a just, caring, and reasonable way.<sup>134</sup> “Green light” futility statutes do not just allow providers to make the right decision, they allow providers to make the

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<sup>126</sup> Deborah Kasman, *When is Medical Treatment Futile? A Guide for Students, Residents, and Physicians*, 19 J. GEN. INTERN. MED. 1053, 1054 (2004), [https://www.academia.edu/10885600/When\\_Is\\_Medical\\_Treatment\\_Futile\\_A\\_Guide\\_for\\_Students\\_Residents\\_and\\_Physicians](https://www.academia.edu/10885600/When_Is_Medical_Treatment_Futile_A_Guide_for_Students_Residents_and_Physicians).

<sup>127</sup> *Id.* at 1055.

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

<sup>129</sup> *In re AB*, 768 N.Y.S.2d at 269.

<sup>130</sup> John Altomare, J.D. & Mark Bolde, *Nguyen v. Sacred Heart Medical Center*, 11 Issues L. & Med. 200 (1995). See Pope, *Medical Futility Statutes*, *supra* note 18, at n. 67.

<sup>131</sup> Interview, *supra* note 32.

<sup>132</sup> Pope, *Mechanisms*, *supra* note 11, at 366.

<sup>133</sup> Interview, *supra* note 32.

<sup>134</sup> See *supra* Part III.

right decision, in the right way, and *at the right time*.<sup>135</sup> Discussing financial constraints in the context of EOL futility decisions is uncomfortable, but providers are tasked with doing just that.<sup>136</sup> They are the ones responsible for maintaining the standard of care within a certain budget, and in the context of futility decisions, every moment of inaction has very real consequences.<sup>137</sup> “Green light” futility statutes enable providers to carry out those decisions in an efficient manner. Still, if more states adopted the “green light” approach, there would be direct and immediate impacts on the effectiveness of certain techniques currently employed by providers in “red” and “yellow light” states.

*B. Approaching Futility Disputes in “Green Light” States: The Case for the Traditional Facilitative Process-Based Approach*

Instead of mediating futility disputes in “green light” states, providers should work toward instituting traditionally facilitative, process-based approaches that would improve understanding and communication between parents and providers. Futility disputes in “red” and “yellow light” states are mediable issues, but that does not hold true in “green light” states.<sup>138</sup> As a result, providers should institute standard procedures that emphasize communication and understanding instead of negotiability. That way, providers could make the right decisions, in the right way, and at the right time.

In “red” and “yellow light” states, mediation has been recognized as a valuable technique in futility disputes.<sup>139</sup> In *Neonatology Life and Death Decisions: Can Mediation Help?*, Professor Kim Kovach discusses how mediation “has been gaining widespread acceptance in courts and committees as a modern method for dispute resolution. . . [and] has been encouraged in the context of end-of-life decision making generally. . .”<sup>140</sup> Mediation, as Kovach explains, is a:

non-adversarial form of dispute resolution. . . where. . . resolutions are sought that consider the interests of the parties and to which all agree. . . In end-of-life decisions generally, it has been maintained that mediation is particularly beneficial in preventing the erosion

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<sup>135</sup> *Id.*

<sup>136</sup> Interview, *supra* note 32.

<sup>137</sup> *Id.*

<sup>138</sup> *See supra* Part III.

<sup>139</sup> *See* Kovach, *supra* note 31.

<sup>140</sup> *See id.*

of the trust that exists between the patient (or family members) and the physician.<sup>141</sup>

Mediation can enhance communication and provide an opportunity for everyone involved to listen to one another,<sup>142</sup> and as a neutral third party, the mediator “will be better at assuring that all parties participate *equally* in the process.”<sup>143</sup> In these states, however, parties locked in a futility dispute over whether to withdraw LSMT from a newborn do not participate *equally* in the process, and the issue only remains mediable because parents have the power to ensure that there remain at least two possible outcomes to futility disputes.<sup>144</sup>

The reason EOL futility decisions are mediable in “red” and “yellow light” states is because the issue is negotiable, as there is a possibility of more than one outcome. In “red light” states, as long as parents insist on LSMT there are at least two possible outcomes: first, that parents will remain steadfast and LSMT will continue to be administered; and second, that the parents will agree with providers that LSMT be withdrawn.<sup>145</sup> Both parents and providers have some authority and resources to resolve the issue, though often parents have much more power than providers. This disparity in bargaining power, however, disincentivizes parents from mediating the issue because usually their best alternative to a negotiated agreement (“BATNA”)<sup>146</sup> is the status quo (i.e. continued administering of LSMT). Consequently, as Pope and Waldman point out, mediation in “red light” states frequently leads to predictable outcomes:

Surrogates adhere to their extreme starting positions, and they seldom come to think more realistically about possible solutions. Providers explain how medically devastated the patient is. Surrogates reassert their positions. Providers back down, and the patient gets the treatment that the surrogates want.<sup>147</sup>

Similarly, the benefits of mediation are limited in “yellow light” states. As Pope and Waldman point out,

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<sup>141</sup> *Id.* at 284.

<sup>142</sup> *See id.* at 285-86.

<sup>143</sup> *Id.* at 285 (emphasis added).

<sup>144</sup> *See id.* at 264.

<sup>145</sup> *See supra* Part III. *See also* ROBERT FISHER, WILLIAM URY, & BRUCE PATTON, GETTING TO YES 99-100 (2011).

<sup>146</sup> *See* FISHER ET AL., *supra* note 145; *see also* Pope & Waldman, *supra* note 65, at 161.

<sup>147</sup> Pope & Waldman, *supra* note 65, at 159.

Substantive uncertainty places party risk-aversion (or risk-attraction) in high relief. Uncertainty about the outcome in court disadvantages the relatively risk-averse party because that party will accept less in order to avoid the gamble inherent in adjudication. Here, health care providers are the risk-averse party.<sup>148</sup>

The uncertainty of litigation creates an environment in which providers are “opposed to exercising any BATNA.”<sup>149</sup> Again, the disparity in bargaining power between surrogates and providers in “yellow light” states has a stymying effect on the effectiveness of mediation.

Pope and Waldman claim that mediation would be more effective in “green light” states, but this paper asserts that mediation would not be an appropriate technique because futility disputes in these states are non-negotiable issues. Pope and Waldman argue that “green light” futility statutes like TADA, empower providers to “stand up to surrogate demands” thereby equalizing bargaining power and creating ripe conditions for mediation.<sup>150</sup> “Green light” futility statutes, however, do not equalize bargaining power; they reassign it completely to providers, and when providers have final authority over withdrawing LSMT, and have deemed a patient futile, the issue is no longer mediable because there is no possibility for any outcome aside from an immediate withdrawal of LSMT.<sup>151</sup> As a result, providers in these states should not focus their energies towards attempting to mediate whether to withdraw LSMT; instead, providers should institute standardized, traditionally facilitative, process-centered techniques to address futility disputes between parents and providers.

The reason why process-based techniques may be more appropriate in “green light” states rests on the premise that providers should strive not to do just the right thing; but to do the right thing, in the right way, and at the right time.<sup>152</sup> Timing in futility disputes is critical, and attempting to mediate a non-negotiable issue will likely waste precious resources and time.<sup>153</sup> Instead, a standardized,

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<sup>148</sup> *Id.* at 180-81.

<sup>149</sup> LEONARD J. MARCUS, RENEGOTIATING: HEALTH CARE RESOLVING CONFLICT TO BUILD COLLABORATION 295 (1995); Pope & Waldman, *supra* note 65, at 186.

<sup>150</sup> *See* Pope & Waldman, *supra* note 65, at 186.

<sup>151</sup> *See supra* Part III.

<sup>152</sup> Interview, *supra* note 32.

<sup>153</sup> *See supra* Part III.

traditionally facilitative, process-based technique that incorporates certain values of transformative mediation would balance efficiency with sensitivity in EOL futility disputes.

A facilitative process-based technique would channel resources into developing standardized operating procedures that are carried out with respect and consideration for parents as well as the healthcare team involved. In such a system, once providers deemed a case futile, they could deploy a specialist who would quickly develop a rigid timeframe with providers and work with parents to limit the notion of negotiability. Drawing on the transformative model of mediation, specialists could emphasize moral growth and improving communication skills between parents and providers.<sup>154</sup> A facilitation specialist could focus on giving a voice to parties that feel neglected so that all the parties involved may hear and understand everyone else. Moreover, transformative mediation's goal of restoring an individual's sense of value by "[evoking]. . . acknowledgment and empathy for the situation and the views of the other,"<sup>155</sup> should remain a cornerstone of the process.

Employing aspects of the ethics facilitation approach, these specialists would work with parents to try and shift their understanding of the dispute towards discussions on clarifying "ethics or value-based concerns."<sup>156</sup> Throughout the process, the facilitation specialist would work to efficiently convey information between parents and providers, and make a good faith effort to remain transparent. While not imposing a single course of action on the parents, the facilitation specialist would explain that the options available are limited to only the manner in which the parents will engage the provider's decision. At that point, the parties would recess for a short period to allow parents to absorb the information and decide how they would like to approach the situation. Finally, all the parties involved, including the EC, would meet to discuss any remaining concerns; immediately thereafter, LSMT would be withdrawn. This approach is intended to balance efficiency with sensitivity by enabling providers to act efficiently, communicate effectively, and maximize resources while remaining sensitive to the fears and concerns of the family and healthcare team involved.

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<sup>154</sup> See Baruch Bush & Ganong Pope, *supra* note 51, at 83.

<sup>155</sup> See BARUCH BUSH & FOLGER, *supra* note 50, at 2.

<sup>156</sup> Scott, *supra* note 36, at 377-78.

To institute these facilitative process-based techniques, providers might consider allotting a certain amount of funds to develop a department that would direct and carry out the process. As specialists acquired more experience, transaction costs would decrease thereby freeing up more resources for the provider to allocate accordingly. Perhaps, the development of an interdisciplinary field of study to bridge the gap between providers and parents in futility disputes would help usher in facilitative process-based techniques in “green light” states.

#### *IV. Conclusion*

As the healthcare industry continues to change and evolve, providers will have to consider new approaches to EOL futility disputes between parents of newborns and treating physicians. When parents disagree with providers over whether to withdraw LSMT from their newborn neonatal futility disputes emerge. Providers must exercise enduring moral agency and defend their ability to act as moral agents, which means discontinuing treatment that is cruel and inhumane. Still, withdrawing LSMT from a newborn is taxing for everyone involved and providers often employ dispute resolution techniques like mediation and facilitation. The appropriateness of these techniques depends on the amount of power the parties are granted by law. In “red” and “yellow light” states parents have more power than providers, but in “green light” states providers retain the power to withdraw LSMT unilaterally.

This paper supports the “green light” approach because providers are the most qualified individuals to make these decisions and are responsible for allocating resources in a just and fair manner. If more states adopt the “green light” approach, however, mediation would no longer be appropriate because futility disputes would be non-negotiable issues with only one possible outcome. Instead of trying to mediate an “un-mediable” issue, providers should institute standardized, traditionally facilitative, process-based techniques to approaching futility disputes. Doing so would enable providers to make the right decision, in the right way, and at the right time, which is in the best interests of all the parties involved. To successfully accomplish this, the development of a new field of study that could bridge the gap between parents and providers would be beneficial. Ideally, training would include dispute resolution and medical education as well as a

background in ethics, philosophy, law, and/or religion.

As different fields of study continue to overlap with healthcare, the development of a field of study to bridge the gap between providers and the public would likely be a worthwhile investment. Providers and educators should work together to develop systems that ensure parents in futility and other disputes are being heard, while striving towards cost-containment and efficiency. To stay ahead of the curve, providers should consider traditionally facilitative process-based approaches when instituting any future changes regarding conflict engagement in EOL futility disputes.



# NOTA: NOT A GOOD ACT FOR TISSUES TO FOLLOW

Emily Largent, JD, PhD, RN\*

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### Introduction

If you have agreed to be an organ donor, for example, by checking that box on your driver's license application, you have likely also agreed to be a tissue donor,<sup>1</sup> as the laws in every state define the word "organ" to include both organs *and* tissues.<sup>2</sup> While 94.9% of the American public supports or strongly supports organ donation,<sup>3</sup> tissue donation is neither as well known nor as well understood.<sup>4</sup> To the contrary, the public "lacks basic knowledge of the differences between organ and tissue donation."<sup>5</sup>

Tissues one can donate after death include tendons, ligaments,

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<sup>1</sup> Joseph Shapiro, *Am I A Tissue Donor, Too?*, NAT'L PUBLIC RADIO (July 18, 2012), <http://www.npr.org/2012/07/18/156968033/am-i-a-tissue-donor-too> ("Lucinda Babers, the director of the D.C. Department of Motor Vehicles, explains that in Washington – and this is the way it works in almost every state – when you obtain a driver's license, or renew it, you're given a choice to donate or not donate. The box says: 'I want to donate my organs and tissue.'"); *see also* Laura A. Siminoff, Heather M. Traino, & Nahida Gordon, *Determinants of Family Consent to Tissue Donation*, 69 J. OF TRAUMA 956, 956 (2010), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3530615/> ("Nearly a quarter of family members interviewed were . . . unaware that a signed donor card was, in effect, an agreement to donate tissues and corneas as well as organs."); Andrew Conte & Luis Fábregas, *Gift of Life Worth Millions to Donation Organizations*, TRIBLIVE (August 21, 2013), <http://triblive.com/news/allegheeny/4408091-74/organ-organizations-procurement#axzz3TdNEjy5t>. People who become tissue donors automatically agree to give tissue in all but three states: Nebraska, North Carolina, and Wisconsin.

<sup>2</sup> *Tissue Donation*, WASH. REGIONAL TRANSPLANT COMMUNITY <http://www.beadonor.org/donation-facts/tissue-donation> (last visited Feb. 19, 2016).

<sup>3</sup> U.S. DEP'T OF HEALTH & HUMAN SERVS, HEALTH RESOURCES & SERVICES ADMINISTRATION (HRSA), 2012 NATIONAL SURVEY OF ORGAN DONATION ATTITUDES AND BEHAVIORS, at 13–4. In 2012, 60.1% of those surveyed said they had granted permission for donation on their driver's license. *Id.* at 18.

<sup>4</sup> Siminoff et al., *supra* note 1, at 956 ("A survey of families who donated tissues indicated only one-half distinguished tissue donation from organ donation. Moreover, the public is generally unaware of the details of tissue donation, such as the preparation and distribution process, which can involve for-profit companies.") (internal citations omitted); *see also* Shannon L. Sander & Barbara Kopp Miller, *Public Knowledge and Attitudes Regarding Organ and Tissue Donation: An Analysis of the Northwest Ohio Community*, 58 PATIENT EDUC. & COUNS. 154, 157 (2005); *Tissue Donation FAQs*, THE BLOOD & TISSUE CTR. OF CENT. TEX. <http://www.inyourhands.org/tissue-center/learn-more/tissue-donation-faq/> (last visited Apr. 23, 2016) ("Most people have heard of organ donation, but tissue donation is not as commonly discussed.").

Tissue donation did receive heightened scrutiny in 2015 after an anti-abortion group, the Center for Medical Progress, accused Planned Parenthood of profiting from a fetal tissue donation program, a charge that Planned Parenthood denied. *E.g.*, Denise Grady & Nicholas St. Fleur, *Fetal Tissue from Abortions for Research is Traded in a Gray Zone*, N.Y. TIMES (Jul. 27, 2015), [http://www.nytimes.com/2015/07/28/health/fetal-tissue-from-abortions-for-research-is-traded-in-a-gray-zone.html?\\_r=0](http://www.nytimes.com/2015/07/28/health/fetal-tissue-from-abortions-for-research-is-traded-in-a-gray-zone.html?_r=0). While this drew attention to tissue donation, debate over fetal tissue clearly implicates the controversy surrounding abortion, which is beyond the scope of this paper.

<sup>5</sup> Siminoff et al., *supra* note 1, at 962.

skin, bones, heart valves, and corneas.<sup>6</sup> After donation, these tissues can be used in a variety of ways—some life saving, some life enhancing, and others more appropriately characterized as frivolous. Skin can be used, for example, in the treatment of burn victims, veins in heart bypass operations, and bone in spinal fusion surgery.<sup>7</sup> Yet, donated tissue might also be “used for . . . elective plastic surgery, like a penis enlargement procedure,”<sup>8</sup> lip plumping, or wrinkle smoothing.<sup>9</sup> The differences between organ and tissue donation are remarkably wide-ranging and encompass who can donate; when donation can occur; how the donated items are procured, processed, and stored; who receives the transplant; why they receive it; and how the respective industries are regulated.

Significantly, the public’s lack of basic knowledge about the differences between organ and tissue donation finds its parallel in the governing federal legislation, the National Organ Transplant Act<sup>10</sup> (NOTA), which fails to differentiate between tissues and organs and

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<sup>6</sup> *What Can Be Donated*, U.S. DEP’T OF HEALTH & HUMAN SERVS., <http://www.organdonor.gov/about/donated.html> (last visited Apr. 23, 2016).

<sup>7</sup> J. Randall Boyer, *Gifts of the Heart . . . and Other Tissues: Legalizing the Sale of Human Organs and Tissues*, 2012 BYU L. REV. 313, 331 (2012), <http://digitalcommons.law.byu.edu/cgi/viewcontent.cgi?article=2641&context=lawreview>; see also *Donation FAQs* MUSCULOSKELETAL TRANSPLANT FOUND (MTF), [http://www.mtf.org/donor\\_faq.html](http://www.mtf.org/donor_faq.html) (“Long bones may be used to replace those invaded by cancer. . . . Smaller sections of bone are used to strengthen areas of a deformed spine and to fill areas where bone has been lost due to conditions that have damaged existing bone. Damaged tendons and ligaments may be reconstructed as well, thus strengthening the joint and assisting the patient in walking or running. Skin can be life-saving for critically burned patients. It is also used for hernia repair, pelvic floor reconstruction, and for breast reconstruction following mastectomy. Heart valves are used to replace damaged heart valves. Saphenous and femoral veins from the legs are used in cardiac bypass surgery for patients who have suffered cardiovascular (heart) disease.”).

<sup>8</sup> Shapiro, *supra* note 1.

<sup>9</sup> See Kate Wilson, Vlad Lavrov, Martina Keller, Thomas Maier, & Gerard Ryle, *Human Corpses are Prize in Global Drive for Profits*, THE INT’L CONSORTIUM OF INVESTIGATIONAL JOURNALISTS (Jul. 17, 2012), <http://www.icij.org/human-corpuses-are-prize-global-drive-profits>.

<sup>10</sup> P.L. 98-507. Passed in 1984, NOTA was Congress’s first attempt to regulate the growing practice of organ donation and transplantation. Debra Budiani-Saberi & Deborah M. Golden, *Advancing Organ Donation Without Commercialization: Maintaining the Integrity of the National Organ Transplant Act*, AM. CONST. SOC’Y (2009), <https://www.acslaw.org/files/Budiani%20Saberi%20and%20Golden%20Issue%20Brief.pdf>.

NOTA’s central feature is the provision that bans the buying and selling of organs. The persistent shortage of organs is often attributed to the requirement that organs be donated altruistically. *E.g.*, Sally L. Satel, *Why People Don’t Donate Their Kidneys*, N.Y. TIMES (May 3, 2014) (“The problem lies in the requirement that all organs be given altruistically . . .”); see generally, Lloyd R. Cohen, *Increasing The Supply Of Transplant Organs: The Virtues Of A Futures Market*, 58 GEO. WASH. L. REV. 1, 11-5 (1989); Henry Hansmann, *The Economics and Ethics of Markets for Human Organs*, 14 J. HEALTH POL. POL’Y & L. 57, 71 (1989).

instead treats them as if they are the same. NOTA seeks to promote the socially valuable use of donated organs in transplantation as well as to resolve deep ethical concerns—namely commodification, coercion, and exploitation—that are raised by transactions involving the human body or parts thereof. To this end, one of NOTA’s central provisions bans the exchange of organs for “valuable consideration.” Yet, because NOTA fails to adequately differentiate organs from tissues, it also fails to resolve satisfactorily these same ethical concerns insofar as they arise in connection with tissues.

This article contributes to the literature by systematically describing the ways in which transplantable tissues and organs differ from one another and articulating the normative implications of these differences for policy. I argue that although the ethical concerns that motivated the passage of NOTA in 1984 may remain relevant to organs, those ethical concerns do not arise in the same way in connection with tissues.<sup>11</sup> Tissues demand their own tailored response. Therefore, I propose that NOTA should no longer be applied to tissues. Instead, I favor limiting NOTA to transplantable organs and creating a new regulatory scheme fitted to cadaveric tissues.

This article proceeds as follows: Part I describes the legal background to organ and tissue donation and outlines the legislative history of NOTA, which gives particular insight into the ethical concerns that motivated its passage. Part II catalogs the five key differences between organs and tissues. Part III argues that tissues are not like organs in the ways that made NOTA an appropriate regulatory scheme for vital organs. Part IV contends that tissues are sufficiently distinct from organs that they should be severed from NOTA and governed by a separate tissue-specific act that emphasizes informed consent, sets a schedule for reasonable profits for the tissue industry, permits the sale of tissues by donors, and requires improved tracking of products made from human tissue. Finally, Part V concludes.

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<sup>11</sup> The tissue industry has evolved significantly in the three decades since NOTA was passed. Cf. Robert A. Katz, *The Re-Gift of Life: Can Charity Law Prevent For-Profit Firms from Exploiting Donated Tissue and Nonprofit Tissue Banks?*, 55 DEPAUL L. REV. 943, 951–971 (2006); see also Julia D. Mahoney, *The Market for Human Tissue*, 86 VA. L. REV. 163, 171 (2000) (“Over the past several decades, however, a revolution in scientific knowledge and medical technology has dramatically increased the potential economic value of the human body.”); Marc O. Williams, *The Regulation of Human Tissue in the United States: A Regulatory and Legislative Analysis*, 52 FOOD AND DRUG L.J. 409, 409 (1997) (“In the five decades that have elapsed since the inception of human tissue banking and transplantation in the United States, both the medical and economic significance of this technology have ballooned.”).

*I. Historical and Legal Background to NOTA*

Organ and tissue transplantation, as we know them today, are the result of longstanding medical innovation. Tissue transplantation came first. The first skin transplant was performed in 1869 and the first cornea transplant in 1906.<sup>12</sup> Then came organ transplantation. The first successful kidney transplant was performed in 1954, when a living donor gave a kidney to his identical twin.<sup>13</sup> In 1967, the first successful heart transplant was performed.<sup>14</sup> It was not until 1983, however, when the U.S. Food and Drug Administration (FDA) approved the immunosuppressant drug cyclosporine, which prevents transplant rejection, that widespread organ transplantation between unrelated individuals became possible.<sup>15</sup>

As a result of the approval of cyclosporine, organ transplantation became a highly publicized issue in the early 1980s: stories about the miracles of organ transplantation were juxtaposed with individuals' desperate pleas for donated organs because no centralized transplantation organization existed.<sup>16</sup> People expressed frustration

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<sup>12</sup> HHS, *Timeline of Historical Events: Significant Milestones in Organ Donation and Transplantation*, U.S. DEP'T OF HEALTH & HUMAN SERVS., <http://www.organdonor.gov/legislation/timeline.html> (last visited Apr. 23, 2016).

The U.S. Navy Established the first tissue bank in 1949. Laura A. Buck, *Regulating Human Tissue Banks*, 20 ST. THOMAS L. REV. 121, 124 (2007). That bank remained the primary tissue bank in the United States for the next three decades. *Id.* Dr. George Hyatt, founder of the Navy's tissue bank, pioneered many techniques still used today, "including freeze-drying tissue for long-term storage, screening [of] donors for [transmittable] disease, . . . obtaining informed consent for donation, and the concept of an independent, free-standing tissue bank that functioned outside of an individual medical center." *Id.* With time, tissue banks were established to serve the needs of local communities; as the market for human tissue expanded, tissue banks began distributing outside of their communities. *Id.* The 1990s saw significant expansion of the tissue industry. *Id.*

<sup>13</sup> Dr. Joseph E. Murray transplanted a healthy kidney from Ronald Herrick to his identical twin, Richard, who had end-stage kidney failure. Richard survived for more than eight years without the use of immunosuppressive drugs. Kelly Ann Keller, *The Bed of Life: A Discussion of Organ Donation, Its Legal and Scientific History, and A Recommended "Opt-Out" Solution to Organ Scarcity*, 32 STETSON L. REV. 855, 865-67 (2003). Because this was a transplant between identical twins, it did not provide insights into how transplanted organs from an unrelated donor could survive in a recipient's body. Most subsequent transplants failed due to rejection by the recipient's immune system until the discovery of cyclosporine.

<sup>14</sup> See generally DONALD MCRAE, *EVERY SECOND COUNTS: THE RACE TO TRANSPLANT THE FIRST HUMAN HEART* 205 (2006).

<sup>15</sup> See N.R. Banner & M.H. Yacoub, *Cyclosporine in Thoracic Organ Transplantation*, 36 TRANSPLANTATION PROCEEDINGS S302, S302-03 (2004) ("The discovery of cyclosporine proved to be a breakthrough that helped transform the status of both heart and lung transplantation from experimental to established therapeutic procedures.").

<sup>16</sup> Gail L. Daubert, *Politics, Policies, and Problems with Organ Transplantation: Government Regulation Needed to Ration Organs Equitably*, 50 ADMIN. L. REV. 459, 462

that, although transplantation was becoming a realistic clinical option for an increasing number of patients, “[a]ccess to transplant surgery depended on factors far removed from technical considerations, and many of these considerations seemed needlessly unfair to individual patients.”<sup>17</sup>

In light of medical progress, it became necessary to establish legal and ethical boundaries for donation and transplantation. While state legislation predated federal legislation, both sought to increase the number of donors and to ensure that the transplantation system retained its altruistic character.<sup>18</sup>

#### *A. Uniform Anatomical Gift Act*

By 1968, forty-two states had adopted some form of organ donation statute allowing a person to bequeath organs for transplantation.<sup>19</sup> These laws did little more than restate common law, and were criticized for being inadequate and confusing.<sup>20</sup> In 1965, the National Conference of Commissioners of Uniform State Laws responded to these critiques by drafting the Uniform Anatomical Gift Act (UAGA).<sup>21</sup> The Commissioners approved the UAGA in 1968, and by 1972, all fifty states and the District of Columbia had enacted it in one form or another.<sup>22</sup> The UAGA’s purpose was to balance the rights and interests of the deceased and their families with society’s need for post-mortem organ donations.<sup>23</sup> Notably, the 1968 UAGA *did not* ban the sale of organs. The UAGA’s Drafting Chair suggested that the

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(1998). Daubert describes how hospitals competed for organs in some regions of the country, while no transplant centers existed in other areas of the country.

<sup>17</sup> Jed A. Gross, *E Pluribus UNOS: The National Organ Transplant Act and Its Postoperative Complications*, 8 YALE J. HEALTH POL’Y L. & ETHICS 145, 175 (2008).

<sup>18</sup> Keller, *supra* note 13, at 879–80, 881–82.

<sup>19</sup> Theodore Silver, *The Case for a Post-Mortem Organ Draft and A Proposed Model Organ Draft Act*, 68 B.U. L. REV. 681, 692 (1988).

<sup>20</sup> *Id.* at 692–93. Additionally, they failed to address interstate transactions, which added to the confusion.

<sup>21</sup> *Id.* at 693.

<sup>22</sup> *Id.*

<sup>23</sup> The 1968 UAGA identified five competing interests in the transplant context: (1) the deceased’s wishes during his or her lifetime; (2) the wishes of the deceased’s next of kin; (3) the state’s interest in performing autopsies to determine the cause of death in a crime; (4) the “need of autopsy to determine the cause of death when private legal rights are dependent upon such a cause;” and (5) the society’s need for “bodies, tissues, and organs for medical education, research, therapy, and transplantation.” Unif. Anatomical Gift Act of 1968 prefatory n., 8A U.L.A. 64. See also Keller, *supra* note 13, at 882–83 (discussing how the UAGA balances these competing interests).

question of compensation “should be left to the decency of human beings.”<sup>24</sup> Moreover, the drafters did not expect compensation to become a major problem and felt crafting a prohibition on compensation would “not be easy.”<sup>25</sup>

The UAGA was amended in 1987 with an eye toward further increasing organ donations and addressing gaps in the 1968 UAGA.<sup>26</sup> Among the notable changes, the 1987 UAGA expressly prohibited the purchase and sale of organs.<sup>27</sup> A bare majority of states have adopted the amended UAGA with the specific prohibitions on sales.<sup>28</sup>

### *B. The National Organ Transplant Act*

NOTA, which passed in 1984 with little debate and bipartisan support,<sup>29</sup> is the controlling federal law.<sup>30</sup> Prior to NOTA’s enactment, regulation of organ donation and transplantation had been exclusively a matter of state law.<sup>31</sup> The objective of NOTA was to articulate a

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<sup>24</sup> Quoted in I.G. Cohen, *Can the Government Ban Organ Sale? Recent Court Challenges and the Future of U.S. Law on Selling Human Organs and Other Tissue*, 12 AM. J. TRANSPLANTATION 1983, 1983 (2012).

