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NOT OF MINOR CONSEQUENCE?: MEDICAL DECISION-MAKING AUTONOMY AND THE MATURE MINOR DOCTRINE

Shawna Benston*

I. INTRODUCTION

The frequently intersecting notions of autonomy and capacity are often seen as divergent in cases of medical decision-making by children. The legal system grants autonomy to make medical decisions to those over the age of 18 and denies it to those under the age of 18, due to an ostensible lack of "maturity" in the latter population sufficient to the legal authority to make such medical decisions. For those under the age of 18, their parents or legal guardians are called upon to formally dictate the direction of medical treatment; meanwhile, doctors and hospitals disagreeing with such parents' instructions can opt to bring the dispute to court. Thus, a child who might otherwise be able to engage, communicate, and participate in

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his medical decision-making might see his medical wishes overridden by others' potentially paternalistic choices.

However, the mature minor doctrine offers the chance—in jurisdictions that recognize it—for minors to be deemed capable of making their own medical decisions. In order for minors to achieve this goal, they must satisfy various criteria predetermined by their respective states' common-law determinations. Having first emerged in the 1960s, notably in *Smith v. Seibly*,[1] which in turn quoted from *Grannum v. Berard*, [2] the mature minor doctrine allows for some flexibility in a court's determination of who can influence and even guide the medical experience of the minor. However, the doctrine merely allows a recognizing court to consider whether a minor can be deemed mature. Furthermore, because of variations in jurisdictions' criteria for what constitutes "maturity" and the intrinsic subjectivity (as discussed below) of the criteria, rulings on mature minor petitions are minimally predictable. Therefore, the mature minor doctrine can lend predictability of process, as well as procedural justice, for minors wishing to challenge their medical teams' decisions, but the doctrine cannot guarantee predictability of outcome of such challenges.

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[1] In Smith v. Seibly, 431 P.2d 719, (Wash. 1967), Plaintiff argued that a medical procedure to which he consented at age 18—when the age of maturity in his state was, at the time, 21—was an assault and battery because true consent had not been given. The court found in favor of Defendant doctor, stating that the "[a]ppellant was married, independent of parental control and financial support and it was for the jury to decide if he was sufficiently intelligent, educated and knowledgeable to make a legally binding decision."

[2] In Grannum v. Berard, 422 P.2d 812, 815 (Wash. 1967), Plaintiff claimed that his doctor committed common law battery by performing a procedure to which Plaintiff had consented as a minor. The court found for Defendant doctor. According to the court,

> [i]n view of this record and the complete absence of medical testimony as to the plaintiff's claimed mental incapacity, we do not believe there is room for reasonable minds to differ that the plaintiff has failed to overcome by clear, cogent and convincing evidence the presumption that he comprehended the nature, terms and effect of the consent given for the surgical operation.

This article explores the mature minor doctrine and how it has emerged in recent cases. It also discusses minors' generally limited autonomy and calls for those in the medical and legal professions to seriously contemplate what can be done to protect minors suffering from unwanted medical treatments—especially those that render life more painful and uncomfortable than happy and satisfying.

II. SUBJECTIVITY OF THE MATURE MINOR DOCTRINE CRITERIA

At common law, minors are deemed incompetent to give consent or refuse medical intervention. It is therefore up to the individual states whether to evaluate a case under the mature minor doctrine, which considers legally relevant the desires, and consent or refusal, of minors who "exhibit[] the 'maturity' of an adult to make decisions that traditionally have been reserved for persons who have attained the age of majority."[3] Because "'maturity' is not a well-defined legal term,"[4] states that elect to conduct a mature minor doctrine analysis have determined sets of criteria that allow for case-specific determinations of a minor's maturity, or lack thereof.

Generally, as law professor Walter Wadlington has summarized, "the cases in which the rule has been applied have had the following factors in common"[5]:

> (1) The treatment was undertaken for the benefit of the minor rather than a third party.
> (2) The particular minor was near majority (or at least in the range of 15 years of age upward) and was considered to have sufficient mental capacity to understand fully the nature and importance of the medical steps proposed.

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[3] Jessica A. Penkower, *The Potential Right of Chronically Ill Adolescents to Refuse Life-Saving Medical Treatment Fatal Misuse of the Mature Minor Doctrine,* 45 DEPAUL L. REV. 1165, 1166 (1996).

[4] *Id.* at 1167.

[5] *Id.* at 1179.

> (3) The [risks of] medical procedures could be characterized by the court as less than 'major' or 'serious.'[6]

The first factor necessarily specifies that any course of treatment or recommendation in question must be of potential benefit to the patient (patient-centered) and not primarily for the benefit of another party. In *Belcher v. Charleston Area Medical Center*, the Supreme Court of West Virginia exemplified how the second factor might be fully analyzed, explaining that whether a minor has sufficient capacity to consent to or refuse medical treatment depends upon:

> [The] age, ability, experience, education, training, and degree of maturity or judgment obtained by the child, as well as upon the conduct and demeanor of the child at the time of the procedure or treatment . . . [and] whether the minor has the capacity to appreciate the nature, risks, and consequences of the medical procedure to be performed, or the treatment to be administered or withheld.[7]

Thus, for a proper analysis under the mature minor doctrine, the court must conduct an intensive investigation into who the minor is, what his life experiences have been prior to the hearing, and whether the minor has exhibited a sufficiently deep and thorough comprehension of his circumstances and treatment risks and benefits.

This type of tailored personal analysis lies in stark contrast to courts' medically inflected investigation of legal adults, who are presumed competent. The only potential roadblock to adults' medical decision-making authority—or

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[6] *Id.* at 1179-80 (drawing from Walter Wadlington, *Minors and Health Care: The Age of Consent*, 11 OSGOOD HALL L. J. 115, 119 (1973)).

[7] Belcher v. Charleston Area Med. Ctr., 422 S.E.2d 827, 838 (W.Va. 1992).

medical autonomy—is a collection of four countervailing state interests: "(1) the preservation of life, (2) the protection of innocent third parties, (3) the prevention of suicide, and (4) the maintenance of the ethical integrity of the medical profession."[8]

While adults can consent to medical treatment with extremely rare controversy[9], the refusal of treatment—especially when such refusal is guaranteed, or even just likely, to result in death—may come under scrutiny by institutional committees or governmental agencies, or may even be condemned in the court of public opinion. Most controversial, of course, is the decision by an adult to hasten death by means of physician-assisted suicide.

The case of *Bouvia v. Superior Court* epitomizes the difficulty that adults may encounter by seeking to remove or refuse life-saving medical intervention, or even hydration and nutrition.[10] In this case the patient in question, Elizabeth Bouvia, was mentally competent but physically suffering from cerebral palsy, in anguish to the point of attempting suicide by means of self-starvation. After hospital staff forcibly inserted a nasogastric tube to keep her alive, Bouvia sought a preliminary injunction from the California trial court that would require the tube's removal and prohibit similar measures. After the trial court denied her preliminary injunction, she sought relief in the Court of Appeals of California. Citing the proclamation from the Council on Ethical and Judicial Affairs of the American Medical Association that "[a]t all times, the dignity of the patient should be maintained,"[11] the Court of Appeals granted Bouvia the right to determine whether she would welcome or shun medical intervention.[12] Ultimately, Bouvia

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[8] Penkower, *supra* note 3, at 1171.

[9] A controversial treatment election might be extreme plastic surgery, for example.

[10] Bouvia v. Superior Court, 179 Cal. App 3d 1127 (1986).

[11] *Id.* at 1141 (quoting the Council on Ethical and Judicial Affairs of the American Medical Association, *Withholding or Withdrawing Life Prolonging Medical Treatment* (Mar. 15, 1986)).

[12] *Id.*

chose not to die by means of self-starvation, citing side effects of her morphine regimen that made starvation unbearable.[13]

Notably, the *Bouvia* court included discussion of two issues crucial to the exploration of the mature minor doctrine: (1) "[w]ho shall say what the minimum amount of available life must be?"[14] and (2) how can we reconcile the doctrine of double effect and the state's concern for preservation of life? The first issue is intrinsically philosophical and ostensibly rhetorical. But it should be answered quite simply with "no one." Realistically, no one can say when another person has lived long enough—whether that other person is aged fifteen or ninety-five.

In the *Bouvia* case, Judge Beach illustrated a prioritization of quality over quantity:

> Does it matter if it be 15 to 20 years, 15 to 20 months, or 15 to 20 days, if such life has been physically destroyed and its quality, dignity and purpose gone? As in all matters lines must be drawn at some point, somewhere, but that decision must ultimately belong to the one whose life is in issue. . . . It is not a medical decision for [the patient's] physicians to make.

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[13] *See* JERRY MENIKOFF, LAW AND BIOETHICS: AN INTRODUCTION 262 (Georgetown University Press, 2001). During a *60 Minutes* segment broadcast on September 7, 1997, the following dialogue took place:

> Mike Wallace: (*voiceover*) 'After several attempt[s] at starvation, Elizabeth told us, it just became physically too difficult to do. She didn't want to die a slow, agonizing death, nor to do it in the spotlight of public scrutiny. And she told us, with great regret, she quietly chose to live.' Ms. Bouvia: 'Starvation is not an easy way to go.' Wallace: 'Oh, no.' Ms. Bouvia: 'You can't just keep doing it and keep doing it. It really messes up your body. And my body was already messed up.'

See also Beverly Beyette, *The Reluctant Survivor: 9 Years after Helping her Fight for the Right to Die, Elizabeth Bouvia's Lawyer and Confidante Killed Himself—Leaving Her Shaken and Living the Life She Dreaded*, LA TIMES (Sept. 27, 1992), http://articles.latimes.com/1992-09-13/news/vw-1154_1_elizabeth-bouvia [http://perma.cc/MTJ2-5QZZ].

[14] Bouvia, 179 Cal. App 3d 1127 at 1143.

> Neither is it a legal question whose soundness is to be resolved by lawyers or judges. It is not a conditional right subject to approval by ethics committees or courts of law. It is a moral and philosophical decision that, being a competent adult, is [the patient's] alone.[15]

Of course, the *Bouvia* court was examining an issue of *adult* competence to make medical decisions; what remains to be explored is whether a capacitated minor can be granted the same freedom to determine for himself how much life devoid of "quality, dignity and purpose" is enough.

The doctrine of double effect "is often invoked to explain the permissibility of an action that causes a serious harm, such as the death of a human being, as a side effect of promoting some good end."[16] Specifically, the doctrine of double effect states that "if doing something morally good has a morally bad side effect," it is ethical to do it as long as the bad side effect was not intended—and even if the bad effect was foreseen as probable.[17] The principle is used to justify a doctor's giving drugs to a terminally ill patient to relieve distressing symptoms even though he knows that doing so may shorten the patient's life. An analysis under this doctrine must examine the "fundamental legal principles of causation and intent"[18] in its determination that a patient's refusal of medical intervention, or consent to aggressive palliative care, results in death from the underlying disease or pathology—not from the withholding of medical care or application of palliative care.[19]

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[15] *Id.*

[16] Alison McIntyre, *Doctrine of Double Effect*, STANFORD ENCYCLOPEDIA OF PHILOSOPHY (Sept. 13, 2014),http://plato.stanford.edu/entries/double-effect/ [http://perma.cc/B3WU-ZY8T].

[17] *See, e.g.*, *Ethics Guide: The Doctrine of Double Effect*, BBC, http://www.bbc.co.uk/ethics/euthanasia/overview/doubleeffect.shtml [http://perma.cc/H2ZD-5SZT] (last visited Oct. 2, 2015).

[18] Vacco v. Quill, 521 U.S. 793, 801 (1997).

[19] *Id.* at 801-02 (quoting Assisted Suicide in the United States, Hearing before the Subcommittee on the Constitution of the House Committee on the Judiciary, 104th Cong. 2d Sess., 367 (1996)).

Such an arguably passive death notably differs from an active death achieved by assisted suicide. It is this distinction between "letting die" and "killing" that underlies many of the arguments against assisted suicide; [20] for purposes of this article, it should be understood as a point of clarity for informed consent cases involving adults: While a competent adult cannot, in most states, legally consent to assisted suicide measures to hasten death, generally (thanks to cases like *Bouvia*), he can refuse life-saving medical intervention, even if it results in his death. This article asks: can mature minors be granted the same sort of autonomy by means of a mature-minor-doctrine analysis, and, if so, why aren't more states conducting mature-minor-doctrine analyses?

III. THE MATURE MINOR DOCTRINE "AT WORK"

To illustrate a court's investigative process under the mature minor doctrine, we turn now to Cassandra C., a 17-year-old Connecticut patient with Hodgkin's lymphoma, whose case provides what might have been deemed an easy one for an application of the mature minor doctrine, even while a mature-minor determination proved impossible. [21] Since her diagnosis in September 2014, Cassandra has asserted her desire not to receive chemotherapy as treatment for her cancer, even though patients with her diagnosis are considered by the oncologic community to have an 80% chance of long-term survival with early treatment. [22] Condemning the chemotherapy as "poison," Cassandra has apparently believed for many years prior to her diagnosis

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[20] Shawna Benston, *Balancing Autonomy and Beneficence: The Legal, Sociopolitical, and Philosophical History of and Support For Legalizing Assisted Suicide*, 24 NYSBA ELDER & SPECIAL NEEDS L. J., 22, 22-28 (2014).

[21] *In Re* Cassandra C., 316 Conn. 476 (2015).

[22] Samantha Masunaga, "Connecticut Teen Fighting State Justices' Ruling on Forced Chemotherapy", L. A. TIMES (Jan. 10, 2015, 8:53 PM), *available at* http://www.latimes.com/nation/la-na-teen-chemo-20150111-story.html [https://perma.cc/B9M8-G44V].

that such treatment would be intolerable to her—in other words, her antipathy was not casually or swiftly determined.[23] Furthermore, not only was Cassandra less than a year away from legal maturity at the time of her case, but her mother fully agreed with and supported her desire to abstain from chemotherapy, despite the potentially dire consequences.[24]

However, after Cassandra and her mother missed some of her medical appointments, "her physicians made a report of possible medical neglect to the Petitioner, Department of Children and Families ('DCF')," [25] which in turn filed a petition for and won an Order of Temporary Custody.[26] A six-month regimen of chemotherapy was begun. Soon thereafter, the Supreme Court of Connecticut affirmed that the state could force a minor to undergo chemotherapy.[27] So, had that court conducted an analysis under the mature minor doctrine?

Yes and no: The Supreme Court of Connecticut stated in its opinion that "because the evidence does not support a finding that Cassandra was a mature minor under any standard, this is not a proper case in which to decide whether to adopt the mature minor doctrine."[28]

However, certainly it is at least a bit nonsensical to say that a doctrine is not being adopted because the case at hand does not satisfy it. In effect, the court did conduct a mature-minor-doctrine analysis, finding that Cassandra did not satisfy the criteria. Thus, Cassandra's case constitutes the first in which the Connecticut Supreme Court considered the mature minor doctrine, setting a precedent that justifiably dismays Cassandra. Indeed, as the American Civil Liberties Union of Connecticut reminded the court in its amicus brief,

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[23] *Id.* at 492.

[24] *Id.*

[25] Joint Brief of Respondent Mother and Minor Child with Separate Index at 1-2, *In re* Cassandra C., 316 Conn. 476 (2015).

[26] *In re* Cassandra C., 316 Conn. 476, 486 (2015).

[27] *Id.* at 500.

[28] *Id.* at 481.

prior to the court's decision Texas had been the only state to reject the mature minor doctrine, while six other states and Washington, D.C. "have held or suggested that mature minors, like other competent people, have the right to consent to or forego medical treatment.[29]

The court, however, found persuasive the argument of DCF's counsel, Assistant State Attorney General John Tucker, that Cassandra and her mother had engaged in "'magical thinking' that '[i]f I closed my eyes to the fact I have this serious illness, then my cancer doesn't exist.'"[30] Tucker further asserted that "[r]eally, it was the mother who was taking the front seat on this. The child was overshadowed by the mother's negative feelings about chemotherapy." [31] However, Cassandra herself defended her mother in an op-ed, stating, "In no way is my mom neglectful. She has always put me before herself. I am offended by anyone who believes otherwise. My mom has been identified as 'hostile,' 'neglectful' and 'unsupportive,' three untrue words that break my heart."[32]

Furthermore, Cassandra's op-ed expressed her firm understanding that her desired abstention from chemotherapy was driven by her own feelings and beliefs

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[29] Christiane Cordero, *State Supreme Court Rules Teen Canate Supreme Cou.*, NBC CONNECTICUT (Jan. 8, 2015, 12:12 PM), http://www.nbcconnecticut.com/troubleshooters/State-Supreme-Court-Hears-Arguments-in-Teen-Chemotherapy-Case-Cassandra-Connecticut-287933331.html [http://perma.cc/TWE7-F7B3]. These six states are "Illinois, Maine, Tennessee, West Virginia, Michigan, and Massachusetts."

[30] Josh Kovner, *Connecticut Supreme Court Upholds Ruling That State Can Force Chemotherapy On Teen*, HARTFORD COURANT, (Jan. 8, 2015, 9:14 PM), http://www.courant.com/news/connecticut/hc-teen-battles-chemo-order-0103-20150102-story.html#page=1 [http://perma.cc/4HQL-4B3J].

[31] *Id.*

[32] Cassandra C., Op-Ed. *Cassandra's Chemo Fight: 'This Is My Life And My Body',* HARTFORD COURANT, (Jan. 8, 2015), http://www.courant.com/opinion/op-ed/hc-op-cassandra-my-body-my-life-0109-20150108-story.html?dssReturn&z=10003 [http://perma.cc/DL6V-6JDH].

about what would be right for her. Her fear and frustration are unequivocal:

> This experience has been a continuous nightmare. I want the right to make my medical decisions. It's disgusting that I'm fighting for a right that I and anyone in my situation should already have. This is my life and my body, not DCF's and not the state's. I am a human—I should be able to decide if I do or don't want chemotherapy. Whether I live 17 years or 100 years should not be anyone's choice but mine. How long is a person actually supposed to live, and why? Who determines that? I care about the quality of my life, not just the quantity.[33]

Bouvia is loudly echoed in this statement, which certainly exhibits the level of maturity required for a judge's ruling that the speaker should be permitted to make her own medical decisions. And yet, Cassandra was forced to continue being injected with what she deemed "poison."[34] What went wrong?

In the Supreme Court of Connecticut's ruling, it appears that the finding that Cassandra was not a mature minor was based on her having either intentionally misrepresented her intentions to the trial court or . . . changed her mind on this issue of life and death [and that] [i]n either case, her conduct amply supports Judge Quinn's finding that the respondents

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[33] *Id.*

[34] Sarah Larimer, *Connecticut's Highest Court Approves Forced Chemotherapy for Teen,* THE WASHINGTON POST (Jan. 8, 2015), http://www.washingtonpost.com/news/morningmix/wp/2015/01/08/connecticuts-highest-court-approves-forced-chemotherapy-for-teen/ [http://perma.cc/6RRJ-3SYL].

[Cassandra and her mother] have failed to prove that Cassandra was a mature minor under any standard.[35]

The court essentially found it more reprehensible that Cassandra had temporarily run away, in order to avoid being medicated against her will, than that she had been "strapped to a bed by [her] wrists and ankles and sedated"[36] and might be again. Because the court found issue with Cassandra's potentially having changed her mind, it can be inferred that in order to make medical decisions, one must never change one's mind. So, should Elizabeth Bouvia have been retroactively found incompetent after she chose to keep on living?

Of course, the answer should be "no." The law does not say that in order to be one's own medical decision-maker, one must be bound to the first opinion or decision one makes, but that in order to make legally valid medical decisions, one must be able to provide competent and informed consent or refusal of medical care. It is common knowledge that throughout a course of treatment—especially for an ongoing and potentially dire condition—a patient might change direction, especially as new or changed information becomes available. It would be unethical to force a patient to stick with his first opinion or decision, in a contract-like arrangement; by extension, it should be unethical to do the same to a minor who would otherwise be deemed mature. And yet, Cassandra was effectively punished for her having even just potentially changed her mind about life's perhaps most confusing issue: what constitutes a life worth living?

It is worth asking whether the judge's ruling would have been different had Cassandra presented a religious basis for her wish to withdraw and withhold medical intervention. The critical mature-minor-doctrine case, *In re E.G.*, found a minor the same age as Cassandra—seventeen—competent to refuse a blood transfusion as part of treatment for leukemia.

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[35] Order at 2, *In re* Cassandra C., 112 A.3d 158 (Conn. 2015) (No. 19426), *available at* http://www.scribd.com/doc/252076272/Cassandra [https://perma.cc/A3WC-2ZWM].

[36] Cassandra C., *supra* note 32.

The basis for this competence was that "acceptance of blood would violate personal religious convictions rooted in [E.G.'s] membership in the Jehovah's Witness faith."[37] Although the court did not base its decision on religious grounds, the religious conviction of the minor is what garnered her sufficient recognition to allow for the court's mature-minor analysis. Specifically, the court compared the E.G. case to two previous cases [38] that involved Jehovah's witnesses, allowing for consideration[39] of E.G.'s case despite its having been rendered moot due to E.G.'s having reached the age of majority.

Although E.G. and her mother provided a constitutional basis—the First Amendment's Free Exercise Clause—for the refusal of the blood transfusion, the judge declined to consider it, saying that "a mature minor may exercise a common law right to consent to or refuse medical care."[40] The judge thereby strengthened the mature minor doctrine by finding it sufficient in itself, without constitutional support, to allow a mature minor to refuse life-saving treatment. Indeed, the *E.G.* court did not wish to find or make an extension of the constitutional right of abortion, which naturally is granted to minors because "[c]onstitutional rights do not mature and come into being magically only when one attains the state-defined age of majority."[41] Thus, it was a rather strange case: while religious reasoning, built on a Free Exercise Clause foundation, helped convince the judge of E.G.'s maturity (in other words, it got E.G.'s foot in the door), a constitutional analysis was found irrelevant. A pivotal statement made in the opinion — "[w]e see no reason

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[37] *In re* E.G., 549 N.E.2d 322, 323 (Ill. 1989).

[38] The two cases were *In re* Estate of Brooks, 205 N.E 2d 435 (Ill. 1965) and People *ex rel.* Wallace v. Labrenz, 104 N.E. 2d. 769 (Ill. 1952).

[39] The court found a public interest exception to mootness because of the frequency of cases involving Jehovah's Witnesses members who refused to consent to blood transfusions. *In re* E.G., 549 N.E.2d 322 at 325.

[40] *In re* E.G., 549 N.E.2d 322 at 328.

[41] *Id.* at 326, *quoting Planned Parenthood v. Danforth*, 428 U.S. 52, 74 (1976).

why this right of dominion over one's own person should not extend to mature minors"[42] — highlights the importance of the finding of maturity, while underscoring that once a minor is found mature, control over his person should be treated as a right.

If proof of a minor's maturity is his religious conviction — if a minor's religious conviction is considered proof that the minor should be taken seriously — what hope do irreligious minors have of proving themselves competent to make their own medical decisions? While one commentator has found that "[t]he disparity among jurisdictions in their use of the [mature minor] doctrine, the inherent vagueness of the concept of maturity, and the complexity of the medical and legal matters involved in treatment refusal cases effectively undermine the doctrine's efficacy," [43] it seems that such vagueness could work as easily *for* minors as against them. Just as not all adults are competent to make their own medical decisions, so, too, are not all minors lacking in the maturity required to do so. There should not be—and, in practice, is not — a bright line dividing adults and minors that, on the former side, includes all competent individuals and, on the latter side, includes all incompetent individuals. A more nuanced analysis is required on a case-by-case basis to determine an individual's medical-decision-making competence, regardless of that individual's age.

IV. CONCLUSION

When are young people old enough to make potentially life or death decisions? We allow 17-year-olds to enlist in the army. Teens as young as 15 are regularly tried as adults in murder cases. So why shouldn't a 17-year-old have the right to decide what medical treatments she will undergo?[44]

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[42] *Id.* at 326.

[43] Penkower, *supra* note 3, at 1191.

[44] W.W., *Cassandra's Catch-22*, THE ECONOMIST (Jan. 14, 2015, 2:57 PM), http://www.economist.com/blogs/democracyinamerica/2015/01/medical-consent [http://perma.cc/97BG-GRNK].

We can easily see divergences in how the law and society view and treat minors, and such divergences have had a notable impact on minors' ability to make their own medical decisions. Indeed, perhaps it is this lack of predictability that particularly harms minors and even their parents, who might — as in Cassandra's case[45] — support their children's desire to withhold or withdraw medical intervention.

However, the solution is not to insert predictability by drawing a bright line at age 18 for purposes of bodily autonomy. Instead, the mature minor doctrine should be employed to make an informed, nuanced analysis of each case. Parental accord with children's wishes should only strengthen a case for finding a minor mature, instead of being ignored simply because such accord does not comport with the medical team's recommendations. States that employ the mature minor doctrine do right to weigh the state interests of "(1) preserving life; (2) protecting third parties; (3) preventing suicide; and (4) maintaining the ethical integrity of the medical profession" against "the strength of the minor's right to refuse treatment."[46] Allowing for a case-by-case analysis is appropriate, considering that no individual—and no minor individual—is the same as any other; one person's medical experiences and personal traits are not necessarily replicated in another's.

Indeed, perhaps the solution lies outside the courtroom setting and should be determined as part of the doctor-patient interaction and with as much concern for a minor's informed consent as for that of an adult patient. Or, should this discussion remain in the courtroom, perhaps a shift of the burden of proof is in order: a minor in his mid-teens should be presumed competent unless proven otherwise.

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[45] *Id.* ("as it happens, Cassandra's mother, Jackie Fortin, supports her daughter's decision to forgo chemotherapy treatments. Is Cassandra's middle-aged mother too immature to make decisions on her daughter's behalf? Presumably not. So what gives?") While the Connecticut Supreme Court ultimately found Cassandra's mother neglectful, certainly such a finding would not in itself override a finding that a minor is sufficiently mature to justify recognition of her own medical decision-making capacity.

[46] Penkower, *supra* note 3, at 1187 (*citing In re* E.G., 549 N.E.2d 322, 328 (Ill. 1989)).

Ultimately, it must be determined what, exactly, "mature" means, both literally and legally. Who determines when another person has become "mature"? What role does, and should, age play in determining someone's "maturity"? How can our legal system grapple with such nebulous terminology? Finally, how can physicians work within the legal system while upholding their oath to do no harm?

As we continue wrestling with such questions, courts would do well to employ the mature minor doctrine in order to lend predictability of process to cases of minors' bodily autonomy, while preserving the states' interests. In this way, analysis using the mature minor doctrine would allow courts to protect immature minors from potentially detrimental medical decisions, which they lack the capacity to make, while honoring mature minors' informed and competent medical decision-making capacity. Such analysis would also provide procedural justice for minors, even if the result is not in their favor.[47]

It is not the age of 18 that should signify maturity and the competence to manage one's own medical treatment, but rather the confluence of emotional maturation, sufficient experience and education, and developed judgment and demeanor at the time of the potential treatment that must be analyzed to determine a minor's capacity to refuse unwanted medical intervention. The legal system, if it is to adequately protect minors, must consider the minor's potential to make well-informed medical decisions.

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[47] Nancy Welsh, *Making Deals in Court-Connected Mediation: What's Justice Got to Do With It?* 79 WASH. U. L.Q. 787, 820 (2001).

A MARKET FOR HUMAN ORGANS: AN ETHICAL SOLUTION TO THE ORGAN SHORTAGE

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ABSTRACT

Over 120,000 people are waiting for an organ transplant. Twenty-one Americans die each day waiting for an organ. This problem is not unique to the United States. Although technological advancements will likely end the organ shortage one day, technological solutions to the shortage are likely decades away. An organ market is the only solution currently available to the organ shortage.

The human organ market is almost universally condemned for ethical reasons. However, the ethical objections to a market do not withstand scrutiny. Only one nation allows individuals to sell their kidneys, and this is the only nation to eliminate its kidney waiting list. Moreover, the poor and middle classes have greater access to kidneys in this nation than any other country. This nation is Iran.

The United States should recognize the success of Iran's kidney system and implement an organ market. Creating an organ market in the United States only requires a few changes to the current organ procurement system. Most importantly, a market will improve health outcomes for those in need of organs and likely reduce healthcare costs as well.

I. INTRODUCTION

In the United States, over 30,000 organ transplants were performed in 2015.[1] Although this is a remarkable number of lives saved, the waiting list for organ transplants is over 120,000 candidates long,[2] and the list keeps growing. A name

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[1] Organ Procurement and Transplantation Network, U.S. DEP'T. HEALTH & HUMAN SERV., https://optn.transplant.hrsa.gov/news/more-than-30-000-transplants-performed-annually-for-first-time-in-united-states/ [https://perma.cc/WHA4-3CMN] (last visited Jan. 29, 2016].

[2] UNITED NETWORK FOR ORGAN SHARING, http://www.unos.org/ [http://perma.cc/375F-LJN3] (last visited Nov. 5, 2015).

is added every twelve minutes.[3] Consequently, a shortage of organs exists. This shortage results in the death of twenty-one Americans each day,[4] and this figure does not include the number of people who die without being placed in the organ queue.[5] Since 1980, more Americans have died waiting for an organ than in all of the nation's wars combined.[6] The dearth of organs is not just an American problem. The world average is four transplantable organs available for every 100 people in need.[7]

In an attempt to procure an organ, some individuals seek directed donations from living donors. Many turn to family and friends. If this option fails, people have solicited strangers to part with their organs using newspaper advertisements, billboards, and websites like jimneedsakidney.com.[8] Directed donation enables the would-be organ recipient to bypass the organ waitlist. However, many are unable to procure an organ through this method. This causes an unknown number of people to turn to the black market in a desperate attempt to save their lives.

One nation has solved its kidney shortage. Since the dawn of the twenty-first century, the country has not had a

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[3] *Facts and Myths*, AM. TRANSPLANT FOUND., http://www.americantransplantfoundation.org/ab-transplant/facts-and-myths/ [http://perma.cc/J8TE-QC76] (last visited Nov. 30, 2015].

[4] *Id.*

[5] Peter Aziz, *Establishing a Free Market in Human Organs: Economic Reasoning and the Perfectly Competitive Model*, 31 UNIV. LA VERNE L. REV. 67, 77 (2009) ("This number does not take into account all the people who have died without being placed on the waiting list.").

[6] Sigrid Fry-Revere & David Donadio, *America's Organ Transplant Law Is Criminally Unfair to Donors*, NEW REPUBLIC (Oct. 23, 2014), http://www.newrepublic.com/article/119963/us-organ-transplant-law-needs-reform-let-donors-get-reimbursed [http://perma.cc/6Y3Y-QXGM].

[7] Sigrid Fry-Revere, *What Can Iran Teach Us About the Kidney Shortage?*, (TEDMED broadcast 2015), *available at* http://tedmed.com/talks/show?id=309108 [http://perma.cc/EZ7Z-8YCU].

[8] Eric Horng & Andrew Fies, *Ads, Billboard Plead for Organ Donations*, ABC NEWS (July 24, 2005), http://abcnews.go.com/WNT/Health/story?id=982806 [http://perma.cc/LMH4-E3FX].

waiting list for kidneys.[9] Technology plays little role in the country's ability to provide organs. In fact, the nation has a small healthcare budget and lacks medical equipment.[10] The country is poor and often regarded as backwards. Nevertheless, by compensating kidney providers, the country has solved a problem that continues to plague the world. The country is Iran.

This paper will provide an overview of the organ shortage and consider various solutions to it. Arguments for and against the market for human organs will be examined. An analysis of organ procurement on the black market and in Iran follows, as they are the only systems currently in operation where organs are exchanged for money. A market for organs in the United States is proposed and the market's probable consequences are considered. A conclusion follows.

II. THE ORGAN SHORTAGE

The organ shortage is a result of medical advancements. The first organ transplant was performed in 1954, and potent anti-rejection drugs were approved in 1983, which greatly expanded the opportunity for successful transplants.[11] Congress passed the National Organ Transplant Act in 1984 ("NOTA") creating a task force to examine "the medical, legal, ethical, economic, and social issues presented by human organ procurement and transplantation."[12] This task force

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[9] Ahad J. Ghods & Shekoufeh Savaj, *Iranian Model of Paid and Regulated Living-Unrelated Kidney Donation*, 1 CLINICAL J. AM S. NEPHROLOGY 1136, 1137 (2006) (stating Iran's renal transplant waiting list was eliminated in 1999).

[10] *See* Ahad J. Ghods, *Renal Transplantation in Iran*, 17 NEPHROLOGY DIALYSIS TRANSPLANTATION 222, 226 (2002) (discussing why renal transplant survival rates may be lower than survival rates in other countries).

[11] *Organ Transplant History*, LIVE ON NY, http://www.donatelifeny.org/all-about-transplantation/organ-transplant-history/ [http://perma.cc/9VND-YJDY] (last visited Nov. 30, 2015].

[12] National Organ Transplant Act [NOTA], Pub. L. No. 98-507, § 101(b)(1)(A), 98 Stat. 2339 (1984).

reflects Congress' concern that the poor would feel pressured to exchange their organs for monetary gain.[13] Accordingly, Congress prohibited the interstate transfer of human organs for profit while permitting organ donations.[14]

Although the sale of organs is prohibited, people are allowed to donate their organs. NOTA created the Organ Procurement and Transplantation Network ("OPTN") to facilitate organ donation.[15] The OPTN created a list of individuals in need of organs, criteria for donor-recipient pairing, as well as guidelines for organ acquisition and transportation.[16] NOTA requires the OPTN's functions to be carried out by "a private nonprofit entity."[17] The United Network for Organ Sharing ("UNOS") received the initial contract in 1986 and has been the OPTN's contractor ever since.[18]

In an effort to increase the supply of organs, the United States Department of Health and Human Services ("HHS") has posted materials on its website to help colleges and hospitals promote organ donation.[19] Additionally, HHS promotes several national events to encourage organ donation, such as National Donor Day (February 14th) and the National Donor Recognition Ceremony & Workshop.[20]

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[13] Gwen Mayes, *Buying and Selling Organs for Transplantation in the US: National Organ Transplant Act of 1984 (NOTA) Bans Buying and Selling*, MEDSCAPE, http://www.medscape.org/viewarticle/465200_2 (last visited Nov. 6, 2015).

[14] 42 U.S.C. § 274e(a) (2015).

[15] 42 U.S.C. § 274 (2015), *available at* http://history.nih.gov/research/downloads/PL98-507.pdf [http://perma.cc/2JJY-UVSN].

[16] NOTA, Pub. L. No. 98-507, § 372(b)(2)(A)(D), 98 Stat. 2344 (1984).

[17] 42 U.S.C. § 274(b)(1)(A) (2015).

[18] *History & NOTA*, U.S. DEP'T. OF HEALTH AND HUMAN SERV., http://optn.transplant.hrsa.gov/governance/about-the-optn/history-nota/ [http://perma.cc/E28D-F2MF] (last visited Nov. 6, 2015).

[19] *Campus Partner Support Materials*, ORGANDONOR.GOV http://www.organdonor.gov/materialsresources/materialscampussupport.html [http://perma.cc/8Y9N-5HU8] (last visited Nov. 6, 2015).

[20] *National Events*, ORGONDONOR.GOV, http://www.organdonor.gov/materialsresources/materialsntlevents.html [http://perma.cc/GC5G-BEQL] (last visited Nov. 6, 2015).

The donations sought are secured by having individuals consent to become donors at death. This occurs by agreeing to become a donor when renewing one's driver's license or through a state online registry.[21] Organs from living donors are also welcomed.[22]

Cadavers are the source of kidneys in about two-thirds of kidney transplants; [23] however, kidneys are the most commonly transplanted organ from live donors.[24] Live kidney donations are common for two reasons. One is that kidneys are the most demanded organ: over 80% of 121,588 people in need of an organ are seeking a kidney.[25] The second reason for the high rate of live kidney donation relative to other organs is that most people have two kidneys, but only need one.[26] This makes removing kidneys a fairly simple procedure and involves few postoperative health risks. The University of Maryland Medical Center states, "[c]urrent research indicates that kidney donation does not change life

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[21] *Organ Donation: The Process*, ORGANDONOR.GOV, http://www.organdonor.gov/about/organdonationprocess.html#process1 [http://perma.cc/9PTM-E9LG] (last visited Nov. 6, 2015).

[22] *Living Donation Information You Need to Know*, UNITED NETWORK FOR ORGAN SHARING (2015), *available at* http://www.unos.org/docs/Living_Donation.pdf [http://perma.cc/8ZPH-EWKC].

[23] *Organ Donation and Transplantation Statistics*, NAT'L KIDNEY FOUND., https://www.kidney.org/news/newsroom/factsheets/Organ-Donation-and-Transplantation-Stats [http://perma.cc/G3BL-L5LH] (last visited Nov. 30, 2015).

[24] *Frequently Asked Questions About Living Donation*, UNOS TRANSPLANT LIVING, http://www.transplantliving.org/living-donation/facts/frequently-asked-questions/#ld [http://perma.cc/96EU-JX2Z] (last visited Nov. 6, 2015).

[25] *Data*, Organ Procurement and Transplantation Network, U.S. DEP'T. HEALTH & HUMAN SERV., https://optn.transplant.hrsa.gov/converge/data/ [https://perma.cc/ET4C-UADA] (last visited Jan. 29, 2016) (follow "National Data"; "select report," then "choose category", "waiting list"; "candidates"; "step 2", overall by organ").

[26] *Living with One Kidney*, NAT'L KIDNEY FOUND., https://www.kidney.org/atoz/content/onekidney [http://perma.cc/Q3KV-RVBK] (last visited Nov. 30, 2015).

expectancy or increase a person's risks of developing kidney disease or other health problems."[27]

Livers are the organ with the second highest demand,[28] and live liver donations can also be made.[29] Nevertheless, donating a liver is much more troublesome than donating a kidney. People only have one liver; thus, the donor's liver must be split by the surgeon to provide for the recipient. Accordingly, approximately one in 300 liver donors die from surgical complications and 30 percent suffer complications.[30] For this reason only about four percent of the liver transplants performed in 2014 used live donors.[31] Likewise, living heart, lung, and other organ donations are extremely rare, so cadavers are the primary source for these organs.[32]

The dearth of organs has resulted in the use of low quality organs.[33] In fact, the organs of cancer patients have been

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[27] *Frequently Asked Questions*, UNIV. MARYLAND MED. CTR., http://umm.edu/programs/transplant/services/kidney/living-donor/faq#q6 [http://perma.cc/9RJL-3PNS] (last visited Nov. 6, 2015).

[28] *Data*, *supra* note 25.

[29] *About Living Donation*, AM. TRANSPLANT FOUND., http://www.americantransplantfoundation.org/about-transplant/living-donation/about-living-donation/ [http://perma.cc/F47S-LCDP] (last visited Nov 6, 2015).

[30] *Q and A on Living Donor Liver Transplantation*, UNIV. MARYLAND MED. CTR., http://umm.edu/programs/transplant/services/liver/living-donor/q-and-a-on-living-donor-liver-transplantation [http://perma.cc/WV8V-8U6B] (last visited Nov. 30, 2015).

[31] *Data*, *supra* note 25. (To find current numbers, follow "National data", "select report, choose category, transplant", "choose organ, liver", "transplants by donor type.").

[32] *Id.* (To find current numbers, follow "National data", "select report, choose category, transplant", "choose organ, all", "transplants by donor type", "change report, heart, lung, intestine, and pancreas.").

[33] Jon Diesel, *Do Economists Reach a Conclusion on Organ Liberalization?*, 7 J. AM. INST. ECON. RES. 320, 322 (Sept. 2010) (discussing how the growth of the organ waiting list has resulted in "expanded criteria" for procuring cadaver organs), *available at* http://econjwatch.org/articles/do-economists-reach-a-conclusion-on-organ-liberalization [http://perma.cc/4YK8-XXVV].

used in transplants.[34] The recipients of these organs have, in some rare cases, developed cancer as a consequence of receiving the organs.[35] Another problem caused by the shortage is poor quality genetic matches between the organ and the recipient. A better match, unsurprisingly, decreases the likelihood of the recipient's body rejecting the new organ.[36] The organ shortage means people have to linger in the organ queue for an average of three to five years.[37] The patient's health is deteriorating during this time and may render a patient ineligible for an organ.[38] Therefore, an organ alternative or a way to increase the supply of human organs is needed.

III. POSSIBLE SOLUTIONS

Outside of a market for human organs, a few solutions exist to alleviate the organ shortage. Technological advances will help alleviate the organ shortage one day. Preventative healthcare is another way to reduce the organ shortage. Presumed consent is a policy successfully used by some countries to increase the organ supply. Addition–ally, donor

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[34] *Can I Donate My Organs If I've Had Cancer*, AM. CANCER SOC'Y, http://www.cancer.org/treatment/survivorshipduringandaftertreatment/can-i-donate-my-organs [http://perma.cc/V7HX-X7GE] (last visited Nov. 6, 2015).

[35] *Id.*

[36] Christoph Frohn et al., *The Effect of HLA-C Matching on Acute Renal Transplant Rejection*, 16 NEPHROLOGY DIALYSIS TRANSPLANTATION 355, 355 (2001) (discussing the desirability of immunologically compatible despite the immunosuppressive drugs), *available at* http://ndt.oxfordjournals.org/content/16/2/355.full [http://perma.cc/LFU5-HXVX].

[37] *The Waiting List*, KIDNEY LINK, http://www.kidneylink.org/TheWaitingList.aspx [http://perma.cc/LRN8-2NH8] (last visited Nov. 6, 2015).

[38] *Glossary*, Organ Procurement and Transplantation Network, http://optn.transplant.hrsa.gov/resources/Glossary#A [http://perma.cc/T6R7-T2HZ] (last visited Nov. 6, 2015).

pairing schemes are posited as a way to help reduce the organ shortage. Each of these options is discussed below.

A. Technology

Stem cells are immature cells and have the ability to become any of the body's specialized cells.[39] The ability of stem cells to transform into any of the body's cells leads scientists and medical professionals to believe stem cells may be able to cure a medley of health problems.[40] For over twenty years, stem cells have been used in bone marrow transplants to help recipients produce healthy white blood cells.[41] In 2013, scientists grew a "mini-kidney."[42] This occurrence was the first time researchers have been able to produce a functioning kidney with stem cells.[43]

Although stem cell research has the potential to solve the organ shortage, the technology is likely over a decade away.[44] Stem cell research is also controversial; however, most of the debate surrounds embryonic stem cell research. The Catholic Church has no qualms with stem cells obtained licitly,

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[39] *Stem Cell Basics*, NAT'L INST. HEALTH, http://stemcells.nih.gov/info/basics/pages/basics1.aspx [http://perma.cc/ZW27-PG8M] (last visited Nov. 30, 2015).

[40] *The Power of Stem Cells,* CALIFORNIA INST. FOR REGENERATIVE MED., https://www.cirm.ca.gov/patients/power-stem-cells [https://perma.cc/F7QZ-UB4V] (last updated Jan. 2015).

[41] Theodore Moore et. al., *Bone Marrow Transplantation*, MEDSCAPE, http://emedicine.medscape.com/article/1014514-overview [https://perma.cc/SEF8-4AWS] (last updated Nov. 7, 2014).

[42] Jonathan Pearlman, *Kidney Grown from Stem Cells by Australian Scientists*, THE TELEGRAPH (Dec. 16, 2013, 10:28 AM), http://www.telegraph.co.uk/news/worldnews/australiaandthepacific/australia/10520058/Kidney-grown-from-stem-cells-by-Australian-scientists.html [http://perma.cc/6G7B-ADVG].

[43] *Id.*

[44] The Associated Press, *Lab-grown Organs Might Be Solution to Transplant Woes*, N. Y. DAILY NEWS (June 17, 2013, 2:22 PM), http://www.nydailynews.com/life-style/health/scientists-work-grow-organs-transplants-article-1.1374818 [http://perma.cc/M5P5-2DQ5].

meaning without destroying human life.[45] The issue presented by embryonic stem cell research is the same issue presented by abortion: When does life begin? The Vatican's statement on the question is, "from the moment the zygote has formed, [it] demands the unconditional respect that is morally due to the human being in his bodily and spiritual totality."[46] Embryonic stem cell research results in the death of embryos, viewed as whole persons by the Catholic Church and many others.[47] Opponents believe the benefits that may result are outweighed by the destruction of life caused by the stem cell research.[48]

Cloning has potential to solve the organ shortage but presents many of the same issues as stem cell research. There are a variety of different types of artificial cloning. Therapeutic cloning is the type most pertinent to the organ shortage as researchers hope to grow organs to replace diseased ones.[49] Indeed, in 2014, stem cells were cloned and now offer the prospect for new transplant operations.[50] As

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[45] William Card. Levada & Luis F. Ladaria, S.I., *Congregation for the Doctrine of the Faith: Instruction Dignitas Personae on Certain Bioethical Questions*, THE VATICAN (June 20, 2008), http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html [http://perma.cc/VB5Z-HLHN].

[46] *Id.*

[47] Nancy Frazier O'Brien, *Embryonic Stem-Cell Research Immoral, Unnecessary, Bishops Say,* AM. CATHOLIC, http://www.americancatholic.org/News/StemCell/ [https://perma.cc/UM3H-TSLG] (last visited Feb. 4, 2016).

[48] *Id. See also Embryonic Stem Cell Research: An Ethical Dilemma,* EUROSTEMCELL, http://www.eurostemcell.org/factsheet/embryonic-stem-cell-research-ethical-dilemma [https://perma.cc/Y2PX-3SPE] (last updated Nov. 5, 2015).

[49] *Cloning*, NAT'L HUMAN GENOME RESEARCH INST., http://www.genome.gov/25020028#al-3 [http://perma.cc/SBN7-86V7] (last updated June 11, 2015).

[50] Sarah Knapton, *Breakthrough in Human Cloning Offers New Transplant Hope*, THE TELEGRAPH (Apr. 17, 2014, 8:04 PM), http://www.telegraph.co.uk/news/science/science-

therapeutic cloning involves stem cells, many of the same objections are raised against it. In fact, the Vatican condemns therapeutic cloning even more harshly than it reprimands reproductive cloning.[51] Therapeutic cloning results in the destruction of stem cells, and the Vatican asserts, "It is *gravely immoral to sacrifice a human life for therapeutic ends*."[52]

A new technology offering a solution to the organ shortage is bioprinting, a form of 3D printing. To provide a very crude description of bioprinting, the 3D printer uses an "ink" composed of cells and a base, usually a hydrogel but sometimes collagen.[53] Layers of the designed structure are printed atop one another producing the desired design.[54] Bioprinting is already being used to create various bone implants.[55] Although functioning organs have not been produced yet, organ prototypes have been successfully bioprinted.[56] The adaptability of stem cells makes their use appealing in bioprinting;[57] however, the use of stem cells, as previously stated, presents ethical issues. Furthermore, 3D printing functional organs is likely decades away.[58] Therapeutic cloning is in its early stages, so creating functional organs through this means is also likely many

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news/10774097/Breakthrough-in-human-cloning-offers-new-transplant-hope.html [http://perma.cc/4WN9-HDTH].

[51] Card. Levada & Ladaria, S.I., *supra* note 45.

[52] *Id.*

[53] Lyndsey Gilpin, *3D 'Bioprinting': 10 Things You Should Know About How It Works*, TECHREPUBLIC (Apr. 23, 2014, 4:00 AM), http://www.techrepublic.com/article/3d-bioprinting-10-things-you-should-know-about-how-it-works/ [http://perma.cc/FG85-HBN5].

[54] *Id.*

[55] Sarah Butler, *Medical Implants and Printable Body Parts to Drive 3D Printer Growth*, THE GUARDIAN (Aug. 24, 2014), http://www.theguardian.com/business/2014/aug/24/medical-implants-drive-3d-printer-growth [http://perma.cc/VV8K-KTEM].

[56] Gilpin, *supra* note 53.

[57] *Id.*

[58] Butler, *supra* note 55.

years away.[59] A more immediate solution to the organ shortage is needed.

B. Presumed Consent

Presumed consent involves changing the law to classify a decedent as a potential organ donor unless that individual had manifested opposition to donation prior to death.[60] Legislation, in favor of presumed consent, will almost certainly increase the number of organs available for transplantation.[61] Hence, Spain, often regarded as the model presumed consent nation, has the highest cadaver organ procurement rate in the world.[62]

The Spanish presumed consent model relies heavily on donor coordinators, of which it has many–at least one in each hospital.[63] Spanish donor coordinators utilize techniques to identify potential donors then attempt to develop a relationship with the donor's family.[64] Spain also reimburses hospitals for the organ donors they provide.[65] In addition to this, education and advertising are part of the Spanish

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[59] Vicki Glaser, Progress in Stem Cell Pluripotency, GEN (Jan. 15, 2014), http://www.genengnews.com/gen-articles/progress-in-stem-cell-pluripotency/5115/?page=2 [https://perma.cc/96FQ-M3L3].

[60] Alberto Abadie & Sebastien Gay, *The Impact of Presumed Consent Legislation on Cadaveric Organ Donation: A Cross-Country Study*, 25 J. HEALTH & ECON. 599, 600 (2006) (defining presumed consent), *available at* http://www.hks.harvard.edu/fs/aabadie/pconsentp.pdf [http://perma.cc/BC7D-YNQ9].

[61] Simon Bramhall, *Presumed Consent for Organ Donation: A Case Against*, 93 ANN. R. COLL. SURG. ENGL. 268, 272 (2011) (stating presumed consent seems like a sure way to increase the organ supply), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3363073/pdf/rcse9304-270.pdf [http://perma.cc/R73N-53TD].

[62] Rafael Matesanz et. al., *Spanish Experience as a Leading Country: What Kind of Measures Were Taken?* 24 TRANSPLANT INT'L 333, 334 (2011), *available at* http://onlinelibrary.wiley.com/doi/10.1111/j.1432-2277.2010.01204.x/epdf [http://perma.cc/EUT9-2DGQ].

[63] Bramhall, *supra* note 61, at 270-71.

[64] *Id.* at 271.

[65] *Id.*

model.[66] The Spanish model has been replicated with success in Italy, implying other nations can adopt the model with similar results.[67]

Presumed consent has a practicality to it. The dead have no use for their organs, and those with disease can benefit tremendously from the organs. Presumed consent has a high social utility; however, presumed consent does not always work. Sweden has adopted presumed consent but has seen no change in its cadaver organ donation rate.[68] Moreover, the citizens of Brazil and France vehemently opposed the introduction of presumed consent.[69] The result of attempted presumed consent legislation was an aversion to organ donation in the two countries.[70]

Although Spain is heralded as the exemplar of a presumed consent regime, the Spanish model does not rely on presumed consent for its success.[71] Spanish physicians can legally harvest a decedent's organs without a family's consent, but doctors usually respect the wishes of the family.[72] Spanish procurement officials are financially rewarded based on the number of donors they recruit,[73] and one assumes monetary incentives affect procurement performance regardless of the law. Perhaps most importantly, the Spanish system offers payments to the decedent's family for funeral expenses.[74] Despite Spain's efforts, the waiting list for kidney transplants in Spain has not been substantially reduced since presumed consent was implemented.[75]

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[66] *Id.*

[67] *Id.*

[68] *Id.*

[69] *Id.*

[70] *Id.*

[71] T. RANDOLPH BEARD ET AL., THE GLOBAL ORGAN SHORTAGE 43 (2013).

[72] *Id.*

[73] *Id.*

[74] *Id.*

[75] Ghods & Savaj, *supra* note 9 at 1144 (discussing the success that the Spanish model has had with increasing the number of organs

Presumed consent presents legal and ethical problems for the United States. It implies the government owns people at the moment of their death, and this is antithetical to the common law tradition that an individual's rights exist even after death.[76] The government claiming dominion over the bodies of the deceased would likely constitute a taking under the Fifth Amendment and require just compensation. This raises the issue of whether the government would be violating NOTA, as it would be providing compensation for the decedent's body when NOTA forbids exchanging valuable consideration for human organs.[77] First Amendment religious liberty issues are also likely to arise if presumed consent is implemented in the United States. In any event, over 99% of deaths do not provide transplantable organs,[78] so a different solution to the organ shortage must be sought.

C. Prevention

Most people on the organ waiting list are there because of preventable disease. Over 80% of Americans waiting for an organ are in line for a kidney.[79] Diabetes is the leading cause of kidney failure in the United States accounting for 43.7% of cases,[80] and the vast majority of diabetics have type 2

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available, but stating that the increase has done little to reduce the shortage).

[76] DANIEL HANNAN, INVENTING FREEDOM 141 (2013).

[77] 42 U.S.C. § 273e(a) (2015).

[78] Fry-Revere, *supra* note 7.

[79] *Data*, *supra* note 25. (To see current information, follow "data", "national data", "select report, choose category, waiting list", click "candidates", and "overall by organ." Divide the kidney total by all organs to arrive at the percentage.)

[80] *High Blood Pressure and Kidney Disease*, NAT'L INST. DIABETES & DIGESTIVE & KIDNEY DISEASES, http://kidney.niddk.nih.gov/KUDiseases/pubs/highblood/ [http://perma.cc/J4MQ-6UP7] (last visited Nov. 30, 2015).

diabetes (roughly 27.85 million of the 29.1 million cases).[81] High blood pressure is the second leading cause of kidney disease accounting for 28.4% of kidney disease in the United States.[82] Diet, exercise, maintaining a healthy bodyweight, limiting alcohol consumption, and not smoking can often prevent high blood pressure and type 2 diabetes.[83] Following these guidelines can also help prevent the need for liver, heart, and other organ transplants.

Although the solution is simple, government attempts to promote healthier lifestyles will likely meet with controversy in the United States. The Affordable Care Act ("ACA") requires health insurance plans to cover counseling for obesity[84] and a myriad of other "free" preventive health services.[85] Recent polling data shows a majority of Americans disapprove of the ACA.[86] Moreover, the ACA's future is uncertain as congressional republicans continue their effort to repeal it.[87]

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[81] *See Statistics About Diabetes*, AM. DIABETES ASS'N (June 10, 2014), http://www.diabetes.org/diabetes-basics/statistics/ [http://perma.cc/5XGC-CUGL].

[82] *High Blood Pressure and Kidney Disease*, *supra* note 80.

[83] *Preventing High Blood Pressure: Healthy Living Habits*, CTR. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/bloodpressure/healthy_living.htm [http://perma.cc/LV68-NKH8] (last updated July 7, 2014).

[84] *Watch Your Weight*, HEALTHFINDER.GOV, http://healthfinder.gov/HealthTopics/Category/health-conditions-and-diseases/diabetes/watch-your-weight#take-action_5 [http://perma.cc/9ZZ5-R7W9] (last updated Sept. 23, 2015).

[85] *Preventive Health Services for Adults*, HEALTHCARE.GOV, https://www.healthcare.gov/preventive-care-benefits/ [https://perma.cc/2QLL-C9MW] (last visited Nov. 30, 2015).

[86] *Public Approval of Health Care Law*, REALCLEAR POLITICS, http://www.realclearpolitics.com/epolls/other/obama_and_democrats_health_care_plan-1130.html [https://perma.cc/7R4W-W7BL] (last visited Feb. 8, 2016).

[87] Jordan Fabian, *Obama Vetoes Health Bill Repeal,* THE HILL (Jan. 8, 2016), http://thehill.com/homenews/administration/265078-obama-vetoes-healthcare-bill-repeal [https://perma.cc/RX7F-2PMF].

The American aversion to the ACA is symbolic of Americans opposition to government interference with their private health choices. Former New York City Mayor Michael Bloomberg's proposed soft drink ban was supported by only 36% of the City's residents.[88] First Lady Michelle Obama's campaign to encourage healthier lifestyles prompted high school students to blame her for their unappetizing lunches with the hashtag #thanksmichelleobama.[89]

Ultimately, any public health policy's effectiveness is contingent on its acceptance by the targeted population. Americans do not seem eager to change their largely unhealthy lifestyles, so prevention, despite its effectiveness, is an unlikely solution to the organ shortage.

D. Facilitate Living Donation

One way of facilitating organ donation is through paired organ donation. Paired donation works by matching an incompatible donor/recipient pair with another incompatible donor/recipient pair. More than two groups of people can be involved in the exchange. Donor exchanges enable patients to get organs their bodies are more likely to accept. As paired donation operates via market mechanism, that is trading an incompatible kidney for a compatible kidney, it raises many of the same ethical questions as monetary purchases of organs.[90] Congress passed the Charlie W. Norwood Living

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[88] Michael M. Grynbaum & Marjorie Connelly, *60% in City Oppose Bloomberg's Soda Ban, Poll Finds*, THE N.Y. TIMES (Aug. 22, 2012), http://www.nytimes.com/2012/08/23/nyregion/most-new-yorkers-oppose-bloombergs-soda-ban.html [http://perma.cc/AS5Z-TFQZ].