<sup>25</sup> *Id.*

<sup>26</sup> Ann McIntosh, *Regulating the “Gift of Life”—The 1987 Uniform Anatomical Gift Act*, 65 WASH. L. REV. 171, 175–76 (1990). The newer version of the UAGA simplified the process of becoming an organ donor by allowing a driver’s license to evidence the intent to make an anatomical gift; mandated routine inquiry about donation; codified NOTA’s prohibition of the sale of organs; and implemented a limited system of presumed consent to organ donation. Sean R. Fitzgibbons, *Cadaveric Organ Donation and Consent: A Comparative Analysis of the United States, Japan, Singapore, and China*, 6 ILSA J. INTL. & COMP. L. 73, 81–83 (1999).

<sup>27</sup> UNIF. ANATOMICAL GIFT ACT (1987) § 10.

<sup>28</sup> Cohen, *supra* note 24, at 1984.

Almost all states have excluded from prohibited sales human by-products such as blood, blood products, hair, in vitro preparations of human cells, sperm, ovum, and other tissues that are readily renewable by the human body. Gloria J. Banks, *Legal & Ethical Safeguards: Protection of Society’s Most Vulnerable Participants in A Commercialized Organ Transplantation System*, 21 AM. J.L. & MED. 45, 73 (1995). Commerce in regenerative tissue is “viewed by state law as the provision of a service instead of the sale of a good because such tissue is considered incidental to the provision of medical services.” *Id.* at 73.

<sup>29</sup> Donald Joralemon, *Shifting Ethics: Debating the Incentive Question in Organ Transplantation*, 27 J. MED. ETHICS 30, 30 (2001) (“The congressional hearings produced Public Law 98-507, ‘The National Transplantation Act’ (1984), which was brought to a vote with an astonishing 90 co-sponsors from both major political parties.”).

<sup>30</sup> Laurel R. Siegel, *Re-Engineering the Laws of Organ Transplantation*, 49 EMORY L.J. 917, 946 (2000) (“Because they pertain to different areas of the law, the federal laws do not necessarily preempt the state laws. The federal laws, particularly NOTA, establish the nationwide organ procurement structure and dictate rules such as the prohibition of sales of organs. State laws, on the other hand, stemming from the UAGA, deal with consent and related procedures. Common law is also a factor, and it may collide with statutory law.”).

<sup>31</sup> Patrick D. Carlson, *The 2004 Organ Donation Recovery and Improvement Act: How Congress Missed an Opportunity to Say “Yes” to Financial Incentives for Organ Donation*, 23

national policy for organ transplantation, to ensure equitable allocation of donor organs, and to increase the number of organs available for transplant.<sup>32</sup>

### C. *NOTA's Key Provisions*

Under the Act, a “human organ” includes:

[T]he human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other organ (or any subpart thereof, including that derived from a fetus) specified by the Secretary of Health and Human Services by regulation.<sup>33</sup>

NOTA established a national system for the matching of donor organs to potential recipients, the Organ Procurement and Transplantation Network (OPTN).<sup>34</sup> The OPTN includes all transplant centers, as well as all organ procurement organizations (OPOs),<sup>35</sup> and is managed by the United Network for Organ Sharing (UNOS), a private, nonprofit entity which has served as the OPTN under contract with the U.S. Department of Health and Human Services (HHS) since 1986.<sup>36</sup> The OPTN is primarily responsible for developing equitable policies for organ allocation and administering the national transplant candidate waiting list.<sup>37</sup>

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J. CONTEMP. HEALTH L. & POL'Y 136 (2006) (“Prior to the enactment of NOTA in 1984, organ donation and transplantation regulation traditionally had been exclusively a matter of state law. At the time of NOTA’s passage, all fifty states and the District of Columbia had adopted, with minor variations, the Uniform Anatomical Gift Act (UAGA), drafted in 1968 by the National Conference of Commissioners on Uniform State Laws to encourage the making of anatomical gifts.”).

<sup>32</sup> Daubert, *supra* note 16, at 463.

<sup>33</sup> 42 U.S.C.A. § 274e.

In 2014, HHS issued a final rule to add vascularized composite allografts (VCAs) to the statutory definition of “organ.” VCAs include “intact vascularized body parts such as hands and faces.” 78 FR 40033 (2014).

<sup>34</sup> 42 U.S.C.A. § 274.

<sup>35</sup> 42 U.S.C.A. § 273.

<sup>36</sup> *National Organ Transplant Act Enacted 30 Years Ago*, UNITED NETWORK FOR ORGAN SHARING, [http://www.unos.org/about/index.php?topic=newsroom&article\\_id=2889](http://www.unos.org/about/index.php?topic=newsroom&article_id=2889) (last visited Apr. 23, 2016).

<sup>37</sup> Rick K. Jones, *The Gift of Life and “Diseases of Language”: Recovering A Lost Distinction in Effectuating the Purpose of the National Organ Transplant Act’s Prohibition on The Transfer of Human Organs for Valuable Consideration*, 80 TEMPLE L. REV. 1067, 1074–75 (2007).

A central provision of NOTA, § 301(a), bans the buying and selling of human organs. NOTA imposes criminal penalties of up to \$50,000 and five years in prison on any person<sup>38</sup> who “knowingly acquire[s], receive[s], or otherwise transfer[s] any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.”<sup>39</sup> Significantly, neither the Act nor its legislative history, which is discussed at greater length below, defines the term “valuable consideration.” Both, however, “provide insight into the term’s meaning by suggesting a congressional concern with the buying and selling of human organs for profit, rather than an attempt to prohibit all transactions in human organs that involve some element of exchange.”<sup>40</sup>

The Act explicitly states that valuable consideration “does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ.”<sup>41</sup> By including an exception for “reasonable payments,” NOTA permits transplant surgeons, transporters, organ processors, and others to receive compensation for their services.<sup>42</sup> Given that § 301 is a criminal statute, it is appropriate to apply the rule of lenity in favor of a narrow reading and, therefore, to understand “valuable consideration” as the outright buying and

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<sup>38</sup> Katz, *supra* note 11, at 952-53. NOTA’s prohibition on the purchase or sale of body parts for transplantation applies to “any person.” That includes both natural persons and legal persons (i.e., tissue banks and processors). Every “person” who receives body parts for use in transplantation is subject to NOTA’s restrictions.

<sup>39</sup> 42 U.S.C.A. §274e(a).

<sup>40</sup> Kieran Healy & Kimberly D. Krawiec, *Custom, Contract, and Kidney Exchange*, 62 DUKE L.J. 645, 661 (2012).

NOTA is consistently interpreted as insufficiently broad to cover the sale of human gametes. Sarah Terman, *Marketing Motherhood: Rights and Responsibilities of Egg Donors in Assisted Reproductive Technology Agreements*, 3 NW J. L. & SOC. POL’Y 167, 12 (2008). In *Flynn v. Holder*, 684 F.3d 852 (9th. Cir. 2012), the Ninth Circuit held that NOTA does not prohibit the common practice of compensating blood donors. *Id.* at 862.

<sup>41</sup> 42 U.S.C.A. §274e(c)(2). The Act also includes an exception for “the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.”

<sup>42</sup> Kristy L. Williams, Marisa Finley, & J. James Rohack, *Just Say No to NOTA: Why the Prohibition of Compensation for Human Transplant Organs in NOTA Should Be Repealed and A Regulated Market for Cadaver Organs Instituted*, 40 AM. J.L. & MED. 275, 291 (2014). This exception is essential, as it is hard (if not impossible) to imagine a distribution network that didn’t cover expenses. However, as a result, even though the initial sale of an organ is prohibited, everyone involved in the process of organ transplantation, except for the donor, is able to profit; Boyer, *supra* note 7, at 334. Current jurisprudence recognizes a legal interest in the organ of each person in each transaction—with the exception of the donor.

selling of organs for money.<sup>43</sup>

*D. NOTA's Legislative History*

One major impetus for including the prohibition of organ purchases in NOTA was the ethical debate sparked by a high-profile proposal to broker human kidneys.<sup>44</sup> In September 1983, Dr. Barry Jacobs, who was the founder of International Kidney Exchange, Ltd. and whose medical license had been revoked as a result of a Medicare mail fraud conviction, caught the attention of the national media.<sup>45</sup> Jacobs sent a brochure to 7,500 American hospitals offering to broker contracts between patients with end stage renal disease<sup>46</sup> and individuals—domestically and abroad—willing to sell a kidney.<sup>47</sup> He proposed to charge a sliding-scale brokerage fee and retain a profit for himself.<sup>48</sup> According to Jacobs, he contacted the FDA and other federal agencies to determine if laws or regulations prohibited his approach and if a license was needed to import organs.<sup>49</sup> Some officials reportedly counseled against the brokerage proposal, but they did not find that it violated any existing regulations.<sup>50</sup> Although Jacobs

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<sup>43</sup> Memorandum from C. Kevin Marshall, Deputy Assistant Attorney Gen., to Daniel Meron, Gen. Counsel, Dep't Health & Human Servs., Legality of Alternative Organ Donation Practices Under 42 U.S.C. § 274(e), at 6 (Mar. 28, 2007), <http://www.justice.gov/sites/default/files/olc/opinions/2007/03/31/organtransplant.pdf>.

<sup>44</sup> Williams et al., *supra* note 42, at 289; *see also* Carlson, *supra* note 31, at 158. Other motivations for NOTA included recent advances in transplant surgery, the FDA's approval of cyclosporine in 1983, the growing asymmetry between supply and demand of transplantable organs, and a series of public appeals by families seeking organs. Phil Gunby, *Bill Introduced to Thwart Kidney Brokerage*, 250 J. AM. MED. ASS'N. 2263, 2263 (1983).

<sup>45</sup> Gross, *supra* note 17, at 178; *see also* Joralemon, *supra* note 29, at 30. In a USA TODAY guest column, Jacobs colorfully wrote that “[c]ompensating the donor for blood or a kidney is the American way. . . . When it comes to deciding what to do with our bodies, Congress is not a better judge than the individual. . . . Only in the Soviet Union do human organs belong to the state.” Gross, *supra* note 17, at 183.

<sup>46</sup> *See generally* Nat'l Inst. of Health, *End-Stage Kidney Disease*, MEDLINEPLUS, <http://www.nlm.nih.gov/medlineplus/ency/article/000500.htm> (last visited Apr. 20, 2016).

<sup>47</sup> *Id.* The letter is reproduced in Hearings Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, Serial No. 98-70, 367 (1984).

<sup>48</sup> The person seeking a transplant would pay for the kidney and an additional \$2,000 to \$5,000 to Jacobs for his services. S.H.D., *Regulating the Sale of Human Organs*, 71 VA. L. REV. 1015, 1015 (1985). Jacobs explained that if the “recipient could afford [it], without indigence—there would be a sliding scale brokerage fee that would cover the cost [International Kidney Exchange, Ltd.] would incur. Then what would be left from the brokerage fee would be used to advance the cost to those who couldn't afford it so they could purchase a kidney, go back to work, reimburse the fund, which would then have the money available for the next person.” H.R. 4080 at 241.

<sup>49</sup> Gunby, *supra* note 44, at 2263.

<sup>50</sup> *Id.*

never managed to get his business off the ground,<sup>51</sup> he came to symbolize “transplantation out of control, and anxieties about the misuse of medical power latched onto him, his business plan, and the entire notion of putting a monetary value on organs.”<sup>52</sup>

Against this backdrop,<sup>53</sup> then-Representative Albert Gore, Jr.,<sup>54</sup> Chair of the House Science and Technology Committee’s Oversight Subcommittee, convened the first of a series of hearings that would culminate in the enactment of NOTA in 1984.<sup>55</sup> Several major challenges emerged as focal points at these hearings. The introduction of the immunosuppressant cyclosporine meant that a lack of two resources—money and donor organs—was likely to limit the number of individuals who would benefit from organ transplantation.<sup>56</sup> An infrastructure to efficiently coordinate organ transfer was also missing.<sup>57</sup> These concerns had an ethical dimension: “[c]oncerns about differential access to transplant surgery and distributive justice . . . surfaced repeatedly as legislators probed the problems of procurement, financing, and organization.”<sup>58</sup> Additionally, Congress felt that the buying and selling of organs ran counter to society’s moral values.<sup>59</sup>

In July and October of 1983, the House Committee on Energy and Commerce’s Subcommittee on Health and the Environment held further hearings on transplant policy under the direction of Subcommittee Chairman Henry Waxman.<sup>60</sup> Although Gore was not a

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<sup>51</sup> Joralemon, *supra* note 29, at 30.

<sup>52</sup> Gross, *supra* note 17, at 185.

<sup>53</sup> Gunby, *supra* note 44, at 2263. In addition to International Kidney Exchange, Ltd., an earlier organ brokerage program in the Northeast never got off the ground, and there may have been a similar effort in the Midwest.

<sup>54</sup> Gross, *supra* note 17, at 180 (“The Congressman had ‘learned that the most pressing problem in caring for end-stage renal disease was availability of suitable organs for transplant’ during 1982 congressional hearings on dialysis and diet. The Congressman’s exposure to the problem also became more personal ‘when one of his constituents sought Gore’s help in securing an organ.’ Around the same time, a Yale pediatrics professor, Dr. Myron Genel, was ‘assigned’ to Gore through the Robert Wood Johnson Health Policy Fellows Program. This new staff affiliate reportedly ‘press[ed] Gore to use his position as chair of an investigative subcommittee to highlight problems [regarding transplantation] and develop a federal government solution.’”).

<sup>55</sup> *Id.*

<sup>56</sup> Gross, *supra* note 17, at 182.

<sup>57</sup> *Id.*

<sup>58</sup> *Id.* at 182–83.

<sup>59</sup> Daubert, *supra* note 16, at 466.

<sup>60</sup> Gross, *supra* note 17, at 181 (noting that Waxman had an “unusually deep familiarity with transplantation” because he first attempted to improve the accessibility of transplantation as a member of the California State Senate).

member of the Subcommittee, he played “a leading role in its hearings by providing extensive testimony about the challenges of organ allocation and transplant financing.”<sup>61</sup> In his testimony, Gore described the buying and selling of organs as “just wrong,”<sup>62</sup> and explained that it:

is against our system of values to buy and sell parts of human beings. It is against our system of values to auction off life to the highest bidder. . . . What we are talking about here is the gift of life and the real problem is how to persuade people to give life, not how to purchase it.<sup>63</sup>

Gore’s testimony reflected his concerns that a market for human organs would result in unethical commodification of the body, exploitation of the poor, and compromises to donor health and well-being.<sup>64</sup> Gore’s concerns were echoed by members of the Subcommittee and those who testified before it. Waxman remarked that “the bill explicitly prohibits organ sales . . . . The specter of individuals coerced to sell their kidneys—placing their lives in jeopardy—represents a form of human exploitation foreign to our concepts of medical and social ethics.”<sup>65</sup> Representative Thomas Bliley, Jr. spoke of “the ill-advised organ sales proposal.”<sup>66</sup> Dr. Edward Brandt, Assistant Secretary for Health, presented the views of the Reagan administration.<sup>67</sup> He opposed the sale of human organs, believing “such activity is immoral and goes against the principles of medical ethics. [The Secretary] and I are particularly concerned about those persons willing to sell their organs who may not fully understand the serious consequences of their action.”<sup>68</sup>

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<sup>61</sup> *Id.*

<sup>62</sup> *National Organ Transplant Act: Hearings before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce House of Representatives*, 98th Cong. 128 (1983), <https://www.hods.org/pdf/HRG-NOTA-%20Jul29.%20Oct17.1983.pdf> [hereinafter, *National Organ Transplant Act Hearings*].

<sup>63</sup> *Id.*

<sup>64</sup> Carlson, *supra* note 31, at 158.

<sup>65</sup> *National Organ Transplant Act Hearings*, *supra* note 62, at 90.

<sup>66</sup> *Id.* at 107.

<sup>67</sup> *Id.* at 238. Barry Jacobs colorfully described Dr. Brandt as “sitting on his butt” at the start of his testimony.

<sup>68</sup> *Id.* at 134. Samuel Gorovitz, a Professor of Philosophy, testified, “The risks to donors are greater than [Barry Jacobs] has admitted . . . . And the scheme makes a mockery of informed consent, as is evident to anyone familiar with Federal regulations protecting human subjects research, which reflect a sensitive awareness that desperate circumstances can be implicitly coercive, and that the provision of excessive inducements to the oppressed can

In the summary of the bill, the Senate Committee on Labor and Human Resources Report No. 98-382, states:

It is the sense of the committee that individuals or organizations should not profit by the sale of human organs for transplantation. This is not meant to include blood and blood derivatives, which can be replenished and whose donation does not compromise the health of the donor. The current state of the law is uncertain with regard to the sale of organs, and the committee believes that legislation is necessary to clarify this issue. The committee believes that human body parts should not be viewed as commodities.<sup>69</sup>

The House Conference Report explains that the final bill “intends to make the buying and selling of human organs unlawful.”<sup>70</sup>

At the signing, President Ronald Reagan explained that:

This bipartisan legislation provides a framework that should help increase the overall supply of much needed organs and improve our ability to match donor organs with individuals in need of transplants. Over the last [three] years, I have urged the American people to remember that many lives could be saved through generous donations of life-saving organs. . . . This act will serve to support this ongoing work.<sup>71</sup>

The legislative history makes clear that those involved in enactment of NOTA were motivated, in part, by moral concerns about commodification of the human body, as well as by the possibility for exploitation and coercion of donors. These ethical considerations underpinned the ban on exchanging human organs for valuable consideration. The Act defined “organ” to include tissue, overlooking (or perhaps simply discounting<sup>72</sup>) key differences between organs and tissues—the topic to which we turn next—and failing to see the

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constitute a violation of their autonomy.” *Id.* at 279.

<sup>69</sup> S. REP. NO. 98-382, at 13, 16–17 (1984).

<sup>70</sup> H.R. Conf. Rep. No. 98-1127, at 16.

<sup>71</sup> THE AMERICAN PRESIDENCY PROJECT: RONALD REAGAN, STATEMENT ON SIGNING THE NATIONAL ORGAN TRANSPLANT ACT (Oct. 19, 1984), <http://www.presidency.ucsb.edu/ws/?pid=39282>; Gross, *supra* note 17, at 178. The White House was particularly interested in pediatric liver transplantation, perhaps because First Lady Nancy Regan’s father, Dr. Loyal Davis, was professional mentor to Thomas Starzl, a pioneering liver transplant surgeon.

<sup>72</sup> Terman, *supra* note 40, at 13 (“The fact that lawmakers referred to “organs” and “body parts” somewhat interchangeably illustrates that they were perhaps generally concerned with protecting the human body, not just organs, from commodification.”).

mismatch between the goals of the legislation and its practical effects when applied to tissues.

## *II. Key Differences Between Tissues and Organs*

The basic unit of every living organism is the cell. It has recently been estimated that the human body has  $3.72 \times 10^{13}$  cells.<sup>73</sup> The number of cells—together with their type and size—ultimately defines the size, structure, and functions of an organism.<sup>74</sup> Some organisms are nothing more than free-living, single cells.<sup>75</sup> Slightly more complex life forms “are organized into masses or aggregates of similar cells with little evidence of cell specialization.”<sup>76</sup> In higher organisms, such as humans, cells are specialized to perform different functions.<sup>77</sup> A tissue is a collection of similar cells that are specialized to perform a particular function.<sup>78</sup> There are four basic types of tissue: connective tissue; epithelial tissue; nerve tissue; and muscle tissue, of which there are three types: smooth, striated, and cardiac.<sup>79</sup> Groups of different tissues can be organized further into complex organs that perform specialized functions.<sup>80</sup>

Although bones and skin—to pick but two examples—are classified as “organs” according to medical definitions, they are considered “tissues” for purposes of organ and tissue donation.<sup>81</sup> According to [organdonor.gov](http://organdonor.gov), which is run by HHS, organs that can be donated include the lungs, heart, liver, pancreas, kidneys, and intestines.<sup>82</sup> Tissues that can be donated include the cornea, whole eye, skin, heart valves, veins, bone, cartilage, and connective tissues.<sup>83</sup>

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<sup>73</sup> Eva Bianconi et al., *An Estimation of the Number of Cells in the Human Body*, 40 ANNALS OF HUMAN BIOLOGY 463, 466 (2013) (reporting estimates in the literature from  $10^{12}$  to  $10^{16}$ ).

<sup>74</sup> *Id.* at 463.

<sup>75</sup> *Id.* (e.g., yeasts and bacteria).

<sup>76</sup> NUFFIELD COUNCIL ON BIOETHICS, HUMAN TISSUE: ETHICAL AND LEGAL ISSUES, 17 (1995) (e.g., sponges).

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

<sup>79</sup> Nat'l Inst. of Health, *Tissue Types*, MEDLINEPLUS, <http://www.nlm.nih.gov/medlineplus/ency/imagepages/8682.htm> (last visited Apr. 24, 2016).

<sup>80</sup> NUFFIELD COUNCIL, *supra* note 76, at 18.

<sup>81</sup> See, e.g., U.S. DEP'T OF HEALTH & HUMAN SERVS., *What Can Be Donated?*, ORGANDONOR.GOV, <http://www.organdonor.gov/about/donated.html> (last visited Apr. 20, 2016).

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

Going forward I will use the terms “organ” and “tissue” in the manner consistent with donation practices.

NOTA’s definition of “human organ,” quoted above, encompasses both organs and tissues. Although tissue transplantation is superficially similar to organ transplantation, the two are meaningfully different.<sup>84</sup> Here, I will highlight differences along five dimensions, focusing primarily on the differences between cadaveric organ donation and cadaveric tissue donation. These dimensions are: the size of the respective donor pools; procurement, storage and processing; allocation; uses; and regulation. While some of these differences are the result of inherent characteristics of organs and tissues, others are the result of the legal frameworks that have been put in place around organs and tissues respectively.

#### *A. Difference 1: Size of Donor Pools*

Tissues and organs can both be procured from living donors.<sup>85</sup> Most donations, however, take place after the donor has died.<sup>86</sup> A far greater number of people are potential cadaveric tissue donors than potential cadaveric organ donors.<sup>87</sup> Legal, ethical, and biological limitations on who can donate restrict the supply of potential organ donors but have much less effect on the pool of potential tissue donors. As a result, whereas organ donation is a possibility in 5% of all deaths, tissue donation is a possibility with 95%.<sup>88</sup>

The “dead donor rule” is an “ethical and legal constraint that holds that doctors cannot remove vital organs necessary to keep bodies

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<sup>84</sup> Cf. Michelle Oberman, *When the Truth is Not Enough: Tissue Donation, Altruism, and The Market*, 55 DEPAUL L. REV. 903, 905 (2006), <http://via.library.depaul.edu/cgi/viewcontent.cgi?article=1371&context=law-review> (comparing the organ transplant and tissue transplant industries).

<sup>85</sup> *What is Living Donation*, GIFT OF LIFE DONOR PROGRAM, <http://www.donors1.org/livingdonation/livingdonationfaq/> (last visited Apr. 20, 2016). For example, a living donor may be able to donate a segment of liver, a lobe of lung, a section of intestine, a portion of pancreas, or a single kidney without being deprived of an essential organ.

<sup>86</sup> *Id.*

<sup>87</sup> Oberman, *supra* note 84, at 908. Oberman notes that “[f]ederal law governing organ transplantation helped to expand the supply of available tissue by requiring hospitals to notify the regional Organ Procurement Organization (OPO) in the event of a potential donor’s death. By making requests for donation routine, these regulations had the indirect effect of enhancing the availability of tissue as well.”

<sup>88</sup> *Organ and Tissue Donation Differences*, UW ORGAN AND TISSUE DONATION, <http://www.uwhealth.org/organ-donation/organ-and-tissue-donation-differences/13825> (last visited Apr. 20, 2016).

alive from patients until they are dead.”<sup>89</sup> Under the Uniform Determination of Death Act (UDDA),<sup>90</sup> which has been adopted by forty-four states and the District of Columbia,<sup>91</sup> “[a]n individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead.”<sup>92</sup> This determination must be made in accordance with accepted medical standards.<sup>93</sup> Brain dead individuals, those in category (2), make ideal organ donors, as their organs continue to receive oxygenated blood from their still-beating heart.<sup>94</sup> By contrast, the organs of patients who experience cardiac death, those in category (1), begin to suffer from ischemia.<sup>95</sup> As a result, the yield of transplantable organs from donation after cardiac death is generally not as favorable as that with donation after brain death.<sup>96</sup> While the pool of potential organ donors is highly restricted, most deceased persons can be tissue donors.<sup>97</sup>

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<sup>89</sup> Seema K. Shah, *Piercing the Veil: The Limits of Brain Death as a Legal Fiction*, 48 U. MICH. J.L. REFORM 301, 326 (2015).

<sup>90</sup> UNIF. DETERMINATION OF DEATH ACT § 1 (1980), [http://people.bu.edu/wildman/courses/thth/projects/thth\\_projects\\_2003\\_lewis/udda.pdf](http://people.bu.edu/wildman/courses/thth/projects/thth_projects_2003_lewis/udda.pdf).

<sup>91</sup> Shah, *supra* note 89, at 308.

<sup>92</sup> UNIF. DETERMINATION OF DEATH ACT § 1.

<sup>93</sup> *Id.*

<sup>94</sup> See Gary Greenberg, *As Good As Dead: Is There Really Such a Thing as Brain Death?*, NEW YORKER (Aug. 13, 2001), <http://www.newyorker.com/magazine/2001/08/13/as-good-as-dead>. (pointing out the resulting paradox: “the need for both a living body and a dead donor.”); Ellen Sheehy et al., *Estimating the Number of Potential Organ Donors in the United States*, 349 NEJM 667, 670 (2003) (estimating that the pool of potential brain dead organ donors in the United States falls between 10,500 and 13,800).

<sup>95</sup> See generally J.L. Bernat et al., *Report of a National Conference on Donation After Cardiac Death*, 6(2) AM. J. OF TRANSPLANTATION 281, 284 (2006) (discussing warm ischemic time).

<sup>96</sup> D.J. Reich et al., *ASTS Recommended Practice Guidelines for Controlled Donation after Cardiac Death Organ Procurement and Transplantation*, 9 AM. J. TRANSPLANTATION 2004, 2004-2005 (2009). Reich et al. also suggest that outcomes might not be as favorable for recipients of DCD organs. *Id.* The subsequent literature is mixed. See, e.g., C.L. Jay et al., *Comparative Effectiveness of Donation After Cardiac Death Versus Donation After Brain Death Liver Transplantation: Recognizing Who Can Benefit*, 18 LIVER TRANSPL. 630, 633 (2012) (“For patients with a MELD score <15, DCD transplantation resulted in greater costs and reduced effectiveness”).

<sup>97</sup> U.S. DEP’T OF HEALTH & HUMAN SERVS., *Organ Donation*, ORGANDONOR.GOV, <http://www.organdonor.gov/about/organdonation.html> (last visited Apr. 21, 2016) (hereinafter HHS, *Organ Donation*); see, e.g., *Frequently Asked Questions*, EYE BANK ASS’N OF AM, <http://www.restore sight.org/about-us/frequently-asked-questions/> (last visited Apr. 24, 2016) (“Who can be a donor? Anyone can. The great thing about corneal tissue is that everyone is a universal donor. Your blood type does not have to match. It doesn’t matter how old you are, what color your eyes are or how good your eyesight is. Aside from those suffering from infections or a few highly communicable diseases such as HIV or hepatitis, most people are suitable donors.”).

The total number of organ donors—living and dead—was 14,412 in 2014.<sup>98</sup> By contrast, approximately 30,000 donors provide tissue each year.<sup>99</sup> Whereas one person can save up to eight lives through organ donation, one person can enhance the lives of fifty or more people through tissue donation.<sup>100</sup> This is due to the fact that many more tissues than organs can be recovered from each donor. Depending on what tissues are recovered, a cadaver can yield up to twenty bones and tendons, as well as 4 square feet of skin, and several heart valves.<sup>101</sup>

*B. Difference 2: Procurement, Storage, and Processing*

Whereas “time is of the essence” in organ donation,<sup>102</sup> it is much less pressing in tissue donation. This is evident in the respective practices related to procurement, storage, and processing of organs and tissues.