[89] Laura Mandaro, *Teens Tweet Gross Lunches, Say #thanksmichelleobama*, USA TODAY (Nov. 22, 2014, 9:52 PM), http://www.usatoday.com/story/news/nation-now/2014/11/22/thanksmichelleobama-school-lunches-pictures-twitter/ 19415567/ [http://perma.cc/T6HP-3A5V].

[90] Sam Crowe et al., *Increasing the Supply of Human Organs: Three Policy Proposals*, THE PRESIDENT'S COUNCIL ON BIOETHICS (2007),

Organ Donation Act in 2007 clarifying that paired donation does not violate NOTA.[91] Since the Act's passage, the kidney waiting list has grown implying paired donation is not the solution to the organ shortage. This is not surprising because barter is an inefficient method of allocating resources.[92]

Another way of increasing the number of living donors is to make donation less burdensome. Traveling and time spent getting evaluated for donation can be expensive. Medical professionals recommend eight weeks for recovery post donation.[93] During this period, the donor still has to pay rent and other expenses, so even the most willing of donors may not be able to afford to donate. The organ recipient can reimburse donors for some of these expenses; however, only recipients with sufficient wealth can afford to do this.[94] A government program, the National Living Donor Assistance Center, provides up to $6,000 of pre-transplant expenses for those living with an income of 300% of the poverty level or below.[95] Insurance or another program may help those with incomes above this level during the pre-transplant phase. Aside from medical care, donors receive little help post-transplant.

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https://bioethicsarchive.georgetown.edu/pcbe/background/increasing_supply_of_human_organs.html [https://perma.cc/9CFD-QXYQ].

[91] Charlie W. Norwood Living Organ Donation Act, Pub. L. No. 110-144, 121 Stat. 1813 (2007).

[92] Gary S. Becker & Julio J. Elias, *Cash for Kidneys: The Case for a Market for Organs*, THE WALL ST. J., http://www.wsj.com/articles/SB10001424052702304149404579322560004817176 [http://perma.cc/ZGP8-WASA] (last updated Jan. 18, 2014, 4:58 PM) [hereinafter *Cash for Kidneys*].

[93] *FAQ: Living Kidney Donor*, UNIV. CALIFORNIA SAN FRANCISCO MED. CTR., http://www.ucsfhealth.org/education/living_kidney_donor/#24 [http://perma.cc/Z3HU-5U2L] (last visited Nov. 30, 2015).

[94] Crowe et al., *supra* note 90.

[95] Nat'l Living Donor Assistance Ctr., *Living Organ Donors: Assistance with Travel, Lodging and Meals*, *available at* https://www.livingdonorassistance.org/documents/NLDAC_Program_Brochure.pdf [https://perma.cc/QN2N-TCSR] (last visited Nov. 30, 2015).

Enabling charities, private individuals, or the government to provide financial assistance to donors makes sense. The American Living Organ Donor Fund ("ALODF") is a private charity that helps donors with postoperative expenses,[96] but the ALODF is operating in a legal gray area due to NOTA's prohibition on offering "valuable consideration" in exchange for human organs. Over a dozen states provide tax incentives to facilitate donations of organs and marrow; nevertheless, these state tax breaks have not increased donation rates.[97] Although payment for organs is illegal, donors should not suffer financially in the aftermath of their beneficent act.[98] Reducing the economic strain of donors will increase donations, but probably will not end the organ waiting list.

IV. ORGAN MARKET ETHICAL ISSUES

Perhaps the most obvious solution to the organ shortage is creating a market for human organs. Basic economics states if the price of a good increases more people will be willing to supply the good.[99] The concept is so natural that soon after antirejection drugs enabled transplants to occur between diverse peoples an international organ market was proposed.[100] Under the proposal, Americans would be allowed to purchase the organs of impoverished citizens of

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[96] *Mission*, AM. LIVING ORGAN DONOR FUND, http://www.helplivingdonorssavelives.org/about-us/our-mission/ [http://perma.cc/C2GJ-JMAJ] (last visited Nov. 30. 2015).

[97] *Tax Incentives and Organ Donation*, AM. TRANSPLANT FOUND. (Nov. 15, 2012), http://www.americantransplantfoundation.org/2012/11/15/tax-incentives-and-organ-donation/ [http://perma.cc/6HCN-8NRY].

[98] *Mission*, *supra* note 96.

[99] Al Ehrbar, *Supply*, LIBRARY ECON. & LIBERTY (2008), http://www.econlib.org/library/Enc/Supply.html [http://perma.cc/3QER-WSAK].

[100] Susan Hankin Denise, *Regulating the Sale of Human Organs*, 71 Va. L. Rev. 1015 (1985) (discussing Barry Jacobs' proposed organ market).

the Third World.[101] Public outrage prompted NOTA, and its prohibition on organ sales.[102] Virtually every country has banned the organ trade. .[103] Countless organizations including the United Nations,[104] American Medical Association ("AMA"),[105] and the Catholic Church[106] have condemned the market for human organs.

Underlying most objections to the organ market are principles of fairness and corruption. The fairness argument is premised on the notion that people are entering the market with unequal bargaining power; therefore, one party has the ability to unduly coerce the other.[107] Accordingly, true mutual consent cannot be obtained in the transaction.[108] For example, the wealth gap between the richest and poorest Americans prevents a fair exchange between the groups—especially for something as important an organ. The fairness objection is amplified by the possibility of wealthy citizens

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[101] *Id.* at 1022.

[102] *Id.* at 1023-24.

[103] Lisanne Denneman & Marianne Mol, *Organ Trade: A Win-Win Situation or Exploitation in Disguise?*, GLOBAL MED. 19 (Nov. 2010), http://e.issuu.com/embed.html#10443465/30247857 [http://perma.cc/3AJT-B3RJ].

[104] Arthur Caplan et al., *Trafficking in Organs, Tissues and Cells and Trafficking in Human Beings for the Purpose of the Removal of Organs*, JOINT COUNCIL EUROPE/UNITED NATIONS STUDY 30 (2009), http://www.coe.int/t/dghl/monitoring/trafficking/Docs/News/OrganTrafficking_study.pdf [http://perma.cc/K97R-SGD5].

[105] *Opinion 2.15-Transplantation of Organs from Living Donors*, AM. MED. ASS'N, http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion215.page [http://perma.cc/3SW5-K2TG] (last updated June 2011).

[106] Pope John Paul II, *Address of the Holy Father John Paul II to the 18th International Congress of the Transplantation Society* (Aug. 29, 2000), http://w2.vatican.va/content/john-paul-ii/en/speeches/2000/jul-sep/documents/hf_jp-ii_spe_20000829_transplants.html [http://perma.cc/TP9R-JDSX].

[107] Michael J. Sandel, *What Money Can't Buy: The Moral Limits of Markets*, THE TANNER LECTURES ON HUMAN VALUES 112 (May 11-12, 1998), http://tannerlectures.utah.edu/_documents/a-to-z/s/sandel00.pdf [http://perma.cc/3AGQ-7NKN].

[108] *Id.*

from around the globe purchasing organs from poor denizens of the world's most impoverished nations. The living standards are so vastly different in some countries that citizens of wealthy countries can basically purchase organs for free.[109] If the organ market is legalized, proponents of the fairness argument fear the rich will come to view the poor as organ banks.[110]

Corruption is the other morality-based argument made by organ market opponents. The corruption argument asserts some things should not be commoditized because putting a price on a thing diminishes it.[111] Human organs are considered by some opponents of an organ market to be outside the commercial sphere and should be treated exclusively as gifts.[112] Following the Kantian tradition, treating organs as commodities diminishes the inherent dignity of human beings by treating people as a means rather

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[109] *GDP Per Capita*, THE WORLD BANK, http://data.worldbank.org/indicator/NY.GDP.PCAP.CD?order=wbapi_data_value_2014+wbapi_data_value+wbapi_data_value-last&sort=asc. Gross domestic product per capita can serve as a proxy for average annual income in a country. Using United States dollars, World Bank data shows Malawi had the lowest GDP per capita in 2014 at $255 and Luxembourg had the highest GDP per capita at $116,664.3. This means Malawi's average GDP per capita is less than one percent of the average Luxembourg citizen's GDP per capita. Consequently, a wealthy individual from Luxembourg can spend less than one percent of her annual income on a kidney from a Malawian, and this transaction would result in the Malawian exceeding his annual income. This is particularly true if the Malawian is poor by the country's standards.

[110] Brian Resnick, *Living Cadavers: How the Poor Are Tricked Into Selling Their Organs*, THE ATLANTIC (Mar. 23, 2012), http://www.theatlantic.com/health/archive/2012/03/living-cadavers-how-the-poor-are-tricked-into-selling-their-organs/254570 [http://perma.cc/4GJW-LW4E].

[111] Sandel, *supra* note 107, at 112.

[112] Julia D. Mahoney, *Altruism, Markets, and Organ Procurement*, 72 Law & Contemp. Probs. 17, 17 (2009), *available at* http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1535&context=lcp [http://perma.cc/QV2A-QMCF].

than an end.[113] Pope John Paul II aligned himself with Kant by stating, "any procedure which tends to commercialize human organs or to consider them as items of exchange or trade must be considered morally unacceptable, because to use the body as an 'object' is to violate the dignity of the human person."[114] Aside from devaluing life, opponents of organ markets assert organ selling violates the medical principle of "do no harm" because extracting an organ harms the provider purely for commercial reasons.[115]

Nonetheless, some who assert that exchanging money for organs is unacceptable would permit certain forms of nonmonetary compensation for donors. Suggested nonmonetary rewards for donation include a donor medal-of-honor and insurance coverage.[116] Interestingly, reimbursing donors for funeral expenses also constitutes a nonmonetary incentive.[117] A small amount, $300, is considered a sign of appreciation and not a payment; plus, the payment is made after the donor's death.[118] The difference between these signs of appreciation and money are symbolic, but organ market opponents think symbols matter.[119] The distinction between

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[113] Susan M. Shell, *Chapter 13: Kant's Concept of Human Dignity as a Resource for Bioethics* in *Human Dignity and Bioethics: Essays Commissioned by The President's Council on Bioethics*, THE PRESIDENT'S COUNCIL ON BIOETHICS (Mar. 2008), https://bioethicsarchive.georgetown.edu/pcbe/reports/human_dignity/chapter13.html [http://perma.cc/PNW9-LJB3].

[114] Pope John Paul II, *supra* note 106.

[115] Arthur Caplan, *Chapter 28: Organ Transplantation* in *From Birth to Death and Bench to Clinic: The Hastings Center Bioethics Briefing Book for Journalists, Policymakers, and Campaigns*, THE HASTINGS CTR. 131 (2008), http://www.thehastingscenter.org/uploadedFiles/Publications/Briefing_Book/organ%20transplantation%20chapter.pdf [http://perma.cc/RQB7-FL2Y].

[116] Francis L. Delmonico et al., *Ethical Incentives—Not Payment—for Organ Donation*, 346 N. ENGL. J. MED. 2002, 2003 (2002), *available at* http://eml.berkeley.edu/~webfac/held/delmonico.pdf [http://perma.cc/55VV-TCW6].

[117] *Id.*

[118] *Id.*

[119] *Id.* at 2004.

expressing gratitude for an organ and buying the organ is analogous to giving a friend a bottle of wine as thank you versus handing him cash.[120]

Appeals to fairness and corruption neither alleviate the organ shortage, nor do they benefit the people prohibition is supposed to protect. These concerns both hinge in part on the possibility of exploitation of the poor resulting from the coercive purchasing power of the rich. Financial pressure affects the poor more than the rich making it unfair, and coercion violates the individual's humanity by disrupting his free will. However, objections based on financial pressure are almost entirely irrelevant in a market for cadaver organs, as the dead cannot be coerced. People vend organs to improve their earthly lives rather than to gain rewards in the afterlife. In the organ market, financial coercion arises from discrepancies in wealth in favor of the buyer. What if the script is flipped and billionaire Bill Gates wants to sell his kidney to a poor Pakistani? Similarly, what if people with equivalent levels of wealth want to enter a transaction for a kidney? Objections to the organ market premised on monetary coercion are more difficult to sustain when the playing field is leveled or tilted in the other direction.

If a market for human organs is legalized, it seems probable that the majority of organ sellers will be poor.[121] However, barring an activity is not justified simply because a majority of people participating in the activity are poor. The indigent shine shoes, mine coal, and engage in various other trades that the rich do not because they are poor.[122]

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[120] *Id.*

[121] Gary S. Becker & Julio Jorge Elias, *Introducing Incentives in the Market for Live and Cadaveric Organ Donations*, 21 J. ECON. PERSPECTIVES 3, 21 (2007) (discussing criticisms of an organ market), *available at* http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.335.4572&rep=rep1&type=pdf [http://perma.cc/5QKE-ZGAA] (hereinafter *Introducing Incentives*).

[122] Sunny Woan, *Buy Me a Pound of Flesh: China's Sale of Death Row Organs on the Black Market and What Americans Can Learn from It*, 47 SANTA CLARA L. REV. 413, 439 (2007).

Prohibiting opportunities to earn money does not improve the condition of those in poverty. An additional point to consider regarding kidney sales is 3 of 10,000 living kidney donors die during the operation,[123] Accordingly, death during a kidney removal operation is lower than the risk of death in common occupations like refuse collector (3.58 per 10,000) and roofer (4.62 per 10,000).[124] The risk of death during kidney donation is substantially lower than the risk of death in the legal commercial fishing industry, which has an annual fatality rate of 12.4 per 10,000 workers.[125] Divers and those employed in various other occupations receive additional pay for taking on jobs that pose high risks to their health.[126] Preventing people from choosing what risks are acceptable in their quest to earn a living is "paternalism in its worst form."[127]

Although shielding the poor from abuse by the wealthy is a purpose of prohibiting organ sales, prohibition has created the black market.[128] A summit representing numerous organizations that oppose the sale of human organs acknowledged that the shortage of organs, caused at least in part by prohibition, has led to undesirable and unethical

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[123] *Living Donors*, NAT'L KIDNEY REGISTRY, http://www.kidneyregistry.org/living_donors.php?cookie=1 [http://perma.cc/U8EL-KLLF] (last visited Nov. 30, 2015).

[124] BUREAU OF LABOR STATISTICS, NAT'L CENSUS OF FATAL OCCUPATIONAL INJURIES IN 2014 (PRELIMINARY RESULTS) 4 (Sep. 17, 2015), http://www.bls.gov/news.release/pdf/cfoi.pdf [http://perma.cc/ABP8-M7SF].

[125] *Commercial Fishing Safety*, CTR. DISEASE CONTROL & PREVENTION, http://www.cdc.gov/niosh/topics/fishing/nationaloverview.html [https://perma.cc/5TRN-JSDE] (last updated Oct. 28, 2014).

[126] J. Savulescu, *Is the Sale of Body Parts Wrong?*, 29 J. MED. ETHICS 138, 139 (2003), *available at* http://jme.bmj.com/content/29/3/137.full.pdf+html [http://perma.cc/LNN2-JANS].

[127] *Id.*

[128] The black market is discussed in greater depth in the following section. The cursory discussion occurring here is simply to an answer an objection to the organ market rather than provide a thorough analysis of the black market.

outcomes such as the black market.[129] All of the legal organ market opponents' worst fears are happening in the underground trade of human organs, and are caused by prohibition.[130] People from wealthy countries routinely purchase organs (usually kidneys) from impoverished citizens of the Third World.[131] Black market transactions are often exploitative and make the transplant process itself extra risky.[132] Seller health erodes substantially after black market operations.[133] Buyers are at high risk of contracting diseases like HIV and have much lower survival rates than when transplants are performed in a proper medical environment.[134]

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[129] *The Declaration of Istanbul on Organ Trafficking and Transplant Tourism*, THE TRANSPLANTATION SOC'Y & INT'L SOC'Y NEPHROLOGY 1 (Apr. 30-May 2, 2008), http://multivu.prnewswire.com/mnr/transplantationsociety/33914/docs/33914-Declaration_of_Istanbul-Lancet.pdf [http://perma.cc/N7C7-XLUZ].

[130] Dominique Martin, *Medical Travel and the Sale of Human Biological Materials: Suggestions for Ethical Policy Development*, 10 GLOBAL SOC. POL'Y 377, 385 (2010) (noting that prohibition likely causes the ethical problems banning organ sales is supposed to prevent).

[131] Nancy Scheper-Hughes, *Parts Unknown: Undercover Ethnography of the Organs-Trafficking Underworld*, 5 ETHNOGRAPHY 29, 33 (2004), *available at* http://www.uky.edu/~tmute2/geography_methods/readingPDFs/scheper-hughes-PartsUnknown.pdf [http://perma.cc/JR3K-BBKF] (discussing how transplant technology has spread to the developing world and how the poor have become a source of organs for the privileged).

[132] L D de Castro, *Commodification and Exploitation: Arguments in Favour of Compensated Organ Donation*, 29 J. MED. ETHICS 142, 145 (2003), *available at* http://jme.bmj.com/content/29/3/142.full.pdf+html [http://perma.cc/QQW9-WGXX] (discussing how prohibiting organ sales does not protect those who are participating in illegal organ operations).

[133] Vivekanand Jha, *Paid Transplants in India: The Grim Reality*, 19 NEPHROLOGY DIALYSIS TRANSPLANTATION 541, 542 (2004), *available at* http://ndt.oxfordjournals.org/content/19/3/541.full.pdf+html [http://perma.cc/LQG3-R77L].

[134] David B. Samadi, *Consequences of the Rise of Illegal Organ Trafficking*, FOX NEWS (May 30, 2012), http://www.foxnews.com/health/2012/05/30/consequences-rise-in-illegal-organ-trafficking/ [http://perma.cc/LQG3-R77L].

The ghoulish outcomes produced by the black market are nonexistent in proper clinical settings. Parting with a kidney should present the same risk regardless of whether the kidney is available because of charitable or commercial motives, because the procedure is the same regardless of the organ provider's motivation. Kidney donation is a fairly safe procedure. In fact, Johns Hopkins Medicine states "donors tend to do as well or better than the general population in regard to long term medical complications."[135] The legality of donation allows donors to receive proper medical care post operation. When things go poorly during donation, the law provides recourse to donors. This grants donors protection from medical mishaps. Furthermore, donors must undergo a screening process to legally donate an organ.[136] The black market has no such vetting process; hence, the vulnerable are at much greater risk of predation in illicit organ transactions. Accordingly, providing a legal framework for organ sales is the best way to prevent unfair transactions that exploit the poverty-stricken.[137]

Fairness may be a stated reason to prevent the organ market, but the impacts of the organ shortage are not fair. Minorities are more likely to suffer from kidney disease than

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[135] Karl Womer, *What Kidney Donors Need to Know: Before, During, and After Donating a Kidney*, JOHNS HOPKINS MED. COMPREHENSIVE TRANSPLANT CTR., http://www.hopkinsmedicine.org/transplant/news_events/media/transcripts/kidney_pancreas/what_kidney_donors_need_to_know.html [http://perma.cc/AML3-P4SM] (last visited Nov. 30, 2015).

[136] *Donor Screening and Testing*, CTR. DISEASE CONTROL & PREVENTION, http://www.cdc.gov/transplantsafety/screening_testing.html [http:// perma.cc/4GVJ-34HJ] (last updated June 17, 2013).

[137] J. Radcliffe-Richards et al., *The Case for Allowing Kidney Sales*, 351 THE LANCET 1950, 1951-52 (1998) *available at* http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(97)08211-1/fulltext [http://perma.cc/2F8M-5SVF] (asserting that exploitation is more likely to occur in illegal activities).

whites.[138] Blacks and Latinos are less likely to be placed on organ waitlists than whites because doctors do not refer nonwhites to transplant centers as frequently as physicians refer whites.[139] Even assuming blacks and whites are placed in the kidney queue at the same time, blacks wait an average of 74% longer than whites to receive a kidney.[140] Interestingly, kidneys are the only organ that matching is a criteria rather than first-in-line status and medical need.[141] Matching seems like a medically neutral criteria, but it has racially disparate impacts. A federal appellate court noted that people with diverse genes have a tougher time finding genetic matches, such as blacks who often have a "mix of African, Caucasian, and Native-American genes."[142] In fact, blacks are only one-tenth as likely as whites to find a perfect match.[143] Kidneys also happen to be the organ that blacks need most disproportionately to whites.[144] Moreover, research indicates tissue matching is not an accurate predictor of transplant outcomes.[145]

The organ shortage not only causes treatment discrepancies based on race but also wealth and status. Money is not explicitly considered in organ distribution; nevertheless, a person with means has an advantage over those who lack resources.[146] The rich can legally purchase

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[138] *Race/Ethnicity and Kidney Disease*, AM. KIDNEY FUND, http://www.kidneyfund.org/are-you-at-risk/risk-factors/race-kidney-disease/ [http://perma.cc/2ZCG-WLHC] (last visited Nov. 30, 2015).

[139] MICHELE GOODWIN, BLACK MARKETS: THE SUPPLY AND DEMAND OF BODY PARTS 90-91 (2006).

[140] *Id.* at 96.

[141] *Id.* at 97.

[142] Flynn v. Holder, 684 F.3d 852, 857 (2011).

[143] GOODWIN, *supra* note 139, at 103.

[144] *Id.* at 97.

[145] *Matching and Compatibility*, U.C. DAVIS HEALTH SYS., http://www.ucdmc.ucdavis.edu/transplant/livingdonation/donor_compatible.html [http://perma.cc/C9LR-XKDP] (last visited Nov. 30, 2015).

[146] Ray Hainer, *Did Steve Jobs' Money Buy Him A Faster Liver Transplant?*, CNN, http://www.cnn.com/2009/HEALTH/06/24/

billboards and other forms of publicity that the poor cannot, and the AMA deems donations resulting from public solicitation ethical.[147] Advertising increases the advertiser's odds of receiving a directed organ donation, giving the rich an advantage over the poor in organ procurement. Wealthy citizens can also circumvent organ waiting lists by having residences in multiple states, and this enables wealthy individuals to be added to the organ waiting list in multiple jurisdictions.[148] This gives the rich an advantage over the poor.[149] Likewise, the rich can afford to engage in transplant tourism while the poor languish in organ queues because the poor lack the financial wherewithal to purchase organs on the black market.[150] Regarding status, Pennsylvania Governor Robert Casey received a heart and liver transplant simultaneously within 24 hours of being placed on the wait list.[151] Ethicists determined Casey did not receive preferential treatment, but his political office and wealth created the public perception that Casey benefitted from his status.[152]

The belief that the body is sacred and organ sales will corrupt its sanctity is a legitimate position. Convincing

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liver.transplant.priority.lists/index.html?iref=24hours [http://perma.cc/86XY-RGJD] (last updated June 24, 2009, 11:29 AM).

147 *Opinion 2.15-Transplantation of Organs from Living Donors*, *supra* note 105.

148 *Cash for Kidneys*, *supra* note 92.

149 Judith Randal, *Mantle's Transplant Raises Delicate Issues About Organ Allocation*, 88 J. NAT'L CANCER INST. 484, 484 (1996), *available at* http://jnci.oxfordjournals.org/content/88/8/484.full.pdf [http://perma.cc/NQA3-VDVR].

150 Henriette Johansen, *Lebanon's Black Market in Refugee Organs*, MIDDLE E. MONITOR (Jan. 5, 2014, 8:52 PM), https://www.middleeastmonitor.com/blogs/lifestyle/9067-lebanons-black-market-in-refugee-organs [http://perma.cc/ELT3-7DZC] (noting that rich Arabs fly to Beirut for transplants, even though buying organs is illegal. Presumably the poor are not doing this.).

151 Claudia Coates, *Casey's Quick Transplant Renews Ethics Debate*, L.A. TIMES (July 25, 1993), http://articles.latimes.com/1993-07-25/news/mn-17587_1_heart-transplant [http://perma.cc/QS7L-QQZ7].

152 *Id.*

someone with this position of the potential benefits of an organ market is unlikely. One assumes this objection is held in good faith; however, it is worth pointing out that opponents of kidney sales have bought organs.[153] High minded positions are easy to take when the position holder is not the one suffering and staring death in the face. Furthermore, it is most peculiar that the medical personnel who perform the transplant are paid; the site of the transplant charges a fee; the organ recipient is able to exchange money for the gift of life; yet the person who makes the procedure possible–the organ provider–cannot be compensated without corrupting the procedure.[154]

In fact, current law allows a form of compensation to organ donors because paired organ donation is legal.[155] Paired donation is not considered corrupting, akin to the wine example above; rather, paired donation is considered altruistic.[156] Professor Richard Epstein calls allowing paired donation while prohibiting purchases "baloney" because paired donation is a "market for barter."[157] There is no practical difference between a trade and a cash transaction. The purpose of the organ transaction is to save lives, so a market provides the most efficient mechanism for facilitating lifesaving organ transplants.[158] Plus, money is provided as a

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[153] SIGRID FRY-REVERE, THE KIDNEY SELLERS 95 (2014).

[154] Charles A. Erin & John Harris, *An Ethical Market in Human Organs*, 29 J. MED. ETHICS 137, 137 (2003), *available at* http://jme.bmj.com/content/29/3/137.full.pdf [http://perma.cc/8SA2-48ZE].

[155] 42 U.S.C. § 274e(a) (2015).

[156] Richard Epstein, *The Economics of Organ Donations: EconTalk Transcript*, LIBRARY ECON. & LIBERTY (June 5, 2006), http://www.econlib.org/library/Columns/y2006/Epsteinkidneys.html [http://perma.cc/RWT6-7VWM].

[157] *Id.*

[158] Nicholas Capaldi, *A Catholic Perspective on Organ Sales*, 6 CHRISTIAN BIOETHICS 139, 145 (2000), *available at* http://www.ualberta.ca/~dcl3/Ref_2007-Aug-17/commercialization%20AND%20health%20policy%20OR%20forecasting%20etc/commercialization_body+parts_catholic+perspective.pdf [http://perma.cc/BF74-M7W7].

gift without denigrating the recipient in various situations such as birthdays, weddings, and baptisms.[159] This may be why the AMA's Council for Ethical and Judicial Affairs has determined there is nothing inherently unethical about an organ market.[160]

Although the law prohibits organ sales, sales occur and little is done to stop them. Sending people to jail who would not be alive but for the organ they illegally purchased strikes most people as unjust. Likewise, sending organ sellers to jail who have sacrificed their bodies so that another may live is equally deplorable. Organ market opponents may object to the market despite the seeming immorality of punishing market participants. Nevertheless, prohibiting the organ market is not practical. The law cannot stamp out all unseemly occurrences, so Thomas Aquinas believed the law should target actions that affect parties who do not consent to the activity like murder and rape.[161] Aquinas would agree the black market in human organs is repugnant and desire its end. Determining an end is only half of the equation– devising a means to practically achieve the objective is the other half.[162] The organ market opponent goal of preventing body defilement is best realized by creating a market where the rule of law governs transactions. This may be why Pope Pius XII left open the possibility of an organ market noting, "[I]t would be going too far to declare immoral every acceptance or every demand of payment."[163]

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[159] L D de Castro, *supra* note 132 (discussing the various situations when money is given as a gift or incentive).

[160] Deborah Josefson, *United States Starts to Consider Paying Organ Donors*, 324 BRIT. MED. J. 446, 446 (2002), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1172054/ [http://perma.cc/A3GS-N3RS].

[161] THOMAS AQUINAS, ON LAW, MORALITY, AND POLITICS 62 (William P. Baumgarth & Richard J. Regan, 2d ed. 2002).

[162] T. Hoffman, *Aquinas on the Nature of Prudence*, http://faculty.cua.edu/hoffmann/courses/769_1081/769_Summary_2a2ae.47.pdf [http://perma.cc/8EH4-NWNJ] (last visited Nov. 30, 2015) (discussing prudence in action in 47.8 c summary section).

[163] Capaldi, *supra* note 158, at 141.

Arguments based on fairness and corruption do not address the question of whether a market for organs would increase the supply of organs. Indeed, some opponents of organ markets assert providing financial compensation for organs would decrease the quantity, as well as the quality, of organs available for transplant. This theory is based largely on Richard Titmuss's 1971 study of the blood supply in England and the United States.[164] During the period of Titmuss's observation, blood sales were illegal in the United Kingdom but legal in the United States.[165] Titmuss found the quality and quantity of blood supply in the United Kingdom was superior to the blood supply in the United States.[166] Titmuss concluded the American system leads to higher costs as well as greater risks of contaminated blood and chronic blood shortages.[167]

This prompted Titmuss to conclude Americans viewed blood as a commodity, so Americans were less likely to donate blood.[168] Although people were allowed to donate blood in the United States, Titmuss theorized donations were crowded out by purchases.[169] Titmuss believed replacing charity with a market would have deleterious effects on altruism in a

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[164] Amy Crawford, *The Trouble with Organ Banking*, Boston Globe (June 1, 2014), https://www.bostonglobe.com/ideas/2014/05/31/the-trouble-with-organ-banking/Gaugdq7GMnEs8mKWISSAyM/story.html [https://perma.cc/E5KC-A3J3]. *See also* Cynthia B. Cohen, *Public Policy and the Sale of Human Organs* 12 KENNEDY INST. OF ETHICS J. 47, 54, *available at* http://www.hawaii.edu/religion/courses/organsale2.htm [https://perma.cc/SD6R-8NFC] (stating "Titmuss's views about the importance of the gift relationship were brought back into public discussion with respect to the sale of kidneys.").

[165] S. M. Rothman & D. J. Rothman, *The Hidden Cost of Organ Sale*, 6 AM. J. TRANSPLANTATION 1524, 1525 (2006), *available at* http://www.societyandmedicine.columbia.edu/organs_challenge.shtml [http://perma.cc/HH9T-PBW2].

[166] Iain McLean, *The Gift Relationship*, POLICY-NETWORK.NET, http://www.policy-network.net/publications_download.aspx?ID=6839 [http://perma.cc/U2TQ-NFKY] (last visited Nov. 30, 2015).

[167] Sandel, *supra* note 107, at 123.

[168] *Id.* at 124.

[169] *Id.*

society.[170] More recent studies support Titmuss's hypothesis. One such study involved an Israeli daycare where tardy parents were fined. When fines of $2.50 were imposed, the number of late pickups increased.[171] When the fine was removed, the tardiness persisted.[172] This implies that placing a price on organs will create a permanent commercial stigma around organs and removal of the price will not necessarily revert social perceptions on organ donations to the way they were pre-commodification.

The impact of commercialization on blood quantity and quality has been well rebutted. At the time of Titmuss's writing, blood screening tests were not prevalent.[173] Modern blood testing mitigates Titmuss's fear of harvesting the blood of skid row donors infected with hepatitis and other blood borne diseases who are looking for money.[174] Regarding the effect of money on the quantity of blood, the United States blood supply is obtained almost entirely from altruistic donors.[175] However, the United States pays plasma providers.[176] Blood shortages are chronic in the United States, but the United States has a plasma surplus and is a plasma exporter.[177] Likewise, organ procurement systems that offer compensation, including Spain discussed *supra* and Iran discussed *infra*, have better organ procurement rates than other systems.[178] This trend strongly suggests that financial incentives will increase the organ supply. Turning to the altruism claim, multiple motives go into most actions. Paying donors may send social signals that contradict the charity motivation.[179] Nevertheless, the key message from

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170 *Id.*
171 Rothman & Rothman, *supra* note 165, at 1525.
172 *Id.*
173 BEARD ET AL., *supra* note 71, at 98.
174 *Id.*
175 *Id.* at 184.
176 *Id.*
177 *Id.* at 99.
178 *Id.*
179 *Id.* at 98-99.

the Israeli example is to provide significant compensation or no compensation at all.[180] Recent research also indicates market incentives may actually increase altruistic behavior.[181]

Putting aside all other arguments, the ability to control what happens to one's own body is a matter of freedom. It seems odd for the government to prevent people from making choices that affect only their own body, and this is the fundamental issue involved in the organ market. One may counter this by pointing out that the same principle applies to prostitution and drug use, yet the government prohibits these activities. However, there is a crucial distinction between the aforementioned activities and the ability to sell one's organs. Drug use and prostitution, although they involve only willing participants, are seldom thought to be a social benefit. On the contrary, organ vending has tremendous social value. A life is saved through this consensual transaction, and human suffering is reduced. The vendor stands to benefit from the transaction as well through the receipt of money and the satisfaction of saving a life. If the vendor did not think the transaction was in her best interest, the vendor would not consent to the agreement.

A financial incentive does not diminish the nobility of a deed. The salaried firefighter who risks his life by running into a flaming house to rescue a child is not less valiant than a volunteer firefighter. American soldiers are not less brave because they receive pay. A person need not sacrifice everything and be unrewarded to perform a worthy feat. For this reason, Professor Nicholas Capaldi asserts, "[T]he for-profit sale of an organ or the acceptance of recompense does not of itself reduce organ donation to a mere instrumental use of the body; it thus does not in itself render the donation

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[180] *Id.* at 99.

[181] Cary Deck & Erik O. Kimbrough, *Do Market Incentives Crowd Out Charitable Giving?*, 47 J. SOCIO-ECON. 8 (2013), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3857091/./ [http://perma.cc/T95F-EFAU].

less morally praiseworthy."[182] Accordingly, it matters not whether organs are provided to those in need by altruism or a commercial transaction. The organ recipient's life is saved by receiving the organ—not by the method used to procure the organ.

People have the right to engage in all sorts of dangerous activities. The government permits cigarette smoking though smoking has no health benefits; in fact, smoking kills 480,000 Americans each year.[183] Not only are people allowed use harmful drugs for recreation, people are allowed to engage in dangerous hobbies. BASE jumping may be the most dangerous hobby, as it has a fatality rate of 40 per 100,000 jumps;[184] therefore, BASE jumping is statistically more dangerous than donating a kidney. Aside from BASE jumping, people are free to sky dive, hang glide, mountain climb, and engage in numerous other inherently hazardous activities. People can even earn a living performing some these activities.[185] If people are allowed to consume cancer sticks and engage in unsafe hobbies, why should competent adults be forbidden from receiving compensation for their organs when the transaction will save a human life?

Americans have a fundamental right to create life.[186] Procreation can cost nothing but can also be rather pricey as sperm and eggs can be purchased. In Vitro Fertilization and surrogate mothers are very expensive. These, especially surrogacy, present similar ethical issues to an organ market, and a powerful argument can be made that the questions

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[182] Capaldi, *supra* note 158, at 142.

[183] *Health Effects Infographics*, CTR. DISEASE CONTROL & PREVENTION (Feb. 27, 2015), http://www.cdc.gov/tobacco/data_statistics/tables/health/attrdeaths/ [http://perma.cc/45YM-YHDF].

[184] K. Soreide et al., *How Dangerous Is BASE Jumping? An Analysis of Adverse Events in 20,850 Jumps from the Kjerag Massif, Norway*, 62 J. TRAUMA 1113 (2007), *available at* http://www.ncbi.nlm.nih.gov/pubmed/17495709 [http://perma.cc/MPY6-YEWZ].

[185] *BASE Jumper*, INSIDE JOBS, http://www.insidejobs.com/careers/base-jumper [http://perma.cc/9NPP-X8V8] (last visited Nov. 30, 2015).

[186] Skinner v. Oklahoma, 316 U.S. 535 (1942).

involved in procreation using artificial methods set society on a slope far slipperier than an organ market. Organ transplantation is a widely accepted medical procedure, even by organizations that oppose organ selling. The Vatican, for example, approves of organ transplants.[187] However, the Vatican categorically opposes "designer babies" because, "[t]he fact that someone would arrogate to himself the right to determine arbitrarily the genetic characteristics of another person represents *a grave offense to the dignity of that person as well as to the fundamental equality of all people.*"[188] Yet to exercise the right to procreate, money can be legally used in the United States. Why is spending money to create a life acceptable while using money in a mutually beneficial transaction to preserve a life is deemed illicit?

American law allows the use of deadly force in self-defense; indeed, self-defense is often regarded as the first law of nature.[189] The United States also allows the use of deadly force to defend another person.[190] The life of a viable fetus can be terminated "when it is necessary to preserve the life or health of the mother."[191] In the United States, force or violence can be used to prevent "trespass against property in

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[187] *Address of the Holy Father John Paul II to the 18th International Congress of the Transplantation Society,* LIBRERIA EDITRICE VATICANA (Aug. 29, 2000), http://w2.vatican.va/content/john-paul-ii/en/speeches/2000/jul-sep/documents/hf_jp-ii_spe_20000829_transplants.html [https://perma.cc/S8ZV-RVFY]. The Vatican is not categorically opposed to an organ market. *See supra* note 158.

[188] *Instruction Dignitas Personae On Certain Bioethical Questions*, CONGREGATION FOR THE DOCTRINE OF THE FAITH, http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html [https://perma.cc/2QKG-PNC7] (last visited Feb. 4, 2016).

[189] Saul Cornell, *Natural Rights, Common Law, and the English Right of Self-Defense*, 14 INSIGHTS ON LAW AND SOC'Y (2013), *available at* http://www.americanbar.org/publications/insights_on_law_andsociety/14/fall-2013/natural-rights--common-law--and-the-english-right-of-self-defens.html [http://perma.cc/LL4L-Q47E].

[190] La. Stat. Ann. § 14:22 (2015).

[191] Roe v. Wade, 410 U.S. 113 (1973).

a person's lawful possession . . . ."[192] The law allows self-defense and defense of property even though these claims may be used to protect a criminal.[193] Similarly, allowing abortions for the health of the mother can, "become a tool for abortions anytime, for any reason."[194] On this basis, Professor Eugene Volokh asserts people have the right to "medical self-defense" when diagnosed with a terminal condition.[195] If an individual can legally kill another human being to preserve her life and violently defend property from trespass, surely she should be allowed to enter a consensual commercial transaction to save her life.

V. MONEY FOR ORGANS

This section examines the two systems where organ providers are compensated: the black market and the Iranian kidney system. The discussion of each market begins with an overview of their history and circumstances leading to their creation. A discussion of how each market operates follows. By nature, the black market has no formal process, so the discussion generalizes how the market operates based upon accounts from various sources. Next, the outcomes of each market are examined. As the Iranian system has both supporters and detractors, arguments and evidence for each position is weighed. The human organ black market is universally condemned; hence, an analysis its of pros and cons is unnecessary.

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[192] La. Stat. Ann. § 14:19 (2015).

[193] Eugene Volokh, *Medical Self-defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV. L. REV. 1813, 1817 (2007).

[194] Kim Painter, *Doctors Say Abortions Do Sometimes Save Women's Lives*, USA TODAY (Oct. 22, 2012), http://www.usatoday.com/story/news/nation/2012/10/19/abortion-mother-life-walsh/1644839/ [http://perma.cc/87RJ-SBX5].

[195] Volokh *supra* note 193, at 1823.

A. Black Market

The black market for human organs is a global enterprise. The illegal organ trade was spawned because a demand existed and the supply was artificially constrained. Legislation cannot stop the law of supply and demand.[196] As one economist notes, "Every time the propensity to exchange is constrained, individuals try to circumvent the constraints in order to obtain what they perceive as the benefits of exchange."[197] Regarding the organ market, individuals diagnosed with organ disease have a tremendous demand for functional organs. For the right price, some people are willing to sell their organs. Kidneys are particularly marketable because, as Judge Guido Calabresi says, "We all have too many kidneys; we have two, and we really only need one."[198] Although the ingredients for a mutually beneficially exchange are in place, most countries prohibit human organ sales placing a price ceiling of zero on all organs.[199] Predictably, the price ceiling on human organs has caused a shortage of organs, reduced quality of available organs, and created a black market.[200]

The demand side of the black organ market consists of wealthy, sick patients.[201] Patients facing certain death or a

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[196] L D de Castro *supra* note 132, at 142.

[197] Pierre Lemieux, *The Underground Economy: Causes, Extent, and Approaches*, MONTREAL ECON. INST. RESEARCH PAPERS 10 (Nov. 2007), http://www.iedm.org/files/cdr_nov07_en.pdf [http://perma.cc/3RXN-F68N].

[198] Guido Calabresi, *Do We Own Our Bodies?*, FACULTY SCHOLARSHIP SERIES 15 (1991), http://digitalcommons.law.yale.edu/cgi/viewcontent.cgi?article=3066&context=fss_papers [http://perma.cc/V4WV-MC29].

[199] Aziz, *supra* note 5, at 68.

[200] Fiona M. Scott Morton, *The Problems of Price Controls*, CATO INST. (2001), http://www.cato.org/publications/commentary/problems-price-controls [http://perma.cc/TXT3-LAK7].

[201] Michael Shafer & Paige Comstock Cunningham, *Medical Exploitation and Black Market Organs: Profiteering and Disparities in Global Medicine*, CTR. BIOETHICS & HUMAN DIGNITY (Nov. 4, 2011),

debilitating life on dialysis are willing to pay well over six figures for a kidney.[202] These patients often travel to foreign countries and in many cases receive poor quality organs that are not proper matches for their body.[203] The organs patients receive frequently have HIV and Hepatitis C.[204] Likewise, proper medical protocols do not have to be followed during illegal operations, so post operation complications are common.[205] These complications are difficult to treat when the patient returns to her home country because proper records are not kept on the black market.[206]

Black market buyers often arrange their illegal transplant through organ brokers. Organ brokers come from all walks of life, from organized crime syndicates to medical professionals.[207] Although the organ provider is usually lured into the transaction by money, physical force and subterfuge are used as well.[208] Organ brokers target the desperately poor from impoverished countries because poverty is the primary reason why individuals sell their body parts.[209] Individuals

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https://cbhd.org/content/medical-exploitation-and-black-market-organs-profiteering-and-disparities-global-medicine [http://perma.cc/R95C-P9WL].

[202] Denis Campbell & Nicola Davison, *Illegal Kidney Trade Booms as New Organ is 'Sold Every Hour'*, THE GUARDIAN (May 27, 2012), http://www.theguardian.com/world/2012/may/27/kidney-trade-illegal-operations-who [http://perma.cc/KLP7-5ZUG].

[203] Kristina Fiore, *Physicians Must Treat 'Transplant Tourists'*, ABC NEWS (Jan. 30, 2010), http://abcnews.go.com/Health/transplant-tourism-hidden-risks/story?id=9702948 [http://perma.cc/VS48-6M84].

[204] Nancy Scheper-Hughes, *Organ Trafficking: A Protected Crime*, THE CONVERSATION (Sep. 3, 2013, 1:50 AM), http://theconversation.com/organ-trafficking-a-protected-crime-16178 [http://perma.cc/8EKQ-LXUZ].

[205] Fiore, *supra* note 203.

[206] *Id.*

[207] *Organs for Sale,* UNITED NATIONS REGIONAL INFO. CENTRE FOR WESTERN EUROPE, http://www.unric.org/en/human-trafficking/27447-organs-for-sale [http://perma.cc/Y6NB-9DPG] (last visited Oct. 27, 2015).

[208] Shafer & Comstock Cunningham, *supra* note 201.

[209] Monir Moniruzzaman, *"Living Cadavers" in Bangladesh: Bioviolence in the Human Organ Bazaar,* 26 MED. ANTHROPOLOGY

who sell their organs are often completely ignorant as to how the organs operate, and this ignorance enables organ brokers to deceive sellers.[210]

Black market kidney providers typically receive around $1,000.[211] In addition to the price of their organs, sellers are promised a myriad of other goodies such as jobs, land, and visas.[212] Sellers are also told the trip to the transplant site will be jolly.[213] Tragically, sellers do not have a pleasant experience. They often wait for the transplant in a small, dingy, crowded apartment that functions as a prison.[214] Attempts to back out of the deal are met by violence.[215] The surgery is unnecessarily harsh too. Kidneys can be removed with a laparoscope.[216] Laparoscopic nephrectomy enables the patient to recover quicker than other methods and leaves a smaller scar.[217] However, black market operators are not willing use laparoscopes because the procedure costs a few hundred dollars more than using a scalpel. [218] Sellers are marked with a 20 inch long scar as a result.[219]

Recovery from the operation takes place in the same dank apartment where the seller was held prior to the surgery.[220] Although the recovery from the surgery takes weeks, sellers are so desperate to escape the apartment that they head

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QUARTERLY 69, 75 (2012), *available at* http://news.msu.edu/media/documents/2012/03/73a832b2-0893-4837-99fb-9ab6d10db302.pdf [http://perma.cc/QZF2-GGML].

[210] *Id.* at 75-76.

[211] Shafer & Comstock Cunningham, *supra* note 201.

[212] Moniruzzaman, *supra* note 209, at 77.

[213] *Id.*

[214] *Id.* at 78.

[215] *Id.*

[216] *Laparoscopic Nephrectomy,* THE JAMES BUCHANAN BRADY UROLOGICAL INST., http://urology.jhu.edu/MIS/lap_nephrectomy.php [http://perma.cc/BLW8-432J] (last visited Oct. 27, 2015).

[217] *Id.*

[218] Moniruzzaman, *supra* note 209, at 78.

[219] *Id.* at 78.

[220] *Id.*

home a few days post operation.[221] This prevents surgical wounds from healing properly.[222] Sellers also lack access to healthcare; hence, sellers struggle with health problems post surgery.[223] Physical issues resulting from the operation prevent sellers from engaging in physical labor; thus, the dire economic prospects that drove sellers to part with their organs are usually exacerbated by the organ sale.[224]

Once their organs are extracted, sellers are routinely not paid in full or denied payment altogether.[225] Sellers do receive the agreed upon sum sometimes; however, this does not ensure they will keep the money. For example, a Brazilian kidney seller returned home from South Africa three days after the operation with the agreed upon amount in his pocket.[226] He was robbed soon after landing.[227] The seller had no recourse because the money was obtained through an illegal transaction. To make matters worse, sellers are socially ostracized.[228] One Moldovan kidney seller says kidney sellers are treated worse than prostitutes.[229]

Although organ sales are forbidden in virtually every nation, the illegal organ trade is booming. The primary organ purchasing countries include Australia, Canada, Israel, Japan, Oman, Saudi Arabia and the United States.[230] These illegal organ purchases result in poor health outcomes for both the buyer and seller.[231] Moreover, coercion is present at

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[221] *Id.*

[222] *Id.*

[223] *Id.* at 78-79.

[224] *Id.* at 79.

[225] *Organs for Sale, supra* note 207.

[226] GOODWIN, *supra* note 139, at 188.

[227] *Id.* at 189.

[228] Moniruzzaman, *supra* note 209, at 78.

[229] Shafer & Comstock Cunningham, *supra* note 201.

[230] Yosuke Shimazono, *The State of the International Organ Trade: A Provisional Picture Based on Integration of Available Information,* 85 BULLETIN OF THE WORLD HEALTH ORGANIZATION 901-980 (2007), *available at* http://www.who.int/bulletin/volumes/85/12/06-039370/en/ [http://perma.cc/D86V-M5NU].

[231] *Id.*

both ends of the transactions. Sellers are generally penniless and ill informed about the risks of the procedure, and buyers are desperate to preserve their lives.

Despite the horrors of the black market and its universal condemnation, prosecutions for illegal organ sales are rare and difficult.[232] Israeli insurers reimbursed citizens for organ transplants performed anywhere in the world until 2008.[233] Still, Israel does not punish organ buyers and sellers because it views these people as victims.[234] Instead, Israeli law directs its wrath at the brokers and insurance companies that facilitate illegal organ operations.[235] The United States has only recently convicted the first person under federal law of organ trafficking in 2011.[236] The organ broker was released in under three years.[237] Though an immigrant, he was allowed to remain in the United States because his crime was not one of "moral turpitude."[238] Perhaps the medical community has reached the same conclusion because it

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[232] Nancy Scheper-Hughes, *Human Traffic: Exposing the Brutal Organ Trade,* NEW INTERNATIONALIST MAGAZINE (May 1, 2014), http://newint.org/features/2014/05/01/organ-trafficking-keynote/ [http://perma.cc/33LZ-2WZH].

[233] Dimitri Linde, *Israel, a Leader in Transplant Tourism, Finds a Formula for Increasing Domestic Donation,* TABLET (Apr. 10, 2014), http://tabletmag.com/jewish-news-and-politics/164976/israel-organ-donation [http://perma.cc/H48X-5HGW].

[234] Asif Efrat, *Combating the Kidney Commerce: Civil Society Against Organ Trafficking in Pakistan and Israel,* 53 BRIT. J. CRIMINOLOGY 764, 777 (Apr. 26, 2013), *available at* http://bjc.oxfordjournals.org/content/early/2013/04/22/bjc.azt025.full.pdf [http://perma.cc/QS55-7AJN].

[235] *Id.*

[236] *Brooklyn Man Pleads Guilty in First Ever Federal Conviction for Brokering Illegal Kidney Transplants for Profit,* FBI (Oct. 27, 2011), http://www.fbi.gov/newark/press-releases/2011/brooklyn-man-pleads-guilty-in-first-ever-federal-conviction-for-brokering-illegal-kidney-transplants-for-profit [http://perma.cc/ADT5-4QHK].

[237] David Glovin, *Organ Broker Skirts Expulsion After 'Victimless' Claim,* BLOOMBERG (Dec. 23, 2014, 7:39 PM), http://www.bloomberg.com/news/articles/2014-12-24/organ-broker-skirts-expulsion-after-victimless-claim [http://perma.cc/5DSB-JL4B].

[238] *Id.*

provides care to patients who illegally buy organs.[239] This encourages people to enter the black market while it penalizes those who follow the law and wait in the organ queue. Black market organ buyers and sellers do so because they have nowhere else to turn.[240] Punishing such people is tough.

B. Iranian Kidney System

Iran's organ transplant system began as part of Eurotransplant,[241] a central registry that stores data from several European countries and uses a compatibility matching system to allocate organs.[242] However, the Iranian Revolution severed the country's relationship with Eurotransplant.[243] The Iran-Iraq War began soon after the Revolution. These circumstances left Iran isolated and economically impaired; hence, Iran struggled to procure dialysis equipment.[244] From 1980 through 1985, dialysis patients in need of transplants had to travel abroad for the transplant, and living related donors provided most of the kidneys.[245]

The Iranian government funded the expensive surgery, and the increasing number of patients on the kidney transplant waiting list caused the Iranian government to establish kidney transplant centers in 1985.[246] The capacity to perform transplants inside Iran was only half the battle.

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[239] Fiore, *supra* note 203.

[240] Woan, *supra* note 122, at 428.

[241] FRY-REVERE, *supra* note 153, at 50.

[242] *Welcome on the Homepage of ETRL,* EUROTRANSPLANT REFERENCE LABORATORY, http://etrl.eurotransplant.org/cms/index.php [http://perma.cc/R643-JXR3] (last visited Nov. 6, 2015).

[243] FRY-REVERE, *supra* note 153, at 50.

[244] Ali Nobakht Haghighi & Nasrollah Ghahramani, *Living Unrelated Kidney Donor Transplantation in Iran,* NATURE CLINICAL PRACTICE NEPHROLOGY (2006), http://www.nature.com/nrneph/journal/v2/n12/full/ncpneph0364.html [http://perma.cc/6ZJW-W2MQ].

[245] Ghods and Savaj, *supra* note 9, at 1137.

[246] *Id.*

As is the case in every nation, the number of Iranians in need of a kidney exceeded the supply of living related donors.[247] A cadaver organ system was impractical in Iran because Iran lacked the infrastructure to preserve and transport organs.[248] Iranians also have a religious taboo against removing organs from the dead.[249] Thus, Iran created "a government-funded, -regulated, and -compensated living-unrelated donor renal transplantation program" in 1988.[250]

Creating a kidney market was not Iran's goal. The exchanges between kidney providers and recipients occurred naturally. Iranian medical personnel simply overlooked the transactions because they did not want their patients to die.[251] Wanting the best for their patients, the Iranian medical community hoped to regulate kidney exchanges.[252] Medical professionals were interested in screening donors and contract enforcement.[253] Individuals seeking to purchase a kidney sought to prevent would-be donors from taking a deposit then absconding from the contract as well as paying to screen individuals who fraudulently stated they were healthy enough to donate.[254] Interestingly, recipients believed the donors deserved higher levels of compensation than recipients were able to provide and wanted to provide donors with health insurance.[255]

Although Iran has a compensated donor program, physicians explain to patients the advantages of using a living related kidney donor over an unrelated donor.[256] If the patient has no living related donor, or decides against using a living related donor, the patient is referred to a non-

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[247] *Id.*
[248] FRY-REVERE, *supra* note 153, at 50.
[249] *Id.* at 134.
[250] Ghods & Savaj, *supra* note 9, at 1137.
[251] FRY-REVERE, *supra* note 153, at 50.
[252] *Id.*
[253] *Id.*
[254] *Id.*
[255] *Id.* at 50-51.
[256] Ghods & Savaj, *supra* note 9, at 1137.

governmental organization,[257] called an *Anjoman*, also referred to as Dialysis and Transplant Patients Associations (DATPA). *Anjomans* oversee Iran's compensated living unrelated kidney donor program and help locate matching kidneys for patients.[258] *Anjomans* serve the same function as brokers do on the black market[259] but are much more than benevolent kidney matchmakers.[260] *Anjomans* seem to genuinely care about their functions; accordingly, they assist patients medically and socially.[261]

Anjomans attempt to make the donor's experience as positive as possible because a donor that is well taken care of will encourage future donations.[262] To accomplish this goal, potential donors are screened by *Anjoman* staff. Potential donors are allowed to part with their kidney only if the *Anjoman* believes participating in the transplant can benefit the donor.[263] If the *Anjoman* thinks the operation will retrogress a seller, the *Anjoman* forbids the individual from donating her kidney.[264] If a kidney provider is approved, *Anjomans* ensure the donor is compensated.[265] The desire to help displayed by *Anjomans* is likely a consequence of their volunteer workforce composed of people who have participated in the transplant process.[266]

The Iranian Ministry of Health began compensating donors in 1987-88, and the Iranian parliament formally approved a payment of one million tomans in 1995 with the goal of eliminating price negotiations during kidney sales.[267] However, inflation eroded the value of the toman, and the

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[257] *Id.*
[258] FRY-REVERE, *supra* note 153, at 51.
[259] Ghods & Savaj, *supra* note 9, at 1137.
[260] FRY-REVERE, *supra* note 153, at 51.
[261] *Id.*
[262] *Id.*
[263] *Id.* at 157.
[264] *Id.* at 140.
[265] *Id.* at 100.
[266] Haghighi & Ghahramani, *supra* note 244.
[267] *Id.* at 83.

government did not increase the price.[268] Consequently, prices are now negotiated.[269] Kidney donors in 2009 received one million toman from the government plus an additional four to five million toman from the recipient on average.[270] Inflation makes comparing Iranian and American currencies difficult,[271] but the average Iranian individual income was approximately $3,000 in 2009.[272] The average price for a kidney during this period was approximately $5,000.[273] When the recipient is poor and unable to afford a kidney, charities compensate the kidney provider.[274]

Aside from donor compensation, other aspects of the transplant process are covered too. Recipients of kidneys can purchase immunosuppressive drugs for a low price because the drugs are subsidized.[275] Charitable organizations provide immunosuppressive drugs for indigent transplant recipients.[276] Iranian kidney donors also receive one year of health care from the government,[277] and in some regions of Iran, health insurance for life.[278] If male, donors are exempted from Iran's mandatory military service.[279] Kidney recipients commonly give the kidney seller more than the negotiated price. Additional compensation can be monetary but may also be in the form of food, clothing, or other goods.[280] In nearly half of kidney transactions between living unrelated donors, the provider and recipient develop a mutual friendship.[281]

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[268] *Id.*
[269] *Id.*
[270] *Id.* at 88.
[271] *Id.* at 22.
[272] *Id.*
[273] *Id.*
[274] Ghods and Savaj, *supra* note 9, at 1138.
[275] *Id.*
[276] *Id.*
[277] Fry-Revere, *supra* note 153, at 51.
[278] *Id.* at 156.
[279] *Id.* at 51.
[280] *Id.* at 92.
[281] *Id.* at 93.