Federal regulations require hospitals to notify their local OPO of every patient whose death is imminent or who has died.<sup>103</sup> The hospital will give the OPO information about the dying or deceased individual to confirm his or her suitability to be a donor. The OPO determines “medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation.”<sup>104</sup>

<sup>98</sup> U.S. DEP’T OF HEALTH & HUMAN SERVS., *The Gap Continues to Widen*, ORGANDONOR.GOV, <http://www.organdonor.gov/about/graphdescription.html> (last visited Apr. 21, 2016).

<sup>99</sup> HHS, *Organ Donation*, *supra* note 97. A 1995 study reported that of 603 donor-eligible families that were asked to donate organs, tissues, or corneas, slightly more than 34% agreed to donate something. Of the 170 organ-eligible cases, only 46.5% donated. Fewer tissue and kidney requests were granted (34.5 and 23.5%, respectively). Laura A. Siminoff et al., *Public Policy Governing Organ and Tissue Procurement in the United States: Results from the National Organ and Tissue Procurement Study*, 123 ANN. INTERN. MED. 10, 14 (1995).

<sup>100</sup> HHS, *Organ Donation*, *supra* note 97.

<sup>101</sup> Mark Katches, William Heisel, & Ronald Campbell, *The Body Brokers: Part 1 - Assembly Line*, ORANGE COUNTY REG., Apr. 17, 2000, [http://www.lifeissues.net/writers/kat/org\\_01bodybrokerspart1.html](http://www.lifeissues.net/writers/kat/org_01bodybrokerspart1.html).

<sup>102</sup> U.S. DEP’T OF HEALTH & HUMAN SERVS., *Organ Donation: The Process*, ORGANDONOR.GOV, <http://organdonor.gov/about/organdonationprocess.html#process4> (last visited Apr. 21, 2016) (hereinafter HHS, *Organ Donation: The Process*) (“Organs must get to their new homes very quickly as they can remain healthy only for short periods of time after removal from the donor.”).

<sup>103</sup> 42 C.F.R. § 482.45 (1996) Condition of Participation: Organ, tissue and eye procurement.

<sup>104</sup> *Id.* The OPO or tissue bank will review the donor’s medical records, inquire into the donor’s social history, and test the donor for transmissible diseases. Katz, *supra* note 11, at

If the patient is a potential candidate for organ donation, an OPO representative immediately travels to the hospital<sup>105</sup> and secures legal consent.<sup>106</sup> If the decision is made to donate after cardiac death, organ recovery may occur if death occurs within the established timeframe after the withdrawal of life-sustaining measures.<sup>107</sup> If a donor has been declared brain dead, that donor is maintained on life support in order to ensure the viability of his organs for transplantation.<sup>108</sup> The OPO representative arranges for recovery of the organs, which is performed in the sterile environment of an operating room.<sup>109</sup> Prior to removal from the donor, “each organ is flushed free of blood with a specially prepared ice-cold preservation solution that contains electrolytes and nutrients. The organs are then placed in sterile containers, packaged in wet ice, and transported to the recipient’s transplant center.”<sup>110</sup> Preservation in this manner buys time, which is essential for organizing staff and facilities, transporting organs, and performing the many procedures necessary for transplantation.<sup>111</sup> Storage times vary in light of the relative speed with which organs begin to deteriorate.<sup>112</sup> In general, “storage times are 30 hours or less for a kidney, less than 12 hours for a pancreas or liver, and less than 6 hours for a heart or

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960–61. Outside the hospital, tissue banks might learn about potential donors from coroners, medical examiners, or funeral home directors. *Id.* at 959. If an individual dies at home, their organs cannot be transplanted; they may, however, be tissue donors. *Frequently Asked Questions*, DONATE LIFE N.C., <https://www.donatelifenc.org/content/frequently-asked-questions#can-my-organs-be-used> (last visited Apr. 21, 2016).

<sup>105</sup> HHS, *Organ Donation: The Process*, *supra* note 102.

<sup>106</sup> *Id.* If the deceased had enrolled as a donor, that will serve as legal consent. If not, the OPO will seek consent from the next of kin.

<sup>107</sup> See generally Robert Steinbrook, *Organ Donation After Cardiac Death*, 357 *NEJM* 209 (2007) (discussing DCD).

<sup>108</sup> See generally D.W. McKeown et al., *Management of the Heartbeating Brain-Dead Organ Donor*, 108 *BRIT. J. ANAESTHESIA* i96, i98 (2012); see also *Critical Pathway for the Organ Donor*, UNOS (2002), [https://www.unos.org/docs/Critical\\_Pathway.pdf](https://www.unos.org/docs/Critical_Pathway.pdf) (recommending physiological goals and an active approach to donor management).

<sup>109</sup> HHS, *Organ Donation: The Process*, *supra* note 102.

<sup>110</sup> *Transplantation: Organ Transplant Process*, N.Y. PRESBYTERIAN, <http://nyp.org/services/transplantation-surgery/organ-transplant-process.html> (last visited Apr. 21, 2016).

<sup>111</sup> Edgardo E. Guibert et al., *Organ Preservation: Current Concepts and New Strategies for the Next Decade*, 38 *TRANSFUS. MED. HEMOTHER.* 125, 126 (2011).

<sup>112</sup> *Id.* Because organs must be transplanted as quickly as possible, they are given first to people who live near the hospital where organs are recovered from the donor. The “[d]istance between the donor’s hospital and the potential recipients’s hospital is more important for matching hearts and lungs than it is for kidneys or livers.” U.S. DEP’T OF HEALTH & HUMAN SERVS., *Organ Matching Process*, [ORGANDONOR.GOV, http://www.organdonor.gov/about/organmatching.html](http://www.organdonor.gov/about/organmatching.html) (last visited Apr. 21, 2016) (hereinafter HHS, *Organ Matching Process*).

lungs.”<sup>113</sup>

If the deceased individual is a suitable tissue donor and consent is secured, the OPO or a tissue bank arranges for the tissue to be recovered within twenty-four hours of the donor’s death.<sup>114</sup> Tissues may be removed in the operating room after organs are recovered,<sup>115</sup> elsewhere in the hospital, or in other locations, such as a funeral home or morgue<sup>116</sup> using aseptic techniques.<sup>117</sup> Tissues typically “go through several levels of handling before transplantation.”<sup>118</sup> Processors, typically for-profit organizations,<sup>119</sup> take the raw tissues from the OPO or tissue bank and transform them into allografts for implantation.<sup>120</sup> The methods used by processors may be patented and/or the allografts themselves may be patented.<sup>121</sup> Once processed, tissues can be stored for an extended period of time before being used.<sup>122</sup> Donated heart valves can be stored for up to 10 years, while other donated tissues can be stored for up to five years.<sup>123</sup>

In exchange for its work with donors, the OPO or tissue bank will receive “reasonable fees,”<sup>124</sup> known as Standard Acquisition Charges,

<sup>113</sup> *FAQ: 24. How Long Can Donated Organ Last Outside the Body?*, UNIV. OF MICH. TRANSPLANT CTR., <http://www.transweb.org/faq/q24.shtml> (last updated Feb. 4, 2010).

<sup>114</sup> Oberman, *supra* note 84, at 910. Many OPOs operate as tissue banks and, thus, are equipped to retrieve and store human tissue. Other OPOs work with independent tissue banks, which will be notified of the family’s consent and will then undertake the retrieval process.

<sup>115</sup> HHS, *Organ Donation: The Process*, *supra* note 102.

<sup>116</sup> Joseph Shapiro & Sandra Bartlett, *The Seamy Side of the Human Tissue Business*, WNPNEWS (Jul. 19, 2012, 3:30 AM), <http://www.npr.org/2012/07/19/156988089/the-seamy-side-of-the-human-tissue-business>.

<sup>117</sup> *About Tissue Transplant*, ALLOGRAFT POSSIBILITIES, <http://allograftpossibilities.org/about-tissue-transplant/>. Bone is replaced with PVC pipe to preserve the body’s appearance for open-casket funerals; *see, e.g.*, ANNIE CHENEY, *BODY BROKERS: INSIDE AMERICA’S UNDERGROUND TRADE IN HUMAN REMAINS* (2007).

<sup>118</sup> Siminoff et al., *supra* note 1, at 961.

<sup>119</sup> Buck, *supra* note 12, at 125–26. Buck notes that for-profit processors have a strong hold on the industry due to their patented processing techniques. Some of the most important advances in the tissue industry are attributable to for-profit tissue banks.

<sup>120</sup> For example, AlloSource “offer[s] more than 200 types of precise bone, skin, soft-tissue and custom-machined allografts for use in an array of life-saving and life-enhancing medical procedures.” ALLOSOURCE, *About AlloSource*, <http://www.allosource.org/about-allosource/>; *see also* ALLOSOURCE, *Products*, <http://www.allosource.org/products/>.

<sup>121</sup> Buck, *supra* note 12, at 125.

<sup>122</sup> Williams et al., *supra* note 42, at 291.

<sup>123</sup> *Tissue Donation After Death*, NAT’L HEALTH SERV. BLOOD & TRANSPLANT, <http://www.nhsbt.nhs.uk/tissuedonation/how-to-become-a-donor/tissue-donation-after-death/> (last visited Apr. 21, 2016); *see also* *Tissue Donation FAQs*, *supra* note 4.

<sup>124</sup> *See* Katches et al., *supra* note 101 (“Companies and tissue banks step around the law by charging marked-up fees to handle and process the body parts. . . . Judy Perkins, executive director of the University of California, San Diego, Regional Tissue Bank, calls fees a euphemism for sales.”).

to cover expenses.<sup>125</sup> Fees for organ retrieval vary across the country; for example, fees for a kidney may vary from \$16,000 to \$30,000.<sup>126</sup> A typical tissue donor produces \$14,000 to \$34,000 in fees for a non-profit OPO.<sup>127</sup> After a tissue processor has treated and rendered the tissue transplantable, the tissue will gain tremendous value.<sup>128</sup> For instance, one cadaveric donor can be worth nearly \$220,000.<sup>129</sup> These gains are realized when the tissues are distributed to doctors, hospitals, or others who use the end products.<sup>130</sup>

### C. *Difference 3: Allocation*

The allocation of organs takes into account medical, logistical, and ethical considerations. For tissue allocation, as the market for tissues currently exists, these concerns are not nearly as relevant.

Many of the criteria for matching organs from deceased donors to potential recipients are the same for all organs.<sup>131</sup> The criteria usually include: “blood type, body size, severity of patient’s medical condition, distance between the donor’s hospital and the patient’s hospital, the patient’s waiting time, and the availability of the potential recipient

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<sup>125</sup> Katz, *supra* note 11, at 961–62. Katz explains that the fee “permits the tissue bank to recoup its actual outlays on tissue recovery, aftercare, education, and ‘other costs associated with operating a tissue recovery program.’ Typically, these fees also include a small percentage or margin that provides the tissue bank with excess revenue for future expansions, savings, and other needs.” *Id.* at 962.

<sup>126</sup> Advisory Committee on Organ Transplantation, Spring Meeting Notes (May 4-5, 2006), <http://organdonor.gov/legislation/acotmay2006notes.html> (last visited Feb. 22, 2016).

<sup>127</sup> Oberman, *supra* note 84, at 909.

Buck, *supra* note 12, at 149 (“[M]oney changes hand from the point of tissue procurement to the final transplantation of the tissue. . . . ‘[Standard Acquisition Charges] vary throughout the United States,’ and differ depending upon the type of tissue collected. Typically, musculoskeletal tissues command fees of \$5500, veins, \$600 per vein, and \$250-\$500 per square foot of skin. Knee tendons, which take minutes to remove from a cadaver, can command a revenue of \$2,500 each, while valves cut out of donated hearts and later sold as transplants go for more than \$7,000 each. Once the human tissue is at the processor, all expenses incurred are part of the fees which ‘the processor charges to the hospital or other purchaser.’”).

<sup>128</sup> See Katz, *supra* note 11, *passim*.

<sup>129</sup> Mark Katches et al., *Body Donors Fueling a Booming Business* (Apr. 17, 2000), SWEETLIBERTY, <http://www.sweetliberty.org/issues/hate/bodybrokers.htm>. (“[S]kin, tendons, heart valves, veins and corneas are listed at about \$110,000. Add bone from the same body, and one cadaver can be worth about \$220,000.”); see also Jean-Paul Pirnay, Alain Vanderkelen, Martin Zizi, Daniel De Vos, Thomas Rose, Geert Laire, Nadine Ectors, & Gilbert Verbeken, *Human Cells and Tissues: The Need for a Global Ethical Framework*, <http://www.who.int/bulletin/volumes/88/11/BLT-09-074542-table-T1.html> (table comparing prices of human cell and tissue products between Belgium and the U.S.).

<sup>130</sup> Oberman, *supra* note 84, at 909.

<sup>131</sup> HHS, *Organ Matching Process*, *supra* note 112.

(e.g., the patient can be contacted and has no current infection or other temporary reason that transplant cannot take place).”<sup>132</sup> Matching is intended primarily to avoid transplant rejection, a process by which the recipient’s immune system attacks the transplanted organ.<sup>133</sup> NOTA, as well as subsequent federal regulation, calls on the OPTN to promote fair and equitable access to organ transplantation.<sup>134</sup>

Tissue recipients do not have to be matched to donors, and rejection is not generally a concern.<sup>135</sup> Potential profits rather than (roughly) prioritarian considerations<sup>136</sup> shape how donated tissues are ultimately allocated. Although transplant surgeons and hospitals doubtlessly profit from organ transplantation,<sup>137</sup> tissue transplantation is a multibillion-dollar industry.<sup>138</sup> A “problematic consequence of the lucrative nature of the market in human tissue has been the emergence of a variety of alliances and exclusive partnerships between for-profit tissue processors and non-profit tissue banks in order to stabilize or increase their supply.”<sup>139</sup> One result of such partnerships is that

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<sup>132</sup> *Id.*

<sup>133</sup> Nat’l Inst. Of Health, *Transplant rejection*, MEDLINEPLUS, <http://www.nlm.nih.gov/medlineplus/ency/article/000815.htm> (last updated Apr. 30, 2015).

<sup>134</sup> *E.g.*, 42 U.S.C.A. § 274(b)(2)(D) (2013) (“[A]ssist organ procurement organizations in the nationwide distribution of organs equitably among transplant patients.”). This is not to say that transplants are inexpensive. In 2011, “[t]he average billed charges per transplant . . . were \$262,900 for a kidney transplant, \$289,400 for a pancreas transplant, \$561,260 for a single lung transplant, \$577,100 for a liver transplant, \$997,700 for a heart transplant, and \$1,206,800 for the transplant of an intestine.” Williams et al., *supra* note 42, at 308.

<sup>135</sup> *Donation FAQs*, MUSCULOSKELETAL TRANSPLANT FOUND., [http://www.mtf.org/donor\\_faq.html](http://www.mtf.org/donor_faq.html) (last visited Apr. 21, 2016); *Tissue Donation FAQs*, *supra* note 4.

<sup>136</sup> See generally Govind Persad, Alan Wertheimer, & Ezekiel J. Emanuel, *Principles for Allocation of Scarce Medical Interventions*, 373 LANCET 423, *passim* (2009) (discussing and critiquing how organs are allocated).

<sup>137</sup> *Flynn v. Holder*, 684 F.3d 852, 861 (9<sup>th</sup> Cir. 2012) (quoting Professor Leon Kass as saying, “Although we allow no commerce in organs, transplant surgeons and hospitals are making handsome profits from the organ-trading business.”).

<sup>138</sup> *E.g.*, Boyer, *supra* note 7, at 313.

Executives of tissue banks routinely earn six-figure salaries. Musculoskeletal Transplant Foundation, one of the largest nonprofit tissue banks in the country, disclosed in its Form 990 for 2000 that it paid its CEO a salary of \$367,951. CALIFORNIA SENATE OFFICE OF RESEARCH, *TISSUE DONATIONS: ISSUES AND OPTIONS IN OVERSIGHT, REGULATION AND CONSENT*, 21 (2003). Pacific Coast Tissue Bank, a nonprofit located in Los Angeles, paid its president \$427,160 that same year, down from \$533,450 in 1997 and 1998. *Id.* at 22.

<sup>139</sup> Oberman, *supra* note 84, at 912. In some instances, for-profit tissue processors are establishing non-profit tissue banks. See, e.g., Buck, *supra* note 12, at 126 (“Today it is the norm for non-profit tissue banks and for-profit banks to create supply agreements, processing contracts, and formal partnerships.”); Katz, *supra* note 11, at 967 (“At least two for-profit processors, Osteotech and RTI, have started nonprofit tissue banks in order to secure a steady and robust supply of tissue for processing.”); Mark Katches et al., *The Body Brokers – Part 5*:

hospitals have difficulty securing enough skin to help burn victims, as donated skin is allocated to more profitable plastic-surgery products.<sup>140</sup>

*D. Difference 4: Uses*

Vital organ transplants are life-saving. In 2014, 29,533 individuals received organ transplants.<sup>141</sup> Yet, on average, twenty-two people die each day waiting for transplants due to the asymmetry between supply and demand.<sup>142</sup> A particularly vivid metaphor is that the number of people who die each year before they can receive an organ transplant is “equivalent [to] 22 jumbo jets crashing every year with no survivors.”<sup>143</sup>

By comparison, millions of patients receive tissues each year.<sup>144</sup> These tissues may be instrumental in healing. However, unlike organ donations, tissue donations are rarely life-saving.<sup>145</sup> Consider the possible uses of donated tissue.

For spinal fusions and the repair of fractures, bone is in greatest demand, but veins may be used for bypass in heart surgery. The membrane around the heart can reupholster the brain after neurosurgery, and the membrane around the muscles of the thigh can sling up sagging bladders to control incontinence. Tendons and

*Pioneers*, ORANGE COUNTY REG., April 17, 2000, [http://www.lifeissues.net/writers/kat/org\\_01bodybrokerspart5.html](http://www.lifeissues.net/writers/kat/org_01bodybrokerspart5.html) (describing how El Gendler co-founded Pacific Coast Tissue Bank, a non-profit that seeks donations, and also co-founded a private for-profit bone-processing firm that gets its materials from Pacific Coast).

<sup>140</sup> William Heisel, Mark Katches, & Liz Kowalczyk, *The Body Brokers: Part II - Skin Merchants*, ORANGE COUNTY REG., April 17, 2000, [http://www.lifeissues.net/writers/kat/org\\_01bodybrokerspart2.html](http://www.lifeissues.net/writers/kat/org_01bodybrokerspart2.html). The skin burn victims need goes to two companies that have contracts with many of the largest tissue banks, which buy all of the skin the tissue banks harvest and transform it into plastic-surgery products.

<sup>141</sup> *Organ Procurement and Transplantation Network*, U.S. DEP'T OF HEALTH & HUMAN SERVS., <http://optn.transplant.hrsa.gov> (last visited Apr. 21, 2016). As of March 2015, 123,296 people need an organ transplant; 78,013 people are active waiting list candidates.

<sup>142</sup> U.S. DEP'T OF HEALTH & HUMAN SERVS., *The Need Is Real: Data*, ORGANDONOR.GOV, <http://www.organdonor.gov/about/data.html> (last visited Apr. 21, 2016) (hereinafter HHS, *The Need is Real: Data*). It has been suggested that this number is too low because it does not take into account the 4,000 plus individuals who are removed from the waiting list each year because they are “too sick to transplant.” *Deaths Equivalent to 22 Jumbo Jets Crashing Every Year Due to Organ Donor Shortage—Press Release*, DONATE LIFE AM. (Jun. 17, 2014), <http://donatelife.net/deaths-equivalent-to-22-jumbo-jets-crashing-every-year-due-to-organ-donor-shortage-press-release/>.

<sup>143</sup> DONATE LIFE AMERICA, *supra* note 142.

<sup>144</sup> John S. DePaolo & James M. Barbeau, *Enhanced Tracking of Tissue for Transplantation*, 309 J. AM. MED. ASS'N. 443, 443 (2013).

<sup>145</sup> Katches et al., *supra* note 101 (“Families are led to believe they are giving the gift of life. . . . The products are rarely life-saving as advertised.”).

ligaments can return mobility. Corneas can restore clear vision. Cartilage can help in facial remodeling. Dead skin can replace burned skin. And collagen can fill wrinkles, plump lips, revive youthful appearance.<sup>146</sup>

While all of these uses are reasonably viewed as life-enhancing for the recipient, some uses—particularly those that are cosmetic in nature—may reasonably be viewed as frivolous by many. Organ donation is often described as the gift of life, however, that description is not equally relevant to tissue donation.

#### *E. Difference 5: Regulation*

The tissue industry is relatively unregulated as compared to the organ industry.<sup>147</sup>

There are fifty-eight federally designated OPOs throughout the United States and its territories.<sup>148</sup> OPOs are non-profit organizations<sup>149</sup> that must be certified by the Centers for Medicare and Medicaid Services (CMS) and abide by CMS regulations.<sup>150</sup> They are the only organizations that can recover organs from deceased donors for transplantation.<sup>151</sup> The Health Resources Services Administration (HRSA), an agency of HHS, “oversees the transplantation of vascularized human organs through the OPTN, which sets policies related to the procurement, transplantation, and allocation of human organs.”<sup>152</sup> In addition, CMS has developed Conditions of Participation for hospitals that wish to be eligible for Medicare

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<sup>146</sup> See Laura A. Siminoff & Heather M. Traino, *Consenting to Donation: An Examination of Current Practices in Informed Consent for Tissue Donation in the United States*, 14 CELL TISSUE BANK 85, 85 (2013).

<sup>147</sup> Katz, *supra* note 11, at 951; see also Joseph Shapiro & Sandra Bartlett, *Little Regulation Poses Problems Tracking Tissue*, NPR (Jul. 18, 2012), <http://www.npr.org/2012/07/18/156933032/little-regulation-poses-problems-tracking-tissue> (“An investigation . . . found that there’s little scrutiny at key points in the tissue donation and transplant process. But . . . the industry trade group, disagrees with that finding. ‘We are very highly regulated,’ . . . noting that medical advances with tissue come so quickly that regulators have a hard time keeping up or staying out of the way.”).

<sup>148</sup> *About OPOs*, ASS’N OF ORGAN PROCUREMENT ORGANIZATIONS, <http://www.aopo.org/about-opos/> (last visited Apr. 22, 2016).

<sup>149</sup> *Organ Procurement and Transplantation Network*, *supra* note 141.

<sup>150</sup> Dept. Health & Human Servs., *Organ Procurement Organizations*, ORGANDONOR.GOV, <http://organdonor.gov/materialsresources/materialsopolist.html> (last visited Apr. 22, 2016).

<sup>151</sup> *About OPOs*, *supra* note 148.

<sup>152</sup> *Organ Procurement and Transplantation Network*, 78 Fed. Reg. 40033, 40034 (Jul. 3, 2014) (to be codified at 42 CFR 121), <https://www.federalregister.gov/articles/2013/07/03/2013-15731/organ-procurement-and-transplantation-network>.

reimbursement for transplant services.<sup>153</sup> These Conditions of Participation are particularly influential because “[m]ost commercial payors follow CMS’ lead regarding transplant center regulation.”<sup>154</sup> Programs that do not obtain Medicare certification must receive approval from the OPTN in order to receive organs.<sup>155</sup>

Federal law does not require tissue banks and processors to be non-profit or tax-exempt, nor does it grant tissue banks a monopoly over tissue recovery within a designated geographic area.<sup>156</sup> The American Association of Tissue Banks (AATB) is the accrediting body for tissue banks, but accreditation is voluntary.<sup>157</sup> Although the AATB has said that the “vast majority” of banks recovering traditional tissues are accredited by the AATB, investigations suggest that only one-third are actually accredited by the AATB.<sup>158</sup> The FDA’s Center for Biologics Evaluation and Records (CBER) regulates human cells or tissues intended for implantation, transplantation, infusion, or transfer into a human recipient.<sup>159</sup> Tissue establishments are required to register and list their tissue-based products with the FDA.<sup>160</sup> However, the typical tissue bank operates for nearly two years before the FDA

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<sup>153</sup> Dept. Health & Human Servs. *Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants*, 72 Fed. Reg. 15198, 15198 (Mar. 30, 2007) (codified at 42 CFR Part 482).

<sup>154</sup> M.M. Abecassis, R. Burke, A.B. Cosimi, A.J. Matas, R.M. Merion, D. Millman, J.P. Roberts, & G.B. Klintmalm, *Transplant Center Regulations—A Mixed Blessing? An ASTA Council Viewpoint*, 8 AM. J. OF TRANSPLANTATION 2496, 2496 (2008).

<sup>155</sup> *Id.* at 2497.

<sup>156</sup> Katz, *supra* note 11, at 956. Though the law does not require it, only non-profit agencies are engaged in soliciting donations and retrieving tissue from human cadavers. *Id.* at 951.

<sup>157</sup> *Accreditation*, AM. ASS’N OF TISSUE BANKS, <http://www.aatb.org/Accreditation> (last visited Apr. 22, 2016).

<sup>158</sup> See Kate Willson et al., *Human Corpses are Prize in Global Drive for Profits*, THE INT’L CONSORTIUM OF INVESTIGATIONAL JOURNALISTS (Jul. 17, 2012, 12:15 AM), <http://www.icij.org/human-corpses-are-prize-global-drive-profits>.

<sup>159</sup> *Tissue & Tissue Products*, FDA, <http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/> (last updated Aug. 7, 2010) (“[21 C.F.R.] Parts 1270 and 1271 require tissue establishments to screen and test donors, to prepare and follow written procedures for the prevention of the spread of communicable disease, and to maintain records. FDA has published three final rules to broaden the scope of products subject to regulation and to include more comprehensive requirements to prevent the introduction, transmission and spread of communicable diseases.”).

For background on how the FDA slowly came to regulate tissue banking, see R. Alta Charo, *Skin and Bones: Post-Mortem Markets in Human Tissue*, 26 NOVA L. REV. 421, 442–449 (2002) (discussing the evolution of the FDA’s regulation of tissue-banking); Williams, *supra* note 11, at 409–21 (tracing the FDA’s reactions to the development of a human tissue industry).

<sup>160</sup> 21 C.F.R. § 1271.1 (2005).

first inspects it.<sup>161</sup> Firms that make medical products out of human tissues are required to report only the most serious adverse events they discover.<sup>162</sup> Only a handful of states require that tissue banks be licensed, and “even fewer states” inspect tissue banks.<sup>163</sup> Due to limited oversight and regulation, tissues have greater potential than organs to pose public health threats.

### *III. Understanding the Ethical Challenges Posed by Tissues*

NOTA had a variety of goals for organ transplantation, including articulating a national policy, increasing the number of organs available, and promoting fairer access to organs.<sup>164</sup> The Act’s various provisions—in particular the ban on exchanging human organs for valuable consideration—were motivated by ethical concerns related to commodification, exploitation, and coercion. Several of the ethical aims of the Act are not presently realized by regulating organs and tissues in the same way, due to the differences between tissues and organs outlined above. Moreover, not all of the ethical aims of NOTA are necessarily appropriate for cadaveric tissues.

#### *A. Commodification*

The term “commodification” describes the actual buying and selling of something.<sup>165</sup> The rhetoric of non-commodification asserts that the buying and selling of organs would erode our respect for human life, and allowing bargained for exchanges would displace civic mindedness.<sup>166</sup> Altruistic donation of organs is said to benefit both donors and recipients. As explained by Margaret Radin,

The altruistic experience of the donor in being responsible (perhaps) for saving a stranger’s life is said to bring us closer together, cementing our community in a way that buying and selling cannot. . . . From the recipient’s perspective, it is said that

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<sup>161</sup> Willson et al., *supra* note 158.

<sup>162</sup> *Id.*

<sup>163</sup> Katz, *supra* note 11, at 956.

<sup>164</sup> Daubert, *supra* note 16, at 463.

<sup>165</sup> Margaret Jane Radin, *Market-Inalienability*, 100 HARV. L. REV. 1849, 1859 (1987) (“Broadly construed, commodification includes not only actual buying and selling, but also market rhetoric, the practice of thinking about interactions as if they were sale transactions, and market methodology, the use of cost-benefit analysis to judge these interactions.”).