Organ transplants in Iran, despite appearances, are not commercial transactions.[282] Transplants are performed in government run hospitals at the government's expense.[283] Any valuable consideration exchanged between the organ provider and recipient is regarded as a token of appreciation.[284] Iranian law reasons a kidney saves the life of the recipient, and life is priceless.[285] No amount of compensation can repay the donor for her sacrifice therefore, emoluments given to the donor are signs of gratitude.[286] Hence, organ transactions are mutual gifting rather than commercial sales under Iranian law.[287] Under Sharia Law, agreements to exchange gifts are legally enforceable.[288]

The gratuitous nature of the transaction means Iranians view those who sell their kidneys as "donors."[289] To understand this view of the Iranian kidney transplant system, the sociological conditions at the time of the system's establishment must be put in context.[290] Years of ruinous war with Iraq had generated a spirit of sacrifice inside Iran.[291] This inspired the Iranian living unrelated donor program where donors are compensated but still regarded as altruistic.[292] Iranian Ayatollah Mohaghegh Damads asserts, "[t]he Qu'ran looks favorably on those who help themselves

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[282] B. Larijani et al., *Ethical and Legal Aspects of Organ Transplantation in Iran,* 36 TRANSPLANTATION PROCEEDINGS 1241, 1242 (2004), *available at* http://ac.els-cdn.com/S0041134504005974/1-s2.0-S0041134504005974-main.pdf?_tid=18e6a234-7834-11e5-bb14-00000aacb35e&acdnat=1445460265_54a892f6601ca925fbf98821649a103d,.

[283] *Id.*

[284] Haghighi & Ghahramani, *supra* note 244.

[285] FRY-REVERE, *supra* note 153, at 99.

[286] *Id.*

[287] *Id.* at 100.

[288] *Id at 101.*

[289] Haghighi & Ghahramani, *supra* note 244.

[290] *Id.*

[291] *Id.*

[292] *Id.*

by helping others."[293] Thus, personal reward does not diminish the donor's sacrifice nor the good done by providing a kidney. The kidney provider saves a life, and the Qu'ran states, "if any saves a life it is as if he saves the lives of all mankind."[294]

Although these are the basics of the Iranian system, *Anjomans* operate slightly different in each region.[295] In Shiraz, using a compensated kidney donor is discouraged.[296] Donors and recipients are prohibited from "commercializing" the transaction beyond the government-guaranteed one million tomans.[297] *Anjoman* personnel in Shiraz deny knowledge of recipients providing donors with additional compensation, and no amount agreed upon would be legally binding in Shiraz.[298] Kermanshah's *Anjoman* treat patients less hospitably than *Anjomans* in other regions; nevertheless, Kermanshah's *Anjoman* manages to protect the interests of donors.[299]

Iranians must donate in their home province.[300] Theoretically, an Iranian could establish residence in another province if he had relatives there. The cost of travel and medical care related to the surgery, as well as the ability to access nonmedical benefits provided by the *Anjoman,* render travel infeasible for most Iranians.[301] Living unrelated donations are also restricted to individuals of the same nationality, and non-Iranian citizens must pay for their own surgery.[302]

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293 FRY-REVERE, *supra* note 153, at 100.
294 e.x. Surat I-maidah 5:32.
295 FRY-REVERE, *supra* note 153, at 112.
296 *Id.* at 57.
297 *Id.* at 59.
298 *Id.*
299 *Id.* at 187.
300 *Id.* at 60.
301 *Id.*
302 *Id.* at 19.

VI. ANALYSIS AND CRITIQUE OF IRAN'S KIDNEY SYSTEM

Following this model, Iran has not had a kidney waiting list since 1999.[303] No other country has been able to eliminate its kidney waiting list.[304] In fact, Iran's kidney program has produced a surplus of willing kidney providers.[305] Although having a surplus of willing donors may appear to be a good situation, the number of Iranians willing to part with their kidneys gives opponents of organ sales reason to question the Iranian system.

Critics of the Iranian system, and organ markets in general, note compensated Iranian donors are usually poor, and donors are compelled by their social condition to sell their kidneys.[306] A study of compensated Iranian kidney donors found 6% of donors were illiterate, 24.4% had only an elementary education, and 63.3% had high school educations, while only 6.3% had attended college.[307] The same study found 84% kidney providers were poor and 16% were middle class.[308] Wealthy Iranians do not part with their kidneys for compensation. There are also reports of the screening process failing to catch financially desperate people.[309] In the six months prior to the compensated kidney donation, the most

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[303] Ghods & Savaj, *supra* note 9, at 1137.

[304] Benjamin E. Hippen, *Organ Sales and Moral Travails: Lessons from the Living Kidney Vendor Program in Iran,* 614 CATO POL'Y ANALYSIS 1, 4 (Mar. 20, 2008), *available at* http://www.cato.org/sites/cato.org/files/pubs/pdf/pa-614.pdf [http://perma.cc/8PVF-EUHL].

[305] Anne Griffin, *Kidneys on Demand,* 334 BRIT. M. J. 502, 504 (Mar. 10, 2007), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1819484/pdf/bmj-334-7592-feat-00502.pdf [http://perma.cc/9WFE-8ALR].

[306] Francis L. Delmonico, *The Alternative Iranian Model of Living Renal Transplantation,* 82 KIDNEY INT'L. 625 (2012).

[307] Ghods & Savaj, *supra* note 9, at 1140.

[308] *Id.*

[309] B. Broumand, *Living Donors: The Iran Experience,* 12 NEPHROLOGY DIALYSIS TRANSPLANTATION 1830, 1831 (1997), *available at* http:// ndt.oxfordjournals.org/content/12/9/1830.full.pdf [https://perma.cc/ F9HD-PK5F].

common life events experienced by donors were increased life expenses, low income, and household duties.[310] These events were usually triggered by financial problems, losing one's job, and a family member's death.[311]

As a majority of compensated donors are poor and not well educated, concerns have been raised about the pre-transplant screening process.[312] There are reports of kidney providers being rushed through the donation process allowing providers with diseases such as HIV and tuberculosis to donate their kidneys.[313] Health is a concern after the operation as well because compensated donors showed poor health three months after the surgery.[314] Most compensated donors are not fully aware of the complications associated with living kidney donation and do not partake in follow up healthcare.[315] Psychological healthcare is an issue for compensated donors as 51% of compensated donors hated the person who received their kidney.[316] Three-quarters of kidney providers did not achieve their financial goals after the compensated donation,[317] so depression may be a problem among compensated donors. Compensated kidney donors also report being socially ostracized.[318] Additionally, the compensated living unrelated donor program is blamed for

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[310] Ali-Akbar Nejatisafa et al., *Quality of Life and Life Events of Living Unrelated Kidney Donors in Iran: A Multicenter Study*, 86 TRANSPLANTATION 937, 938 (2008), *available at* https://www.researchgate.net/publication/23317754_Quality_of_Life_and_Life_Events_of_Living_Unrelated_Kidney_Donors_in_Iran_A_Multicenter_Study [https://perma.cc/5BZ8-X9HW?type=source.]

[311] *Id.*

[312] E.J. Gordon & J.S. Gill, *Where There Is Smoke There Is Fire: The Iranian System of Paid Donation,* 13 AM. J. TRANSPLANT 3063 (2013).

[313] Broumand, *supra* note 309, at 1831.

[314] Nejatisafa et al., *supra* note 310, at 940.

[315] Gordon & Gill, *supra* note 312, at 3064.

[316] Javaad Zargooshi, *Iranian Kidney Donors: Motivations and Relations with Recipients,* 165 J. UROLOGY 386-392 (2001).

[317] *Id.*

[318] FRY-REVERE, *supra* note 153, at 88.

impeding the development of Iran's cadaver donation program.[319]

Most studies suggest the majority of compensated donors are poor, but some report the preponderance of compensated donors are middle class.[320] Regarding concerns about exploitation of the Iranian poor, it is important to note that the majority of Iranian kidney purchasers are poor.[321] Iranians would rather compensate a live donor and receive a kidney quickly than wait to accept a free kidney from a cadaver .[322] If the poor are exploited by the Iranian kidney market, Afghan refugees in Iran are prime candidates for exploitation as these Afghans are among the Earth's most impoverished people.[323] There are no known cases of Afghans participating in compensated donation of their kidneys with non-Afghans.[324] Interestingly, approximately 80% of Afghans who receive kidney transplants in Iran use paid living unrelated donors.[325] For this reason, Iran's kidney system is credited with providing equal access to kidney care "regardless of gender and economic circumstances."[326]

Aside from eliminating the kidney waiting list, Iran's system has greatly reduced the presence of coercion in kidney transactions.[327] The regulated infrastructure prevents the horrors of the black market.[328] Brokers have incentives to deceive both the patient and organ provider because a

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[319] Gordon & Gill, *supra* note 312, at 3064.

[320] Fry-Revere, *What Can Iran Teach Us About the Kidney Shortage?*, *supra* note 7.

[321] Ghods & Savaj, *supra* note 9, at 1140.

[322] FRY-REVERE, *supra* note 153, at 132-33.

[323] Ghods & Savaj, *supra*, note 9, at 1141.

[324] *Id.*

[325] *Id.*

[326] Behzad Einollahi et al., *Deceased-donor Kidney Transplantation in Iran; Trends, Barriers, and Opportunities,* 4 J. MED. ETHICS 70 (2007) *available at* http://ijme.in/index.php/ijme/article/view/536/1396 [https://perma.cc/Z3Q2-8KK8].

[327] *Id.*

[328] Haghighi & Ghahraman, *supra* note 244.

broker's payment hinges on the deal going through.[329] Plus, buyers and sellers have no legal recourse against organ brokers. Brokers are not necessary in Iran because compensated donors choose to present themselves for the kidney transaction.[330] Iran's kidney system is governed by nonprofit entities that are staffed by volunteers, so these institutions have no incentive to disenfranchise donors or recipients.[331] Therefore, providing a legal framework to compensate kidney donors has prevented the exploitation associated with sales on the black market.[332]

Financial coercion is often cited as the reason for preventing organ sales; nevertheless, there are other forms of coercion. Family pressure can be even more daunting than financial pressure, and the Iranian kidney system prevents familial coercion to donate an organ.[333] Iranian males must serve in the military.[334] However, men can be exempted for medical reasons, to care for elderly relatives, and to pursue an education.[335] The Iranian parliament considered a proposal allowing men to purchase an exemption, but this proposal was shutdown as discriminatory against the indigent.[336] Donating a kidney enables men to avoid conscription;[337] thus, the ability to choose whether to donate a kidney reduces the government's coercive power over Iranian men.

Although the health of compensated donors was worse three months after the donation than prior to the donation, the health of Iranian donors made a full recovery by the end

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329 Hippen, *supra* note 304, at 4.

330 *Id.* at 7.

331 *Id.* at 4.

332 Haghighi & Ghahramani, *supra* note 244.

333 Larijani, *supra* note 282, at 1242.

334 *Iran's New Military Policy Could Boost Birthrates,* AL-MONITOR (Oct. 12, 2014), http://www.al-monitor.com/pulse/originals/2014/10/iran-military-conscription-service.html# [https://perma.cc/4SSH-KGBC].

335 *Id.*

336 *Id.*

337 FRY-REVERE, *supra* note 153 at 51.

of the year.[338] The criticism leveled at Iran for not following kidney providers post operation is a consequence of limited resources.[339] Compensated donors often live far from the transplant center and are unable or uninterested in journeying back to the medical facility for a checkup.[340] Of the donors that were followed, a majority of compensated donors were satisfied with the transaction and suffered no serious health problems.[341] The social stigma mentioned by some kidney providers is likely an outcome of compensated donors being perceived as unable to earn money through more conventional methods.[342]

The account cited *supra* stating compensated donors are displeased with having donated their kidney was from a sample of 100 Iranians taken over 20 years ago.[343] Moreover, the study was performed in one province, Kermanshah.[344] Dr. Sigrid Fry-Revere's 2008-2009 study examined multiple regions, and she had the lowest regard for the system in Kermanshah.[345] Accounts that blame Iran's living donor program for the country's low cadaver donor rate are similarly flawed as each region of the country acts differently. Shiraz has been acknowledged by critics of the Iranian kidney system as "exemplary" in procuring and performing cadaver transplants.[346] Since Iran legalized

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[338] Nejatisafa et al., *supra* note 310, at 940.

[339] Ghods, *supra* note 10, at 226.

[340] *Id.*

[341] Heidary Rouchi et al., *Compensated Living Kidney Donation in Iran: Donor's Attitude and Short-term Follow-up,* 3 IRANIAN J. OF KIDNEY DISEASES 34, 34-39 (2009), *available at* http:// applications.emro.who.int/imemrf/ijkd_2009_3_1_34.pdf.

[342] Fry-Revere, *supra* note 153, at 89.

[343] Zargooshi *supra* note 316.

[344] *Id.*

[345] *Id.* at 178.

[346] Delmonico *supra* note 306, at 626.

cadaver donation in 2000, Iran has proceeded with cadaver donation much like other nations.[347]

Iran's kidney system is not perfect. No agency monitors the long-term outcome of kidney donations in Iran,[348] so conclusions about the system are made with limited information. Likewise, physical and mental health services should be provided to kidney providers long after the transaction.[349] The Iranian system has not completely eliminated the black market either.[350] The government payment system has not kept pace with the cost of living, and this has caused would-be recipients and donors to negotiate a price—the very thing the government payment was supposed to prevent.[351] Nevertheless, Iran has eliminated its kidney waiting list. A feat that has yet to be replicated.

Iran is not a free country.[352] The Iranian government is a tyranny.[353] Iran is not an adherent of laissez-faire economics. On the contrary, Iran's economy is one of the world's most restricted, ranked 171 out of 178.[354] This aversion to freedom has not prevented Iran from using market based incentives as a solution to the kidney shortage. Other countries should take note.

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[347] Mitra Mahdavi-Mazdeh et al., *Renal Replacement Therapy in Iran,* 4 UROL. J. 66, 67 (2007), *available at* http://www.sid.ir/En/VEWSSID/J_pdf/83020070203.pdf. [http://perma.cc/KWF6-2KYH].

[348] Bobak Zonnoor, *How to Sell Your Kidney: A Brief Overview of the Iranian Model for Kidney Transplantation,* IN-TRAINING (Mar. 21, 2014), in-training.org/sell-kidney-brief-overview-iranian-model-kidney-transplantation-5682 [http://perma.cc/4BCC-8N6M].

[349] Nejatisafa et al., *supra* note 310, at 940.

[350] Zonnoor, *supra* note 348.

[351] FRY-REVERE, *supra* note 153, at 83.

[352] *Iran,* FREEDOM HOUSE (2015), https://freedomhouse.org/report/freedom-world/2015/iran#.VQiww47F8uc [https://perma.cc/WE8U-VN8D].

[353] Behrooz Behubudi, *Iran: 35 Years of Religious Tyranny,* THE MIDDLE EAST http://www.themiddleeastmagazine.com/wp-mideastmag-live/2014/02/iran-35-years-of-religious-tyranny/ [http://perma.cc/GK2Y-BUZW] (last visited Jan. 2, 2016).

[354] *Country Rankings,* 2016 INDEX OF ECONOMIC FREEDOM, http://www.heritage.org/index/ranking [https://perma.cc/HM6E-EY66].

VII. AN ORGAN MARKET IN THE UNITED STATES

This section sets forth two organ markets. One is a market for live organs, and the other is a cadaver market for all organs. In the live market, kidneys are the focus. This is because kidney extraction is relatively simple compared to other organ extractions but also because kidneys are the organ most in demand. The cadaver market will be for all organs because there is less risk of harm when extracting organs from cadavers.

A. Live Organ Market

There is only one system where compensating organ providers is legal. Accordingly, the best organ purchasing mechanism system is unknown. This does not mean implementing a market for organs is a step into totally foreign terrain. On the contrary, the market for organs could operate just like the current United States' transplant system. Organ Procurement Organizations operate very similar to Iranian *Anjomans*.[355] UNOS can act as a monopsony, and a monopsony is the only ethically plausible system for an organ market.[356] Turning UNOS into a monopsony allows UNOS to distribute organs just as it currently does. The method used to pair organ providers and recipients is unaffected by whether the organ is purchased or donated. The same holds true for the medical process. Transplant teams will not alter their technique based upon the reason the organ has become available.

Most aspects of the transplant system will remain the same once payment for organs is allowed, but determining the price and the best method of distributing compensation to organ providers is a task that will require study. Experimentation with various aspects of the market should

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[355] Hippen, *supra* note 304, at 9.

[356] BEARD ET AL., *supra* note 71, at 194.

be allowed to occur.[357] A federalist approach to the organ market is well suited for such experimentation. As Justice Louis Brandeis noted, "It is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."[358] Allowing states to design their own systems enables the states to account for their own unique populations, cultures, and geographies.[359] Plus, permitting diverse compensation systems provides empirical data on whether compensation can increase the organ supply, and if so, what is the best method of providing compensation to organ providers.[360]

Although a federalist approach is suggested, the federal government should set certain guidelines for states. The organs will be purchased through a federal monopsony, so the federal government should set the price for organs. The federal amount will serve as the price floor, but states may choose to provide additional compensation to organ providers. Such compensation can be in the form of tax breaks, vouchers, employment preferences, or other means the state deems legitimate.

Calculating organ prices is difficult because organ sales are prohibited virtually everywhere. Nevertheless, various methods have been proposed to measure the value of organs. One way to value organs is using tort judgments. Tort awards are not appropriate for accessing the price of organs during a sale because the purpose of tort is "making the plaintiff

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[357] Hippen, *supra* note 304, at 11.

[358] *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932). (Brandeis, J., dissenting).

[359] Michele Goodwin, *Rethinking Federal Organ Transplantation Policy: Incentives Best Implemented by State Governments,* in WHEN ALTRUISM ISN'T ENOUGH: THE CASE FOR COMPENSATING KIDNEY DONORS 111, 121 (Sally Satel ed., 2008), *available at* http://www.aei.org/wp-content/uploads/2014/07/-when-altruism-isnt-enough_161836373082.pdf [http://perma.cc/RQ38-VAWB].

[360] *Id.*

whole."[361] In organ sales, the recipient is being made whole, not the seller. Hence, tort awards are not a proper fit to gauge the market price of a kidney. The other means of assessing an organ price is to use information from the available markets. On the black market, organ prices vary widely.[362] This is due in part to transactions occurring around the globe and in many currencies. In United States dollars, kidneys have been sold for as little as $650[363] and bought for as much as $300,000.[364]

Iran probably provides the best measure of kidney price. The average kidney "price" in Iran is approximately twice the mean Iranian income when the government, *Anjoman*, and recipient payments are summed.[365] In 2013, the United States average per capita income was $28,155.[366] Accordingly, valuing a kidney at roughly $50,000 seems like a reasonable rate of compensation for an American kidney. This does not mean all kidneys must be sold for the same price though as certain kidneys may be more desirable than others.[367] A formula that considers factors such as the

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[361] Jill Wieber Lens, *Honest Confusion: The Purpose of Compensatory Damages in Tort and Fraudulent Misrepresentation,* 59 KAN. L. REV. 231, 235 (2010), *available at* https://law.ku.edu/sites/law.drupal.ku.edu/files/docs/law_review/v59/02-Lens_Final.pdf [https://perma.cc/BS2K-K28M].

[362] *Organ Trafficking Prices and Kidney Transplant Sales*, HAVOCSCOPE, http://www.havocscope.com/black-market-prices/organs-kidneys/ [https://perma.cc/BC46-6J8J] (last visited Feb. 4, 2016).

[363] Gitonga Njeru, *Kenya: Sex-trafficked Women and Girls Also Vulnerable to Organ Trafficking,* WOMEN NEWS NETWORK (Sep. 13, 2011), http://womennewsnetwork.net/2011/09/13/kenya-women-girls-organ-traffickin/ [http://perma.cc/Y4FH-2V6L] (last visited Oct. 22, 2015).

[364] Jason Gale & Quah Chin Chin, *Singapore Tycoon to Be Jailed in Cash-for-Kidney Case,* BLOOMBERG (Sep. 3, 2008) http://www.bloomberg.com/apps/news?pid=newsarchive&sid=a0vvBzm2UVzg&refer=asia [http://perma.cc/Q683-TVYA].

[365] FRY-REVERE, *supra* note 153, at 220.

[366] *State & County QuickFacts,* U.S. CENSUS BUREAU, http://quickfacts.census.gov/qfd/states/00000.html (last updated Sept. 30, 2015) [http://perma.cc/U27C-FBM3].

[367] BEARD ET AL., *supra* note 71, at 196.

seller's age, rarity of blood type, and family medical history would be fair to include in kidney valuation. Thus, the price floor for kidneys should be set at a minimum of $50,000.

Distributing money to sellers presents challenges too. There are two issues to consider in disbursing the funds. One is whether to provide a lump sum or periodic payments. The other issue is whether to provide the payment immediately or defer the payment. States will have the option to choose how to allot the funds and can select one or more methods. Below, the four ways to approach the two issues are presented with their potential pros and cons.

1.) Immediate lump sum payment: Providing sellers with the full price of their kidney upfront probably provides the most powerful incentive for an individual to sell her kidney. The lump sum option enables sellers to improve their lives substantially and quickly. Putting $50,000 towards paying off debt, starting a business, or other use can have a sudden and dramatic positive impact on the seller's life. Contrarily, placing all of the money in the seller's hands at one time means there is a chance the money can disappear immediately. People who suddenly receive large sums of money at once, such as Lottery winners, often squander it.[368] Organ vendors going into financial ruin soon after the operation is bad for the individual, and the purpose of legalizing the market is to improve the lives of both the organ recipient and provider. Plus, news of organ sellers worsening their lives by vending their organs will discourage future sales. The purpose of the market is to increase the supply of organs; hence, it is imperative that sellers have positive experiences.

2.) Immediate periodic payments: Providing sellers with small periodic payments immediately after selling should minimize the odds of whimsical spending. This reduces the odds of sellers ending up in a worse financial position than

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[368] The Associated Press, *'I Had to Adapt to This New Life:' As Powerball Drawing Nears, Former Lottery Winners Say Hitting the Jackpot Comes at a Price*, N.Y DAILY NEWS (Nov. 28, 2012) http://www.nydailynews.com/news/national/mega-lottery-winners-sound-advice-article-1.1209336?localLinksEnabled=false [http://perma.cc/XGA4-6ZTS].

they were before the sale. It also provides a steady stream of income, even if the payments are only a few hundred dollars per month. Stretching the payments can make the money last longer as the amount will collect interest. The downside of periodic payments is the incentive may not be as powerful as the lump sum payment because the periodic payments do not have the instant effect that the lump sum does. Accordingly, periodic payments may not result in as many sales as lump sum payments, at least in the short run.

3.) Deferred lump sum payment: Deferring the payment virtually eliminates the possibility of duress playing a role in the transaction because the seller will receive no immediate benefit from the sale. Interest is also accruing on the payment while the sum remains in the bank. However, as the interval between the organ extraction and the payment increases, the number of people interested in selling their organs may decrease. The pain and risks of the operation are instantaneous, so deferring payment may lead people to assume the risk is not worth the reward. On the other hand, people who choose to undergo the procedure for a delayed benefit are more likely to have a plan for how they will use the proceeds of the sale. Presumably, such individuals are more likely to use the money prudently than they are to spend it on frolics.

4.) Deferred periodic payments: Deferred periodic payments operate very much like a pension and could feasibly be fused with a retirement package. The danger of placing payments for an organ in a retirement fund is the retirement fund could go broke. It would be tragic if organ providers exchanged their organs for a sum of money they will never see. For this reason, deferred periodic payments may not be attractive to potential sellers. Nevertheless, this option may be appealing to some. Knowing a sum of money is guaranteed regardless of how the stock market or their retirement fund performs could be attractive. Plus, the sum is generating interest payments during the deferment.

Regardless of how the states choose to distribute the money, the federal government should ensure states meet certain criteria. The purpose of these criteria is to protect the financial and physical wellbeing of vendors. Six safeguards are listed below.

1.) The live organ market should be limited to kidneys initially. This is because kidney extraction is the safest of the organ extractions,[369] and this fact will presumably make a kidney market more palatable to opponents of organ sales. Kidneys are also the organs most in demand. Eliminating the kidney shortage erases roughly 100,000 names from the organ queue. If the kidney market proves successful, then expanding the market to include other organs will make sense.

2.) Organ providers post operative living expenses should be covered. Although sellers are compensated for the transaction, providing an organ for transplant currently cost donors an average of $5,000.[370] This cost should be made clear to sellers, so they know to subtract $5,000 from the purchase price. Health insurers nor the government need necessarily be responsible for the post operative care. Charities will likely assist organ providers, both sellers and donors, once doing so is legal.[371] Currently, the ALODF attempts to allay the burden on donors by providing financial support.[372] ALODF is operating in a legal gray area. If the law clearly allowed organ providers to receive "valuable consideration," one assumes more assistance would be available to donors.

3.) Health insurance should be provided to all organ providers. The organ provider is undergoing a risk for the

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[369] Katrina A. Bramstedt, *Living Liver Donor Mortality: Where Do We Stand?,* 101 Am. J. Gastroenterology 1, 4 (2006), *available at* http://www.clevelandclinic.org/bioethics/documents/LiverDonorMortality.pdf [http://perma.cc/H72D-VC4T].

[370] Am. Transplant Found. & Lisa Shankar, *Understanding the Barriers to Living Donation,* AM. TRANSPLANT FOUND. http://www.americantransplantfoundation.org/programs/ mentorship-program-2/mentor/living-donor-connectors/understanding-the-barriers-to-living-donation/ [http://perma.cc/YWS3-7JFW] (last visited Oct. 22, 2015).

[371] Hippen, *supra* note 304, at 9.

[372] *Mission,* AM. LIVING ORGAN DONOR FUND, http:// www.helplivingdonorssavelives.org/about-us/our-mission/ [http:// perma.cc/CG47-42U3] (last visited Oct. 22, 2015).

purpose of saving a life. Protecting the organ provider's health is a logical way to compensate the provider for the risk. Health insurance should be provided to donors as well as sellers. Congressional republicans continue attempting to repeal the ACA,[373] but regardless of whether they ever succeed, healthcare can be offered to organ providers through government exchanges, Medicaid, Medicare, or a fully refundable health insurance tax credit. Even the libertarian Cato Institute is open to providing organ sellers and donors with healthcare.[374]

4.) Minimum organ seller-screening criteria should be established. A goal of legalizing the organ market is to reduce exploitation of the poor and incompetent. Setting forth a minimum waiting period prior to selling a kidney reduces the likelihood of a duress-induced sale. Similarly, psychological testing should occur to ensure the seller is competent and is aware of the risks of the procedure.

5.) Exempt kidneys and all organs, as well the proceeds of organ sales, from seizure. As preventing exploitation of sellers is a motivation for legalizing organ sales, prohibiting creditors from establishing claims to the organs of a debtor is imperative. Similarly, creditors should be barred from claims against money received from organ sales. Organ sellers have earned this money by sacrificing their bodies to save a life. Creditors should not be able to collect money that was earned from organ sales because the purpose of the market is to encourage consensual life saving transactions.

6.) The market should be limited to Americans. On the basis of practicality, accessing medical records of Americans is easier than accessing the medical records of foreign citizens.[375] The organ provider's medical history is highly germane to the transplant procedure. Ensuring the organ provider receives adequate post-operative care and healthcare subsequently requires the organ seller to be an American domiciliary.[376] Restricting the market to Americans decreases the likelihood of exploitation of citizens

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373 Fabian, *supra* note 87.
374 Hippen, *supra* note 304, at 10.
375 BEARD ET AL., *supra* note 71, et al. at 204.
376 *Id.*

from impoverished foreign nations though the screening process should detect and remove such people from the market.

B. Cadaver Organ Market

Becoming a cadaver organ seller can occur through the same channels one currently becomes an organ donor postmortem. The complicating factor is having the future organ seller allocate the payment after his death; however, this obstacle is easily overcome. The best solution would be having the seller allocate the money in a testament. In the absence of a written will, the money could be distributed via the laws of intestacy. A voucher for funeral expenses may also be an effective way of compensating organ providers, as demonstrated by Spain.[377]

Establishing a price for cadaver organs is complicated for the same reason as establishing a price for live organs: there are not many legal examples. One scholar suggested setting a cadaver price for each major organ at $864.27 in 2008,[378] roughly $938, adjusting for inflation.[379] Although the sale of cadavers is illegal, firms charge to process and store cadavers.[380] Corpses can be procured for $10,000 and generate up to $200,000 from the tissues.[381] Therefore, a lump sum payment of $1,000 is a reasonable base rate for

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[377] See discussion of the Spanish system *supra.*

[378] Lloyd R. Cohen, *Directions for the Disposition of My (and Your) Vital Organs,* REGULATION 33 (Fall 2005), http://object.cato.org/sites/cato.org/files/serials/files/regulation/2005/9/v28n3-1.pdf [http://perma.cc/XXB2-TPYA].