<sup>166</sup> *See, e.g., id.* at 1913-14.

knowing one is dependent on others' altruism rather than on one's own wealth creates solidarity and interdependence, and that this knowledge of dependence better preserves and expresses the ideal of sanctity of life.<sup>167</sup>

NOTA was intended to promote altruism and function as a bulwark against commodification.<sup>168</sup> As described previously, NOTA's drafters believed that "individuals or organizations should not profit by the sale of human organs for transplantation."<sup>169</sup>

Under NOTA, a donor may give away but not sell his or her tissues. From the donor's perspective, tissues are market inalienable.<sup>170</sup> Nevertheless, as discussed above, there are many intermediaries between tissue donors and the ultimate allograft recipients.<sup>171</sup> Fees change hands at each stage of the tissue transplant process subsequent to donation.<sup>172</sup> As a result, "some tissue[s] come to resemble a commercial product."<sup>173</sup> While many transactions are protected under NOTA's "reasonable payment" exception,<sup>174</sup> some intermediaries exploit the "reasonable payment" loophole by recouping more than their expenses plus normal profits—that is, they receive unreasonable payments.<sup>175</sup> When this happens, they are paid something for the tissue itself—they capture some of its value for themselves—rather than re-gifting the value of the tissue to the ultimate recipient.<sup>176</sup> The U.S. "government takes almost no steps to stop intermediaries from selling tissue or (which amounts to the same thing) earning super-normal profits."<sup>177</sup> That is to say, tissues are routinely commodified after they are altruistically donated.

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<sup>167</sup> *Id.* at 1913-14.

<sup>168</sup> See, e.g., David Horton, *Indescendibility*, 102 CAL. L. REV. 543, 553 (2014).

<sup>169</sup> S. REP. NO. 98-382, at 16 (1984).

<sup>170</sup> Radin, *supra* note 165, at 1852-53.

<sup>171</sup> See Robert A. Katz, *The Re-Gift of Life: Who Should Capture the Value of Transplanted Human Tissue?*, 18 HEALTH LAW. 14, 15 (2006) ("Many people stand between [tissue] donors and recipients—including tissue banks, processors, health care providers, and firms that distribute allografts to these providers").

<sup>172</sup> See Katz, *supra* note 11, at 961-62.

<sup>173</sup> Siminoff et al., *supra* note 1, at 961.

<sup>174</sup> MICHELE GOODWIN, BLACK MARKETS: THE SUPPLY AND DEMAND OF BODY PARTS 19 (2006).

<sup>175</sup> Cf. Katz, *supra* note 171, at 15. Nonprofit tissue banks "typically sell tissue for no more than what it costs them to procure, handle, inspect, and ship [tissue], plus earn normal profits (5-10%) for overhead, capital improvements, and the like." For-profit tissue banks, by contrast, typically seek super-normal profits.

<sup>176</sup> *Id.*

<sup>177</sup> *Id.* at 15.

Yet, this is not, at bottom, a non-enforcement problem. Commodification concerns cannot be resolved simply by doing a better job of enforcing NOTA. Our intellectual property (IP) regime undermines NOTA's cap on what intermediaries may earn.<sup>178</sup> As mentioned above, some tissue processors use patented methods to process tissues and/or to make patented allografts.<sup>179</sup> Patent holders are given the exclusive right to an invention for a period of years and can thereby earn monopoly profits.<sup>180</sup> Robert Katz points out:

After a certain point, it becomes exceedingly difficult to distinguish between: (a) the super-normal profits that NOTA prohibits intermediaries from earning for their transplantation-related activities; and (b) the unlimited profits that patent law lets patent-holders earn so as to encourage investment in socially useful innovations.<sup>181</sup>

Because of the manner in which donated tissues are processed and distributed, the tendency toward commodification is a natural one for tissues in a way that it is not for organs. One might reasonably conclude that some degree of commodification is unavoidable.

Therefore, the debate over the commodification of cadaveric tissue is arguably not about commodification at all, but rather about who should capture the value of these cadaveric tissues.<sup>182</sup> This is not an argument for commodification of tissues per se. Rather, the narrower claim is that commodification is already occurring, in part because NOTA fails to adequately differentiate tissues from organs.

### *B. Exploitation*

At the most general level, exploitation occurs when one individual takes unfair advantage of another.<sup>183</sup> Exploitation arises when, due to an asymmetry of bargaining power, one party to a transaction insufficiently benefits or assumes an unfair share of the burden as

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<sup>178</sup> *Id.*

<sup>179</sup> *Id.*; see also Buck, *supra* note 12, at 125.

<sup>180</sup> Katz, *supra* note 171, at 15.

<sup>181</sup> *Id.*

<sup>182</sup> See Mahoney, *supra* note 11, at 165; see also Katz, *supra* note 171, at 15 ("The most pressing normative question is not *whether* cadaveric tissue should be sold, but *who* should capture its value.").

<sup>183</sup> Alan Wertheimer & Matt Zwolinski, *Exploitation*, STAN. ENCYC. OF PHIL. (Dec. 20, 2001), <http://plato.stanford.edu/archives/spr2013/entries/exploitation/>.

compared to other parties.<sup>184</sup> One of the concerns behind NOTA was that living kidney donors would not get an adequate payment in the bargained for exchange—that is, the rich would exploit the desperately poor by paying them too little for their organs.<sup>185</sup> The solution identified by NOTA’s drafters was to ban sales.<sup>186</sup>

However successful NOTA’s ban has been in protecting living organ donors from exploitation, it has not succeeded in avoiding the exploitation of cadaveric tissue donors.<sup>187</sup> The U.S. tissue transplantation industry is worth multiple billions of dollars, and its profits are a reflection of the system of altruistic tissue donation established by NOTA.<sup>188</sup> Tissue processors who pursue super-normal profits capture the economic value of donated tissues, rather than acting as stewards of the value as it passes from the altruistic donor to the allograft recipient.<sup>189</sup> The selflessness of altruistic donors “makes it more difficult to come to terms” with the multibillion-dollar tissue industry<sup>190</sup> and could lead one reasonably to conclude that donor altruism is routinely exploited.

Yet, the moral weight of such a claim is not immediately clear.<sup>191</sup> Perhaps, for instance, cadaveric tissue donors would prefer to donate their tissues *in spite of* the unfair distribution of financial benefits. They, or their family members who consent to postmortem donation,

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<sup>184</sup> *Id.*

<sup>185</sup> This concern is too simplistic, as it overlooks the possibility that the exploitation is mutually advantageous. For a discussion of mutually beneficial exploitation in organ transplants, see I. Glenn Cohen, *Transplant Tourism: The Ethics and Regulation of International Markets for Organs*, 41 J.L. MED. & ETHICS 269, 274-77 (2013) (“Labeling a transaction as mutually advantageous exploitation does not render it *per se* unproblematic, but it requires us to determine if the seller is nonetheless treated unfairly.”).

<sup>186</sup> *Id.* at 276 (noting that an alternative way to avoid exploitation would, of course, be to set a price floor rather than to set a price ceiling of zero).

<sup>187</sup> *Cf.* Katz, *supra* note 171, at 14-15. Nonprofit tissue banks “typically sell tissue for no more than what it costs them to procure, handle, inspect, and ship [tissue], plus earn normal profits (5-10%) for overhead, capital improvements, and the like.” *Id.* at 15. For-profit tissue banks, by contrast, typically seek super-normal profits. *Id.* See also Michelle Goodwin, *Altruism’s Limits: Law, Capacity, and Organ Commodification*, 56 RUTGERS L. REV. 305, 395 (2004) (“The regulatory silence on payments for tissues between public and private industries and agencies blurs notions of pure altruism and exploits the unaware donor and public”).

<sup>188</sup> Carlson, *supra* note 31, at 137.

<sup>189</sup> Katz, *supra* note 171, at 14-15.

<sup>190</sup> Andrew Conte & Luis Fábregas, *Gift of Life Worth Millions to Donation Organizations*, TRIBLIVE, (Aug. 31, 2013), <http://triblive.com/news/allegheeny/4408091-74/organ-organizations-procurement#axzz3TdNEjy5t>. Conte and Fábregas quote Peter A. Clark, a medical ethics professor, “if donor families even know that these people are making money off their tissues? I don’t think so . . . Where’s the fairness?” *Id.*

<sup>191</sup> Wertheimer & Zwolinski, *supra* note 183.

may feel like they benefit sufficiently from the knowledge that they are helping others. While such a transaction may (by definition) be unfair, it should not necessarily be stopped if the parties to it reasonably conclude that they benefit by transacting. Outright prohibition might be overly paternalistic, in addition to being socially undesirable because of the lost benefits to tissue recipients, on this account.<sup>192</sup>

While the account just provided is plausible, I do not wish to suggest that exploitation of tissue donors is necessarily unproblematic. Here, it is helpful to draw a distinction between consensual and non-consensual exploitation.<sup>193</sup> Although consent is required for donation, examination of informed consent practices for tissue donation suggests there are numerous shortcomings.<sup>194</sup> Many family members making decisions about the donation of a deceased loved one's tissues are not receiving information that might reasonably be considered material, especially information about potential monetary considerations.<sup>195</sup> For example, less than half of tissue requests include information pertaining to the potential involvement of for-profit companies, or the potential use of donated tissue for cosmetic procedures.<sup>196</sup> Simply put, "[p]eople who donate have no idea tissue is being processed into products that per gram or per ounce are in the price range of diamonds."<sup>197</sup>

On the basis of this empirical evidence, I would argue that there is presently pervasive non-consensual exploitation of tissue donors, and it could even be said that some tissues are obtained fraudulently. This type of donor exploitation is deeply problematic—and it is problematic however one might feel about the permissibility of consensual, mutually beneficial exploitation. NOTA, rather than stamping out exploitation, has fostered it by making it possible for everyone but the donor to benefit from tissue donation and by not making this immediately clear to donors and their families.

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<sup>192</sup> Cf., Emily A. Largent, *For Love and Money: The Need to Rethink Benefits in HIV Cure Studies*, J. MED. ETHICS, doi:10.1136/medethics-2015-103119 (2016) (discussing hard and soft paternalistic justifications for regulating altruistic acts).

<sup>193</sup> Cohen, *supra* note 24, at 274. Consent should be voluntary, informed, and competent. *Id.* at 277.

<sup>194</sup> See generally Siminoff & Traino, *supra* note 146, at 91.

<sup>195</sup> *Id.*

<sup>196</sup> *Id.* Information included in less than half of the tissue requests pertained to the processing, storage, and distribution of the donated tissue; the potential involvement of for-profit as well as not-for-profit companies, the potential use of donated tissue for cosmetic procedures.

<sup>197</sup> Katches et al., *supra* note 101 (quoting ethicist Arthur Caplan).

C. *Coercion (or Undue Inducement)*

An oft-cited concern with allowing a market in organs is that the poor will be “coerced” to sell their organs to the highest bidder without regard for the health or safety of the donor.<sup>198</sup> Indeed, the design of International Kidney Exchange, Ltd. seemed calculated to provoke precisely such fears.<sup>199</sup> Understood in this way, coercion serves as an interesting counterpoint to exploitation: the exploitation fear is that the prospective donor will be offered *too little* payment, whereas the coercion fear is that the individual will be offered *too much* payment and that said offer will be too good to refuse despite the potentially damaging consequences.<sup>200</sup>

Yet, coercion is, according to many prominent accounts, the use of a threat of harm—whether to make a person worse off than at her baseline or to violate her rights—to compel another to do something against his or her will.<sup>201</sup> The threat narrows an individual’s options such that his only reasonable choice is to comply. Thus, coercion does not properly describe what happens when tissues or organs are sold.<sup>202</sup> Genuine offers of money (e.g., as payment for receipt of an organ) are, by definition, *not* threats—they expand, rather than narrowing the individual’s options—and therefore aren’t coercive.<sup>203</sup> This does not, however, mean that offers of payment are ethically unproblematic. Objections regarding the effect money can have on the potential donor are more appropriately characterized as concerns about undue

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<sup>198</sup> Williams et al., *supra* note 42, at 309; *see, e.g.*, Flynn v. Holder, 684 F.3d 852, 860 (9th Cir. 2012).

<sup>199</sup> Gross, *supra* note 17, at 185.

<sup>200</sup> Cohen, *supra* note 185, at 276-77. The relationship between undue inducement and exploitation has been described as a paradox: the higher the monetary benefit, the less likely exploitation is, yet, the higher the monetary benefit, the more likely that individuals are unduly influenced. *See* Ruth Macklin, *The Paradoxical Case of Payment as Benefit to Research Subjects*, 11 IRB: ETHICS & HUM. RES. 1, 1 (1989).

<sup>201</sup> *See, e.g.*, Scott Anderson, *Coercion*, THE STAN. ENCYC. OF PHIL. (Feb. 10, 2006), <http://plato.stanford.edu/archives/sum2015/entries/coercion/>; *see also* Christine Grady, *Payment of Clinical Research Subjects*, 115 J. OF CLINICAL INVESTIGATION 1681, 1683 (2005) (defining coercion as involving a threat of physical, psychological, or social harm in order to compel an individual to do something).

<sup>202</sup> This is not to claim that coercion could never be a problem. Someone might, of course, be threatened with death, e.g., if they do not donate a kidney.

<sup>203</sup> *C.f.*, Alan Wertheimer & Franklin G. Miller, *Payment for Research Participation: a Coercive Offer?*, 34 J. MED. ETHICS 389, 391 (2008). *But see* David Zimmerman, *Taking Liberties: The Perils of “Moralizing” Freedom and Coercion in Social Theory and Practice*, 28 SOC. THEORY & PRACTICE 577-609 (2002).

inducement.<sup>204</sup> Undue inducement “occurs through an offer of excessive, unwanted, inappropriate or improper reward or other overture in order to obtain compliance.”<sup>205</sup> Undue inducements are widely thought to have two concerning cognitive effects. They may impair an individual’s ability to exercise proper judgment, encouraging them to engage in activities that unreasonably contravene their best interests,<sup>206</sup> and/or prompt individuals to lie, deceive, or conceal information that, if known, would disqualify them from a particular course of action.<sup>207</sup> The second effect, deceit, is less concerning in the context of tissue donation because objective factors like blood tests, rather than self-report, can be used to determine donor eligibility.<sup>208</sup> The first effect, however, appears to be at the heart of so-called “coercion” concerns addressed by NOTA.

Terminology aside, the fear that individuals will be motivated by money to do something that contravenes their best interests (or the best interests of a deceased family member) is dramatically reduced when tissues are donated after death. Unlike living organ donors, whose health and well-being may clearly be harmed by donation,<sup>209</sup> cadaveric

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<sup>204</sup> Emily A. Largent & Holly Fernandez Lynch, *Paying Research Participants: Regulatory Uncertainty, Conceptual Confusion, and a Path Forward*, YALE J. HEALTH POL L & ETHICS, forthcoming (distinguishing coercion from undue inducement as it relates to offers of money).

<sup>205</sup> THE NAT’L COMM’N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979), <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>.

<sup>206</sup> Ezekiel J. Emanuel, *Ending Concerns About Undue Inducement*, 32 J. OF LAW, MED., & ETHICS 100, 100 (2004). Philosophers Alan Wertheimer and Franklin Miller are emphatic that “[a]s a general category, an inducement is undue only when it predictably triggers *irrational* decision-making given the agent’s own settled (and reasonable) values and aims. . . . Distortion of judgment is the key.” Wertheimer & Miller, *supra* note 203, at 391.

<sup>207</sup> Cf. Ruth Macklin, *‘Due’ and ‘Undue’ Inducements: On Paying Money to Research Subjects*, 3 IRB: ETHICS & HUM. RES. 1, 2 (1981) (discussing lying in the context of human subjects research); see also U.S. DEP’T OF HEALTH & HUM. SERV., INSTITUTIONAL REVIEW BOARD GUIDEBOOK, Chapter 3 (1993) (warning that undue inducements “may prompt subjects to lie or conceal information that, if known, would disqualify them from enrolling—or continuing—as participants in a research project”); but see Emanuel, *supra* note 206, at 100 (stating that it is unclear whether lying is a general problem).

<sup>208</sup> Cf., Holly Fernandez Lynch, *Human Research Subjects as Human Research Workers*, 14 YALE J. HEALTH POL L & ETHICS 122, 162 (2014) (discussing how to avoid lying by research participants).

<sup>209</sup> See Debra Budiani-Saberi & Deborah M. Golden, *Advancing Organ Donation Without Commercialization: Maintaining the Integrity of the National Organ Transplant Act*, AM. CONST. SOC’Y (June 2009), <https://www.acslaw.org/files/Budiani%20Saberi%20and%20Golden%20Issue%20Brief.pdf> (describing an impoverished Egyptian man who sells his kidney and subsequently regrets the decision when he experiences lingering health effects); but see Eugene Volokh, *Medical Self-*

tissue donors do not assume *health* risks by donating because they are already dead. Admittedly, cadaveric tissue donation may be inconsistent with a donor's values or with wishes and desires expressed while the donor was alive.<sup>210</sup> For example, "Jewish law proscribes desecration of the dead, which has been interpreted by many to mean that Judaism prohibits organ donation."<sup>211</sup>

What, if any harm, might individuals suffer if they posthumously become tissue donors in contravention of values or preferences expressed while they were alive?<sup>212</sup> It is controversial that the dead can suffer any harm at all. If one does not believe the dead can be harmed,<sup>213</sup> undue influence is not a concern *at all* in the context of cadaveric tissue donation. If, however, one believes that the dead can suffer harm, these are most likely to be dignitary harms.<sup>214</sup> One might argue that, insofar as undue inducement is the relevant concern, potential post-mortem harms to dignity are much less worrisome than potential harms to health and well-being faced by living donors. This may be because the magnitude of the harm is smaller, the probability of the harm is lower, for example, because relatively few potential donors have deeply-held values and interests of the kind that tissue donation would contravene, or both.

The essential point is that while NOTA's drafters feared donors would make irrational choices motivated by money, undue inducement appears much less likely to occur—or might not occur at all—in connection with cadaveric tissue donation.

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*Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV. L. REV. 1813, 1841 (2007) ("Some argue that allowing organ sales would unduly pressure poor providers to put their health and lives at risk. Yet the risk is modest.") (internal citations omitted).

<sup>210</sup> Lior J. Strahilevitz, *The Right to Destroy*, 114 YALE L. J. 781, 823 (2005) ("In the organ donation case, religion, superstition, and aesthetic considerations may explain why someone would want his organs to decay upon his death").

<sup>211</sup> Danielle Ofri, *In Israel, a New Approach to Organ Donation*, N.Y. TIMES, (Feb. 16, 2012, 9:00 AM), [http://well.blogs.nytimes.com/2012/02/16/in-israel-a-new-approach-to-organ-donation/?\\_r=0](http://well.blogs.nytimes.com/2012/02/16/in-israel-a-new-approach-to-organ-donation/?_r=0).

<sup>212</sup> Obviously, there may be broader social harms if people routinely see that the wishes of the dead are set aside to make organ and tissue donation possible. If this becomes sufficiently widespread, the living may experience some harm from anticipating that their wishes will be overridden. Strahilevitz, *supra* note 210, at 806.

<sup>213</sup> *E.g.*, John A. Robertson, *Paid Organ Donations and the Constitutionality of the National Organ Transplant Act*, 40 HASTINGS CONST. L.Q. 221, 272 (2013) ("At that point the deceased donor has no interests to be protected").

<sup>214</sup> Strahilevitz, *supra* note 210, at 823.

*IV. Proposal: An Act Tailored to Tissues*

In 2007, Senator Chuck Schumer introduced legislation that would have established mandatory requirements for what tissue banks had to tell donor families<sup>215</sup> and required the Secretary of HHS to promulgate regulations defining “reasonable payments” for the purposes of NOTA.<sup>216</sup> The bill died after heavy lobbying by the industry.<sup>217</sup> While Senator Schumer’s legislation had merit, it did not go far enough in creating a distinct and more comprehensive regulatory structure for tissues.

For the reasons outlined above, tissues and organs are best understood as distinct from one another, and there is an uncomfortable fit between the ethical concerns that motivated NOTA and the present-day realities of the tissue industry. Moreover, current regulatory frameworks have not responded sufficiently to the distinct challenges posed by tissue transplantation. My proposal is to sever tissues from NOTA and create a stand-alone tissue-specific act. Although state laws regulate tissues and organs, legislative changes should initially occur at the federal level. It is likely that once tissues are severed from NOTA, and new federal legislation changes the scheme by which tissues are donated, states will follow.

My proposal has four central elements (1) strengthening informed consent, (2) establishing a schedule of “reasonable payments,” (3) permitting the sale of tissues by donors, and (4) tracking products made from human tissue.

*A. Enhance Informed Consent Requirements*

Informed consent is a procedural requirement intended to secure 2 core values: (1) respect for individuals’ autonomy and (2) protection of individuals’ well-being.<sup>218</sup> With adequate information, tissue donors

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<sup>215</sup> S. 1479, 110th Cong. § 4 (2007). This would have required consent regarding “(A) the type of human cells, tissues, or cellular or tissue-based product to be donated; (B) the purpose for which such human cells, tissues, or cellular or tissue-based products shall be used, such as transplantation for medical purposes, transplantation for cosmetic purposes, therapy, research, or medical education; and (C) other matters as determined appropriate by the Secretary.” Failure to comply with the model form would be subject to a civil penalty of not more than \$5,000.

<sup>216</sup> S. 1479, 110th Cong. § 6 (2007).

<sup>217</sup> Kate Wilson, *Abusing the ‘Gift’ of Tissue Donation*, INT’L CONSORTIUM OF INVESTIGATIVE J. (July 19, 2012, 12:15 AM), [www.icij.org/tissue/abusing-gift-tissue-donation](http://www.icij.org/tissue/abusing-gift-tissue-donation).

<sup>218</sup> Emily A. Largent, David Wendler, Ezekiel J. Emanuel, and Franklin G. Miller, *Is Emergency Research without Informed Consent Justified? The Consent Substitute Model*, 170

(or their surrogates) should be able “to make an informed decision and weigh their own dignitary interests against financial and altruistic interests to determine whether to donate.”<sup>219</sup>

Unfortunately, as discussed above, empirical evidence supports the claim that consent for tissue donation is often misleading<sup>220</sup> Michelle Oberman has identified three problematic aspects of the present, unregulated consent process:

First, the most obvious nondisclosure problem lies in the fraudulent claims made by those who assure donors that their loved one’s tissue will be used for “medical” or “life-saving” purposes. . . . A broader risk of fraud lies in the problem of delineating the possible end uses of donated tissue. For instance, one might believe that cosmetic surgery is a relatively frivolous endeavor and that donors might be disinclined to make a gift of their loved ones’ tissue if they knew that it would be used to enhance the puffiness of someone’s lips or penis. . . . A third nondisclosure concern pertains to the monetary gains associated with a tissue’s use.<sup>221</sup>

Keeping these three non-disclosure problems in mind, tissue banks should be required to disclose the range of non-profit and for-profit intermediaries that work with donated tissue; the various ways in which intermediaries might process or distribute this tissue; and the ways in which tissue is routinely used.<sup>222</sup> In addition to disclosure of this material information, individuals should be given the option of deciding whether for-profit companies can use donated tissues and of delimiting which uses are acceptable (e.g., “Yes, this donated skin can be used to treat burn victims, and no, it cannot be used for penis plumping.”).

Disclosure is necessary because tissue banks undoubtedly have far

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ARCHIVES OF INTERNAL MED. 668, 669 (2010).

<sup>219</sup> Williams et al., *supra* note 42, at 313.

<sup>220</sup> See Siminoff & Traino, *supra* note 146.

<sup>221</sup> Oberman, *supra* note 84, at 914-15 (“[O]ne might identify at least three aspects of nondisclosure in the present, unregulated solicitation process. First, the most obvious nondisclosure problem lies in the fraudulent claims made by those who assure donors that their loved one’s tissue will be used for “medical” or “life-saving” purposes. . . . A broader risk of fraud lies in the problem of delineating the possible end uses of donated tissue. For instance, one might believe that cosmetic surgery is a relatively frivolous endeavor and that donors might be disinclined to make a gift of their loved ones’ tissue if they knew that it would be used to enhance the puffiness of someone’s lips or penis. . . . A third nondisclosure concern pertains to the monetary gains associated with a tissue’s use”).

<sup>222</sup> *Id.* at 924.

greater information about the commercial potential of donated tissues than do potential donors.<sup>223</sup> Moreover, disclosure is consistent with existing law regarding property (or lack thereof) in the body. In *Moore v. Regents of the University of California*,<sup>224</sup> the court refused to recognize a property interest in tissues or cells that had been removed from one's body for therapeutic purposes; rather, its reasoning rested on the doctrine of informed consent.<sup>225</sup>

Although HHS previously declined to adopt a mandatory disclosure rule,<sup>226</sup> several states already have mandatory disclosure laws.<sup>227</sup> In California, for example, “[t]he revised consent form or procedure shall separately allow the donor or donor’s representative to withhold consent for any of the following: (A) Donated skin to be used for cosmetic surgery purposes; (B) Donated tissue to be used for applications outside of the United States; (C) Donated tissue to be used by for-profit tissue processors and distributors. . . .”<sup>228</sup> In Wisconsin, the record of the gift must include the following:

I understand that donated bones or tissues, including skin, may have numerous uses, including for reconstructive and cosmetic purposes, and that multiple organizations, including nonprofit and for-profit organizations, may recover, process, or distribute the donations. I further understand that I may, by this record, limit the use of the bones or tissues, including skin, that are donated or types of organizations that recover, process, or distribute the

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<sup>223</sup> Cf. Russell Korobkin, “No Compensation” or “Pro Compensation”: *Moore v. Regents and Default Rules for Human Tissue Donations*, 40 J. HEALTH. L. 1, 21 (2007) (“[R]esearch scientists undoubtedly have far greater access to information concerning the legal rules governing tissue transfers and the commercial potential of biomedical research than do potential donors”).

<sup>224</sup> 51 Cal. 3d 120, 129-32 (1990).

<sup>225</sup> *Id.* at 147.

<sup>226</sup> In 2006, HHS issued a final rule regarding conditions for coverage for OPOs. Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs), 42 C.F.R. pts. 413, 441, 486 & 498. Although HHS initially proposed that consent contain “information (such as for-profit or non-profit status) about the organizations that will recover, process, and distribute the tissue,” this parenthetical requirement was left out of the final rule. 42 C.F.R. § 486.342 (2006). HHS explained, “We believe the most appropriate course of action is to allow each OPO to determine independently what information it needs to disclose about the various organization that will be involved in the donation process. Thus, we have not finalized a requirement for OPOs to disclose the profit status of tissue banks to families of potential donors and other decision makers.” 71 Fed.Reg. 30982, 31020 (May 31, 2006) (codified at 42 C.F.R. pts. 413, 441, 486 & 498).

<sup>227</sup> I.C. § 39-3413A (repealed 2007).

<sup>228</sup> West’s Ann.Cal.Health & Safety Code § 7158.3 (2010), amended by 2015 Cal.Legis. Serv. Ch. 303 (A.B. 731 (WEST)).

donation.<sup>229</sup>

Three objections should be considered. First, some commentators have vocalized their support for legislative consent—also known as presumed consent—with the possibility of opting out as a way of addressing the severe shortage of vital organs for transplantation.<sup>230</sup> That is, individuals would be organ and tissue donors at the time of death *unless* they specifically stated during their lifetime that they did not wish to donate. My proposal is inherently at odds with presumed consent schemes, but this is not a problem, as presumed consent schemes are untenable. Arguably, the very phrase “presumed consent” is a bit of a misnomer. It is not a type of actual consent, but signifies a situation in which there is compelling reason to believe that a given individual, if able to do so, would willingly consent to an intervention.<sup>231</sup> The paradigmatic case is that of the unconscious patient who comes to the emergency room and is treated—without explicit consent—to avoid death or severe incapacity.<sup>232</sup> There are not, however, good empirical grounds for claiming that even though decedents have not given consent, they would consent to organ donation if they could be asked. Philosopher Robert Veatch asserts that “it is empirically wrong to presume consent of deceased persons to be donors of organs for transplant.”<sup>233</sup> In 1986, the HHS Task Force on Organ Transplantation cited public opposition “as the sole basis for rejecting the presumed consent approach.”<sup>234</sup>

Second, “some industry actors fear that publicizing the

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<sup>229</sup> WIS. STAT. ANN. § 157.06 (2014). It is also required that the person making the anatomical gift sign to acknowledge that he or she has read these sentences, or that the sentences have been read aloud to him or her. A line or space must be provided for the person making the gift to specify a limitation, if any, on the use of bones or tissues or on the types of organizations that may recover, process, or distribute the donation.

<sup>230</sup> See, e.g., Linda C. Fentiman, *Organ Donation As National Service: A Proposes Federal Organ Donation Law*, 27 SUFFOLK U. L. REV. 1593, 1598 (1993); see generally David Orentlicher, *Presumed Consent to Organ Donation: Its Rise and Fall in the United States*, 61 RUTGERS L. REV. 295, 305 (2009) (arguing that presumed consent reached its peak in the United States in 1990).

<sup>231</sup> Robert M. Veatch, *Implied, Presumed, and Waived Consent: The Relative Moral Wrongs of Under-and Over-Informing*, 7 AM. J. BIOETHICS 39, 40 (2007).

<sup>232</sup> *Id.*

<sup>233</sup> *Id.*; see also Michele Goodwin, *Rethinking Legislative Consent Law?*, 5 DEPAUL J. HEALTH CARE L. 257, *passim* (2002) (discussing racial and religious reasons for rejecting presumed consent and the inadequacy of opt-out provisions).

<sup>234</sup> Orly Hazony, *Increasing the Supply of Cadaver Organs for Transplantation: Recognizing That the Real Problem is Psychological Not Legal*, 3 HEALTH MATRIX 219, 245 (1993).

involvement of for-profit businesses in the tissue industry will discourage donations.”<sup>235</sup> This is an empirical claim, and a plausible one.<sup>236</sup> In a 2010 study, researchers found that less than a quarter of families agreed or strongly agreed that it is acceptable for donated tissues to be processed and distributed by for-profit companies.<sup>237</sup> After the California state legislature mandated consent procedures, the number of donors withholding consent to for-profit involvement has increased.<sup>238</sup> Yet, these empirical results are better interpreted as favoring a disclosure requirement, rather than as offering suitable grounds for objection to one. Although the right to destroy one’s life-enhancing tissues is questionable on welfarist grounds,<sup>239</sup> a reasonable person may remain sympathetic to individuals’ desires to control what happens to their tissues after they die. The documented change in donor behavior following disclosure shows that for-profit involvement is *clearly* material to many. Therefore, any policy of deliberately concealing for-profit involvement raises serious ethical problems. What some might characterize as minor obfuscations of the truth for access to the social benefits that accrue from having more tissues for transplantation is a profound miscalculation.<sup>240</sup> Obscuring the truth surrounding tissues has the potential to damage the climate of trust, not just for life-enhancing tissue donation, but also for life-saving organ donation. This is a cost we cannot bear.

Finally, Michelle Oberman has suggested that “[t]hose engaged in the retrieval and processing of human tissue might object to [disclosure] regulations by arguing that they impermissibly limit free

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<sup>235</sup> Katz, *supra* note 11, at 945; *see also* Katches et al., *supra* note 101 (“Industry leaders say donations would plummet if families knew their gifts generate profits.”); Katz, *supra* note 171 (“One suspects that if more people knew that some processors are for-profit businesses, they would refuse to let for-profits process their donations, or refuse to donate tissue altogether. According to *The Christian Century*, a prominent Protestant journal, “[p]eople who are happy to offer their heart to save a life are not necessarily eager to donate their skin to . . . [increase] someone else’s bank account.”).

<sup>236</sup> Katches et al., *supra* note 101 (“I thought I was donating to a nonprofit. I didn’t know I was lining someone’s pocket,” said Sandra Shadwick of Burbank, whose brother died two years ago. Shadwick gave her brother’s remains to a Los Angeles tissue bank. “It makes me angry. It makes me appalled. If it’s not illegal, it ought to be. It’s certainly immoral.”).

<sup>237</sup> Siminoff et al., *supra* note 1, at 959. Only 12% of families knew that for-profit companies might sell some of the donated tissue. *Id.* at 961–62.

<sup>238</sup> Katz, *supra* note 11, at 958, n.92.

<sup>239</sup> *Cf.* Strahilevitz, *supra* note 210, at 806 (discussing the right to destroy organs).

<sup>240</sup> *Cf.* Sissela Bok, *Shading the Truth in Seeking Informed Consent for Research Purposes*, 5 KENNEDY INST. OF ETHICS J.1, 2 (1995) (discussing the importance of not obscuring the truth in research ethics).

speech rights.”<sup>241</sup> Yet, she argues that such objections are unlikely to succeed.<sup>242</sup> The Court has found that the government’s goal of protecting the public from fraud must be balanced against charities’ First Amendment rights.<sup>243</sup> Regulations must, therefore, be precisely tailored to the state’s interest and must not be unduly burdensome on the right to free speech.<sup>244</sup> The apparently materiality of the information that I propose to disclose can be defended as consistent with state common law governing fraud—nondisclosure or partial disclosure is almost certain to mislead prospective donors, whereas disclosure enables donors to make more informed choices about whether and how to donate.<sup>245</sup>

*B. Establish and Enforce a Schedule of “Reasonable Profits”*

NOTA’s exception for reasonable payments doubtlessly serves an important purpose in tissue transplantation. Functioning markets spur innovation—as mentioned above, there is an important role for IP in the tissue industry—and ensure that tissues are harvested and become available for transplantation.<sup>246</sup> It is, therefore, neither feasible nor desirable to prohibit money from exchanging hands when developing a new, tissue-specific act. At the other extreme, it is not desirable that the costs of transplantable tissues go entirely unregulated. This would only serve to exacerbate the existing shortage of tissues for important but less-lucrative applications and further distort allocation in a way that favors those recipients with greater ability to pay rather than those with greater medical need. These latter concerns are rooted in respect for distributive justice.<sup>247</sup>

Furthermore, though it is perhaps counter-intuitive, the tissue

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<sup>241</sup> Oberman, *supra* note 84, at 922. “The informed consent paradigm is misplaced in the context of the solicitation of human tissue. There are no fiduciaries in transactions involving the solicitation of human tissue from families of the deceased. No matter how sensitively they solicit donations, OPO agents are just that—employees of the OPO. These agents are not fiduciaries for the families of the deceased. Even if their solicitations occur in the hospital, gaining a family’s consent to a donation is not akin to gaining a patient’s consent to treatment.” *Id.* at 918.

<sup>242</sup> *Id.* at 922.

<sup>243</sup> *Id.* at 922-23 (citing *Riley v. Nat’l Fed’n of the Blind of N. C. Inc.*, 487 U.S. 781, 800 (1988)).

<sup>244</sup> *Id.* at 923.

<sup>245</sup> *Id.* at 923-24.

<sup>246</sup> See Mahoney, *supra* note 11, at 185.

<sup>247</sup> See Persad et al., *supra* note 136, *passim* (discussing how different allocation schemes affect distributive justice).

industry itself is best served in the long run by a constrained market. Many members of the public still find the sale of tissues unsavory. Persistent discomfort with the practice of brokering body parts clearly emerged in the debates waged after an anti-abortion group accused Planned Parenthood of selling fetal tissue for profit in 2015 though, of course, that particular discourse was heavily shaded by the controversy surrounding abortion.<sup>248</sup> While I argued above that the concerns about commodification reflected in NOTA are misplaced with respect to tissues because the commodification of tissue is a natural outgrowth of the nature of tissues, I recognize that it is improbable hearts and minds will be changed overnight. Public sentiment, then, also favors establishing a schedule of reasonable payments.

HHS should avoid either extreme—either forbidding payments or leaving transactions unregulated—and establish a schedule of “reasonable profits” for each tissue type.<sup>249</sup> Having an administratively set schedule that allows for fees as well as some level of profit in transactions involving tissues would limit the ability of the tissue processing industry to capture the economic value of tissues while also accommodating the fact that some processors have patent-protected products and processes and deserve to profit from their IP.<sup>250</sup> In setting a price, it will be important to ensure that it does not seriously increase the cost of tissue donation,<sup>251</sup> which would compound existing distributive justice concerns.

### *C. Establish a Weak No-Compensation Default Rule*

Tissue donors are critical to making the tissue industry’s profits

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<sup>248</sup> See generally Cathy Lynn Grossman, *The Hidden Ethics Battle in the Planned Parenthood Fetal Tissue Scandal*, WASH. POST (July 23, 2015), [http://www.washingtonpost.com/national/religion/the-hidden-ethics-battle-in-the-planned-parenthood-fetal-tissue-scandal/2015/07/23/1186d368-3173-11e5-a879-213078d03dd3\\_story.html](http://www.washingtonpost.com/national/religion/the-hidden-ethics-battle-in-the-planned-parenthood-fetal-tissue-scandal/2015/07/23/1186d368-3173-11e5-a879-213078d03dd3_story.html); (noting tissue was to be used in research rather than in transplantation, but it was governed by NOTA. Planned Parenthood denied selling the tissue for profit.); see also Grady & St. Fleur, *supra* note 4.

<sup>249</sup> Williams et al., *supra* note 42, at 314 n.333 (setting the price of tissue “very specifically, for example: \$200 for a tendon; \$500 for a heart valve; and \$500 for a piece of skin measuring no more than four square inches . . . would be tedious to set up by may go the farthest towards compensating the [donor’s] estate for the items being used and remedying the current inequities where tissues generate large amounts of money for tissue banks.”).

<sup>250</sup> Katz, *supra* note 11, at 981.

<sup>251</sup> See Cohen, *supra* note 185, at 35 (“If the [price is imposed legislatively], it must be a politically acceptable price, in the sense that it is generous enough to bring to the market those who are in the relatively price elastic portion of the supply curve, and yet not so generous as to seriously increase the cost of organ transplantation.”).

possible, and should—as a matter of equity—be able to receive compensation.<sup>252</sup> As part of the schedule of reasonable profits discussed above, HHS should determine specific amounts that would be acceptable to pay to cadaveric tissue donors (or, more precisely, to decedents’ families). Such payments would not need to reflect the entire value of the tissue but could be characterized as a token of appreciation or donation incentive; moreover, such payments would alleviate the exploitation of donors.<sup>253</sup> Establishing a set rate of compensation addresses concerns that families would need to negotiate prices for tissues (i.e., parts of a loved one) while grieving,<sup>254</sup> which would be both difficult and unseemly, and addresses the asymmetry of knowledge between donors and tissue banks and processors about the market value of tissues.

After the schedule is established, individuals can decide whether to be paid or to act as purely altruistic donors. In the context of use of tissues for research purposes, Russell Korobkin has argued for a weak default rule of no compensation.<sup>255</sup> He explains:

In addition to establishing the default rule, the law must determine what amount of evidence will constitute an agreement by the parties to set their own term, or “contract around” the default. A “strong” default rule requires a clear contractual statement by the parties of a different allocation of resources before the rule is overridden. A “weak” default rule, in contrast, is one that courts will determine to have been overridden by the parties in the event of more ambiguous evidence that the parties wished a different resource allocation.

A weak no-compensation default is also appropriate when tissue is donated for transplantation. Some will demand payment regardless of the default; others will eschew payment regardless of the default.

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<sup>252</sup> Cf. *Moore v. Regents of the University of California*, 793 P2d 479 (Cal 1990) (Mosk, J. dissenting) (calling it “both inequitable and immoral” that the defendants would deny Moore, whose “contribution to the venture is absolutely critical . . . any share in the proceeds.”); see also Oberman, *supra* note 84, at 940 (“Justice and fairness [would be] further enhanced by requiring those who benefit from tissue donations, regardless of whether they are nominally structured as for-profit or nonprofit entities, to pay something for their raw material.”).

<sup>253</sup> As discussed above, I find the non-consensual aspect of the current regime more obviously problematic than the existence of exploitation *per se*. A robust informed consent requirement addresses non-consensuality. Payment at the level I imagine may not resolve exploitation, but it should make the transaction fairer by allowing donors to share in the financial benefits of tissue donation/transplantation.

<sup>254</sup> Oberman, *supra* note 84, at 939.

<sup>255</sup> Korobkin, *supra* note 223, *passim*.

As Korobkin has pointed out, however, the preferences of a third group will be strongly shaped by the default.<sup>256</sup> A no-compensation default rule will reinforce social norms that favor altruism, but will not unacceptably (i.e., paternalistically) impinge on the autonomy of donors (or their surrogate decision-makers) and tissue banks to contract.

There are several potential objections to this proposal. First, by permitting donors to be paid for their tissues, some may argue that we are introducing the possibility of undue inducement. Even if payment is offered to cadaveric tissue donors, there could rarely be undue inducement. People are currently asked to donate cadaveric tissues for free, and the request to donate—coupled with an offer of payment—will not change the risks or burdens associated with tissue donation.<sup>257</sup> If the risks are reasonable when donation is altruistic, the introduction of compensation does not somehow make them unreasonable. Of course, the offer of payment may enhance the perceived benefits of post-mortem tissue donation—and indeed, it hopefully will, in order to offset the decline in tissue donation that may occur in the wake of a requirement for greater disclosure as part of the informed consent process. The offer of payment may even result in a net increase in the number of people who can benefit from allografts.<sup>258</sup> The offer of payment would certainly be an inducement, but that does not make it *undue*. Fears of undue inducement should be further allayed because, on my proposal, (1) there is a weak default rule of no compensation, meaning that not all people will receive payment, and (2) payments to cadaveric tissue donors' families will be set by HHS, a party external to transactions that occur between donors and processors, and will be modest. Although it is difficult, if not impossible, to draw a bright line between due and undue inducements,<sup>259</sup> they should be less worrisome when an offer of payment is relatively small—that is, relatively less enticing.

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<sup>256</sup> *Id.*

<sup>257</sup> *Cf.* Robertson, *supra* note 213, at 266 (“The risk [organ donors] are taking is not unreasonable, because altruistic donors have long assumed them without paid inducement.”).

<sup>258</sup> Katz, *supra* note 171, at 16. In 2012, one-quarter of the population “reported that a financial incentive would make them more likely to donate their organs.” U.S. DEP’T OF HEALTH & HUMAN SERVS. (HHS), HEALTH RESOURCES & SERVICES ADMINISTRATION (HRSA), 2012 NATIONAL SURVEY OF ORGAN DONATION ATTITUDES AND BEHAVIORS, at 52.

<sup>259</sup> *E.g.*, Wertheimer & Miller, *supra* note 203, at 391 (“[The] distinction between an unproblematic . . . inducement and an undue inducement is not a feature of the inducement itself. It is a function of the relation between the inducement and the subject’s response to it.”).

Second, there may be religious strictures, or other value strictures, that prevent some people from selling their tissues. For example, Pope John Paul II explicitly addressed the sale of tissues at the First International Congress of the Society for Organ Sharing in 1991, where he said, “[T]he human body is always a personal body, the body of a person. The body cannot be treated as a merely physical or biological entity, nor can its organs and tissues ever be used as item for sale or exchange.”<sup>260</sup> The weak default rule of no compensation would allow people who object to payment, on whatever grounds, to donate their tissues after death altruistically. Thus, this system allows altruistic donation and compensated donation to peaceably co-exist.

Third, some may object that this is simply commodification. It is, however, incomplete commodification—something less than a *laissez-faire* market regime.<sup>261</sup> Although non-commodification may be the ideal, to achieve justice in non-ideal circumstances (such as those in which we live), we have to choose the best alternative available to us. Margaret Radin has argued, “[W]e should understand there to be a continuum reflecting degrees of commodification that will be appropriate in a given context.”<sup>262</sup> She distinguishes two aspects of incomplete commodification: the participant aspect, which draws attention to the meaning of an interaction for those who engage in it, and the social aspect, which uses regulation to limit the choice set.<sup>263</sup> Tissues are a possible example of incomplete commodification. The personal importance that many of us attach to tissue donation will not be understandable entirely in monetary terms, even if we demand or accept money.<sup>264</sup> There is a deeply personal aspect to seeing your loved one’s tissues going to another. Establishing a weak no-compensation default should be seen to promote the non-market significance of tissue. Moreover, establishing a fixed price to be paid to tissue “donors” prevents this from being a bare-knuckled fight in the markets.

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<sup>260</sup> Paolo Bruzzone, *Religious Aspects of Organ Transplantation*, 40 *TRANSPLANTATION PROCEEDINGS* 1064, 1064 (2008) (quoting Pope John Paul II).

<sup>261</sup> Radin, *supra* note 165, at 1856.

<sup>262</sup> *Id.* at 1918.

<sup>263</sup> *Id.*

<sup>264</sup> *Cf. id.* (giving the example of a home, which has market value but also “a nonmonetizable, personal aspect”).

*D. Require Tracking of Tissue Products*

Tissues donated by one person may yield more than 100 tissue grafts for transplantation.<sup>265</sup> Although millions of patients safely receive tissue transplants each year, there are risks associated with tissue transplantation.<sup>266</sup> More than 50 tissue-transmitted infections have been reported in the literature since 1998, but the actual number may be higher due to “the lack of active surveillance for donor-derived infection or of an efficient means for reporting suspected infection in recipients.”<sup>267</sup> Another obstacle to complete data is the incomplete identification of co-recipients, or the various individuals who receive transplants from a single donor.<sup>268</sup> Additionally, an adverse event may occur soon after transplantation or it may occur many years later, when it is less likely to be attributed to the transplant.<sup>269</sup>

Clusters of transplant-transmitted infections—which variously resulted from deliberate misconduct,<sup>270</sup> error,<sup>271</sup> or technological inadequacy<sup>272</sup>—have highlighted the challenges of tracking donated tissues from an infected donor to numerous recipients.<sup>273</sup> Existing practices for tissue tracking “do not ensure rapid communication through the distribution chain as soon as a problem is discovered.”<sup>274</sup> There are several reasons for this, each of which must be addressed to protect health and promote public trust.

First, there is a lack of common coding and nomenclature for tissue.<sup>275</sup> At present, it is left to the individual tissue bank to determine

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<sup>265</sup> Reena Mahajan & Matthew J. Kuehnert, *How Can We Improve Tracking of Transplanted Tissue in the United States?*, 15 CELL TISSUE BANK 287, 287 (2014).

<sup>266</sup> DePaolo & Barbeau, *supra* note 144, at 443.

<sup>267</sup> Matthew J. Kuehnert, Krista L. Yorita, Robert C. Holman, D. Michael Strong, and AABB Tissue Task Force, *Human Tissue Oversight in Hospitals: An AABB Survey*, 47 TRANSFUSION 194, 197 (2007).

<sup>268</sup> *Id.*

<sup>269</sup> *Id.*

<sup>270</sup> DePaolo & Barbeau, *supra* note 144, at 443 (describing how “Biomedical Tissue Services Ltd. distributed tens of thousands of illegally obtained and improperly processed tissues throughout the world . . . placing thousands of tissue recipients at risk”).

<sup>271</sup> Mahajan & Kuehnert, *supra* note 265, at 288 (describing how positive nucleic acid test results were misread as negative due to a laboratory error, resulting in an infected graft being implanted into an infant).

<sup>272</sup> Kuehnert et al., *supra* note 267, at 198 (describing how “[n]ew results can . . . occur when donors are retested due to advances in technology, such as advanced generations of test development”).

<sup>273</sup> Mahajan & Kuehnert, *supra* note 265, at 288.

<sup>274</sup> DePaolo & Barbeau, *supra* note 144, at 444.

<sup>275</sup> Mahajan & Kuehnert, *supra* note 265, at 288.

what to call each graft type it distributes.<sup>276</sup> By contrast, “a common coding and nomenclature . . . exists for most other healthcare products of human origin, such as blood and blood products, and it is being developed for cellular therapy products, human milk banking, ocular tissue, and other tissue types.”<sup>277</sup> This system is known as the ISBT-128.<sup>278</sup> Common coding and nomenclature should be required for tissues.

Second, tissue banks are required only to track tissue to the healthcare facility level. Notification of tissue use to the supplier by a healthcare facility (e.g., a hospital notifying a tissue processor that an allograft has been implanted in a patient) is currently voluntary, and notification rates are variable.<sup>279</sup> As a result, tissue banks “may be unaware of whether tissue has been implanted, stored, or discarded.”<sup>280</sup> As tissues from a single donor are distributed more widely (and sometimes globally), investigations of potential transplant-transmitted infections are becoming increasingly complex and can require mechanisms to both traceback and traceforward tissue.<sup>281</sup> Investigations are particularly challenging when tracking mechanisms are inadequate.<sup>282</sup>

Third, within most healthcare facilities, tissue is managed in a decentralized fashion, and a standardized tracking system to the patient-level is lacking.<sup>283</sup> This makes it difficult to locate physicians as well as to notify and test patients if potential transmissions occurred that involved a common donor.<sup>284</sup> Reliable systems to share and record information about tissue products—and a requirement to use them—from producer to end-user and at all the stages in between are essential.

Fourth, tissue manufacturers are required to report serious communicable disease related adverse events to FDA; however, surveillance is fundamentally passive, relying on physicians to

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<sup>276</sup> *Id.* (“[T]issue graft names can be proprietary, but most often the graft is simply named differently by different tissue banks (i.e. an iliac crest wedge can also be named a tricortical wedge).”).

<sup>277</sup> *Id.*

<sup>278</sup> See generally P. Distler, *Traceability and Unique Identifiers*, 9 ISBT SCIENCE SERIES 98, *passim* (2014).

<sup>279</sup> *Id.*

<sup>280</sup> Mahajan & Kuehnert, *supra* note 265, at 288.

<sup>281</sup> Kuehnert et al., *supra* note 267, at 197.

<sup>282</sup> *Id.*

<sup>283</sup> Mahajan & Kuehnert, *supra* note 265, at 289.

<sup>284</sup> *Id.*

recognize and report allograft-related infections.<sup>285</sup> Providers should be mandated to report adverse events if they suspect a transmission-related event.

Changes to enhance patient safety will require addressing a lack of infrastructure for tissue traceability that exists in most healthcare facilities.<sup>286</sup> This may increase the cost of tissue transplantation for the industry and for recipients but is nonetheless worthwhile given the safety implications.

### *V. Conclusion*

I have argued that, although NOTA does not distinguish between tissues and organs, tissues and organs are meaningfully different. I advocate crafting a new regulatory scheme for donated cadaveric tissues that (1) emphasizes greater disclosure of industry practices as part of the informed consent process to promote respect for autonomy; (2) establishes a schedule of reasonable profits to make sure that tissue banks and processors are not capturing the full value of tissues, thereby reducing commodification concerns; (3) introduces a weak no compensation default rule that allows donors, should they wish, to sell their tissues to reduce exploitation of altruistic donors; and (4) requires improved tracking of products made from human tissue to promote patient safety.

An advantage of this proposal is that tissues can be severed from NOTA, while leaving NOTA—and the ethically motivated scheme it established for donation and transplantation of organs—substantially intact. However, acceptance of this proposal is not inconsistent with also holding the view that a regulated market for organs is desirable and that the ethical concerns animating the passage of NOTA in 1984 are no longer valid with respect to organs. The Institute of Medicine (IOM) published a report in 2006, *ORGAN DONATION: OPPORTUNITIES FOR ACTION*, in which it stated: “There are powerful reasons to preserve the idea that organs are donated rather than sold.”<sup>287</sup> Yet, this idea is increasingly coming under attack. Even if one thinks that

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<sup>285</sup> Sanjaya Dhakal et al., *Assessment of Tissue Allograft Safety Monitoring with Administrative Healthcare Databases: A Pilot Project Using Medicare Data*, 15 *CELL TISSUE BANKING* 75, 76 (2014).

<sup>286</sup> Mahajan & Kuehnert, *supra* note 265, at 289.

<sup>287</sup> COMMITTEE ON INCREASING RATES OF ORGAN DONATION, INST. OF MED., *ORGAN DONATION: OPPORTUNITIES FOR ACTION* 15 (James F. Childress & Catharyn T. Liverman, eds., 2006).

NOTA should be substantially revised, it will be desirable to have a tissue-specific act given the differences between tissues and organs outlined above. A second advantage of this proposal is that a tissue-specific act could be expanded to accommodate living as well as cadaveric tissue donors, as well as fetal tissue donations, and this idea merits further consideration.

# USING PATENTS TO SPUR PHARMACEUTICAL INNOVATION: HOW GILEAD PHARMACEUTICALS' MIRACLE DRUG'S HIGH PRICE TAG RESULTS IN FUTURE REWARD

Abigail J. Masenheimer\*

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\* J.D., 2016, Quinnipiac University School of Law; BA in Print Journalism, 2013, American University. First and foremost, I would like to thank my father, David L. Masenheimer, Esq., for always being willing to extend a helping hand and reminding me that it is all worth it in the end. I would also like to thank my mother, Jana, for forever being my biggest fan and personal cheerleader. I am truly indebted to you both.

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### *Introduction*

Imagine a world where there is a miracle drug that cures liver cancer. All cancer patients covet this drug, but it comes at a steep price. The drug costs nearly \$100,000 for a course of treatment, averaging about \$1,000 per pill. The high cost of the treatment burdens both patients and the Medicare system with steep payments.. This pill, however, is the difference between life and death for many. Meanwhile in a sunny corner office in California, the CEO of a large pharmaceutical company watches his bank account grow exponentially. His phone rings and his lawyer informs him that a lawsuit has been filed, claiming the company's patent for the miracle cancer drug infringes on another large pharmaceutical company's patent.

There is currently no miracle cure for liver cancer. Medical developments, however, have led to other so-called miracle drugs for other diseases, such as hepatitis C, which left untreated can progress to liver cancer.<sup>1</sup> The scenario discussed above parallels the current position of the hepatitis C "miracle drugs" Sovaldi and Harvoni, which are being described as "blockbuster drug[s]."<sup>2</sup> Not only are Sovaldi and Harvoni important developments in medical science, they are creating a stir in the legal community where large pharmaceutical companies are battling with one another in the patent arena to gain a piece of the proceeds.<sup>3</sup> The patent system's impact on drugs like Sovaldi and Harvoni is sure to influence future miracle drugs as well.

This Note will trace the development of Sovaldi and Harvoni, the

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<sup>1</sup> Kim Peterson, *\$1,000-a-day miracle drug shocks U.S. healthcare system*, CBS NEWS (Apr. 3, 2014, 8:27 AM), <http://www.cbsnews.com/news/1000-a-day-miracle-drug-shocks-us-health-care-system/>.

<sup>2</sup> Ed Silverman, *Hepatitis C Spurs Unusual Patent Wars Among Big Drug Makers*, WALL ST. J.: L. BLOG (Jul. 21, 2014, 10:22 AM), <http://blogs.wsj.com/pharmalot/2014/07/21/hepatitis-c-spurs-unusual-patent-wars-among-big-drug-makers/>.

<sup>3</sup> *Id.*

legal complications the drug treatments face in the patent system, and the drugs' impact on both the patent system and public health. The first part of this Note will discuss necessary background information about hepatitis C, including what it is, how it is transmitted, and how it affects the body. The second part will introduce older hepatitis C treatments and discuss how Sovaldi and Harvoni have positively affected the treatment of patients with hepatitis C. The third part will address the numerous patent lawsuits and debate the effect of the patent system on miracle cure drugs. The fourth part of this Note will examine how the patent system affects public health and hinders patients' efforts to obtain the so-called miracle drugs required to treat their conditions. The fifth part of this Note will review possible solutions to maintain the inventor's right to exclusivity, while maximizing public health benefits and access to these lifesaving treatments. Finally, this Note concludes that the best solution is to allow the patent system to operate the way it was intended—by rewarding innovators for their genius and creating an incentive to invent.

### *I. Background*

Hepatitis C is a liver disease that comes in two forms: acute and chronic. Acute hepatitis C is short term, whereas chronic hepatitis C is long term.<sup>4</sup> Acute hepatitis C occurs within six months after a person is exposed to the virus, while chronic hepatitis C occurs when the virus remains in a person's body.<sup>5</sup> Not all patients with acute hepatitis C develop chronic hepatitis C. In fact, 15-45% of all infected persons will clear the virus without any treatment within six months.<sup>6</sup> However, the remaining 55-85% will progress to chronic hepatitis C.<sup>7</sup>

Chronic hepatitis C can last for the duration of the patient's life and can cause serious liver damage.<sup>8</sup> Additionally, chronic hepatitis C

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<sup>4</sup> *Hepatitis C FAQs for the Public*, CTR. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/hepatitis/hcv/cfaq.htm> (last visited Aug. 6, 2016) [hereinafter *Hepatitis C FAQs*].

<sup>5</sup> *Id.*

<sup>6</sup> *Hepatitis C*, WORLD HEALTH ORG., <http://www.who.int/mediacentre/factsheets/fs164/en/> (last updated Jul. 2016) [hereinafter *Hepatitis C*, WHO].