[379] *CPI Inflation Calculator,* Bureau of Labor Statistics, http://www.bls.gov/data/inflation_calculator.htm [http://perma.cc/W65P-QULE] (last visited Apr. 8, 2015).

[380] Kate Wilson et al., *Skin, Bones and Tissue for Sale: How the Dead Are Being Used for Grisly Trade in Human Body Parts* (July 18, 2012), http://www.dailymail.co.uk/news/article-2175006/Skin-bones-tissue-sale-How-dead-used-grisly-trade-human-body-parts [http://perma.cc/7LD4-L5QH].

[381] *Id.*

each cadaver organ. The sum could be even higher as only about one percent of cadaver organs are transplantable. However, there may be bars on payment in some cases. The law should not create an incentive for people to pull the plug on their parents nor commit suicide as a means of bettering their family financially. Keeping a brain-dead person alive already costs families, so money is already an issue in the equation. Suicide is the more challenging issue, particularly in right to die states.

VIII. CONSEQUENCES OF ORGAN MARKET

The intended and presumable consequence of an organ market is an increase in the number and quality of organs available.[382] The poor will likely have better access to organs, as evinced by the Iranian example; thus, a legal organ market will provide more equitable health outcomes than the current system.[383] More organs means less time waiting for the needed organ,[384] and less time waiting for organs results in better health outcomes for the organ recipient.[385] Plus, the increased supply of organs should result in better matches for the recipient's body.[386] A greater supply of organs means more transplants can be performed, so more lives will be saved.

Regarding kidney transplants, the procedure is highly preferable for most patients with end stage renal disease from both economic and health perspectives.[387] Gary Becker

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[382] Andrew V. Scott & Walter E. Block, *Organ Transplant: Using the Free Market Solves the Problem,* 2 J. CLINIC. RES. BIOETHICS 1, 2 (2011), *available at* http://omicsonline.org/organ-transplant-using-the-free-market-solves-the-problem-2155-9627.1000111.pdf [http://perma.cc/GW2X-2276].

[383] Capaldi, *supra* note 158, at 12.

[384] *Cash for Kidneys*, *supra* note 92.

[385] *Introducing Incentives*, *supra* note 121, at 14-15

[386] Aziz, *supra* note 5, at 81.

[387] Alan Langnas & Daniel R. Salomon, Op-Ed, *Remove Disincentives to Organ Donation*, THE N.Y. TIMES (Aug. 21, 2014), http://

and Julio Elias write, "Most of those on dialysis cannot work, and the annual cost of dialysis averages about $80,000. The total cost over the average 4.5-year waiting period before receiving a kidney transplant is $350,000, which is much larger than the $150,000 cost of the transplant itself."[388] The price of immunosuppressant drugs is much cheaper than dialysis,[389] so even factoring drug expenditures, savings are accrued. Lower doses of immunosuppressant drugs will be required with better organ matches resulting in further savings.[390] Providing dialysis patients with timely transplants could save the federal government $200,000 per year per patient.[391] The total cost of kidney transplants may decrease as well because the market should reduce kidney procurement costs.[392] Additionally, the stress on patient families will be ameliorated. Similar patient outcomes are expected for those in need of organs other than kidneys because a market for cadaver organs will increase the supply of all organs.

Aside from saving American lives, legalizing the organ market will damper the horrid happenings of the black market. Legalization is the most effective way to destroy underground markets. There is nothing inherently evil involved in giving up a kidney for money. The malevolence associated with black market organ sales germinates in the darkness of the underworld. Providing a legal framework

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www.nytimes.com/roomfordebate/2014/08/21/how-much-for-a-kidney/remove-disincentives-to-organ-donation [http://perma.cc/7ZAA-XZLK].

[388] *Cash for Kidneys, supra* note 92.

[389] *Mycophenolate Mofetil Prices, Coupons and Patient Assistance Programs,* DRUGS.COM (Oct. 23, 2015) http://www.drugs.com/price-guide/mycophenolate-mofetil [http://perma.cc/5298-MEGR] (showing that mycopheonlate mofetil tablets cost $122.44 for 100 capsules at 500mg).

[390] Brochure, *From Me To You—So Your Relative Needs a Kidney,* RENAL RESOURCE CENTRE, (Apr. 8, 2015), http://www.renalresource.com/brochures/syrnak.php [http://perma.cc/9DV5-E53J].

[391] FRY-REVERE, *supra* note 153, at 206.

[392] *Cash for Kidneys*, *supra* note 92*; Introducing Incentives, supra* note 121, at 12.

offers protection to buyers and sellers. Both parties are fully informed of the risks of the operation, and both parties can use the law in their favor. Sellers will be ensured they receive their wage. If they do not, the courts offer a legitimate mechanism for righting wrongs occurring during the process. Organ recipients have no need to worry about the quality of their surgeon or the organ's quality as proper medical protocol governs the transplant in legal operations. Those on transplant waiting lists will have less incentive to explore illegal organ procurement options because more legal organs will be available. Likewise, desperate and incompetent people are shielded from exploitation in a legal market.

A potential ancillary benefit of legalizing the organ market is improved public health.[393] Most transplants arise from preventable, obesity related conditions such as type 2 diabetes and hypertension. If only non-obese individuals are allowed to sell their organs, people have an additional reason to control their weight. Even people who have no intentions of selling a kidney while alive may be interested in selling their organs postmortem. This incentive does not intrude into peoples' lives and is in no way paternalistic. It simply provides a potential reward for a healthy lifestyle. An improved level of public health would reduce the number of transplants needed.

IX. CONCLUSION

The American and international organ procurement laws are not designed to increase organ supply; instead, the legal framework hopes to prevent commodification of the body.[394] This may be a worthy goal, but it does not save lives. Thousands of people waste away on dialysis each year due to the kidney shortage. An unknown number of others forego the wait and take their chances on the black market. Unfortunately, this desperate attempt to save their own lives often results in the exploitation of the indigent.

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[393] Scott & Block, *supra* note 382, at 2.

[394] Mayes, *supra* note 13, at 2.

There are two hopes for alleviating the organ shortage. Technology holds tremendous promise, but thousands of lives will be lost before technology offers a remedy to the organ shortage. These deaths are unnecessary because there are viable organs available for transplant. However, the owners of these organs lack incentives to part with their organs. Altruism, the engine of the current organ procurement model, simply is not enough.[395] Therefore, a market based approach should be applied to the organ shortage.

Though some oppose markets, legalizing the organ trade best addresses market opponents concerns. A legal framework protects sellers from the wretched, exploitive practices that are commonplace on the black market. Recipients and sellers both receive better care when the procedure is legal because the law offers them quality assurances. Furthermore, equitable access to transplants is better ensured under a legal organ market. The same exact organ distribution procedures that are in place at present can continue even if monetary incentives are involved.

Some may fear creating a market for organs allows humans to buy more life; that is, those with means can keep purchasing replacement parts indefinitely. This concern is irrelevant to an organ market for a few reasons. First of all, a market for organs would simply make a widely accepted medical procedure–organ transplantation–more efficient. Legalizing the organ trade does not open any new doors from a medical technology perspective. Building off the first objection, the second objection is that it is theoretically possible for an individual to procure an unlimited supply of new body parts already. An individual can legally persuade people to donate their organs; thus, a patient in need of an organ with the oratory ability of Clarence Darrow may be able to convince multiple people to part with their organs. Additionally, a person in need of a transplant with a large squadron of exceptionally generous friends can engage paired donations endlessly essentially enabling a person to obtain an infinite number of organ transplants via barter. A more

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[395] *Introducing Incentives*, *supra* note 121, at 22.

likely scenario would be a supremely wealthy individual who keeps purchasing organ transplants on the black market.

There are valid concerns about how far science should go in its efforts to save a life. At what point do efforts to preserve life begin to create a Frankenstein? For example, should 3D printed organs be better than "natural" human organs? Failure of the heart's left main artery causes heart attacks, so researchers are already trying to design hearts with two left main arteries making death by heart attack much less likely.[396] Genetic engineering presents similar issues and arguably raises more complex ethical challenges. Doctors have tried transplanting animal organs into humans, known as xenotransplantation, for over 50 years.[397] Xenotransplants originally achieved very limited success.[398] However, genetic engineering has the potential to transform pig organs into a viable medical option for humans in need of organs.[399] These issues are certainly worthy of discussion, but they have little relevance to a market for organs. A market is not a biomedical breakthrough. On the contrary, a market may be the most basic mechanism for allocating resources.

Only one country has eliminated its kidney shortage. Unsurprisingly, this is the only country with a market style incentive for kidney providers. Basic economics and experience demonstrate a market for organs can end the organ shortage. Legalizing the trade in organs also happens to be the most ethical option at this time. It reduces suffering and death, respects individual autonomy, distributes organs in a socially desirable fashion, saves money, and helps end the maleficent underground organ trade.

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[396] John Graber, *Report Predicts Possible Ban on Bioprinting by 2016,* 3D PRINTER WORLD (Feb. 14, 2014), www.3dprinterworld.com/article/report-predicts-possible-ban-bioprinting-2016 [http://perma.cc/ZE85-ZAS7].

[397] Shima Benham Manesh et al., *Ethical Issues of Transplanting Organs from Transgenic Animals into Human Beings,* 16 CELL J. 353, 354 (Aut. 2014), *available at* www.ncbi.nlm.nih.gov/pmc/articles/PMC4204195/pdf/Cell-J-16-353.pdf. [http://perma.cc/2LCK-REDF].

[398] *Id.*

[399] *Id.*

HUMAN ORGAN DONATIONS UNDER THE "IRANIAN MODEL": A REWARDING SCHEME FOR U.S. REGULATORY REFORM?

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ABSTRACT

The National Organ Transplant Act has been unsuccessful in overcoming human organ shortages in the United States. There are calls for compensating human organ donations that refer to the "Iranian Model." The Iranian model is a compensated scheme for organ donations that is often mistakenly thought of as a "sale" of organs. The reality is, within the context of the Iranian legal system, the compensation is for the *act* of donation and is characterized as a contract of "reward." Given the specific regulations on the different forms of contract under the Iranian Civil Code, this characterization holds significant legal and ethical importance. A sale of human organs under the Civil Code would result in the immediate ownership of the organ by the purchaser, whereas this would be an absurd result under Iranian law. A proper understanding of the Iranian model is essential for potential regulatory reform in the United States. This paper sets out a precise clarification of the legal intricacies of human organ donations in Iran.

Keywords: Organ Donation, Health Policy, Medical Law, Iran, Contracts, Law and Religion, Islam.

I. INTRODUCTION

While transplanting human organs is currently a widely accepted practice, ethical concerns continue to exist about certain aspects of this procedure[1] that affect national legal

[1] Such concerns existed from the very first organ transplant, *see* Cornelia Dean, *A Conversation with: Joseph E. Murray; On Surgical Innovation and the Questions It Can Raise*, N.Y. TIMES (Sept. 25, 2001), http://www.nytimes.com/2001/09/25/health/conversation-with-joseph-e-murray-surgical-innovation-questions-it-can-raise.html [http://perma.cc/HD3Y-S6EP] (discussing the late Dr. Joseph E. Murray who performed the first kidney transplant in 1954 and how he was criticized for "playing God" for intending to do the transplant). The ethical aspects and concerns surrounding human organ transplants have also been echoed in international fora. *See* World Health Org. [WHO], *Ethics, Access and Safety in Tissue and Organ Transplantation: Issues of Global Concern*, at

frameworks for human organ transplants. Of particular concern are compensated schemes for organ donations and the attendant possibility of commercialization. Although providing compensation to organ donors is currently banned in most countries and by international regulations on human organ transplants,[2] there are calls by academics and activists

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9, WHO/HTP/EHT/T-2003.1 (Oct. 6-9, 2003), *available at* http://www.who.int/ethics/Tissue%20and%20Organ%20Transplantation.pdf [http://perma.cc/7E9B-DFGF] ("[Dr Biller-Andorno] enumerated ethical concerns that can arise in the areas of deceased and living donors as well as tissue and xenotransplants. Common to all four areas are questions of eligibility and safety of donor and recipient, use of financial and other incentives, equitable access and allocation and issues of cross-border exchanges and Commercialization. She pointed out some of the major issues that need to be addressed, keeping the 1991 Guiding Principles in mind. These include on what grounds live donation can still be considered subsidiary to cadaveric donation, continuing and more complex issues of donor and recipient safety, voluntary status of consents and how best to preserve the principle of non-commercialization."); *see also* World Health Assembly [WHA], *WHO Guiding Principles on Human Organ Transplantation*, Res. WHA44.25 (May 13, 1991), *available at* http://www.transplant-observatory.org/SiteCollectionDocuments/wha44resen.pdf [http://perma.cc/7EBK-U84A] (The "Guiding Principles on Human Organ Transplantation" were developed by the World Health Organization and declared on May 13, 1991, by a resolution of the World Health Assembly. The resolution contains nine Guiding Principles that are "intended to provide an orderly, ethical, and acceptable framework for regulating the acquisition and transplantation of human organs for therapeutic purposes."); *see also* WHO, *WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation* [hereinafter *WHO Guiding Principles*], *available at* http://www.who.int/transplantation/Guiding_PrinciplesTransplantation_WHA63.22en.pdf?ua=1 [http://perma.cc/E5JZ-P52P] (developing the Guiding Principles into eleven principles that was issued in another resolution of the WHA in 2010).

[2] *See* WHO, *supra* note 1; *see also* Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Transplantation of Organs and Tissues of Human Origin, art. 21, *opened for signature* Jan. 24, 2002, C.E.T.S. No. 186, *available at* http://conventions.coe.int/Treaty/en/Treaties/Html/186.htm [http://perma.cc/L5J4-4SFX] ("1- The human body and its parts shall not, as such, give rise to financial gain or comparable advantage. The aforementioned provision shall not prevent payments which do not constitute a financial gain or a comparable advantage, in particular: compensation of living donors for loss of earnings and any other justifiable expenses caused by the removal or by the related medical examinations; payment of a justifiable fee for legitimate medical or related technical services rendered in connection with transplantation;

to enable some form of compensation to donors in order to overcome the organ shortage that is costing thousands of lives every year.[3]

In the United States, the National Organ Transplant Act of 1984 prohibits organ purchases but permits certain forms of compensation, including for lost wages and hospital costs.[4] However, this and other incentives in force in the United States have proved insufficient to encourage live organ donations. Deceased donor organs fall far short of what is needed to prevent the suffering and death of thousands of people, such that 4,300 people died in the United States while on the transplant waiting list in 2013 alone.[5] As a result, providing compensation to organ donors is currently being discussed as one of the means of providing sufficient incentive to live donors and to overcome the organ shortage in the United States.

A recurring reference in the discussions on compensated organ donations is Iran's organ transplant system. Iran's incentivized system of organ donations includes a scored system of transplant waiting lists for organ recipients,[6] exemption of organ donors from military service,[7] and a

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compensation in case of undue damage resulting from the removal of organs or tissues from living persons. 2- Advertising the need for, or availability of, organs or tissues, with a view to offering or seeking financial gain or comparable advantage, shall be prohibited.").

[3] *See generally* SALLY SATEL, WHEN ALTRUISM ISN'T ENOUGH: THE CASE FOR COMPENSATING KIDNEY DONORS (2008); SIGRID FRY-REVERE, THE KIDNEY SELLERS: A JOURNEY OF DISCOVERY IN IRAN (2014); Sally Satel et al., *State Organ-Donation Incentives Under the National Organ Transplant Act,* 77 L. & CONTEMP. PROBS. 217 (2014).

[4] 42 U.S.C. § 274e (2015).

[5] Satel et al., *supra* note 3, at 217.

[6] For example, if a candidate for transplant is an organ donor, they are accorded four points on the waiting list, thus receiving higher priority over a non-organ donor candidate. *See* MASHHAD UNIV. OF MED. SCI. TRANSPLANT PROCUREMENT UNIT, PROTOCOL-E PAIVAND-E KOLLIE [KIDNEY TRANSPLANT PROTOCOL] 23-24 (2011), *available at* http://www.mums.ac.ir/shares/tmc/arghamia2/maghalat/prokidnynomosavab.pdf [http://perma.cc/JWT9-XZUA]. (The original source and its translation are on file with the *Indiana Health Law Review*.).

[7] *Ehda Konandegan Ozv az Sarbazi Moaf Mishavand* [*Organ Donors Will Be Exempt from Military Service*], IRANIAN STUDENTS' NEWS AGENCY (Iran), May 20, 2013, *available at* http://tinyurl.com/m9wvllg [http://

compensated scheme of organ donations. The latter aspect of the Iranian system has been of interest in the debates on compensated organ donations, but has invariably been misunderstood as a system that authorizes the *sale* of organs. The payment of compensation is not synonymous with the sale and purchase of organs. The possibility of providing some form of compensation, regardless of whether or not it is done with the purpose of providing financial incentives to donors, does not necessarily mean that human organs are being bought and sold. Conflating the two has led to some ambiguities and misunderstandings about the regulated framework of organ transplants in Iran, to such an extent that the terms "kidney sellers,"[8] "organ sales" [9] and "kidney eBay" [10] have been used in describing the "Iranian model."[11]

This confusion is understandable, since the term "sale" is sometimes loosely used in connection with organ donations within Iran itself, particularly by laypersons. Also, the majority of Iran's population are Shiite Muslims, and many of the decrees issued by leading Shiite clerics have also used the term "sale and purchase" of organs when responding to questions on the religious aspects of organ donations. However, it must be emphasized that this is not a correct characterization.[12] In fact, Iran's regulations have not used this term with respect to human organ donations, and the

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[8] FRYE-REVERE, *supra* note 3.

[9] Benjamin E. Hippen, *Organ Sales and Moral Travails: Lessons from the Living Kidney Vendor Program in Iran*, CATO INST. (March 20, 2008), http://www.cato.org/publications/policy-analysis/organ-sales-moral-travails-lessons-living-kidney-vendor-program-iran [http://perma.cc/ MRL8-726W].

[10] Saeed Kamali Dehghan, *Kidneys for Sale: Poor Iranians Compete to Sell Their Organs*, GUARDIAN (May 27, 2012), http://www.guardian.co.uk/world/2012/may/27/iran-legal-trade-kidney?INTCMP=SRCH [http://perma.cc/N62D-MKQV].

[11] This phrase has been used to describe the specific scheme of organ donations in Iran whereby certain cases may be compensated. *See* Hippen, *supra* note 9; Ahad J. Ghods & Shekoufeh Savaj, *Iranian Model of Paid and Regulated Living-Unrelated Kidney Donation*, 1 CLINICAL J. AM. SOC'Y NEPHROLOGY 1136 (2006).

[12] As will be seen below, the views of Shiite clerics are not uniform on this either.

official terms used are "donation" (*e'ta*) and "gift" (*ehda*). Far from being merely pedantic, this characterization has considerable ethical and legal significance under Iran's legal system. A contract of sale is a specific type of contract in Iran's Civil Code and has a well-defined regime. If the donation is deemed a sale, one may be faced with the scene depicted by Shakespeare in the *Merchant of Venice* where Shylock insists on having his pound of flesh:

> The pound of flesh, which I demand of him,
> Is dearly bought; 'tis mine and I will have it.
> If you deny me, fie upon your law!
> There is no force in the decrees of Venice.
> I stand for judgment: answer; shall I have it?[13]

In the case of legal organ transplants, the life of any given "Antonio" may not necessarily be endangered quite as depicted by Shakespeare.[14] However, the question whether or not human organs may be deemed to be property, or for some reason subject to purchase and ownership, may raise a host of other issues. Such issues may include the donors' consent, defining an acceptable transaction in form and substance, and the plethora of issues that arise from attributing ownership rights to human organs, such as the various legal relations between the donors, recipients, and third parties.

The fact that Iranian regulations differentiate between transplants using cadaveric organs and those provided by live donors is relevant here. With respect to organs obtained from live donors, a certain sum may be paid as a reward for

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[13] WILLIAM SHAKESPEARE, THE MERCHANT OF VENICE act 4, sc. 1. Although Shakespeare was not addressing a question of organ donation or sale, the nature of the transaction under which donations are made may well result in such a scenario if the matter is not addressed sufficiently. It is essential that even in a compensated scheme for organ donations, safeguards be established to protect the rights and freedoms of the parties involved.

[14] *Id.* Shylock, through his hatred of Antonio, insists that he must cut the flesh closest to Antonio's heart: "So says the bond: doth it not, noble judge? 'Nearest his heart': those are the very words."

the "sacrifice" the donor has made,[15] although the donor may decide to forego such compensation for altruistic or other reasons. However, no such compensation has been allowed in cadaveric organ transplants. Providing safeguards against ownership claims to human organs and for ensuring a donor's consent throughout a transplant procedure are extremely important.[16]

An incorrect portrayal of the Iranian system may result in a demand for similar systems being established elsewhere without enough attention to the safeguards inherent in the nature of the act of donation under Iranian law and the additional assurances of propriety included in relevant regulations and enforcement mechanisms. Certainly, the Iranian system itself requires further elaboration of regulations and strengthening of mechanisms and safeguards. Also needed is greater national awareness of the range of relevant ethical and legal aspects of transplants and a much necessary clarification of the transactions being conducted outside the defined legal scheme for live unrelated donations.[17] However, despite the shortcomings of the Iranian system, there are legal safeguards that must be taken into account when considering the "Iranian model."

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[15] Known as "*hediye'ye isar*", literally meaning "gift of sacrifice." The term is also used in regulations concerning disability pay for certain veterans.

[16] The case of Mr. Hu Jie, a migrant worker who changed his mind about undergoing a transplant in China but was nevertheless stripped of his kidney, illustrates this importance all too well. *See* Nicola Davison, *In China, Criminals Fill the Kidney Donor Deficit*, GUARDIAN (May 27, 2012, 15:00 EDT), http://www.guardian.co.uk/world/2012/may/27/china-kidney-donor-shortage-crime [http://perma.cc/35EJ-UUZF].

[17] Although there are guidelines and information pamphlets on many of the websites and centers relevant to organ transplants, *see, e.g.*, SHAHID BEHESHTI U. MED. SCI. ORGAN PROCUREMENT UNIT, http://ehda.sbmu.ac.ir/?fkeyid=&siteid=489&pageid=34190 [https://perma.cc/WP22-DFK5] (last visited Dec. 2, 2015). There are at times incorrect portrayals of the system in popular media that may lead to further ambiguities or misunderstandings about organ donation. Furthermore, the law is ambiguous on the nature of human organs and the non-systemic transactions conducted by the public. These ambiguities are addressed below. (The original source and its translation are on file with the *Indiana Health Law Review.*).

This matter is of no small importance in view of the ethical and legal ramifications of compensated organ donations, the millions of people who stand to benefit from a healthier life, and the immense financial aspects involved. Therefore, with the purpose of disambiguation, a brief overview of the regulatory framework of the Iranian model is provided, and the legal nature of donations under that system is analyzed.

II. IRAN'S REGULATORY CONTEXT

Iran is an "Islamic Republic." This phrase means that while certain processes and institutions of government are republican in form and structure, according to Article 4 of the Iranian Constitution "All, civil, penal financial, economic, administrative, cultural, military, political, and other laws and regulations must be based on Islamic criteria." [18] Furthermore, by virtue of Article 170 of the Iranian Constitution, judges shall not give effect to laws or regulations that contradict Islamic criteria. [19] Thus, the

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[18] QANUNI ASSASSI JUMHURII ISLAMAI IRAN [THE CONSTITUTION OF THE ISLAMIC REPUBLIC OF IRAN] 1358 [1980], art. 4. This article's Islamic principle "governs absolutely and generally all articles of the Constitution, as well as all other laws and regulations, and the duty to ascertain this matter devolves on the jurists of the Guardian Council." The Constitution mentions such determination is to take place by the six clergy members of the Guardian Council or "*fuqaha*," a term that has been incorrectly translated to "the wise persons," *see, e.g.*, *Iran-Constitution,* http://www.servat.unibe.ch/icl/ir00000_.html [http://perma.cc/PH3U-ZJ5W] (last visited Feb. 1, 2016), or simply "jurists," *see, e.g.*, ISLAMIC PARLIAMENT OF IRAN, http://en.parliran.ir/index.aspx?siteid=84&pageid=3053 [https://perma.cc/27Q8-6QJP] (last visited Oct. 26, 2015). It must be noted that the Guardian Council consists of twelve members, six of whom are legal jurists and six who are Islamic jurists (*faqih*). A determination on the compatibility of laws and regulations with Islamic *Shari'a* is incumbent on the Islamic jurists, and ascertaining the compatibility with the Constitution rests with all twelve members of the Council.

[19] QANUNI ASSASSI JUMHURII ISLAMAI IRAN [THE CONSTITUTION OF THE ISLAMIC REPUBLIC OF IRAN] 1358 [1980], art. 170. "Judges are obliged to refrain from" executing byelaws "and regulations of the government that are in conflict with the laws or the norms of Islam," or have been adopted by the Executive *ultra vires*. Anyone has the right to "demand

drafters of the Iranian Constitution have posited Islamic *Shari'a* as the general moral theory of the entire legal system of Iran, permeating all laws and regulations, and determined by the clerical members of the Guardian Council. [20] Obviously, not all issues have been addressed in the *Shari'a* and modern advances in science and technology may pose a challenge to legislation on a strict reading of this provision.

Interestingly, the Iranian Constitution has used different terms concerning the relation of legislation and *Shari'a*. For example, Articles 4 and 94 provide that legislation has to correspond to "Islamic criteria;" a different phrase in Articles 72, 85, 91 and 96 indicates that legislation must not contradict the "rules of Islam."[21] The Guardian Council has commented on this differentiation in defining its work[22] and

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the annulment of any such regulation from the Court of Administrative Justice."

[20] By virtue of Article 12 of the constitution, the official school of Islamic *Shari'a* incumbent on the State has been declared to be that of the *Twelver Ja'faris*. QANUNI ASSASSI JUMHURII ISLAMAI IRAN [THE CONSTITUTION OF THE ISLAMIC REPUBLIC OF IRAN] 1358 [1980], art. 12. This article provides:

> The official religion of Iran is Islam and the *madhhab* (school of law) is the *Twelver Ja'farí* school, and this article will remain forever unalterable. Other legal schools (*madhãhib*) including the *Hanafi*, *Shãfi'í*, *Mãlikí*, *Hanbalí*, and *Zaydí*, are accorded full respect, and their followers are free to perform their religious rites in accordance with their own *fiqh*. These schools are officially recognized by the courts in matters pertaining to religious education and training, personal status (marriage, divorce, inheritance, and wills), and any related litigation. In any region where the followers of any of these schools constitute a majority, the local regulations will be in accordance with that school within the jurisdiction of the local councils, with due observance of the rights of the adherents of other schools.

For a definition of *madhhab* and further resources on the subject, *see* ENCYCLOPEDIA OF ISLAM (P. Bearman, et al. eds., 2nd ed. 2012), *available at* http://referenceworks.brillonline.com/entries/encyclopaedia-of-islam-2/madhhab-SIM_8798 [http://perma.cc/QVL7-PWWJ].

[21] QANUNI ASSASSI JUMHURII ISLAMAI IRAN [THE CONSTITUTION OF THE ISLAMIC REPUBLIC OF IRAN] 1358 [1980], arts. 4, 72, 85, 91, 94, 96.

[22] *See About the Guardian Council*, GUARDIAN COUNCIL, http://www.shora-gc.ir/Portal/Home/ ShowPage.aspx?Object=News&ID=7ca3f12d-47c1-4ac5-a088-397771794abb&LayoutID=e3152b95-620e-

has held that the former formulation refers to the general principles of *Shari'a* such as justice, fairness, and human dignity, whereas the latter denotes such specific rules[23] that have expressly been set forth in the Quran and the *Sunnat*.[24] The Council believes these formulations are co-extensive and there is no contradiction between them.[25] Instead, the Iranian Constitution provides a broader discretion to the Council in ascertaining that legislation "corresponds to Islamic criteria" and is more restrictive if legislation is found to "contradict specific rules of Islam."[26]

This system enables the Guardian Council to take into consideration various policy issues when reviewing legislation passed by Parliament (the *Majlis*) and possibly to opt for an interpretation of *Shari'a* that would meet modern policy necessities. This is important since Islamic law may lack specific rules on issues raised by the advent of new technologies and advances in science, and such a reading provides more leeway for enacting any legislation that may be required for regulating such advances. Furthermore, the most prominent Islamic Jurists (*fuqaha*) hold differing views on many issues, [27] including the question of organ transplants, and these views may in certain exceptional circumstances be a source for adjudication of particular legal claims in courts of law.

4dfd-97f1-1fefd0f696b1&CategoryID=8fac823a-5745-41b6-a9e2-b879c74deb7b [http:// perma.cc/55t9-CX4Y] (last visited Oct. 26, 2015). (The original source and its translation are on file with the *Indiana Health Law Review.*).

[23] *See Encyclopedia of Islam, Second Edition: Ahkam*, BRILLONLINE REFERENCE WORKS, http://referenceworks.brillonline.com/entries/encyclopaedia-of-islam-2/ahkam-SIM_0376 [http://perma.cc/WKC3-Q3YG] (last visited Oct. 28, 2015).

[24] Also written as "*Sunna*" or "*Sunnah*," generally meaning the practice and custom of Prophet Mohammad, which in addition to the Quran, is a source of Islamic law, *see Encyclopedia of Islam, Second Edition: Sunna*, BRILLONLINE REFERENCE WORKS, http://referenceworks.brillonline.com/entries/encyclopaedia-of-islam-2/sunna-COM_1123 [http://perma.cc/T2X2-BCJE] (last visited Oct. 28, 2015).

[25] *Infra* note 29.

[26] *See About the Guardian Council supra* note 22.

[27] *See* Abdulaziz Sachedina, ISLAMIC BIOMEDICAL ETHICS: PRINCIPLES AND APPLICATIONS (2009), *available at* http:// course.sdu.edu.cn/Download/20130908092939153.pdf [http://perma.cc/ V9S4-4WJG].

Finally, in the event that there is a difference of opinion between the Parliament and the Guardian Council on necessary policy considerations and Islamic criteria, the Constitution has established the Expediency Assembly to resolve the dispute between the two entities.[28] This is to prevent a stalemate between the legislative policy requirements of everyday life as determined by Parliament and the possible inflexibility of the Guardian Council on a specific issue.[29]

As a result, the drafting process for legislation, and even regulation by entities other than Parliament, necessarily takes into consideration the dictates of *Shari'a* with regard to any given issue. This is not to say that other facets are ignored *in toto*. In drafting legislation, regard is also given to Iran's international obligations, policy requirements and questions of practicality, and the results of studies in various sciences relevant to the issue. However, the tenets of *Shari'a* and the views of the most highly regarded and most authoritative Islamic jurists of the Shiites (*Maraji*') will

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[28] THE CONSTITUTION OF THE ISLAMIC REPUBLIC OF IRAN Oct. 24, 1979, art. 112. Article 112 of the Iranian Constitution reads in part: "The State Expediency Assembly will meet by the order of the Leader to decide what is most expedient whenever the Guardian Council considers a bill approved by the Islamic Parliament of Iran to be contrary to the principles of the Shari'a or the Constitution and the Parliament is unable to secure the satisfaction of the Guardian Council on the basis of national expediency. The State Expediency Assembly will also meet to consult on any issue referred to it by the Leader or related to its duties as mentioned in this Constitution."

[29] In an interpretation of Article 4 of the Constitution by the Guardian Council, even the Expediency Assembly is barred from approving any legislation that contradicts Islamic criteria. Majmuahi Nazariati Shurai Nigahban [Compilation of the Opinions of the Guardian Council] Tehran 1993, Op. 4575. However, since this opinion appeared to contradict the very *raison d'être* of the Expediency Assembly, it was asked to elaborate its position. Letter from Expediency Assembly, Letter No. 3786/2409 (June 24, 1993). The Guardian Council responded by pointing to the differentiation between the primary and secondary rules of Shari'a and declared that the Constitutional provision on the Expediency Assembly's purview relates to that of secondary rules. Guardian Council, Op. 4872 (1993). In practice, once the Expediency Assembly approves an Act of Parliament, it is published in the Official Gazette as law and becomes binding. (The original sources and their translations are on file with the *Indiana Health Law Review*.).

usually hold sway over conclusions that may be drawn from other moral theories that dominate either the international or "Western" policy deliberations. As a result, different regulatory conclusions may be reached in a setting where concepts such as autonomy, dignity, equality, liberty, and harm may have different meaning, scope, or importance in moral and policy deliberations.

III. SHIITE APPROACHES TO HUMAN ORGAN TRANSPLANTS

Notwithstanding the provisions of the Constitution for the purpose of legislation and the role of the Guardian Council, any real or legal person may seek the views of the Shiite Maraji' resulting in religious decrees (*fatawa*) with regard to questions of *Shari'a* requirements on certain issues. In turn these views may affect the regulatory process and content of any legislation or regulation on the matter. However, such decrees are not always uniform, and at least for legislative purposes in Iran, the Guardian Council will invariably be the ultimate source of authority on questions of *Shari'a*. Still, a review of the different *fatawa* will serve to provide a clearer picture of the context of the Iranian regulations on organ donation.

In the context of organ transplants, the criteria for death, donors and recipients, the possibility of compensation for donation, and even the sale and purchase of organs have been the subject of numerous decrees issued by a number of the *Maraji'*. A review of the said decrees shows a variety of views ranging from rejecting cadaveric organ transplants to their acceptance and a range of approaches on the many questions pertaining to each position.[30] There is also a general

[30] The review undertaken for this study consisted of decrees issued by fifty-two of the living and deceased *Maraji'*. These are Grand Ayatollahs: Mirza Javad Gharavi Aliari, Abdollah Javadi-Amoli, Sayyid Abdul-Karim Mousavi Ardebili, Ali Asghar Rahimi Azad, Sayyid Ali Mohammad Dastgheib Shirazi, Mirza Yadollah Duzduzani, Mohammad Ishaq Fayyadh, Mohammad Hossein Fazlollah, Mohammad Taghi Bahjat Foomani, Ali Safi Golpaygani, Lotfollah Safi Golpaygani, Mohammad Ali Gerami, Sayyid Mohammad Ali Alavi Hosseini Gorgani, Sayyid Kazim Hussaini Haeri, Sayyid Mohammad Saeed Tabatabai Hakeem, Hossein Noori Hamedani, Sayyid Kamal Heydari, Mohammad Ebrahim Jannaati, Sayyid Mohammad Ali Moosavi Jazayeri, Qorban Ali Kaboli, Sayyid Ali

acceptance of the possibility for the sale of organs by live donors for the purpose of transplantation, sometimes expressly restricted to cases where a life may be saved by the process. Of course, not every one of the said *Maraji'* has addressed every aspect of organ transplants. However, for the purposes of this paper, the decrees will be categorized on the basis of their rejection or acceptance of cadaveric transplants and the question of compensation for organs.[31]

A. Transplant of Cadaveric Organs

Among the Shiite religious authorities, some have considered certain cadaveric transplants contrary to *Shari'a* and thus have declared them wrong and prohibited. Such decrees generally emanate from a rejection of the brain death

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Hoseyni Khamenei, Sayyid Abolghasem Khoei, Sayyid Ruhollah Khomeini, Hossein Vahid Khorasani, Mohammad Fazel Lankarani, Moslem Malakouti, Hossein Mazaheri (Esfahani), Sayyid Mohammad Taqi Modarresi, Mohammad Asif Mohseni, Hossein Ali Montazeri, Bashir Hussain Najafi, Muhammad Hussain Najafi, Sayyid Reza Hosseini Nassab, Mohammad Reza Nekoonam, Sayyid Mohammad Sadeq Hosayni Rohani, Yousuf Saanei, Sayyid Mohammad Shahroudi, Sayyid Mahmoud Hashemi Shahroudi, Naser Makarem Shirazi, Sayyid Mohammad Hussaini Shirazi, Sayyid Sadiq Hussaini Shirazi, Sayyid Ali Husayni Sistani, Ja'far Sobhani, Mirza Javad Tabrizi, Sayyid Yousef Madani Tabrizi, Saleh Taei, Mohammad Sadeghi Tehrani, Mojtaba Tehrani, Shamsodin Vaezi, Mohammad Yaqoobi, Asadollah Bayyat Zanjani, Sayyid Mohammad Ezodin Hosseini Zanjani. Of this group of fifty-two, twenty-three have issued decrees on the question of organ transplants. For a list of living and deceased *Maraji' see* Maraji'-e Taghlid-e Shiie [Shiite *Maraji'*] http://fa.wikishia.net/view/%D9%85%D8%B1%D8%A7%D8%AC%D8%B9_%D8%AA%D9%82%D9%84%DB%8C%D8%AF_%D8%B4%DB%8C%D8% B9%D9%87 [https://perma.cc/UN6Z-8V3L] (last visited Jan. 9, 2016).

[31] Decrees concerning other indirectly relevant matters shall not be addressed in their own right, but only insofar as they may shed light on the issues covered in this paper. The decrees issued by some of the *Maraji'* cover such questions as: xenotransplants; the cleanliness of an organ in the religious sense (*tahara*); whether or not there is any difference between organs of Muslims and non-Muslims; the special status of people condemned to death; the responsibility of medical professionals in conducting transplants; and whether blood money (*diya*) should be paid for transplants.

criterion,[32] or what the relevant *Marja'* considers to be the desecration of a Muslim's corpse;[33] but some *Maraji'* clearly state that extraction of organs for the purpose of transplants is not desecration[34] and even consider it to be a duty to save lives.[35] In cases where the brain death criterion has been rejected, cadaveric transplants have been deemed permissible where the Islamic criteria for death are met,[36]

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[32] Mohammad Taghi Bahjat Foomani, Jarahi, Tashrih, va Paivand [Surgery, Autopsy, and Transplantation], *fatwa No. 1173*, http://www.bahjat.ir/index.php/ahkam-2/esteftahat/192-2011-09-06-10-13-34.html [http://perma.cc/EP3W-R2J9] (last visited Oct. 28, 2015); Hossein Vahid Khorasani, *Ehdaye Ozv Dar Soorate Marge Maghzi* [*Organ Donation in Case of Brain Death*], THE OFFICE OF GRAND AYATULLAH AL-UZMA SHAYKH HUSAYN VAHID KHORASANI, http://www.wahidkhorasani.com/web/index.php?option=com_quickfaq&view=category&cid=50&Itemid=704&lang=fa [http://perma.cc/] (last visited Oct. 30, 2015); Sayyid Ali Husayni Sistani, MINISTRY OF HEALTH & MED. EDUC., http://www.behdasht.gov.ir/ index.aspx?siteid=1&pageid=13186&newsview=4767 [http://perma.cc/ QBM6-KM7E] (last visited Nov. 1, 2015); MINISTRY OF HEALTH & MED. EDUC., http://www.behdasht.gov.ir/ index.aspx?siteid=1&pageid=13186&newsview=4763 [perma.cc/AKT4-KZZR] (last visited Nov. 1, 2015); MINISTRY OF HEALTH & MED. EDUC., http://www.behdasht.gov.ir/index.aspx?siteid=1&pageid=13186&newsview=4762 [perma.cc/R9E5-AZPK] (last visited Nov. 1, 2015). (The original sources and their translation are on file with the *Indiana Health Law Review.*).

[33] TOZIH-OL MASA'EL [CATECHISM] 574 (n.d.), *available at* http://www.sistani.org/files-new/book-pdf/persian-tozih-edition32.pdf [https://perma.cc/23JU-QE2G]. (The original source and its translation are on file with the *Indiana Health Law Review.*).

[34] Sayyid Mohammad Sadeq Hosayni Rohani, http://www.rohani.ir/istefta-772.htm [http://perma.cc/2JF8-PMB3] (last visited Nov. 1, 2015). (The original source and its translation are on file with the *Indiana Health Law Review.*).

[35] MOHAMMAD SADEGHI TEHRANI, RESALE-YE-TOZIH-OL-MASAELE NOVIN [CATECHISM ON NEW PROBLEMS], 450 Question 997 (3rd ed. 2005), *available at* http://forghan.org/images/book/pdf/Resale%20NOVIN.pdf [https://perma.cc/G9CV-G93V]. (The original source and its translation are on file with the *Indiana Health Law Review.*).

[36] Sayyid Mahmoud Hashemi Shahroudi, Marge Maghzi [Brain Death], http://hashemishahroudi.org/fa/pages/print.php?page=question&id=629; Sayyid Mahmoud [https://perma.cc/7USV-76LR]; Hashemi Shahroudi, Pezeshki [Medicine], http://hashemishahroudi.org/fa/pages/question.php?id=133 [https://perma.cc/XJ2U-79BK]. (The original sources and their translation are on file with the *Indiana Health Law Review.*).

even in the absence of a will and testament concerning organ donation and with the sole purpose of saving a Muslim life.[37]

The general contention that Muslims do not regard the definition of death as a merely scientific determination and that "the most critical issues in the determination of the time of death are essentially religious and ethical, not medical or scientific[,]"[38] is true in the majority of cases, and most of the *Maraji'* contend that brain death in itself is insufficient to consider a person dead.[39] But a number of the *Maraji'* have ceded such determination to medical professionals, thereby accepting the brain death criterion, [40] and one very authoritative *Marja'* considers death as being defined by the "custom of experts"–that of medical professionals.[41]

There are also nuances among the majority on cadaveric transplants, brought about by individual appreciations of changes in socio-cultural circumstances and developments in medicine, and some have accepted transplants using organs from brain dead persons in order to save lives without addressing the criterion of death itself.[42] Interestingly, one

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[37] Foomani, *supra* note 32, *fatwa No. 1178-1183*.

[38] Sachedina *supra* note 26, at 145-46.

[39] For instance, Sayyid Mohammad Ezodin Hosseini Zanjani references a verse of the Quran, *Zumar* 42, and clearly states that brain death does not constitute death in the religious sense. Nevertheless, he believes that if brain death is irreversible by any means and the brain dead person has expressed consent to donation of organs, that person's organs may be extracted and used in transplants, Shokoohe Marja'iat [Glory of Religious Authority], Montakhab-e Estefta'at-e Jadid [Selection of New *Fatwas*] http://azanjani.blogfa.com/8908.aspx [http://perma.cc/46XZ-DTCJ] (last visited Nov. 1, 2015). (The original sources and their translation are on file with the *Indiana Health Law Review*.).

[40] Mohammad Ishaq Fayyadh, ALFAYADH.ORG, http://alfayadh.org/fa/#post?type=post&id=1079 [http://perma.cc/8SX6-NHMB] (last visited Nov. 1, 2015); Naser Makarem Shirazi, Ahkame Shar'i-e Mortabet ba Marg-e Maghzi [Shari'a Decrees on Brain-Death], http://makarem.ir/main.aspx?typeinfo=21&lid=0&catid=667&mid=9990 [https://perma.cc/V8ZG-A6Q3] (last visited Jan. 13, 2016). (The original sources and their translation are on file with the *Indiana Health Law Review.)*.

[41] HOSSEIN ALI MONTAZERI, AHKAM-E-PEZESHKI [MEDICAL DECREES] 120 (3rd ed. 2002) (question 268). (The original source and its translation are on file with the *Indiana Health Law Review.)*.

[42] Sayyid Kazim Hussaini Haeri, Alestefta'at [Requests for *fatwas*], http://www.alhaeri.org/main.php#qa [http://perma.cc/ 3WY4-D8JC]

Marja' makes a distinction between the brain death criterion for the purpose of organ transplants, and the *Shari'a* criteria of death for other legal or religious purposes such as power of attorney or burial.[43]

According to the majority position, cadaveric transplants may take place if the life of a Muslim is dependent on the procedure.[44] This approach also has a number of variations. For instance, certain *Maraji'* have held that if a Muslim's life is in danger, the organs of a cadaver may be used to save that person's life, even without the consent of the decedent or any other third party.[45] At times, the transplant of organs has been made conditional—it must take place with the sole purpose of saving a life (or a Muslim life) and it is forbidden if it is known to be futile.[46]

(follow "Masa'el fi-Tashrih wa Naghl-ol-A'aza [Questions on Autopsy and Transplantation of Organs]). (The original sources and their translation are on file with the *Indiana Health Law Review.*).

[43] Naser Makarem Shirazi, Payvande Ozve Kasi ke Marge Maghzi Shodeh [Transplanting the Organ of Someone who is Brain-Dead], http://makarem.ir/main.aspx?typeinfo=21&lid=0&catid=28962&mid=2372 [https://perma.cc/77X9-KFGP] (last visited Jan. 13, 2016). (The original source and its translation are on file with the *Indiana Health Law Review.*).

[44] Haeri, *supra* note 42.

[45] Mohammad Taghi Bahjat Foomani, Pezeshki [Medicine] *fatwa No. 544*, http://www.bahjat.org/index.php/ahkam-2/esteftahat/105-2011-09-06-09-19-55.html [http://perma.cc/3GZC-DLYG] (last visited Nov. 1, 2015). (The original sources and their translation are on file with the *Indiana Health Law Review.*).

[46] MONTAZERI, *supra* note 41, at 129 (question 286); Foomani, *supra* note 45, *fatwa No. 552*; Mohammad Ishaq Fayyadh, ALFAYADH.ORG, http://alfayadh.org/fa/#post?type=post&id=1084 [https://perma.cc/D564-UVA2]; Sayyid Mohammad Saeed Tabatabai Hakeem, http://alhakeem.com/persian/pages/quesans/listgroup_ques.php?Where=236 [http://perma.cc/ AU2U-Q9QU] (last visited Nov. 1, 2015). The current Leader of Iran, Sayyid Ali Hoseyni Khamenei, does not differentiate between Muslims and non-Muslims, *see* Sayyid Ali Hoseyni Khamenei, http://nahad.sbmu.ac.ir/?siteid=269&pageid=20612 [http://perma.cc/A2ZD-PTMB] (last visited Nov. 1, 2015). But the former leader did make such a differentiation, *see* Sayyid Ruhollah Khomeini, *Tashrih-o Paivand* [*Autopsy and Transplantation*], ISLAMIC THOUGHT FOUND., www.imam-khomeini.com/web1/persian/showitem.aspx?cid=915&pid=2014&h=1&f=2 [http://perma.cc/2LHK-SQ74] (last visited Nov. 1, 2015). (The original sources and their translation are on file with the *Indiana Health Law Review.*).

B. Compensation for Human Organs

On the question of compensation or sale and purchase of organs, the approach of the *Maraji'* in the past has been to ban such sale on the grounds that it was futile and would not have any reasonable benefit, because a human organ was considered to be economically worthless.[47] In view of medical developments that have made organ transplants highly beneficial in saving lives and restoring good health, decrees have been issued to reflect the economic aspect of these developments and thus to enable such transactions.[48] A majority of the *Maraji'* have clearly stated that the sale and purchase of organs is permissible,[49] while others have cautioned that the transaction should be conducted under another contractual category, such as release, assignment, gift, license, or mutual good deed (reciprocity).[50]

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[47] *See* Mir Sajjad Hashemi, *Asare Hoghooghie Vagozarie Ozve Ensane Morde Ya Mobtala be Marge Maghzi* [*Legal Consequences of Transferring the Organs of a Deceased or Brain-Dead Person*], Andisheh Taghrib Periodical 50-71 (2006). (The original sources and their translation are on file with the *Indiana Health Law Review.*).

[48] Sayyid Ali Hoseyni Khamenei, Estefta'at-e Jadid [New Questions], www.leader.ir/tree/print.php?catid=49&nodeid=n14609 [http://perma.cc/JH9E-4LMX] (last visited Jan. 14, 2016). (The original sources and their translation are on file with the *Indiana Health Law Review.*).

[49] This is usually with the caveat that the transplant must not be harmful to the donor. Hossein Ali Montazeri uses the "serious and irreversible harm" formula, MONTAZERI *supra* note 41, at 131 (question 296); Sayyid Ali Husayni Sistani only mentions "serious harm", CATECHISM, *supra* note 33 at 575. Some of the *Maraji'* have stated that while it is permissible, it is best to be abstained from, Mohammad Ebrahim Jannaati, http://www.jannaati.com/far/index.php?page=6&row= 6&start=36 [http://perma.cc/GR7R-AKDU], while others have not mentioned such a restriction, Khomeini, *supra* note 46; Hossein Mazaheri (Esfahani), www.almazaheri.ir/farsi/Print/Print.aspx?TBlName= PublicQuestion&ID=484 [http://perma.cc/8QJL-L5WJ] (last visited Nov. 1, 2015); TEHRANI, *supra* note 35, 451 *fatwa* No. 1000. (The original sources and their translations are on file with the *Indiana Health Law Review.*).

[50] Mohammad Ali Gerami uses the term *Raf'e yad* (dispossession). *See* Mohammad Ali Gerami, GERAMI.ORG, www.ayat-gerami.ir/ data.asp?L=1&id=3048 [http://perma.cc/K33R-SEGK] (last visited Nov. 1, 2015). Sayyid Ali Hoseyni Khamenei uses the term *foroosh* (sell) on

It appears that these decrees have been issued with the belief that due to developments in modern medicine, the trade of human organs may be considered rationally beneficial and hence, capable of being transferred in a sale and purchase agreement.[51] However, there are decrees that restrict this position. The position that a transplant should take place only in cases where it offers hope for saving a life and is not futile also applies to the sale and purchase of organs.[52]

Some of the *Maraji'* have also declared the sale of organs by persons condemned to death to be illegal.[53] However,

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three occasions, *see* Khamenei *supra* note 48; Sayyid Ali Hoseyni Khamenei, http://www.leader.ir/tree/index.php?catid=11 [http://perma.cc/ 8HGD-Y2EE] (last visited Nov. 1, 2015) (questions 1291 and 1518). But, in another *fatwa*, he specifies that organ donation may be carried out as "assignment," Khamenei, *supra* note 46. Naser Makarem Shirazi believes "license" is the better form of transaction, *see* Naser Makarem Shirazi, Paivande Tokhmdane Zan-e Ajnabi be Zojeh [Transplantation of an Unrelated Woman's Ovary to a Married Woman] http://makarem.ir/main.aspx?typeinfo=21&lid=0&catid=28962&mid=2435 [https://perma.cc/P6H9-TK8Y]. Sayyid Mohammad Sadeq Hosayni Rohani has classified the transfer of gametes and embryos as a "gift," Sayyid Mohammad Sadeq Hosayni Rohani http://www.rohani.ir/istefta-777.htm [http://perma.cc/Q936-GR8W] (last visited Nov. 1, 2015), and believes that the sale of organs or cadavers for conducting autopsies is impermissible, Sayyid Mohammad Sadeq Hosayni Rohani http://www.rohani.ir/istefta-1336.htm [http://perma.cc/U52Q-7534] (last visited Nov. 1, 2015). Yousuf Saanei believes that while the sale and purchase of organs is permissible *per se*, the transaction is best to be carried out under some other rubric, such as a mutual good deed. He believes the sale and purchase of organs may result in the belittlement of the Islamic Republic [of Iran]. *See* YOUSUF SAANEI, ESTEFTAAT-E-PEZESHKI [RELIGIOUS DECREES ON MEDICINE] 138-139 (12th ed. 2009). (The original sources and their translation are on file with the *Indiana Health Law Review*.).

[51] HOSSEIN NOORI HAMEDANI, HEZAR-O YEK MAS'ALEH FIQHI [A THOUSAND AND ONE PROBLEMS OF *FIQH*], 255 (n.d.), *available at* http://www.noorihamedani.com/files/51d16dbcb0642.pdf [https://perma.cc/Y5D6-P4EZ]. (The original source and its translation are on file with the *Indiana Health Law Review*.).

[52] Foomani, *supra* note 45, Pezeshki [Medicine] *fatwa No. 506*; Sayyid Mohammad Shahroudi, *fatwa No. 1793*, www.shahroudi.com/Portal.aspx?pid=71243&CaseID=34311 [http://perma.cc/E8K3-MN33] (last visited Nov. 1, 2015). (The original sources and their translation are on file with the *Indiana Health Law Review*.).

[53] Foomani, *supra* note 45, Pezeshki [Medicine] *fatwa No. 543*.

there are decrees that provide the possibility of donating organs to benefit from a lesser punishment. For instance, Sayyid Kazim Hussaini Haeri has issued a decree stating that in cases where a person who is condemned to death is willing to donate an organ to benefit from a lesser punishment and the judge has the power and discretion to issue a lesser punishment, such donation is permissible.[54] This *fatwa* does not address the issue of monetary compensation; rather it addresses a non-monetary incentive that seriously calls into question the autonomy of such donors.

There is also general agreement that the sale of organs does not devolve upon the heirs of a decedent by way of inheritance. Such heirs may only endorse or reject the donation of the decedent's organs, but may not receive any sums for such donation.[55] This is a peculiar position and it raises the question whether the Shiite *Maraji'* consider organs to be the property of a person.

This is a peculiar position and it raises the question whether the Shiite *Maraji'* consider organs to be the property of a person. If so, why do they conclude that the appertaining property rights do not pass on to a person's heirs?[56] However, if human organs are not considered to be one's property, the question would arise as to the basis of the *fatawa* for considering the sale and purchase of organs to be permissible, since the *fatawa* that have been issued in allowing such sales are based on the rational benefit and worth of such organs. In fact, only two of the *Maraji'* have

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[54] Haeri, *supra* note 42. *See also* MONTAZERI, *supra* note 41, at 130 (question 289); *see also* Yousuf Saanei, http://www.saanei.org/?view=01,05,13,49,0 [https://perma.cc/YGA4-43TE]. (The original sources and their translation are on file with the *Indiana Health Law Review*.).

[55] Foomani, *supra* note 32, Jarahi, Tashrih, va Paivand [Surgery, Autopsy, and Transplantation], *fatwa No. 1171*; Sayyid Kazim Hussaini Haeri also mentions that an advance directive to the effect that the decedent's organs be sold after death is void, Haeri, *supra* note 42. *Contra* Mohammad Ebrahim Jannaati, http://www.jannaati.com/far/index.php?page=6&row=6&start=42 [http://perma.cc/ZJN6-TMH2] (last visited Nov. 1, 2015). (The original sources and their translation are on file with the *Indiana Health Law Review.)*.

[56] For an exploration of the issue *see* Mir Sajjad Hashemi, *supra* note 47.

explicitly stated that humans do not have ownership of their organs as they would of other property,[57] but they may nonetheless transfer their organs in lieu of compensation. These *Maraji'* have not specified the form and legal qualification of such a transaction. This peculiarity is further complicated by other aspects of the positions of *Maraji'* that consider the sale and purchase of organs permissible. For instance, in case such a transaction is for any reason void and the donor decides to renege on the transaction, what is to become of the organ? Should it be transplanted back to the donor? Also, what would be the consequence of not include the necessary contractual safeguards for termination? If a donor were to rescind her offer to "sell" her organ, would she nonetheless be forced to undergo the transplant procedure for failing to incorporate a termination clause in the agreement?

One of the *Maraji'* has been asked to comment on the consequence of a void sale of a human organ and his response has been that the recipient may resell the organ to the donor.[58] This is not the consequence of a void sale agreement according to Shiite *fiqh* and the stated position requires further clarification by the *Marja'*. The fact that there is no requirement for a written contract of sale in Islamic *fiqh* and that many consequences of a void sale agreement of a human organ would be left unanswered underscores the need for further thought and deliberation on the nature of human organs and the acceptable form of their transfer to others by the *Maraji'* that have issued *fatawa* on these issues.

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[57] Mohammad Yaqoobi, A'ttabaro' Bel A'aza [Organ Donation], http://yaqoobi.com/arabic/index.php/103/126/668.html [https://perma.cc/YGA4-43TE] (last visited Jan. 15, 2016); Sayyid Mahmoud Hashemi Shahroudi, Kharido Forooshe A'azaye Badan [Purchase and Sale of Organs] http://hashemishahroudi.org/fa/pages/print.php?page=question&id=996 [https://perma.cc/HEW7-HQ3E] (last visited Jan. 15, 2016). (The original sources and their translation are on file with the *Indiana Health Law Review.*).