<sup>7</sup> *Id.*

<sup>8</sup> *Hepatitis C FAQs*, *supra* note 4.

can progress to other liver diseases such as cirrhosis and liver cancer.<sup>9</sup> People with chronic hepatitis C have an estimated 15-30% chance of developing cirrhosis within 20 years.<sup>10</sup> In 2014, there were approximately 30,500 reported cases of acute hepatitis C in the United States.<sup>11</sup> Currently, there are between 2.7 and 3.9 million people in the United States who have been diagnosed with chronic hepatitis C.<sup>12</sup> Worldwide, approximately 130-150 million people are infected with chronic hepatitis C.<sup>13</sup> Many of those infected with chronic hepatitis C are not aware they are infected, because they do not appear or feel sick.<sup>14</sup> Each year, approximately 700,000 people die from liver diseases related to hepatitis C.<sup>15</sup>

Hepatitis C is found in blood. There are numerous ways in which the virus can be transmitted, including through the use of shared needles for injecting drugs, through reused or inadequate sterilization of medical equipment, and through blood transfusions.<sup>16</sup> Although uncommon, it can also be transmitted sexually and through childbirth.<sup>17</sup> Sharing razors, toothbrushes, and other personal care items that may have come into contact with blood can also result in hepatitis C transmission.<sup>18</sup>

Although there is currently no vaccine for preventing hepatitis C,<sup>19</sup> there are treatments for curing the infection.<sup>20</sup> Hepatitis C does not always require treatment, as the immune system will often remove the infection on its own.<sup>21</sup> When treatment is necessary, several factors need to be taken into consideration, as there are different approaches to take for different strains and types of patients.<sup>22</sup> Currently, the standard treatment is a “combination antiviral therapy with interferon and ribavirin, which are effective against all the genotypes of hepatitis

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<sup>9</sup> *Id.*

<sup>10</sup> *Hepatitis C*, WHO, *supra* note 6.

<sup>11</sup> *Hepatitis C FAQs*, *supra* note 4.

<sup>12</sup> *Id.*

<sup>13</sup> *Hepatitis C*, WHO, *supra* note 6.

<sup>14</sup> *Hepatitis C FAQs*, *supra* note 4.

<sup>15</sup> *Hepatitis C*, WHO, *supra* note 6.

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> *Hepatitis C FAQs*, *supra* note 4.

<sup>19</sup> See discussion *infra* Section V(c) discussing development of a hepatitis C vaccine.

<sup>20</sup> *Hepatitis C*, WHO, *supra* note 6.

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

viruses (pan-genotypic).<sup>23</sup> These treatments are complex due to unavailability and patient intolerance.<sup>24</sup> Still, this treatment can be the difference between life and death.<sup>25</sup> In addition, there are other therapies called “oral directly acting antiviral agent therapies,” which have been increasing cure rates.<sup>26</sup> The downside to this type of treatment is that it is quite expensive—more than \$1,000 a pill per day.<sup>27</sup>

## II. Hepatitis C Treatments

### A. Inefficient Older Treatments

In 2011, the FDA approved Incivek (telaprevir) and Victrelis (boceprevir), two competing anti-viral drugs that were taken with a combination of interferon and ribavirin.<sup>28</sup> When Incivek was introduced, it was one of the “fastest drug launches ever,” with over 100,000 people taking it since its introduction.<sup>29</sup> Incivek and Victrelis work by interfering with the ability of the virus to grow.<sup>30</sup>

Multiple pills are taken each day and the price quickly adds up. For example, patients taking Victrelis will consume 12 pills per day.<sup>31</sup> Three of the 12 pills in the cocktail are Victrelis; the remainder are ribavirin and interferon.<sup>32</sup> The wholesale market price of Victrelis at its introduction in 2011 was \$1,100 a week, with the full course of treatment costing between \$26,300 to \$48,400 depending on the length of the patient’s treatment.<sup>33</sup> All of the pills are essential, as patients who miss a pill or two risk the possibility of the virus becoming resistant to treatment.<sup>34</sup>

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<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> See Peterson, *supra* note 1.

<sup>28</sup> Gina Shaw, *Medications for Hepatitis C*, WEBMD, <http://www.webmd.com/hepatitis/features/treatment> (last visited Aug. 6, 2016).

<sup>29</sup> Robert Weisman, *Vertex to stop selling hepatitis C drug Incivek*, BOSTON GLOBE (Aug. 12, 2014), <http://www.bostonglobe.com/business/2014/08/12/vertex-stop-selling-hepatitis-drug-incivek/EI0jtOpH9I1CaIqQpSUKWO/story.html>.

<sup>30</sup> Shaw, *supra* note 28.

<sup>31</sup> Andrew Pollack, *Merck’s Hepatitis C Drug Wins F.D.A. Approval*, N.Y. TIMES (May 13, 2011), [http://www.nytimes.com/2011/05/14/business/14drug.html?\\_r=0](http://www.nytimes.com/2011/05/14/business/14drug.html?_r=0).

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

The price paid for the pills is not the only cost to the patient. Patients taking either pill have the possibility of developing a laundry list of serious side effects, including fatigue, flu-like symptoms, stomach problems, skin rashes, anxiety and depression, and anemia.<sup>35</sup> Additionally, interferon may lower white blood cell counts, which can affect the body's ability to fight the infection.<sup>36</sup>

Despite the high monetary and health-related costs associated with these treatments, Incivek and Victrelis increased cure rates for hepatitis C patients.<sup>37</sup> Prior to the introduction of the drugs in 2011, cure rates for genotype 1 hepatitis C were less than 50%.<sup>38</sup> Incivek and Victrelis increased cure rates to between 80% and 100%, respectively.<sup>39</sup> However, Incivek and Victrelis are no longer for sale in the U.S.<sup>40</sup>

### *B. Sovaldi and Harvoni*

After Incivek and Vitrelis spent two years on the market, the FDA approved a new hepatitis C drug called Sovaldi (sofosbuvir) produced by Gilead.<sup>41</sup> The new drug covers more genotypes of hepatitis C than its predecessors and promises a shorter treatment period.<sup>42</sup> Sovaldi has been approved for treating genotypes one through four, whereas its predecessors only treated genotype one. The treatment period has been shortened to 12 weeks for genotypes 1 and 4, compared to the previous 48 weeks.<sup>43</sup> The drug also boasts a 90% cure rate for genotype 1 and a 96% cure rate for genotype 4.<sup>44</sup>

Like the two treatments that came before it, Sovaldi is a triple therapy medicine—sofosbuvir is taken in combination with interferon

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<sup>35</sup> Shaw, *supra* note 28.

<sup>36</sup> *Id.*

<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

<sup>39</sup> *Id.*

<sup>40</sup> Peter Loftus, *Merck Will No Longer Sell its Victrelis Hepatitis C Drug in the U.S.*, WALL ST. J.: L. BLOG (Jan. 21, 2015, 11:01 AM), <http://blogs.wsj.com/pharmalot/2015/01/21/merck-will-no-longer-sell-its-victrelis-hepatitis-c-drug-in-the-u-s/>.

<sup>41</sup> SOVALDI, <http://www.sovaldi.com> (last visited Aug. 15, 2016).

<sup>42</sup> *Id.*

<sup>43</sup> *SOVALDI combination therapy cure rates in clinical studies*, SOVALDI, <http://www.sovaldi.com/about-sovaldi/study-results> (last visited Aug. 15, 2016) (hereinafter *Sovaldi Study Results*).

<sup>44</sup> *Id.*; *see also Sofosbuvir (Sovaldi)*, HEPATITIS C ONLINE, <http://www.hepatitisc.uw.edu/page/treatment/drugs/sofosbuvir-drug> (last visited Aug. 15, 2016).

and ribavirin.<sup>45</sup> Although the drug must still be used in combination, it is used for a shorter period of time and fewer pills are consumed per day. To treat genotype 1, patients take Sovaldi once a day, ribavirin twice a day, and interferon once a week.<sup>46</sup>

In addition to shorter treatment periods, higher cure rates, and fewer pills per day, patients also benefit from fewer serious side effects. While patients are still at risk for experiencing tiredness, headaches, nausea, insomnia, and low red blood cell counts, the threat of developing rashes has been eliminated from the list of side effects.<sup>47</sup> Greater success rates and fewer symptoms come, however, with a high price. Sovaldi retails for \$1,000 per pill and \$84,000 for the entire treatment.<sup>48</sup>

In early October 2014, the FDA approved another hepatitis C combination drug by Gilead known as Harvoni.<sup>49</sup> It is a combination of sofosbuvir (the drug compound in Sovaldi) and a new medicine called ledipasvir.<sup>50</sup> The combination of the two compounds allows patients to consume only one pill per day. Unlike Sovaldi and its predecessors, Harvoni does not require additional drugs to be effective.<sup>51</sup> This means patients do not have to also receive doses of interferon and ribavirin, making Harvoni truly a once-a-day dose.

Like Sovaldi, Harvoni comes at a steep price. In fact, Harvoni is even more expensive than Sovaldi, retailing for \$1,125 per pill.<sup>52</sup> Although the price-per-pill is more costly, it is expected that the overall treatment price for Harvoni will be less than Sovaldi because some

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<sup>45</sup> *How Do I Take Sovaldi?*, SOVALDI, <http://www.sovaldi.com/what-is-sovaldi/how-to-take-sovaldi> (last visited Aug. 15, 2016).

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

<sup>47</sup> *Important Safety Information*, SOVALDI, <http://www.sovaldi.com/what-is-sovaldi/sovaldi-safety-information> (last visited Aug. 15, 2016) [hereinafter *Sovaldi Safety Information*].

<sup>48</sup> Jason Millman, *The new \$84,000 hepatitis C treatment is losing momentum, for now*, WASH. POST: WONKBLOG (Sept. 18, 2014), <http://www.washingtonpost.com/blogs/wonkblog/wp/2014/09/18/the-new-84000-hepatitis-c-treatment-is-losing-momentum-for-now/>.

<sup>49</sup> Andrew Pollack, *Harvoni, a Hepatitis C Drug From Gilead, Wins F.D.A. Approval*, N.Y. TIMES (Oct. 10, 2014), [http://www.nytimes.com/2014/10/11/business/harvoni-a-hepatitis-c-drug-from-gilead-wins-fda-approval.html?\\_r=0](http://www.nytimes.com/2014/10/11/business/harvoni-a-hepatitis-c-drug-from-gilead-wins-fda-approval.html?_r=0).

<sup>50</sup> *Id.*

<sup>51</sup> *Id.*

<sup>52</sup> *Ledipasvir-Sofosbuvir (Harvoni)*, HEPATITIS C ONLINE, <http://www.hepatitisc.uw.edu/page/treatment/drugs/ledipasvir-sofosbuvir> (last visited Aug. 15, 2016).

patients will be able to recover in just eight weeks.<sup>53</sup> The eight-week treatment will cost \$63,000, making the treatment cheaper than the 12-week treatment of Sovaldi at \$84,000.<sup>54</sup>

### C. *AbbVie's Hepatitis C Drugs*

AbbVie, another pharmaceutical company, is currently producing its own hepatitis C drug known as Viekira Pak.<sup>55</sup> Viekira Pak is ombitasvir, paritaprevir, and ritonavir tablets, plus dasabuvir tablets.<sup>56</sup> Like Gilead's hepatitis C treatments, neither of AbbVie's treatments requires interferon injections.<sup>57</sup> "Viekira, with or without ribavirin, was clinically proven to cure 95%-100% of the people who took it."<sup>58</sup> These drugs were created to compete directly against Sovaldi and Harvoni. "AbbVie plan[s] to contend with Gilead on the fledgling market for injection-free hep C treatments."<sup>59</sup>

The FDA approved Viekira Pak, a combination of Viekirax and Exviera, for chronic genotype 1 hepatitis C on December 19, 2014.<sup>60</sup>

### III. *Patent Wars*

The U.S. Constitution grants Congress the power "to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."<sup>61</sup> Patents grant the inventor the right to exclude<sup>62</sup> others from "making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States."<sup>63</sup> In other words, patent holders like Gilead have the right to

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<sup>53</sup> *Id.*

<sup>54</sup> *Id.*; Sovaldi Safety Information, *supra* note 47.

<sup>55</sup> *About Viekira*, VIEKIRA PAK, <https://www.viekira.com/about-viekira> (last visited Aug. 16, 2016) [hereinafter *Viekira*].

<sup>56</sup> *Id.*

<sup>57</sup> Troy Brown, *EMA Panel Backs Exviera, Viekirax for Chronic Hepatitis C*, MEDSCAPE (Nov. 21, 2014), <http://www.medscape.com/viewarticle/835328>.

<sup>58</sup> *Viekira*, *supra* note 55.

<sup>59</sup> Damian Garde, *AbbVie vies for the hep C spotlight on the eve of its Gilead battle*, FIERCEBIOTECH (Nov. 11, 2014, 10:37 AM), <http://www.fiercebiotech.com/story/abbvie-vies-hep-c-spotlight-eve-its-gilead-battle/2014-11-11>.

<sup>60</sup> *FDA approves Viekira Pak to treat hepatitis C*, U.S. FOOD & DRUG ADMIN. (Dec. 19, 2014), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm427530.htm>.

<sup>61</sup> U.S. CONST. art I, § 8, cl. 8.

<sup>62</sup> *See* F. SCOTT KIEFF, ET AL., *PRINCIPLES OF PATENT LAW: CASES AND MATERIALS* 2 (6<sup>th</sup> ed. 2013).

<sup>63</sup> 35 U.S.C. §154(a)(1) (2014).

prevent other pharmaceutical companies from selling drugs that infringe on their patents. By patenting drugs, pharmaceutical companies can prevent other companies from duplicating their products and selling them at a lower cost for 20 years from the filing date.<sup>64</sup>

*A. Generic Drugs and The Hatch-Waxman Act*

Generic drugs are chemically identical counterparts to branded drugs.<sup>65</sup> The main difference between generic and brand name pharmaceuticals is that generics are sold at steep discounts.<sup>66</sup> This makes treatments more affordable and therefore, more patients are able to receive the treatment they need.<sup>67</sup> “According to the Congressional Budget Office, generic drugs save consumers an estimated \$8 to \$10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics.”<sup>68</sup> However, generic drugs cannot be sold until the patent term of the brand-name drug expires.<sup>69</sup> This gives the inventing pharmaceutical company a chance to regain its investment and in turn encourages the development of future drugs by allowing the company to funnel the profit back into research.<sup>70</sup>

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act.<sup>71</sup> Also called the Hatch-Waxman Act, the statute was enacted to “balance between the interests of generic and pioneer drug companies.”<sup>72</sup> This balance is important as it continues to fulfill the policy of patent law by “encourag[ing] innovators to continue investing in the research and development of new drugs,” but also improves generic drug competition, which “lower[s] drug prices

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<sup>64</sup> *Id.*; 35 U.S.C. §154(a)(2) (2014).

<sup>65</sup> *Generic Drugs: Questions and Answers*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm> (last visited Aug. 16, 2016).

<sup>66</sup> *Id.*

<sup>67</sup> *See generally id.*

<sup>68</sup> *Id.*

<sup>69</sup> *Id.*

<sup>70</sup> *Id.*

<sup>71</sup> The Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360 (cc) (2000), 35 U.S.C. §§ 156, 271, 282 (2000)), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108173, 117 Stat. 2066 (2003).

<sup>72</sup> Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD DRUG L.J. 417, 417-18 (2011).

and consumer costs for drugs.”<sup>73</sup>

The Hatch-Waxman Act revised how new drugs are approved and added a mechanism that allowed for an Abbreviated New Drug Application (“ANDA”) for generic drugs manufacturers.<sup>74</sup> When manufacturers create new drugs, they must undergo a lengthy and costly process to gain approval from the FDA.<sup>75</sup> Under the ANDA process, generic manufacturers can streamline FDA approval by establishing that the generic they are creating is a “bioequivalent” to an already approved drug.<sup>76</sup> The ANDA must include the following information: “(1) the active ingredient of the generic drug is the same as that of the pioneer drug; (2) the generic drug has the same route of administration, dosage form and strength as the pioneer drug; and (3) the generic drug’s labeling must be [the] same as the labeling of the pioneer drug.”<sup>77</sup> Basically, the Hatch-Waxman Act creates a process that allows drug companies to quickly have their generics approved and on the market, thus benefitting consumers who previously were paying higher prices for name brand drugs.

Hatch-Waxman also contains a provision that extends patent terms for drugs that are subject to FDA approval before sale.<sup>78</sup> To qualify for the extension, the application must be filed within 60 days of FDA approval.<sup>79</sup> The patent term will be extended “by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued.”<sup>80</sup> The extension can be extended for a maximum of 5 years or an effective life post-FDA approval of 14 years, whichever is less.<sup>81</sup> In other words, if the effective life of a patent after FDA approval is 17 years, then the patent will not be extended.

Because patents grant the holder a limited monopoly, the price for

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<sup>73</sup> *Id.* at 417.

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

<sup>75</sup> *Id.* at 417, 426.

<sup>76</sup> *Id.* at 417.

<sup>77</sup> *Id.* at 423; *see also* 21 U.S.C. § 355(j) (2000).

<sup>78</sup> 35 U.S.C. § 156 (2014).

<sup>79</sup> 35 U.S.C. § 156(a)(1) (2014).

<sup>80</sup> 35 U.S.C. § 156(c) (2014).

<sup>81</sup> 35 U.S.C. 156(c)(3) (2014); *see also Small Business Assistance: Frequently Asked Questions on the Patent Term Restoration Program*, U.S. FOOD & DRUG ADMIN. (Apr. 22, 2015), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069959.htm>.

drugs can be steep.<sup>82</sup> Although a limited monopoly effectively encourages innovation by allowing companies to be rewarded, it is not necessarily in the best interests of public health. Patent terms last for 20 years from the filing date and how long the treatment is covered by the patent depends on how quickly the treatment reaches marketability.<sup>83</sup> Then, once the patent expires, generics can be made and sold.<sup>84</sup> After patent expiration, the Hatch-Waxman act cuts some time out of the FDA approval process by only requiring generic manufacturers to submit data that the generic is the “bioequivalent” to the brand-name drug.<sup>85</sup> Three patents protect Sovaldi.<sup>86</sup> The latest filing date was 2012.<sup>87</sup> This means Sovaldi may be capable of being made as a generic in 2032. Until then, patients have the choice between paying the exorbitant prices for novel treatments or receiving alternative forms of treatment.

*B. A multi-front battle—Gilead takes on Roche, Merck, and AbbVie*

**Table A: Key Players**

Key Players	Role
Gilead	Manufactures Sovaldi (sofosbuvir) and Harvoni (ledispavir). <sup>88</sup> Acquired Pharmasset in 2012. <sup>89</sup>
Pharmasset	Developed Sovaldi. <sup>90</sup> Purchased by Gilead. <sup>91</sup> Collaborated with Roche. <sup>92</sup>

<sup>82</sup> Kelly, *supra* note 72, at 463.

<sup>83</sup> *Small Business Assistance: Frequently Asked Questions on the Patent Term Restoration Program*, U.S. FOOD & DRUG ADMIN. (Apr. 22, 2014), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069959.htm>.

<sup>84</sup> *Id.*

<sup>85</sup> *Id.*

<sup>86</sup> *See* U.S. Patent No. 7,964,580 (filed Mar. 21, 2008); U.S. Patent No. 8,334,270 (filed May 3, 2011); U.S. Patent No. 8,580,765 (filed Sept. 11, 2012).

<sup>87</sup> *See supra* note 86, citations therein.

<sup>88</sup> *See* SOVALDI, *supra* note 41.

<sup>89</sup> Ed Silverman, *Hepatitis C Spurs Unusual Patent Wars Among Big Drug Makers*, WALL ST. J. (Jul. 21, 2014, 10:22 AM), <http://blogs.wsj.com/pharmalot/2014/07/21/hepatitis-c-spurs-unusual-patent-wars-among-big-drug-makers/> [hereinafter Silverman, *Hepatitis C Spurs*].

<sup>90</sup> *See id.*

<sup>91</sup> *See id.*

<sup>92</sup> *See* COOLEY, LLP, CASE IN POINT: F. HOFFMANN-LA ROCHE V. GILEAD SCIENCES, INC. (2014), <http://www.cooley.com/files/uploads/pages/case-in-point/pdf/cip-gilead.pdf>.

Roche	Collaborated with Pharmasset, which resulted in the production of “PSI-6130.” <sup>93</sup> Claims “PSI-6130” is a “prodrug” of Sovaldi. <sup>94</sup>
Merck	Holds patents for an active metabolite contained in sofosbuvir. <sup>95</sup>
AbbVie	Holds a patent for combining sofosbuvir and ledispavir. <sup>96</sup>

Usually pharmaceutical companies assert their patents to prevent other companies from manufacturing generic drugs before the patent term is over.<sup>97</sup> “The hepatitis-C battle is unusual because it pits branded drug maker against branded drug maker, in disputes more typical of smartphone manufacturers and other tech companies.”<sup>98</sup> Gilead is involved in legal disputes with Roche, Merck, and most significantly, AbbVie, as discussed below.

### 1. *Roche v. Gilead*

Roche claims it has rights to Sovaldi “thanks to a decade-old research collaboration with Pharmasset.”<sup>99</sup> Part of the agreement between the two companies was that Roche would have an exclusive license to “PSI-6130,” a drug developed collaboratively by Roche and Pharmasset.<sup>100</sup> Pharmasset then developed Sovaldi and subsequently was purchased in 2012 by Gilead for more than \$11 billion.<sup>101</sup> Because of the relationship between Pharmasset and Roche, Roche claims Gilead infringed its rights and Roche, therefore, deserves an exclusive license to the hepatitis C treatment.<sup>102</sup>

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

<sup>94</sup> *See id.*

<sup>95</sup> *See* Complaint, Gilead Scis., Inc. v. Merck & Co, Inc., 2013 WL 4813101 (N.D.Cal. 2013) (No. 3:13CV04057) [hereinafter Gilead Merck Complaint].

<sup>96</sup> *See* Complaint, AbbVie Inc., Gilead Scis., Inc., Case No. 1:14-cv-00379-GMS, 2014 WL 1313554 (D.Del. filed Mar. 25, 2014) (No. 13-2034) [hereinafter AbbVie Complaint].

<sup>97</sup> *See* FED. TRADE COMM’N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (2002), [https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy\\_0.pdf](https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf).

<sup>98</sup> Peter Loftus, *Lucrative Drug Niche Sparks Legal Scramble: Battle Escalates for Dominance in Treatments for Hepatitis C*, WALL ST. J. (Jul. 20, 2014, 7:17 PM), <http://online.wsj.com/articles/lucrative-drug-niche-sparks-legalscramble-1405898259>.

<sup>99</sup> Silverman, *Hepatitis C Spurs*, *supra* note 89.

<sup>100</sup> COOLEY, LLP, *supra* note 92.

<sup>101</sup> Silverman, *Hepatitis C Spurs*, *supra* note 89.

<sup>102</sup> *Id.*

The two parties went to arbitration, where Roche “asserted that sofosbuvir was a ‘prodrug’<sup>103</sup> of PSI-6130,” therefore entitling it to an exclusive license and that Sovaldi sales violated its patent rights.<sup>104</sup> The arbitration panel found for Gilead. Roche “failed to establish any of its claims to sofosbuvir, the key ingredient in Sovaldi, according to a filing from Gilead.”<sup>105</sup> In other words, Roche has no claim to Sovaldi. This is good news for Gilead, as analysts claim this was the most important of all the litigation because “Roche essentially claimed it had actual rights to the drug,”<sup>106</sup> as opposed to Merck, which claims the rights to an active metabolite contained in Sovaldi, as discussed below. “It was theoretically possible that Roche could get the rights to . . . Sovaldi which would be a huge loss and obviously was a major long-term, legal risk factor for [Gilead].”<sup>107</sup>

## 2. *Gilead v. Merck*

On August 30, 2013, Gilead filed a complaint seeking a declaratory judgment against Merck.<sup>108</sup> The judgment seeks a declaration of non-infringement and invalidity of Merck’s Patent Nos. 7,105,499 (“the ‘499 patent’”) and 8,481,712 (“the ‘712 patent’”).<sup>109</sup> Gilead filed the complaint after it received a phone call from a Merck employee requesting that the company purchase a license for the two patents.<sup>110</sup> Gilead then received a letter requesting the same.<sup>111</sup> The

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<sup>103</sup> A prodrug is “a precursor (forerunner) of a drug. A prodrug must undergo chemical conversion by metabolic processes before becoming an active pharmacological agent.” *Definition of Prodrug*, MEDICINENET, <http://www.medicinenet.com/script/main/art.asp?articlekey=23992> (last visited Aug. 18, 2016).

<sup>104</sup> COOLEY, LLP, *supra* note 92.

<sup>105</sup> Michael Calia, *Gilead Notches Win Over Roche in Hepatitis C Rights Dispute: Arbitration Panel Rules for Gilead Sciences Regarding Claims on Key Sovaldi Ingredient*, WALL ST. J. (Aug. 15, 2014, 10:08 AM), <http://online.wsj.com/articles/gilead-notches-victory-over-roche-in-hepatitis-c-drug-race-1408100076>.

<sup>106</sup> Linda Nguyen, *Gilead shoves off Roche’s claim on Sovaldi hep C drug*, TECH TIMES (Aug. 15, 2014, 4:04 PM), <http://www.techtimes.com/articles/13160/20140815/gilead-shoves-off-roche-s-claim-on-sovaldi-hep-c-drug.htm#ixzz3HIAYbCNz>.

<sup>107</sup> *Id.*

<sup>108</sup> See generally Thomas Long, *Merck’s misconduct against Gilead made hepatitis drug patents unenforceable; \$200M verdict tossed*, WOLTERS KLUWER INTELL. PROP. L. DAILY (Jun. 7, 2016), [http://www.dailyreportingsuite.com/ip/news/merck\\_s\\_misconduct\\_against\\_gilead\\_made\\_hepatitis\\_drug\\_patents\\_unenforceable\\_200m\\_verdict\\_tossed](http://www.dailyreportingsuite.com/ip/news/merck_s_misconduct_against_gilead_made_hepatitis_drug_patents_unenforceable_200m_verdict_tossed).

<sup>109</sup> Gilead Merck Complaint, *supra* note 95, at 15.

<sup>110</sup> *Id.*

<sup>111</sup> *Id.*

two patents in question are held by Merck and are titled “Nucleoside Derivatives as Inhibitors of RNA-Dependent RNA Viral Polymerase.”<sup>112</sup> These patents do not claim the underlying compound in Sovaldi (sofosbuvir); rather, they claim an active metabolite contained in sofosbuvir.<sup>113</sup>

Merck claimed sofosbuvir reads on its two patents and therefore, demanded 10% in royalty fees on all products containing sofosbuvir.<sup>114</sup> This would mean Gilead would have to pay 10% royalty fees on both Sovaldi and Harvoni if sofosbuvir were found to infringe Merck’s patents. A claim construction hearing was scheduled for April 3rd, 2015 to determine meanings of “administering,” “compound,” and “in combination with.”<sup>115</sup> The two parties eventually agreed on the construction of “in combination with” and “compound.”<sup>116</sup> They only disputed the meaning of “administering.”<sup>117</sup>

The parties determined that “in combination with” means “‘together with,’ whether given separately at different times during the course of therapy or concurrently in divided or single combination forms.”<sup>118</sup> They also determined that “compound” means “a substance that consists of two or more chemical elements in union.”<sup>119</sup> The court then adopted Merck’s interpretation of “administering,” which means “providing a compound of the invention or a prodrug of a compound of the invention to the individual in need.”<sup>120</sup> By rejecting Gilead’s definition of “administering,” the court declined to read two limitations proposed by Gilead into the claim construction.<sup>121</sup> On May 18, 2015, the court granted a joint stipulation to extend discovery through mid-June 2015.<sup>122</sup> In March 2015, a federal jury found Gilead had infringed

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<sup>112</sup> *Id.* at 16, 20.

<sup>113</sup> *Gilead Sciences: Clear the Docket and Settle with Merck Already*, SEEKING ALPHA (Oct. 21, 2014), <http://seekingalpha.com/article/2578465-gilead-sciences-clear-the-dockets-and-settle-with-merck-already> [hereinafter *Gilead Sciences: Clear the Docket*].

<sup>114</sup> *Id.*; see also *Gilead Merck Complaint*, *supra* note 95, at 53.

<sup>115</sup> *Gilead Sciences: Clear the Docket*, *supra* note 113.

<sup>116</sup> *Gilead Scis., Inc. v. Merck & Co, Inc.*, No. 13-CV-04057-BLF, 2015 WL 2062575, 2 (N.D. Cal. May 1, 2015) (Order Construing Claims).

<sup>117</sup> *Id.* at 1.

<sup>118</sup> *Id.* at 2.

<sup>119</sup> *Id.* at 2-3.

<sup>120</sup> *Id.* at 6.

<sup>121</sup> *Id.*

<sup>122</sup> *Gilead Scis., Inc. v. Merck*, Case No. 5:13-cv-04057-BLF, (N.D. Cal.) (May 18, 2015) (Joint Stipulation and Proposed Order).

Merck's patents.<sup>123</sup> Merck was awarded \$200 million in damages.<sup>124</sup> A judge subsequently overturned the jury's damages award after finding "Merck engaged in misconduct in its efforts to obtain patents for hepatitis C drugs."<sup>125</sup>

### 3. *Gilead v. AbbVie*

On December 18, 2013, Gilead sued AbbVie and its parent company, Abbott Laboratories, claiming "[AbbVie] falsely and knowingly represented to the United States Patent and Trademark Office ("PTO") that they invented highly valuable methods of treating [hepatitis C] that were, in fact, invented by . . . Gilead."<sup>126</sup> AbbVie responded by filing its own lawsuit, claiming Gilead was focusing on profits to recover what it paid to acquire another pharmaceutical company.<sup>127</sup> In its complaint, Gilead claims its primary reason for acquiring Pharmasset was to create a combination drug therapy using Pharmasset's sofosbuvir and Gilead's independently created ledipasvir.<sup>128</sup>

Since 2012, Abbott Laboratories has applied for numerous patents, which have since been issued.<sup>129</sup> The two relevant patents in this lawsuit are Patent Nos. 8,466,159 (the '159 patent) and 8,492,386 (the '386 patent), which were issued on June 18 and July 23, 2013, respectively.<sup>130</sup> These patents claim AbbVie invented a method for treating hepatitis C by combining sofosbuvir and ledipasvir.<sup>131</sup> Gilead disputes this patent claim, stating it was the inventor of the combination therapy.<sup>132</sup>

Although AbbVie may hold the patent for the combination

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<sup>123</sup> Rory Carroll and Andrew Chung, *Gilead ordered to pay Merck \$200 million in hepatitis C drug patent dispute*, REUTERS (Mar. 24, 2016, 9:58 PM), <http://www.reuters.com/article/us-gilead-sciences-merck-co-damages-idUSKCN0WR00V>.

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

<sup>125</sup> Peter Loftus, Judge sides with Gilead against Merck in case over hepatitis C drug patents, WALL STREET JOURNAL (June 7, 2016, 9:04 PM), <http://www.wsj.com/articles/judge-sides-with-gilead-against-merck-in-case-over-hepatitis-c-drug-patents-1465331073>.

<sup>126</sup> Complaint at 1, *Gilead Scis., Inc. v. Abbott Labs., Inc.*, No. CV 13-2034-GMS, 2015 WL 1191129 (D. Del. Mar. 13, 2015) [hereinafter *Gilead Complaint*].

<sup>127</sup> *AbbVie Complaint*, *supra* note 96, at 40, 47; Loftus, *supra* note 98.

<sup>128</sup> *Gilead Complaint*, *supra* note 126, at 4.

<sup>129</sup> See U.S. Patent No. 8,466,159 (filed Sept. 4, 2012); U.S. Patent No. 8,492,386 (filed Sept. 4, 2012).

<sup>130</sup> *Gilead Complaint*, *supra* note 126, at 6.

<sup>131</sup> *Id.* at 16.

<sup>132</sup> *Id.* at 6.

drug,<sup>133</sup> it cannot lawfully “make, use or sell the Gilead Combination.”<sup>134</sup> This is because the two underlying compounds claimed in AbbVie’s patents are patented by Gilead.<sup>135</sup> Although Gilead’s patents protect the underlying compounds, AbbVie’s patent recites a “method of use” claim.<sup>136</sup>

A method of use claim, also known as a process claim, is “a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.”<sup>137</sup> In other words, a method claim is the directions on how to make something. In this case, Gilead’s compounds are the ingredients in AbbVie’s recipe for creating other combination therapies.<sup>138</sup> Thus, AbbVie is stating how to use Gilead’s patented compounds in another way.

If AbbVie’s patent is upheld, all AbbVie would gain from asserting its patent against Gilead is royalty payments.<sup>139</sup> AbbVie has no legal right to the two underlying compounds, therefore it cannot assert its patent and enter the market with its own combination drug using sofosbuvir and ledipasvir until Gilead’s patent terms expire. Thus, AbbVie is effectively acting like a “patent troll.”<sup>140</sup> This is reflected in the complaint’s accusation that “[AbbVie’s] patenting activity for [sofosbuvir-containing] therapies has only one potential purpose—to enforce them against the Gilead Combination or future Gilead combinations, either to attempt to block them from the market or to extract royalties from Gilead.”<sup>141</sup>

Interestingly, AbbVie is producing its own hepatitis C combination drug.<sup>142</sup> AbbVie claims the development of this new drug

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<sup>133</sup> See AbbVie Complaint, *supra* note 96, at 4.

<sup>134</sup> Gilead Complaint, *supra* note 126, at 6.

<sup>135</sup> *Id.* Three patents protect Sovaldi (sofosbuvir): Nos. 7,964,580, 8,334,270, and 8,580,765. Patents Nos. 8,088,368, 8,273,341, and 8,575,118 protect ledipasvir.

<sup>136</sup> See AbbVie Complaint, *supra* note 96, at 1, 4.

<sup>137</sup> *Cochrane v. Deener*, 94 U.S. 780, 788 (1876).

<sup>138</sup> *Gilead Sciences Gets Ambushed By The Patent Troll*, AbbVie, SEEKING ALPHA (Nov. 12, 2014), <http://seekingalpha.com/article/2674915-gilead-sciences-gets-ambushed-by-the-patent-troll-abbvie> (explaining that AbbVie does not own patents for the underlying compounds in Harvoni and instead owns patents for combining the two underlying compounds).

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

<sup>140</sup> See generally Mark A. Lemley & A. Douglas Melamed, *Missing the Forest for the Trolls*, 113 COLUM. L. REV. 2117, 2118 (2013) (explaining that patent trolls are entities that hold patents solely to collect payments from others who allegedly infringe their patents. These entities do not assert their patents in the marketplace.)

<sup>141</sup> Gilead Complaint, *supra* note 126, at 20.

<sup>142</sup> AbbVie Complaint, *supra* note 96, at 13.

is the reason why it filed for the combination patents.<sup>143</sup> The FDA approved the treatment, Viekira Pak, in late 2014.<sup>144</sup> Gilead argues AbbVie's drug will be inferior to its combination drug and therefore, the company is trying to eclipse the market.<sup>145</sup> "The ultimate goal for Abbott had nothing to do with the advancement of science or the welfare of individuals afflicted with [hepatitis C]."<sup>146</sup>

AbbVie merely wants a share of the money. Because AbbVie's patent would effectively block Gilead from producing its combination drug (Harvoni), it would "make it commercially unfeasible for [AbbVie's] competitors to continue to develop, test clinically, obtain regulatory approval for, and eventually market and sell their own combination drug therapies."<sup>147</sup> AbbVie's patents not only block Gilead from distributing its combination drug, it also would block other hepatitis C combination drugs not yet invented because Abbott's patent claims cover "potentially thousands" of combinations.<sup>148</sup>

Recently, Gilead has filed another declaratory judgment against AbbVie, which alleges that AbbVie's newly-issued 9,034,832 ("the '832 patent") is invalid because it covers a component of Harvoni.<sup>149</sup> The lawsuits have all been consolidated.<sup>150</sup> A trial has been scheduled for July 31, 2017.<sup>151</sup>

#### IV. Price Concerns

*"Everybody is trying to figure out how best to deliver needed treatments without blowing out resources because of the cost." - Brendan Buck, spokesman for America's Health Insurance Plans.<sup>152</sup>*

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<sup>143</sup> Gilead Complaint, *supra* note 126, at 20.

<sup>144</sup> *FDA approves Viekira Pak to treat hepatitis C*, FDA (Dec. 19, 2014), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm427530.htm>.

<sup>145</sup> Gilead Complaint, *supra* note 126, at 93.

<sup>146</sup> Gilead Complaint, *supra* note 126, at 93.

<sup>147</sup> *Id.* at 95.

<sup>148</sup> *Id.* at 98.

<sup>149</sup> Complaint for Declaratory Judgment, *Gilead Scis., Inc. v. AbbVie, Inc.*, Case 1:15-cv-00399-GMS (2015) [hereinafter Declaratory Judgment].

<sup>150</sup> *Id.* *Gilead Sciences, Inc. v. AbbVie Inc.*, Civil Action Nos. 13-cv-2034-GSM, 14-cv-209-GMS, and 14-379-GMS (consolidated).

<sup>151</sup> [Joint Proposed] Scheduling Order, Case 1:15-cv-00399-GMS, Doc 19 (2015).

<sup>152</sup> Michelle Andrews, *Insurers may Cover Costly Hepatitis C Drugs Only for the Very Ill*, NPR SHOTS (Oct. 28, 2014, 11:20 AM), <http://www.npr.org/blogs/health/2014/10/28/359553282/insurers-may-cover-costly-hepatitis-c-drugs-only-for-the-very-ill>. "AHIP has been an outspoken critic of high prices for specialty drugs, including those for hepatitis."

At \$1,000 and \$1,125 a pill, Sovaldi and Harvoni, respectively, are sure to make a dent in the patient's pocket.<sup>153</sup> The \$84,000 treatment “would buy a Maserati SQ4 (with \$10K in change) or a double-wide mobile home, or feed a thrifty family of four for 11 years.”<sup>154</sup> The \$84,000 price tag is only for the shortest treatment.<sup>155</sup> Patients who require longer treatments will pay over \$100,000.<sup>156</sup> These miracle drugs have the ability to cure hepatitis C patients, prevent a slow death,<sup>157</sup> and stop the transmittable disease in its tracks, but only if consumers and taxpayers are willing to pay the price.

Although these treatments are expensive, six-figure pharmaceuticals are not unusual.<sup>158</sup> Drugs that treat rare diseases also come at a high price. These drugs are known as “orphan drugs.”<sup>159</sup> For example, a drug called Vimizim (elosulfase alfa), made by BioMarin Pharmaceutical, costs \$380,000 a year.<sup>160</sup> The drug is an enzyme replacement therapy for Morquio A syndrome, which is a rare metabolic disease “estimated to occur in one of every 200,000 births.”<sup>161</sup> Unlike Morquio A syndrome, hepatitis C is not a rare disease. “Sovaldi is priced at an orphan drug price for a population that is not an orphan drug population. So it's priced really at a premium that we can't sustain.”<sup>162</sup>

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<sup>153</sup> Millman, *supra* note 48. *Ledipasvir-Sofosbuvir (Harvoni)*, *supra* note 52.

<sup>154</sup> Terry J. Allen, *The Pandemic We Are Ignoring: A Possible Cure for Hep-C Comes at Great Cost to the Sick*, IN THESE TIMES (Oct. 14, 2014), [http://inthesetimes.com/article/17249/hep\\_c\\_profit\\_tier\\_pricing](http://inthesetimes.com/article/17249/hep_c_profit_tier_pricing).

<sup>155</sup> *Id.*; *Sovaldi Study Results*, *supra* note 43.

<sup>156</sup> See *Sovaldi Study Results*, *supra* note 43 (stating some patients taking Sovaldi will require a 24-week treatment).

<sup>157</sup> Allen, *supra* note 154.

<sup>158</sup> See generally Alex Philippidis, *The High Cost of Rare Disease Drugs: Six-figure treatment prices continue to climb for orphan therapeutics*, GEN EXCLUSIVES (Mar. 4, 2014), <http://www.genengnews.com/insight-and-intelligence/the-high-cost-of-rare-disease-drugs/77900055/> (discussing the high price of drugs that treat rare diseases).

<sup>159</sup> Sheena Harrison, *New Hepatitis C drug Sovaldi raises workers compensation costs concerns*, BUS. INSURANCE (Dec. 21, 2014), <http://www.businessinsurance.com/article/20141221/NEWS08/312219988/new-hepatitis-c-drug-sovaldi-raises-workers-compensation-cost?tags=%7C74%7C79%7C92%7C304>.

<sup>160</sup> Tracy Staton, *BioMarin's \$380K price tag on Vimizim is high, but far from the highest*, FIERCEPHARMA (Feb. 20, 2014, 6:35 AM) <http://www.fiercepharma.com/sales-and-marketing/biomarin-s-380k-price-tag-on-vimizim-high-but-far-from-highest>.

<sup>161</sup> *Mucopolysaccharidoses Fact Sheet*, NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE, [http://www.ninds.nih.gov/disorders/mucopolysaccharidoses/detail\\_mucopolysaccharidoses.htm](http://www.ninds.nih.gov/disorders/mucopolysaccharidoses/detail_mucopolysaccharidoses.htm) (last modified Feb. 23, 2016).

<sup>162</sup> Harrison, *supra* note 159 (quoting Brigette Nelson, senior vice president of worker's compensation clinical management for Express Scripts).

*A. The Prison Problem*

Treating hepatitis C in a cost-effective manner is a particularly large concern in prisons. “Nationwide, at least half a million inmates have chronic hepatitis C — and the net costs of treating them all with Sovaldi could exceed \$30 billion.”<sup>163</sup> In California alone, there are 17,405 prisoners with hepatitis C.<sup>164</sup>

Although nearly 20,000 inmates in California have hepatitis C, only 162 prisoners in California have received or are currently receiving Sovaldi.<sup>165</sup> Interestingly, a recent study found sofosbuvir-based treatments like Sovaldi and Harvoni are cost-effective for correctional institutions.<sup>166</sup> This is because these treatments are highly effective when compared to the previous hepatitis C treatments, as well as shorter in duration.<sup>167</sup> Although the researchers concluded the treatment was cost-effective, they were careful to note affordability may still be a problem.<sup>168</sup>

Affordability has become an issue for correctional systems. One example is corrections in San Francisco where the city only has \$2.3 million to pay for all necessary medication for its inmates.<sup>169</sup> To cover the 108 inmates in San Francisco infected with hepatitis C, the city would need 4.5 times that amount of money.<sup>170</sup> Therefore, most prisoners are denied a “safe, effective therapy” because the treatment is simply too expensive.<sup>171</sup>

This presents a problem for prison wardens, as the government is required to provide medical care for prisoners who need it or run the risk of inflicting unnecessary pain, which would constitute cruel and unusual punishment.<sup>172</sup> Inmates are forced to “rely on prison

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<sup>163</sup> Stephanie M. Lee & Joe Garofoli, *Prisons balk at Sovaldi's \$84,000 cost for hepatitis C treatment*, SFGATE (Oct. 20, 2014, 8:54 PM), <http://www.sfgate.com/health/article/Prisons-balk-at-Sovaldi-s-84-000-cost-for-5835860.php>.

<sup>164</sup> *Id.*

<sup>165</sup> *Id.*

<sup>166</sup> Shan Liu et al., *Sofosbuvir-Based Treatment Regimens for Chronic, Genotype 1 Hepatitis C Virus Infection in U.S. Incarcerated Populations: A Cost-Effectiveness Analysis*, 161 ANNALS INTERNAL MED. 546 *passim* (2014) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4313741/pdf/nihms656648.pdf>

<sup>167</sup> *Id. passim.*

<sup>168</sup> *Id. passim.*

<sup>169</sup> Lee & Garofoli, *supra* note 163.

<sup>170</sup> *Id.*

<sup>171</sup> *Id.*

<sup>172</sup> See *Estelle v. Gamble*, 429 U.S. 97, 104 (1976) (holding “deliberate indifference to serious medical needs of prisoners constitutes the ‘unnecessary and wanton infliction of pain,’

authorities to treat [their] medical needs; if the authorities fail to do so, those needs will not be met. In the worst cases, such a failure may actually produce physical ‘torture or a lingering death.’”<sup>173</sup> Patients with the worst cases of hepatitis C potentially face death if they are not treated.<sup>174</sup> Therefore, the patients in prison not receiving the care they need for Hepatitis C could find themselves subject to cruel and unusual punishment.

Clearly, hepatitis C treatment is needed in the correctional system, as adequate medical treatment is required by the Eighth Amendment.<sup>175</sup> However, the high price of the drugs acts as a bar to inmates receiving the drugs they need to be cured. Treating the prison population is only one part of the problem created by the high cost. Patients requiring treatment also encounter difficulty receiving the medications under Medicare, Medicaid, and other forms of insurance.

#### *B. Medicare, Medicaid, and Private Insurers*

Doctors want to prescribe Sovaldi for their patients.<sup>176</sup> The problem is Medicaid and private insurance companies do not want to pay for it.<sup>177</sup> Insurers are taking measures to limit their coverage.<sup>178</sup> For example, some insurers are limiting coverage to patients whose doctors are either hepatologists or gastroenterologists.<sup>179</sup> Doctors who specialize in HIV (which is commonly transmitted with hepatitis C) treatment and infectious disease doctors have found themselves prohibited from being able to prescribe the hepatitis C miracle drugs for their patients because insurance companies do not want to pay the high price.<sup>180</sup>

Finding a doctor to prescribe the hepatitis C treatments under

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proscribed by the Eighth Amendment.”).

<sup>173</sup> *Id.* at 103.

<sup>174</sup> See *Hepatitis C FAQs*, *supra* note 4 (explaining that hepatitis C can lead to liver cancer).

<sup>175</sup> See *Estelle v. Gamble*, *supra* note 172.

<sup>176</sup> David Heitz, *Doctors Battle Insurers for Access to Pricy Hepatitis C Drugs*, HEALTHLINE (Sept. 5, 2014), <http://www.healthline.com/health-news/doctors-battle-insurers-for-hep-c-drugs-090514#1> (stating that HIV and infectious disease doctors say they’ve been treating people with hepatitis C and should be given leeway to prescribe the new drug Sovaldi).

<sup>177</sup> *Id.* (explaining that insurance companies . . . keep [doctors] from prescribing lifesaving hepatitis C medications).

<sup>178</sup> *Id.*

<sup>179</sup> *Id.*

<sup>180</sup> *Id.*

insurance is only half the battle for patients. Both public and private insurance companies have also been restricting who can receive the pricey drugs.<sup>181</sup> Some have only agreed to cover the drugs for those who already have significant liver damage.<sup>182</sup> This decision was based on a practice guideline issued by the American Association for the Study of Liver Disease.<sup>183</sup> This creates a problem because early treatment prevents patients from becoming sicker, as hepatitis C can progress to cirrhosis of the liver or liver cancer.<sup>184</sup> The sicker the patient, the more likely the length of the treatment will be longer than the minimum. Although it may be rational to treat those who are the sickest first, refusing treatment to those who are not as ill may cost more in the long run, due to the potentially longer duration of treatment.<sup>185</sup>

Even if a patient has found an insurance-approved doctor to prescribe the medicine and has sufficient liver damage, there are still potential barriers to the patient receiving full treatment. Some insurance companies require “early proof the drug is working before continuing with treatment.”<sup>186</sup> This means insurers could drop a patient’s treatment coverage if early test results do not show he is recovering, even if there is a strong likelihood of recovery upon completion of treatment.

Medicaid programs have a larger problem than private insurers, as they cover a disproportionate amount of patients with hepatitis C.<sup>187</sup> A study shows that “more than 750,000 Americans with chronic hepatitis C receive state-funded health care through Medicaid or the prison system.”<sup>188</sup> The high number of Medicaid patients with hepatitis C,

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<sup>181</sup> Andrews, *supra* note 152.

<sup>182</sup> *Id.*

<sup>183</sup> *Id.*; see generally *Recommendations for Testing, Managing, and Treating Hepatitis C*, AM. ASS’N. FOR THE STUDY OF LIVER DISEASE, <http://www.hcvguidelines.org/> (last visited Sept. 15, 2016).

<sup>184</sup> *Id.*

<sup>185</sup> For example, patients with genotype 3 of hepatitis C will require a 24 week treatment period of Sovaldi. Genotype 3 is known to cause liver disease to develop more rapidly than other genotypes. Genotype 1 is the most common form. See *Sovaldi Study Results*, *supra* note 43; Rob Volansky, *The Challenge of Genotype 3*, HEALIO (Sept. 2014), <http://www.healio.com/infectious-disease/hepatitis-c/news/print/hcv-next/%7Bb54ab60b-f456-4fa8-b7e8-d448c1fe6c76%7D/the-challenge-of-genotype-3>.

<sup>186</sup> Andrews, *supra* note 152.

<sup>187</sup> Chris Kardish, *The Risky Business of Limiting Medicaid Access to Sovaldi*, GOVERNING (Aug. 19, 2014), <http://www.governing.com/topics/health-human-services/gov-hepatitis-coverage-solvaldi-lawsuits.html>.

<sup>188</sup> Steve Miller, *State governments may spend \$55 billion on hepatitis C medications*,

creates a significant issue with providing coverage for those who need it. “A rough estimate indicates that Sovaldi, if dispensed to all Medicaid enrollees and prisoners with Hepatitis C, could result in a 3% to 5% increase in total state government expenditures.”<sup>189</sup> State Medicaid programs do have one price advantage—they are entitled to a standard 23% discount on all FDA-approved prescription drugs,<sup>190</sup> as mandated by the federal Omnibus Budget Reconciliation Act of 1990.<sup>191</sup> However, because the price is steep to begin with, the price after the discount still presents a problem.

To solve this quandary, states are creating a variety of policies to restrict who can receive coverage through Medicaid. The Center for Evidence-based Policy assessed 35 state policies and found only seven have no restrictions on coverage.<sup>192</sup> Like private insurers, states have restricted Sovaldi prescriptions to those with severe hepatitis C, early treatment success, and/or a prescription from approved doctors. Additionally, 22 states require substance abuse treatment or sobriety before patients can receive the treatment.<sup>193</sup> These restrictions are problematic for patients attempting to receive the treatment they need to survive. Legal experts, advocates for hepatitis C patients, and policy analysts predict lawsuits will come, as patients fight for coverage for these medications.<sup>194</sup>

*1. Southeastern Pennsylvania Transportation Authority  
(SEPTA) v. Gilead Pharmaceuticals*

In fact, the Southeastern Pennsylvania Transportation Authority (SEPTA) has recently filed a complaint against Gilead.<sup>195</sup> Since 2014,

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THE LAB (July 17, 2014), [http://lab.express-scripts.com/insights/specialty-medications/state-governments-may-spend-\\$55-billion-on-hepatitis-c-medications](http://lab.express-scripts.com/insights/specialty-medications/state-governments-may-spend-$55-billion-on-hepatitis-c-medications).

<sup>189</sup> Christopher F. Koller, *Sovaldi Redux—The States Muddle Through*, <http://www.milbank.org/the-view-from-here/sovaldi-redux-the-states-muddle-through> (last visited Sept. 15, 2016).

<sup>190</sup> *Id.*

<sup>191</sup> Michael Ollove, *How Some State Medicaid Programs Limit Drugs to Only the Sickest Patients*, GOVERNING (Oct. 6, 2014), <http://www.governing.com/topics/health-human-services/how-some-state-medicare-programs-limit-drugs-to-only-sickest-patients.html>.

<sup>192</sup> *Id.*

<sup>193</sup> *Id.*

<sup>194</sup> Kardish, *supra* note 187.

<sup>195</sup> Class Action Complaint, *Southeastern Pennsylvania Transportation Authority v. Gilead Sciences*, No. 2:14-cv-06978 (E.D. Pa. 2014) [hereinafter Patent Abuse Lawsuit]; Jason Millman, *A new lawsuit claims \$84,000 is way too much for this lifesaving drug*, WASH. POST (Dec. 11, 2014), <http://www.washingtonpost.com/blogs/wonkblog/wp/2014/12/11/a-new->

SEPTA has paid more than \$2.9 million for Sovaldi prescriptions for its employees.<sup>196</sup> The complaint alleges “Gilead is abusing its rights as a patent holder ‘by charging discriminatory prices that apparently have no other rational basis other than to inflate the company’s bottom line.’”<sup>197</sup> SEPTA argues that Gilead is engaging in “price gouging” or taking advantage of its monopoly under the patent system and charging an excessive amount for the hepatitis C drugs. The complaint references the lower prices paid for the drugs in other countries and questions why the United States must continue to pay a much steeper price, arguing there is no reason to price gouge the drugs than to “inflate the bottom line.”<sup>198</sup>

The plaintiff’s (SEPTA) main argument claims patent law does not justify the exorbitant price. Just because a patent grants the holder a limited monopoly, it does not mean the patent allows the holder to price the consumer out of the market.<sup>199</sup> Additionally, the plaintiff notes that Gilead’s patents may not even be valid.<sup>200</sup> As previously discussed, there are numerous lawsuits challenging the validity of the Sovaldi patents.<sup>201</sup> The complaint argues that because Gilead’s patents may not even be valid, there is no reason to allow it to continue to sell Sovaldi and Harvoni at such a high cost.<sup>202</sup> Additionally, even if the patents are valid, the plaintiffs claim that the price gouging is so extreme that it results in an unjust enrichment to the pharmaceutical company at the expense of the consumer.<sup>203</sup>

Although the plaintiff tried to get redress for individual patients, the court ultimately denied the plaintiff’s efforts. The court stated, “Access to needed pharmaceuticals is uneven, and there is no shortage of discontent with this status quo. But nothing in the [plaintiff’s complaint] permits redress of plaintiffs’ particular grievances in federal court.”<sup>204</sup> A similar lawsuit has been filed in Europe, also arguing that

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lawsuit-claims-84000-is-way-too-much-for-this-lifesaving-drug/ [hereinafter Millman, *A new lawsuit*].

<sup>196</sup> Patent Abuse Lawsuit, *supra* note 195, at 8; Harrison, *supra* note 159.

<sup>197</sup> Millman, *A new lawsuit*, *supra* note 195.

<sup>198</sup> Patent Abuse Lawsuit, *supra* note 195, at 3, 6. SEPTA brings a number of claims, including unjust enrichment and violations of antitrust laws, among others.

<sup>199</sup> *See id.* at 3 (discussing how the alleged price gouging has priced consumers out of the market).

<sup>200</sup> *Id.* at 33.

<sup>201</sup> *See* section III.b., *supra*.

<sup>202</sup> *See* Patent Abuse Lawsuit, *supra* note 195.

<sup>203</sup> *Id.*

<sup>204</sup> *Id.* at 26-27.

Gilead is abusing its patent and charging too much for the treatment.<sup>205</sup>

### C. Worker's Compensation

Employers may face payment for hepatitis C under worker's compensation claims. "Healthcare workers, emergency first responders, and other workers who are regularly exposed to body fluids are most likely to file for workers comp[ensation] benefits related to hepatitis C."<sup>206</sup> Workers who are exposed to bodily fluids are encouraged to be tested.<sup>207</sup> If the test is positive and exposure can be linked to the workplace, employees have grounds to file a worker's compensation claim.<sup>208</sup> Employers must pay for hepatitis C treatments for successful worker's compensation claims, which can be costly. "[S]pending for hepatitis C medications in worker's comp[ensation] increased 135% in the first six months of 2014[,] compared with the same period in 2013. About 66% of that increase is attributed to Sovaldi prescriptions."<sup>209</sup> The number of worker's compensation claims for hepatitis C at Express Scripts, a pharmacy benefit manager, fell from 92 at the beginning of 2013 to 79 at the beginning of 2014.<sup>210</sup> Despite the decrease in prescriptions, the price soared dramatically.<sup>211</sup>

## V. Trying to Find a Solution

### A. Prescription Providers

Gilead has been striking exclusive deals with various prescription providers, including CVS/Caremark.<sup>212</sup> These exclusive deals give Gilead's treatments "either preferred or exclusive formulary status."<sup>213</sup>

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<sup>205</sup> Ed Silverman, *Gilead faces Sovaldi patent challenge in Europe by a non-profit group*, WALL STREET J. (Feb. 10, 2015, 10:13 AM), <http://blogs.wsj.com/pharmalot/2015/02/10/gilead-faces-sovaldi-patent-challenge-in-europe-by-a-non-profit-group/>.

<sup>206</sup> Harrison, *supra* note 159.

<sup>207</sup> CAL. DEP'T. OF HEALTH SERV., WORKPLACE EXPOSURE TO HEPATITIS C (1998), <http://www.cdph.ca.gov/programs/hesis/Documents/hcv.pdf>.

<sup>208</sup> *Id.*

<sup>209</sup> Harrison, *supra* note 159.

<sup>210</sup> *Id.*

<sup>211</sup> *Id.*

<sup>212</sup> Meg Tirrell, *Gilead fights back: CVS to cover its hepatitis C drugs exclusively*, CNBC (Jan. 5, 2015), <http://www.cnbc.com/id/102310444>.

<sup>213</sup> Ed Silverman, *The Hepatitis C Scorecard: Gilead is trouncing AbbVie, but at a price*, WALL STREET J. (Feb. 12, 2015), <http://blogs.wsj.com/pharmalot/2015/02/12/the-hepatitis-c-scorecard-gilead-is-trouncing-abbvie-but-at-a-price/> [hereinafter *HCV Scorecard*].

A formulary is a list of both generic and brand name prescription drugs that are preferred by a health plan.<sup>214</sup> In other words, hepatitis C patients on prescription plans covered by CVS/Caremark will only have coverage for Sovaldi and Harvoni.<sup>215</sup> Even if the patient's doctors opt to prescribe an alternative treatment for hepatitis C, such as AbbVie's product, the pharmacy's prescription plans may only cover Gilead's treatments.<sup>216</sup> Ultimately, a patient may pay more if his plan does not cover the drug of the doctor's choice.

Interestingly, Express Scripts has struck a deal with AbbVie to exclusively cover its treatment, Viekira Pak.<sup>217</sup> Express Scripts is the largest U.S. pharmacy benefit manager, covering drugs for 25 million Americans. Express Scripts negotiated a "significant discount" for Express Script's formulary.<sup>218</sup> AbbVie's product has a list price of \$83,319—a high price, but still less costly than Gilead's treatments.

Although Express Scripts is able to provide its prescribers with a cheaper, alternative treatment for hepatitis C, it is questionable whether the treatment is better overall. In fact, some analysts have questioned Express Scripts decision because the AbbVie treatment requires multiple pills per day, while Harvoni is merely one.<sup>219</sup> Thus, AbbVie's treatment is inferior, at least in terms of ease of use.

These exclusive deals lower consumer ability to make the best choice for treatment, while minimizing cost. The exclusive deals do, however, offer an opportunity for the prescription plan providers to offer the life saving treatments at a lower rate than market price. At this time, it is unclear whether Gilead and CVS were able to strike a deal in which CVS would provide Sovaldi and Harvoni to its customers at a discount.<sup>220</sup> Patents give pharmaceutical companies great leverage in negotiating these deals. However, the public will only benefit from a lowered price if the companies are willing to negotiate. Because the patent holder has great power to charge a price for its highly coveted product, the public is unlikely to benefit unless excessive profit motive

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<sup>214</sup> Michael Bihari, *Understanding your health plan drug formulary—Drug formulary: what you need to know*, ABOUT HEALTH (Dec. 29, 2014), [http://healthinsurance.about.com/od/prescriptiondrugs/a/understanding\\_formulary.htm](http://healthinsurance.about.com/od/prescriptiondrugs/a/understanding_formulary.htm).

<sup>215</sup> *See id.* "Your health plan may only pay for medications that are on this 'preferred' list."

<sup>216</sup> *Id.*

<sup>217</sup> Tirrell, *supra* note 212.

<sup>218</sup> *Id.*

<sup>219</sup> *HCV Scorecard*, *supra* note 213.

<sup>220</sup> Tirrell, *supra* note 212.

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### *B. Price Negotiations*

Governmental price negotiations could alleviate cost for Medicare. Currently, federal law bans negotiations between Medicare and pharmaceutical companies over how much Medicare will pay for its product.<sup>221</sup> However, President Obama has proposed federal negotiations with pharmaceutical companies for the most expensive drugs.<sup>222</sup> This proposal is nothing new—liberals have been arguing that Medicare should be able to negotiate prices for all prescription drugs, like private insurance providers can.<sup>223</sup> This plan is sure to alienate the pharmaceutical industry. The negotiations may have the effect of lowering the price and therefore, cutting into the research budget,<sup>224</sup> thus affecting the ability of companies to invest in new treatments. Additionally, “[c]ritics, including Republicans, say price ‘negotiations’ would actually turn into price controls, given Medicare’s purchasing power. . . .”<sup>225</sup> Economic studies show that price controls would only result in a short term benefit to consumers. In the long run, consumers would be negatively impacted because there would be fewer new drugs on the market. And because it takes a long time to develop and approve a new drug, the long-term effects would not be “fully felt for several decades.”<sup>226</sup>

While the United States remains conflicted over the proper way to balance how to pay the high price for these miracle drugs against the necessity of patients receiving the treatment, other countries have taken initiative to combat the high prices by enacting price controls or developing licensing agreements with the pharmaceutical companies.

#### *1. French Price Controls & US Lack Thereof*

In France, Gilead has agreed to sell Sovaldi “at the lowest price in

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<sup>221</sup> Sam Baker, *Obama Wants Price Negotiations for High Price Drugs*, THE NAT’L J. (Feb. 2, 2015), <http://www.nationaljournal.com/health-care/obama-wants-price-negotiations-for-high-cost-drugs-20150202>.

<sup>222</sup> *Id.*

<sup>223</sup> *Id.*

<sup>224</sup> *Id.*

<sup>225</sup> *Id.*

<sup>226</sup> *The Effect of Price Controls on Pharmaceutical Research*, NAT’L BUREAU OF ECON. RES., <http://www.nber.org/digest/may05/w11114.html> (last visited Feb. 15, 2015).

Europe,” after the French government threatened to tax hepatitis C producers for charging exorbitant prices.<sup>227</sup> The deal struck between the French government and Gilead also states that if Sovaldi hits certain targets, the price will go down.<sup>228</sup> France has also agreed to fully fund the treatments for patients.<sup>229</sup> European regulators additionally have recently approved Harvoni for sale and “negotiations for a long-term deal are underway.”<sup>230</sup>

These price controls used in France are one example of a solution for controlling the price for blockbuster drugs. The US has no price controls on any drugs.<sup>231</sup> However, “the pharmaceutical industry argues [price controls] would discourage the high-risk investment that drug makers need to develop breakthrough cures and treatments.”<sup>232</sup> The argument that price controls would discourage high-risk investment goes hand-in-hand with the purpose of the patent system. A limited monopoly is necessary for the companies to reap the benefit of being the only company to manufacture and sell its product. By allowing a company exclusively to produce its product for a limited time, it allows the company to recapture the money spent developing the product and hopefully turn a profit. The cycle then continues with the next drug.

## 2. India's Answer

For over 30 years, India had excluded pharmaceutical products from patent protection, allowing the country to become “a world leader in high-quality generic drug manufacturing.”<sup>233</sup> Beginning in 1995, India joined the World Trade Organization (WTO). By joining the WTO, India was compelled to apply “internationally-accepted criteria

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<sup>227</sup> Tracy Staton, *France Strikes Big Hep C Deal for Gilead's Sovaldi*, FIERCEPHARMA (Nov. 11, 2014), <http://www.fiercepharma.com/story/france-strikes-big-hep-c-treatment-deal-gileads-sovaldi/2014-11-20>.

<sup>228</sup> *Id.*

<sup>229</sup> *Id.*

<sup>230</sup> *Id.*

<sup>231</sup> Gardiner Harris, *Maker of Costly Hepatitis C Drug Sovaldi Strikes Deal on Generics for Poor Countries*, N.Y. TIMES (Sept. 16, 2014), [http://www.nytimes.com/2014/09/16/business/international/maker-of-hepatitis-c-drug-strikes-deal-on-generics-for-poor-countries.html?\\_r=2](http://www.nytimes.com/2014/09/16/business/international/maker-of-hepatitis-c-drug-strikes-deal-on-generics-for-poor-countries.html?_r=2).

<sup>232</sup> Ollove, *supra* note 191.

<sup>233</sup> Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491 (2007).

for granting patents” and begin granting patents on pharmaceutical products.<sup>234</sup> Although India has revoked its policy that pharmaceutical products should be excluded from patent protection, it has taken various other steps to protect public health and keep the price of medical necessities low.

For example, India was one of the first countries to negotiate a deal with Gilead.<sup>235</sup> Gilead negotiated with seven generic drug manufacturers in India to sell a lower cost version of Sovaldi.<sup>236</sup> In addition to licensing the Indian manufacturers to sell a lower cost generic, Gilead has also said it would sell Sovaldi in India “at a fraction of the price it charges in the United States.”<sup>237</sup> Under the licensing agreement, the generic drug manufacturers will pay royalties to Gilead to manufacture the drug for 91 developing countries. Sovaldi will be sold for about \$10 a pill in these countries, at 1% the price of a pill in the United States.<sup>238</sup>

Although Gilead’s willingness to negotiate a lower price for lower income countries is good news for the rest of the world, negotiation in the United States is unlikely. Pharmaceutical companies can make most of their profit in the United States because drug prices are not controlled.<sup>239</sup> Additionally, the United States bans most prescription drug imports and “often seizes individual shipments.”<sup>240</sup> This prevents Americans from traveling to foreign countries where they can purchase drugs also available in the United States. For example, in the 2013 film *Dallas Buyer’s Club*, an AIDS patient traveled abroad to purchase treatments that had not yet been approved by the FDA.<sup>241</sup> He then smuggled these treatments into the United States and sold them to other AIDS patients.<sup>242</sup>

India has also denied Gilead’s Sovaldi patent application.<sup>243</sup> The

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<sup>234</sup> *Id.*

<sup>235</sup> Harris, *supra* note 231.

<sup>236</sup> *Id.*

<sup>237</sup> *Id.*

<sup>238</sup> *Id.*

<sup>239</sup> *Id.*

<sup>240</sup> *Id.*

<sup>241</sup> See generally DALLAS BUYERS CLUB (Focus Features 2013), [http://www.focusfeatures.com/dallas\\_buyers\\_club](http://www.focusfeatures.com/dallas_buyers_club).

<sup>242</sup> *Id.*

<sup>243</sup> Ed Silverman, *India Rejects Gilead Patent Bid for Sovaldi Hepatitis C Treatment*, WALL ST. J. PHARMALOT (Jan. 14, 2015, 2:25 PM), <http://blogs.wsj.com/pharmalot/2015/01/14/india-rejects-gilead-patent-bid-for-its-sovaldi-hepatitis-c-treatment/>.

patent office found that sofosbuvir was similar to another compound and that for sofosbuvir to be patented, Gilead had to show sofosbuvir “offered improved efficacy over that earlier compound.”<sup>244</sup> The application for sofosbuvir was declined because the patent office determined that sofosbuvir did not meet the improved efficacy threshold.<sup>245</sup> Therefore, the Indian pharmaceutical companies that did not have a license agreement with Gilead can now produce generic versions of Sovaldi, which will reduce prices for the treatment. Now countries that were not part of the original license agreement will be able to receive reduced prices for the treatment.<sup>246</sup> The key to affordability for these important treatments is licensing.<sup>247</sup> “Getting Sofosbuvir out of the stronghold of Gilead’s monopoly will be crucial to expanding treatment for people with hepatitis C globally.”<sup>248</sup>

### C. Corporate greed?

Patents are essential to help the holder recoup his research costs. Without the ability to recoup an investment, an inventor would be stuck penniless and without the means to continue research and potentially develop new ideas. This would hinder innovation and society would be worse off. While Gilead is clearly making high profits from the price of its treatments, it is using some of the money to continue research efforts. Whether the pharmaceutical company is taking advantage of its patent<sup>249</sup>, it is preferable for society to allow a company to recoup its investment—corporate greed and all.

When Gilead purchased Sovaldi from Pharmasset in 2012, Pharmasset had expected to sell the drug for \$36,000.<sup>250</sup> Why exactly

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<sup>244</sup> *Id.*

<sup>245</sup> *Id.*

<sup>246</sup> Amanda Rupp, *India denies Gilead’s hepatitis C drug patent*, VACCINE NEWS DAILY (Jan. 19, 2015, 12:40 PM), <http://vaccinenewsdaily.com/news/332600-india-denies-gileads-hepatitis-c-drug-patent/>.

<sup>247</sup> Katharine W. Sands, *Prescription Drugs: India Values Their Compulsory Licensing Provision—Should the United States Follow in India’s Footsteps?*, 29 HOUSTON J. OF INT’L LAW 226 (2006). “A license preempts patent exclusivity, and generic drugs not only decrease prices but also allow newcomer’s entry into the market without having to put up substantial capital costs.”

<sup>248</sup> Rupp, *supra* note 246 (quoting Dr. Manica Blasegaram, executive director of the Doctors Without Borders’ MSF Access Campaign).

<sup>249</sup> See generally Patent Abuse Lawsuit, *supra* note 195 (arguing Gilead is taking advantage of its patent and causing an undue burden on consumers).

<sup>250</sup> Andrew Westney, *Senators Demand Pricing Details on \$1,000 Per Pill Sovaldi*, LAW360 (July 30, 2014), <http://www.law360.com/articles/556824/senators-demand-pricing->

is Sovaldi so expensive? The drug is not terribly expensive to manufacture. According to a study by Liverpool University, it costs \$101 to manufacture one entire course of the treatment.<sup>251</sup> “It is unclear how Gilead set the price for Sovaldi. That price appears to be higher than expected given the costs of development and production and the steep discounts offered in other countries,” according to Senate Finance Committee Chairman, Ron Wyden, D-Ore. and senior Finance Committee member Chuck Grassley, R-Iowa.<sup>252</sup> After an 18-month investigation, Wyden and Grassley concluded: “Fostering broad, affordable access was not a key consideration in the process of setting the wholesale prices.”<sup>253</sup> The Senators are correct that the price is steep and the treatments more costly than in other countries.<sup>254</sup> Their investigation, however, focused solely on present perceived harm and failed to consider the future benefits that can and have followed the high price of Sovaldi.

Because Gilead did not develop sofosbuvir, the cost it seeks to recoup is the purchase price of Pharmasset, which was nearly \$11 billion.<sup>255</sup> At the time of the Pharmasset acquisition, Gilead was expected to earn \$20 billion in hepatitis treatments by 2020.<sup>256</sup> Thus, Gilead expected to nearly double its investment in Pharmasset. In 2014, Gilead earned nearly \$25 billion, more than doubling its revenue from the prior year.<sup>257</sup> The majority of the growth was due to Sovaldi

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details-on-1-000-per-pill-sovaldi.

<sup>251</sup> Rupp, *supra* note 246.

<sup>252</sup> Westney, *supra* note 250.

<sup>253</sup> U.S. SENATE COMM. ON FIN., *Wyden-Grassley Sovaldi Investigation Finds Revenue-Driven Pricing Strategy Behind \$84,000 Hepatitis Drug* (Dec. 1, 2015), <http://www.finance.senate.gov/ranking-members-news/wyden-grassley-sovaldi-investigation-finds-revenue-driven-pricing-strategy-behind-84-000-hepatitis-drug>.

<sup>254</sup> See Shannon Pettypiece and Ketaki Gokhale, *Patients Get Extreme to Obtain Hepatitis Drug That's 1% the Cost Outside U.S.*, BLOOMBERG (June 1, 2015, 5:01 PM), <http://www.bloomberg.com/news/articles/2015-06-01/hepatitis-cruise-india-trips-among-plans-to-save-on-1-000-pill>.

<sup>255</sup> Margaret Tirrell, *Gilead to Buy Pharmasset for 11 Billion to Win in Hepatitis*, BLOOMBERG BUS. (Nov. 21, 2011, 5:24 PM), <http://www.bloomberg.com/news/articles/2011-11-21/gilead-to-acquire-pharmasset-for-11-billion-to-add-hepatitis-c-medicines>; see Lewis Krauskopf and Anand Basu, *Gilead bets \$11 billion on Hepatitis in Pharmasset deal*, REUTERS (Nov. 21, 2011, 5:02 PM) <http://www.reuters.com/article/us-gilead-pharmasset-idUSTRE7AK0XU20111121> (quoting Brian Skorney, an analyst with Brean Murray, Carret & Co. who stated the acquisition was high-risk, but “could pay off in dividends”).

<sup>256</sup> *Id.*

<sup>257</sup> David Belk, *Gilead Sciences: A Profile in Congressionally Guaranteed Profiteering*, HUFFINGTON POST (Feb. 9, 2015), [http://www.huffingtonpost.com/david-belk/gilead-sciences-a-profile\\_b\\_6641194.html](http://www.huffingtonpost.com/david-belk/gilead-sciences-a-profile_b_6641194.html).

sales.<sup>258</sup>

Judging by the numbers, Gilead has more than recouped its investment in sofosbuvir and it is likely profits will only continue to grow. The patents covering Sovaldi and Harvoni are still in the beginning of their respective patent terms.<sup>259</sup> Gilead still has ten years left to exclusively market the underlying compounds for its hepatitis C treatments.<sup>260</sup> The money Gilead is currently making from Sovaldi and Harvoni sales can be used on research. Between 2003 and 2013, Gilead spent \$12.4 billion on research, which comprised about 20% of its combined revenue for the time period.<sup>261</sup> In 2014, Gilead spent \$2.85 billion on research, which was about a quarter of its profit for the year.<sup>262</sup>

In fact, Gilead is already putting money back into research for other hepatitis C treatments.<sup>263</sup> In October 2015, Gilead announced it had submitted a new drug application to the FDA for approval for a new hepatitis C treatment.<sup>264</sup> This treatment, like Harvoni, is a combination drug.<sup>265</sup> The new drug is a combination of sofosbuvir (Sovaldi) and “velpatasvir (VEL), an investigational pan-genotypic NS5A inhibitor, for the treatment of chronic genotype 1-6 hepatitis C virus (HCV) infection.”<sup>266</sup> The treatment is the “first fixed-dose combination of two pan-genotypic, direct-acting antivirals.”<sup>267</sup> This drug is an improvement because it covers all genotypes, whereas Sovaldi covers genotypes one through four and Harvoni covers one and four through 6.<sup>268</sup> Because the new treatment is pan-genotypic, it has

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<sup>258</sup> *Id.*

<sup>259</sup> See *supra* note 86, citations therein.

<sup>260</sup> *Id.* (assuming the challenged patents will remain valid and Gilead will maintain its limited monopoly).

<sup>261</sup> Belk, *supra* note 257.

<sup>262</sup> *Id.*

<sup>263</sup> *Gilead Submits New Drug Application to U.S. Food and Drug Administration for Fixed Dose Combination of Sofosbuvir/Velpatasvir for Treatment of All Six Genotypes of Hepatitis C*, GILEAD SCI. (Oct. 28, 2015, 5:33 PM), <http://www.gilead.com/news/press-releases/2015/10/gilead-submits-new-drug-application-to-us-food-and-drug-administration-for-fixeddose-combination-of-sofosbuvirvelpatasvir-for-treatment-of-all-six-genotypes-of-hepatitis-c>.

<sup>264</sup> *Id.*

<sup>265</sup> *Id.* Harvoni Prescribing Information, GILEAD, [https://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/harvoni/harvoni\\_pi.pdf](https://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/harvoni/harvoni_pi.pdf).

<sup>266</sup> *Gilead Submits New Drug*, *supra* note 263.

<sup>267</sup> *Id.*

<sup>268</sup> *SOVALDI combination therapy cure rates in clinical studies*, SOVALDI, <http://www.sovaldi.com/about-sovaldi/study-results>. Harvoni Prescribing Information, *supra* note 265.

“the potential to simplify treatment and eliminate the need for HCV genotype testing.”<sup>269</sup> Ninety-eight percent of patients who received the treatment achieved the primary efficacy endpoint of SVR12<sup>270</sup> leading the FDA to assign a “Breakthrough Therapy” designation to the treatment.<sup>271</sup> Breakthrough Therapy designations are given to “investigational medicines that may offer major advances in treatment over existing options.”<sup>272</sup> The results from the experimental trials, coupled with the FDA’s designation, show that Gilead has, once again, revolutionized hepatitis C treatments. In June 2016, the FDA approved this treatment, known as Epclusa.<sup>273</sup> This is a clear example of how Gilead has been able to use the revenue generated from Sovaldi and Harvoni sales to create improved treatments.

Another argument for the patent system is that it encourages invention because competitors will attempt to find a way to design around an existing patent to create a new product.<sup>274</sup> In the case of hepatitis C drugs, pharmaceutical companies are looking to vaccines as a new way to solve the hepatitis C problem.

Currently, a research team at the University of Oxford is developing a hepatitis C vaccination it hopes to use to prevent hepatitis C.<sup>275</sup> Researchers observed that in approximately 25% of cases, the immune system is capable of overcoming the infection and naturally removing the virus.<sup>276</sup> Using this observation, the team sought to use the body’s natural reaction of developing T cells in the vaccination.<sup>277</sup>

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<sup>269</sup> *Gilead Submits New Drug*, *supra* note 263.

<sup>270</sup> Lucina K. Porter, *Hepatitis C SVR12 vs SVR24: Trusting that we are truly cured*, Hep (Feb. 9, 2015), <https://www.hepmag.com/blog/hepatitis-c-treatment-svr>. The medical term for a successful hepatitis C treatment outcome is sustained virus response (SVR). SVR12 means that hepatitis C is undetectable for 12 or more weeks after the end of treatment.

<sup>271</sup> *Gilead Submits New Drug*, *supra* note 263.

<sup>272</sup> *Id.*

<sup>273</sup> *U.S. Food and Drug Administration approves Gilead’s Epclusa® (sofosbuvir/velpatasvir) for the treatment of all genotypes of chronic hepatitis C*, GILEAD (June 28, 2016) <http://www.gilead.com/news/press-releases/2016/6/us-food-and-drug-administration-approves-gileads-epclusa-sofosbuvirvelpatasvir-for-the-treatment-of-all-genotypes-of-chronic-hepatitis-c>.

<sup>274</sup> See Bob DeMatteis, *From Patent to Profit: Secrets and Strategies for the Successful Inventor 30* (3rd E. 2005) (discussing the process of designing around an existing product).

<sup>275</sup> Suzie Marshall, “Promising” Results in Oxford Trials of Hepatitis C Vaccine, *CHERWELL* (Nov. 22, 2014), <http://www.cherwell.org/news/academic/2014/11/21/quotpromisingquot-results-in-oxford-trials-of-hepatitis-c-vaccine>.

<sup>276</sup> *Id.*

<sup>277</sup> *Id.* T cells are “a type of white blood cell that is of key importance to the immune system and is at the core of adaptive immunity.”

The first trial of this vaccine in humans “has demonstrated safety and unprecedented immune responses.”<sup>278</sup> A second trial will be conducted using intravenous drug users.<sup>279</sup>

Although it is yet unclear whether the vaccine really works,<sup>280</sup> the promise of an alternative to the pricey hepatitis C treatments is welcoming. A vaccine that would prevent hepatitis C could stop the virus in its tracks. Inmates entering the prison system could be vaccinated to prevent the spread of the disease from behind the bars. Other high-risk individuals could be vaccinated as well. By taking preventative measures, the spread of the virus can be reduced and fewer patients would require hepatitis C treatment. This in turn would reduce the overall amount spent on expensive hepatitis C treatment.

The development of a vaccine shows the genius behind the patent system. Because patents encourage other inventors to work around the existing patents, other solutions to the problem can be developed.<sup>281</sup> Although a monopoly exists in one area, a patent gives the opportunity to another to come up with a different solution to the problem. The incentives behind the patent system are great, but when faced with a life and death situation, they are not ideal for those seeking cost effective treatment.

#### *D. Changing the System*

Changing the patent system may alleviate the inaccessibility to high cost prescription drugs. One option would be to disallow all pharmaceutical patents. Without patent protection, generic drug manufacturers would be able to replicate a novel treatment. India had been disallowing pharmaceutical patents for years under the India Patents Act of 1970.<sup>282</sup> Under the act, the country saw an “increase in domestic generic drug manufacturing and a sharp decline in the price of medicine.”<sup>283</sup> If the U.S. were to adopt a similar system, the same

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<sup>278</sup> David Heitz, *Scientists See Success in First Human Trial of Hepatitis C Vaccine*, HEALTHLINE (Nov. 9, 2014) <http://www.healthline.com/health-news/success-in-first-human-trial-hepatitis-c-vaccine-110914#1>.

<sup>279</sup> *Id.*

<sup>280</sup> *Id.* (quoting Ellie Barnes of Nuffield Department of Medicine at Oxford University, “But we won’t know if it really works — if it is able to prevent hepatitis C infection — until we have the results of the efficacy studies in the U.S.”).

<sup>281</sup> See DeMatteis, *supra* note 274.

<sup>282</sup> Mueller, *supra* note 233, at 497.

<sup>283</sup> *Id.* at 514.

would likely occur; there would be an increase in competition in the marketplace, which would allow consumers to purchase drugs for a lower price.

Although this proposition may sound ideal for consumers, it would likely have unintended consequences. Instead of helping consumers, it would harm consumers in the long run by creating a disincentive to fund research projects. Additionally, the US would not be in compliance with the World Trade Organization (WTO) and its agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).<sup>284</sup> TRIPS covers a number of subjects, including pharmaceutical patents and “attempts to strike a balance between the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions and creations.”<sup>285</sup>

TRIPS establishes “minimum universal standards” for intellectual property, including patents.<sup>286</sup> It also requires universal patent protection for all types of technology. All WTO member countries that did not previously recognize pharmaceutical patents (like India) were required to amend their patent legislation. Any country that fails to conform to the TRIPS agreement may receive sanctions.<sup>287</sup> Therefore, if the United States were to amend its patent legislation to exclude protection for pharmaceuticals, it would face sanctions by the WTO.

Another option would be to shorten the duration of pharmaceutical patents. The current patent term is 20 years. If the patent term were to be shortened to say, 10 years, the developers would still be able to recoup at least some of their investment by exclusively selling the drug for the patent term. The shortened time frame would then allow for generic drug manufacturers to create identical medications.

Although this proposition sounds like a win-win situation, it would face extreme opposition from large pharmaceutical companies

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<sup>284</sup> *TRIPS and pharmaceutical patents: fact sheet*, WORLD TRADE ORG., [https://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm00\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm00_e.htm) (last visited Sept. 20, 2016).

<sup>285</sup> *Id.*

<sup>286</sup> *Id.*

<sup>287</sup> SIRIPEN SUPAKANKUNTI, ET. AL., IMPACT OF THE WORLD TRADE ORGANIZATION TRIPS AGREEMENT ON THE PHARMACEUTICAL INDUSTRY IN THAILAND, BULL. OF THE WORLD HEALTH ORG. (2001), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2566431/pdf/11417042.pdf>.

and would require legislative action.<sup>288</sup> Pharmaceutical companies that are putting billions of dollars into research would be less likely to make risky investments without the promise of a sufficient patent term. The assurance of a limited monopoly to recoup the investment is crucial to allow innovators to spend the money to research and create. Without that promise, companies would likely spend less money on research, which would result in creation of fewer solutions to medical problem. Shortening the patent term would only be a Band-Aid solution, as it would only benefit consumers in the short term by allowing for generics to be produced sooner than they would be under the current 20-year term. In the long run, society would lose out on the introduction on new life saving treatments because pharmaceutical companies would not have the resources to invest in research, due to the shorter period in which they can recoup their investment.

#### *VI. Conclusion*

It is evident that there is no clear answer on how to solve this pharmaceutical public health problem. Patents are a valuable tool for encouraging inventors to make the risky investments necessary to develop a solution to a problem. Without the reward of an exclusive monopoly, inventors may choose not to create because of the financial risk involved. And without profit motive, the drug would not be invented at all. The public, however, is then at the mercy of the patent holder when something important and life saving is developed. The creator has the ability to negotiate with other key players and recoup his investment. Because of supply and demand, this results in a high price for the consumer.

While numerous countries have taken various approaches to fixing the problems caused by pharmaceutical patent terms, the best solution may be to just let the patent system operate the way it was intended. By continuing to encourage innovation by developing around existing patents, new and creative minds may develop novel, less costly solutions to the problem. Although blockbuster drugs like Sovaldi and Harvoni are sold at such a high price, the profits made from the sale of these drugs will then be put back into research, allowing for the invention of new and useful treatments. Patents may

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<sup>288</sup> See U.S. SENATE COMM. ON FIN., *supra* note 253 (noting legislative action may be on the horizon, as the Senate Committee on Finance released a report on December 1, 2015 criticizing Gilead's pricing strategy).

create a high price for public health, but in the long run, society will benefit as a whole from the incentive to invent and create. After all, “necessity is the mother of invention.”<sup>289 290</sup>

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<sup>289</sup> Quotes by Plato, OXFORD DICTIONARY OF QUOTATIONS (7th ed. 2009); BRAINY QUOTE, <http://www.brainyquote.com/quotes/quotes/p/plato163267.html> (last visited Sept. 30, 2016).

<sup>290</sup> Because this topic is continuously updating, please be aware that this Note is only current through November 1, 2016.

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