[58] Mohammad Ali Gerami, *Masaeli Dar Babe Kharido Forooshe A'za* [*Issues on Purchase and Sale of Organs*], GERAMI.ORG, www.ayat-gerami.ir/data.asp?L=1&id=3048 [http://perma.cc/7FFJ-D58S] (last visited Oct. 16, 2015). (The original sources and their translation are on file with the *Indiana Health Law Review.*).

IV. THE REGULATION AND LEGAL NATURE OF ORGAN TRANSPLANTATION IN IRAN

The first kidney transplant in Iran was carried out in 1968 using the organ of a live donor and the first cadaveric transplant was performed four years later in 1972. [59] However, the first regulation on transplants was a provision in a Byelaw issued in 1976 by the Council of Ministers in respect of Article 42 (3) of the General Penal Code of 1973.[60] According to Article 2 of the Byelaw, if a medical specialist determined the necessity of an organ transplant, the transplant required obtaining the written consent of the organ donor. Furthermore two other specialists had to verify that extracting the organ would not pose a foreseeable physical or mental danger to the donor. [61]

This provision was repeated verbatim in a corresponding article in the superseding Byelaw of 1978.[62]

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[59] *History of Nephrology in Iran*, IRANIAN SOCIETY OF NEPHROLOGY (Dec. 2008), http://www.isn-iran.org/mainPage.php?lang=en [http://perma.cc/496R-8AWV] (follow "Nephrology in Iran" hyperlink; then follow "History" hyperlink).

[60] RUZNAMEHI RASMI KISHVARI SHAHANSHAHI IRAN [THE IMPERIAL IRANIAN OFFICIAL GAZETTE], Aiin Nameye Ejrai-e Band-e 3 Madeh-ye 42 Ghanoon-e Mojazat-e Omoomi [Implementing Byelaw on Paragraph 3 of Article 42 of the General Penal Code] Oct. 27 1976, No. 9272, *available at* http://dastour.ir/brows/?lid=93275 [http://perma.cc/Z5NM-XGSL]. (The original source and its translation are on file with the *Indiana Health Law Review.*).

[61] *Id.* at art. 2. Article 42 (3) of the General Criminal Code provided that any surgical or medical act carried out with the consent of the right-holder and in conformity with regulations adopted and declared by the State is not a crime. GHANOON-E MOJAZAT-E OMOOMI [GENERAL PENAL CODE] Tehran 1352 [1973] (Iran), art. 42. That provision is now reinstated with minor amendments as Article 59 (2) of the Islamic Criminal Code. (The original source and its translation are on file with the *Indiana Health Law Review.)*.

[62] RUZNAMEHI RASMI JUMHURI ISLAMI IRAN [THE OFFICIAL GAZETTE OF THE ISLAMIC REPUBLIC OF IRAN], Tasvibname Darbareye Aiin Nameye Ejrai-e Band-e 3 Madeh-ye 42 Ghanoon-e Mojazat-e Omoomi [Byelaw on the Implementing Byelaw on Paragraph 3 of Article 42 of the General Penal Code] Jan. 3 1979, No. 9895 *available at* http://dastour.ir/brows/?lid=%20%20%20%20%2098292 [https://perma.cc/67CC-2PXD]. (The original source and its translation are on file with the *Indiana Health Law Review.*).

A. Compensated Live Organ Donations

After the Islamic Revolution and almost twenty years after the aforesaid regulation, the Cabinet issued another Byelaw in 1997 simply titled "Byelaw on Kidney Donors" providing for a monetary gift to be paid to kidney donors with the intention of facilitating kidney transplants and encouraging donations.[63] According to this Byelaw, the sum of ten million (10,000,000) Rials shall be granted to kidney donors as reward for their good deed by the Foundation for Special Diseases."[64] This is included in the national budget and paid to the Foundation by the Executive.[65] Hence, although the regulation itself has been passed by the Cabinet, the monetary compensation in lieu of organ donations receives the assent of Parliament when the Budget is approved each year.

There are several interesting considerations in this provision. The Byelaw only mentions kidney transplants and has not addressed other forms of organ donations that were being carried out even then. Also, the amount is granted to the donors as a reward for their altruistic act, commonly known as the "gift of sacrifice." It is not compensation for the sale and purchase of kidneys, but for the *act* of donation, or "their good deed."[66] The difference between these two will be explored in more detail below, but it is important to highlight that the Iranian legal system differentiates these two

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[63] RUZNAMEHI RASMI JUMHURI ISLAMI IRAN [THE OFFICIAL GAZETTE OF THE ISLAMIC REPUBLIC OF IRAN], Byelaw on Kidney Donors of Feb. 25, 1997, No. 15146, *available at* http://dastour.ir/brows/?lid=165176 [http://perma.cc/N7D7-U6F4] (last visited Jan. 15, 2016). (The original source and its translation are on file with the *Indiana Health Law Review.*).

[64] *Id.*

[65] The Charity Foundation for Special Diseases was established in 1996 and is a non-governmental organization that also receives donations from private persons. CHARITY FOUNDATION FOR SPECIAL DISEASES, http://www.cffsd.org/about-us [http://perma.cc/YA9U-YKFH](last visited Oct. 16, 2015). (The original source and its translation are on file with the *Indiana Health Law Review.*).

[66] Byelaw on Kidney Donors, *supra* note 63.

transactions and the regulated scheme for compensation is not one of human organ purchase and sale.

The amount provided in the Byelaw was over forty-eight times higher than the monthly minimum wage at that time. Hence, it provided a significant financial incentive to donors, and thereby effectively overcame the kidney shortage prevalent at the time. However, this amount has remained unchanged over the years, despite the monthly minimum wage having had a twentyfold increase.[67] Even if the rather conservative and cautious rates of inflation declared by the Central Bank of Iran for the past fifteen years are not factored in the equation, [68] the amount that would be commensurate with the original provision's ratio to minimum wage should be considerably higher today, standing close to two hundred and ninety four million (293,855,140) Rials. The fact that no change has been made to the "Gift of Sacrifice" has caused potential donors to seek compensation elsewhere, by advertising their readiness to "sell" their kidneys to those who need one and are willing to pay the price requested by the donors.

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[67] *See* KHABARONLINE, Negahi be Hadeaghal Dastmozd Taye 34 Sale Gozashte: Faseleye Hadeaghale Dastmozd va Nerkhe Tavarom Cheghadr Ast? [A Look at the Minimum Wage over the past 34 Years: What is the Gap between the Minimum Wage and the Rate of Inflation?] www.khabaronline.ir/print/275142/economy/macroeconomics [http://perma.cc/W7BZ-FP53] (last visited Jan. 15, 2016) (showing data published by the Central Bank of Iran that minimum wage was 207,210 Rials in 1997 and 3,900,000 Rials in 2012). *Minimum wage was 608 dollars*, ALEF.IR, http://alef.ir/vdcbw9b59rhb8sp.uiur.html?219589 [http://perma.cc/738C-3NYW] (last visited Oct. 16, 2015) (showing that in both 2013 and 2014 the minimum wage was again increased and now stands at just over 6,089,000 Rials). (The original sources and their translations are on file with the *Indiana Health Law Review.*).

[68] *See The Real Rate of Inflation is Above 50%*, TABNAK (Oct. 16, 2012), www.tabnak.ir/fa/print/279113 [http://perma.cc/8EJR-DLEB] (showing that the rate of inflation declared by the Central Bank of Iran (CBI) is often disputed: while average inflation for 2012-13 has been estimated at under 30 percent by the CBI, some estimates put this at over 50% or higher, going up as much as 196%). *See also Growth of 97% inflation in 20 months*, ALEF.IR (Jan. 6, 2013, 11:17 AM), http://alef.ir/vdchimnzx23nqid.tft2.html?175223 [http://perma.cc/8UBH-KPGZ] (giving an average inflation for the months of March 2011 to November 2012 estimated at 97%). (The original source and its translation are on file with the *Indiana Health Law Review.*).

The Directive on Kidney Donations and Transplants from Live Donors issued in 2008 by the Ministry of Health[69] is also worthy of mention here. This Directive sets out the regulations for live donations in five sections: 1) the criteria for live unrelated donors; 2) medical tests and examinations prior to donation; 3) transplants for foreign nationals; 4) other provisions; and 5) monitoring.[70]

Section one of the Directive sets forth several factors for living unrelated donors, including age (between the age of 18-45, and over 25 for unmarried female donors), informed written consents by the donor and the donor's spouse (if married) or parents (if single), nationality, "thorough medical examinations and tests" to be carried out by specialized medical doctors which are further stipulated under section two of the Directive and detailed in relevant protocols. Furthermore, this section absolutely bars habitual intravenous drug users from donating their kidneys.[71] These provisions do not stipulate a definition of "unrelated donors" or a method of verifying such status. This loophole is an oversight that is conducive to dealings whereby parties may claim to be related, thereby "selling" their organs on the market and foregoing the reward foreseen in the regulatory framework altogether, which is currently of little to no value.

In addition to the provision in section one of the Directive requiring the donor and recipient to be nationals of the same State, section three provides further provisions to ban transplants between people of different nationalities.[72] This section states that transplants for non-Iranians may only

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[69] Dastoor-ol Amal-e Ehda va Paivand Kollieh az Ehda Konandegan-e Zendeh [Directive on Kidney Donations and Transplants from Live Donors] of 20 October 2008, [hereinafter Directive on Kidney Donations and Transplants from Live Donors] *available at* http://www.behdasht.gov.ir/index.aspx?siteid=1&pageid=13401&newsview=5813 [https://perma.cc/ BDM9-AQDU]. The Directive was prepared through a collaborative undertaking by the following: Academy of Medical Sciences, Iranian Society of Organ Transplantation, Transplantation and Dialysis Council, Medical Ethics Research Center of Tehran University of Medical Sciences, and the Legal Department of the Ministry of Health and Medical Education. (The original source and its translation are on file with the *Indiana Health Law Review*.).

[70] *Id.*

[71] *Id.* § 1(5).

[72] *Id.*

take place between those who are nationals of the same State.[73] The only exception is that of married couples who may have different nationalities.[74] By virtue of this section, transplants for all foreign nationals requires specific written license. Furthermore, according to a separate Byelaw issued on the subject of transplants for foreign nationals, such license may only be given by the Center for Dialysis and Organ Transplants of Iran. The license must be in writing and issued upon satisfaction of the relevant criteria for transplants for foreign nationals.[75]

Under section four of the Directive, any organized coordination with the purpose of organ donations by Iranians in other States has been prohibited.[76] This section also prohibits any advertising or notice for donation and threatens legal action for any violations by those who place or publish a notice or advertisement for requesting an organ.[77] It further prohibits any brokerage or trade in the process of kidney donations from live donors. Monitoring these regulations has been entrusted to the "experts of the Department of Transplants and Special Diseases of the Ministry of Health" and "the experts of medical sciences universities across the nation", the sanction for violations being the complete shutdown of the transplant ward.[78]

B. Cadaveric Organ Transplants

Separate regulations govern the transplant of cadaveric organs. Regulating cadaveric organ transplants in Iran has not been an easy task due to the religious obstacles involved. However, with the issuance of *fatawa* on the matter, the Parliament of Iran enacted a law on April 5, 2000 entitled:

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[73] *Id.* § 3(1)

[74] *Id.* § 3(2)

[75] Vct.kmu.ac.ir, A'in Nameye Payvande Kollieye Atba'e Khareji [Organ Transplant of Foreign Nationals Byelaw], http://vct.kmu.ac.ir/Images/UserUpload/Document/VCT/darman/aeen%20name.pdf [https://perma.cc/S9JX-Z4TA] (last visited Jan. 15, 2016). (The original source and its translation are on file with the *Indiana Health Law Review.*).

[76] Directive on Kidney Donations and Transplants from Live Donors, *supra* note 69, § 4(3).

[77] *Id.* § 4(1).

[78] *Id.* § 5.

"Transplant of Organs from Deceased Patients or Patients with Evident Brain Death" (hereafter the Brain Death Law or BDL).[79] The law was neither approved nor rejected by the Guardian Council and thus entered into force in accordance with Article 94 of the Constitution.[80] Furthermore, a Byelaw issued on the 18th of June 2001 was issued to complement the BDL.[81]

The BDL provides that equipped hospitals may use the healthy organs of deceased patients, or patients who have been ascertained to be brain dead by experts, for transplanting to patients whose life depend on the organ(s).[82] This is subject to the deceased or brain dead patients' will and testament, or the consent of their heirs. It also requires the hospital to have obtained written authorization from the Ministry of Health for this purpose.[83]

Several points are noteworthy. The question of consent has been highlighted in the BDL and further elaborated in the BDL Byelaw. The donor may have declared consent orally

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[79] Law on the Transplant of Organs from Deceased Patients or Patients with Evident Brain Death of 5 Apr. 2000 (Iran), [hereinafter Law on the Transplant of Organs from Deceased Patients] *available at* dastour.ir/Print/?lid=188843 [https://perma.cc/KM2M-WMCD]. (The original source and its translation are on file with the *Indiana Health Law Review*.).

[80] ISLAHAT VA TAQYYRATI VA TATMIMAH QANUNI ASSASSI [AMENDMENT TO THE CONSTITUTION] 1368 [1989], art. 94 (Iran). Article 94 states that: "[a]ll legislation passed by the Islamic Consultative Assembly must be sent to the Guardian Council. The Guardian Council must review it within a maximum of ten days from its receipt with a view to ensuring its compatibility with the criteria of Islam and the Constitution. If it finds the legislation incompatible, it will return it to the Assembly for review. Otherwise the legislation will be deemed enforceable."

[81] Implementing Byelaw for the Law on the Transplant of Organs from Deceased Patients or Patients with Evident Brain Death of 18 June 2001 [hereinafter Implementing Byelaw] *available at* http://dastour.ir/brows/?lid=258228 [https://perma.cc/ Z2HX-23W2] (last visited Oct. 16, 2015). *See also* DASTOUR.IR, http://dastour.ir/brows/?lid=260706 [https://perma.cc/SMJ4-C6QQ] (last visited Oct. 16, 2015) (detailing a minor amendment to the BDL Byelaw that was made on 4 September 2002). (The original source and its translation are on file with the *Indiana Health Law Review*.).

[82] Directive on Kidney Donations and Transplants from Live Donors, *supra* note 76, § 5.

[83] *Id.*

or in writing prior to death, or the heirs may provide consent post mortem. The heirs or "*wali*" is defined in the BDL Byelaw based on descent and distribution provisions of the Civil Code.[84] Where the decedent donor has given consent orally prior to death, consent may be evidenced by a written declaration of a single legal heir.[85] Also, if the written consent of the deceased is not readily available, any legal heir who is certain of the will of the deceased to donate may sign a declaration and testify to that effect.[86]

Experts who are authorized to determine brain death are appointed by the Ministry for a period of four years and stationed in equipped public university hospitals, their determination of brain death must be based on a protocol prepared by the Ministry,[87] and they cannot be members of a transplant team.[88] The BDL Byelaw provides that these experts must consist of four medical doctors specializing in neurology, neurosurgery, internal medicine, and

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[84] *See* QANUNI MADANI [CIVIL CODE] Tehran 1314 [1935], art. 862 (Iran). Article 7 of the BDL Byelaw has departed from the definition of *wali* under Article 1180 *et seq.* of the Civil Code and has defined this according to the provisions on inheritance. The Byelaw defines the *wali* of the deceased as legally adult heirs who can consent to the organ transplant. *See also id.*, art. 862 (defining heirs as: 1 – Father and mother and children, and grandchildren; 2 - Grandparents, brother and sister and their children; 3 - Paternal uncles and paternal aunts, maternal uncles and maternal aunts and their children). *See also id.* art. 864 (defining the spouse of a deceased person as an heir by cause of marriage). *Cf.* QANUNI MOJAZATE ESLAMI [ISLAMIC PENAL CODE] Tehran 1370 [1991], art. 261 *available at* http://dastour.ir/Print/?lid=143178 [https://perma.cc/A224-ZRRF] (also defining the *wali* as heirs of the decedent, except that the BDL Byelaw is inclusive of the spouse of the deceased and it requires the written consent of all heirs, meaning those who would be first in line as descendants for the purpose of inheritance). (The original sources and their translations are on file with the *Indiana Health Law Review.*).

[85] Implementing Byelaw, *supra* note 81, art. 6.

[86] *Id.*

[87] *See* Protocol-e Taiin-e Marg-e Maghzi [Protocol on the Determination of Brain Death], ASS'N OF ORGAN DONATION SUPPORTERS, http://www.nafase-javid.ir/showthread.php?tid=71 [https://perma.cc/YL39-AKVN] (last visited Jan. 16, 2016). (The original source and its translation are on file with the *Indiana Health Law Review.*).

[88] Law on the Transplant of Organs from Deceased Patients, *supra* note 79; Implementing Byelaw, *supra* note 81 arts. 2 & 3.

anesthesiology.[89] Their examination of the patient must take place independently of the others and if their determination is unanimous, an expert in legal medicine shall verify their determination.[90]

While the BDL does not provide a definition of brain death, Article one of the BDL Byelaw defines this as the "complete and irreversible cessation of all cortical, subcortical and brain stem activity."[91] The various tests for this determination have been set out in the protocol. This provides practical finality to the differing *fatawa* on the matter and establishes a legal frame of reference on the question of brain death. Furthermore, an Explanatory Note issued by the Legal Department of the Judiciary on 12 May 2008 states that brain death is synonymous with death and entails all legal consequences of death.[92]

Last but not least, no compensation has been allowed in the regulations for the donation of cadaveric organs. In addition to the *fatawa* holding that no compensation may be made for consenting to the use of cadaveric organs by the heirs of the deceased, the websites of the various transplant authorities in Iran have also mentioned this restriction.[93]

C. The Legal Nature of Compensated Live Organ Donation

The legal nature of donations under the current regulations of Iran must be assessed against the background of the more general provisions of the Iranian legal system, particularly the Civil Code. The Code, modeled after the French *Code Civil* and drawing upon Islamic *fiqh* of the Twelver persuasion, has differentiated between various kinds of contracts. Article 10 of the Code recognizes the

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[89] Implementing Byelaw, *supra* note 81, art. 2.

[90] *Id.* arts. 2 & 3.

[91] Implementing Byelaw, *supra* note 81, art. 1.

[92] Opinion Number 7/1004, May 12, 2008, *available at* http:// dastour.ir/brows/?lid=335364. (The original source and its translation are on file with the *Indiana Health Law Review.*).

[93] *See, e.g.*, EHDA.IR, http://ehda.sbmu.ac.ir/?fkeyid=&siteid= 489&pageid=34591[https://perma.cc/3C8P-UHNQ] (last visited Jan. 17, 2016). (The original source and its translation are on file with the *Indiana Health Law Review.*).

general freedom to contract,[94] and rules governing the general law of contracts and obligations have been set forth in various provisions. A number of specific types of contracts have been addressed and subjected to separate rules, each type of contract having a special regime.

It has already been clarified that no compensation is due for cadaveric organs and that the Byelaw on Kidney Donors of 1997 has only established a framework for compensated live organ donation as described above. The legal nature of this undertaking is best characterized as a contract of reward[95] or *ju'alah*, as defined by article 561 of the Civil Code as engaging a person to make a payment in exchange for an act even if the other party is not known. This provision provides the possibility of compensating any act that is not illegal or unreasonable.[96] This latter condition should be read in tandem with the general provision for the object of transactions under the Civil Code, whereby the object of a contract must be valuable and provide for a "reasonable and legitimate advantage."[97] As noted previously, the transfer of organs was traditionally considered to lack a reasonable and legitimate advantage. However, with the possibility of transplanting organs to save lives and restore health, the numerous *fatawa* issued by the most senior *Maraji'*, and the resultant laws and regulations on transplants, there is no question as to the reasonable advantages of such transactions or to their legality.

The contract of reward may be offered to a specific person or the general public, thereby permitting the public tender of an act such as kidney donation. Furthermore, a contract of

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[94] QANUNI MADANI [CIVIL CODE] Tehran 1314 [1935], art. 10. Article 10 provides that: "private contracts shall be binding on those who have signed them, providing they are not contrary to the explicit Provisions of a law." (The original source and its translation are on file with the *Indiana Health Law Review.*).

[95] *See* MUHAMMAD AYUB, UNDERSTANDING ISLAMIC FINANCE, 351 (2009); *see also* MUHAMMAD YUSUF SALEEM, ISLAMIC COMMERCIAL LAW, 61-64 (2013) (for a general explanation of this type of contract in Islamic law).

[96] QANUNI MADANI [CIVIL CODE] Tehran 1314 [1935], art. 570 (Iran). (The original source and its translation are on file with the *Indiana Health Law Review.*).

[97] *Id.* at art. 215.

reward creates an obligation of result for the agent[98] and is a voidable contract. Article 565 of the Civil Code provides that either party in a contract of reward [ju'alah] may withdraw because the contract is permissive.[99] If the person paying the reward terminates the contract while the act is being carried out, the agent must still be compensated reasonably for the act.[100] This ensures that the organ donor may terminate the undertaking at any time, thereby safeguarding the donor's consent.

This is exactly the legal qualification of the Byelaw of 1997, where the State has offered a certain sum of money as a reward to whosoever may donate their kidney.[101] The protocols in place protect the consent of donors by ensuring that they may rescind their decision to donate at any time. The compensation for donation is provided to the donors only after the transplant takes place. Therefore, the official compensated scheme for human organ transplants only applies to live donors and is a reward for the *act of donation*, not the *sale and purchase* of kidneys.

V. AMBIGUOUS TRANSACTIONS AND ABSURD CONSEQUENCES

A particular ambiguity exists with respect to the current agreements reached by individuals outside the official framework described above. As was noted, the compensation provided by the State has not been increased over the years and has lost any meaning as an incentive. The result is that notices are now illegally posted on websites or the walls and adjacent streets of transplant centers whereby offers are made to "purchase" kidneys of particular blood types needed by potential recipients.[102] This raises an important question: if such transactions take place between private parties, what would be the legal qualification of the transaction?

This is further complicated by the numerous *fatawa* that have authorized the sale and purchase of organs. The lack of an express prohibition on the sale of human organs in Iranian

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98 *Id.* at art. 567.

99 *Id.* at art. 565.

100 *Id.*

101 Byelaw on Kidney Donors *supra* note 63.

102 Dehghan, *supra* note 10.

law and the possibility of resorting to *fatawa* by virtue of Article 3 of the Civil Procedure Code in certain cases[103] further complicates the issue. The said article, with the intent to prevent a *non liquet*, provides:

Justices of the Courts [judges of the courts] shall adjudicate claims, issue judgments, and settle disputes based on law. If positive [posited] laws are incomprehensive or unspecific or contradictory or non-existent in the case in question, they shall issue their ruling of the case by reference to reputable Islamic sources or reputable *fatawa* and legal principles that don't contradict the criteria of *Shari'a*, and they may not refrain from hearing claims and issuing judgments due to the silence or deficiency or brevity or contradiction of the law, else they shall be held to be in denial of justice and convicted accordingly.

Note- If a judge is a *mujtahid* and considers the law to be in violation of *Shari'a*, the case shall be referred to another Chamber for adjudication.[104]

Of course this provision in and of itself may not result in uniform jurisprudence on issues that are inadequately regulated. The Iranian judicial system is based on the French Civil Law system, and the sole authority capable of creating uniform judicial practice in Iran is the Supreme Court. Therefore, courts of first instance and of equal standing do not have to abide by each other's decisions. In view of the various approaches in the *fatawa* on human organ donation, particularly the legal qualification of such donations, it will ultimately fall on the Supreme Court to decide on divergent judgments from the lower courts on issues such as the sale and purchase of organs. However, the question remains that in view of the silence of the law, would a judge who is confronted by a claim of organ purchase with the intent to transplant, rule in favor of the "purchaser" and force the "seller" to undergo a transplant operation? Alternatively, would the court order compensation for breach of contract instead of specific performance? This is particularly important in that the majority of *fatawa* do not

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[103] AINI DADRASSII MADANI [Civil Procedure Code] Tehran 1379 [2000] art. 3 (Iran) (The original source and its translation are on file with the *Indiana Health Law Review.*).

[104] *Id.*

seem to have taken into account the wider policy implications of the possibility for the sale and purchase of organs.

The advisory opinions issued by the Legal Bureau of the Judiciary [105] (the Bureau) are also indicative of a legal conundrum on this question. The Bureau appears to be unable to decide on the legal nature of the donation of organs. In an advisory opinion[106] issued in 2005 and citing the BDL, it has declared that the sale or donation of organs for transplants is permissible, but appears to be at a loss as to what consequences may arise if the heirs of a decedent who has "sold" or donated her organs reject the procurement procedure.[107] The Bureau, somewhat befuddled, states that apart from filing a civil action against the heirs to fulfill the obligation of the decedent, no other recourse appears to be available.[108] The Bureau has also used the term "sale" in another of its opinions,[109] surprisingly by reference to the BDL, which makes no reference to the legal qualification of the transfer of cadaveric organs. It declares that the sale and purchase of human organs is illegal except in the framework of the BDL and its Byelaws. This position of the Bureau is particularly interesting in that it also contradicts many of the *fatawa* on the donation of cadaveric organs.

The Bureau appears to consider the BDL as an exception to a general prohibition of organ extractions and, in fact, uses the term "donation" of organs in other opinions and insists that the act of donation should not contravene human

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[105] This Bureau is part of Iran's judicial structure. Among other things, it is tasked with providing advisory opinions on judicial matters and publication of these opinions for reference by the courts. However, its opinions are not binding and even the website of the Bureau has a disclaimer to the effect that the advisory opinions do not necessarily reflect the official positions of the Judiciary. *See* Legal Bureau of the Judiciary, http://www.edarehoquqy.ir/ [http://perma.cc/8ZX8-QNQ3]. (The original source and its translation are on file with the *Indiana Health Law Review.*).

[106] Opinion Number 7/7712, January 3, 2005, File No. 83-30-1770. (The original source and its translation are on file with the *Indiana Health Law Review.*).

[107] *Id.*

[108] *Id.* ¶ 2.

[109] Opinion Number 7/770, Apr. 29, 2009, File No. 88-30-47. (The original source and its translation are on file with the *Indiana Health Law Review.*).

dignity,[110] and is mindful of humanitarian and ethical considerations.[111] Another widely cited opinion of the Bureau that has also been referenced by the monthly publication *Dadrasi*, has stated that human organs cannot be sold because they are not property, but an individual may donate them to others when alive or after death and receive compensation.[112]

In view of the foregoing and the fact that the Supreme Court has not yet issued a judgment on the matter, it is uncertain how the courts in Iran would handle a case of organ sale. On the one hand, the general freedom of contract and the silence of the law on the sale of human organs, coupled with the *fatawa* that are permissive of such sales, may be considered to provide license for the sale of human organs. If so, the courts would have to enforce an agreement for the sale, either issuing a judgment reminiscent of Shakespeare's *Merchant of Venice* to the effect that the seller should check into a transplant center and have his or her organ removed and surrendered to the purchaser, or ordering compensation for breach of contract.

This conclusion may also appear to be supported by reference to the provisions of the Iranian Civil Code on sales, which in Article 339 provides that a sale is concluded by offer and acceptance without requiring a written contract.[113] The Code goes on to provide in Article 362 that upon such conclusion, the buyer becomes the owner of the object of sale and the seller is responsible for surrendering the object of sale to the buyer.[114] Furthermore, contrary to a contract of

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[110] Opinion Number 7/4067, Oct. 2, 2010. (The original source and its translation are on file with the *Indiana Health Law Review.*).

[111] Opinion Number 7/5077, Oct. 10, 2005, File No. 84-30-172. (The original source and its translation are on file with the *Indiana Health Law Review.*).

[112] Markaze Tahghighate fiqhi-e Ghoveye Ghazaie [The *fiqh* Research Center of the Judiciary], *Estefta'ate Fiqhi-Ghazaii (dar omoore hoghooghi)* [*Judicial/Islamic Opinions (on civil matters*)], 43 Dadrasi Journal, 44, 45 (2004), (referencing Opinion Number 7/1558, Sept. 24, 1997). (The original source and its translation are on file with the *Indiana Health Law Review.*).

[113] QANUNI MADANI [CIVIL CODE] Tehran 1314 [1935], art. 339 (Iran). (The original source and its translation are on file with the *Indiana Health Law Review.*).

[114] *Id.* at art. 362 (Iran).

reward, a contract of sale is not a voidable contract and failing an agreement by both parties to revoke, or in case the various reasons for termination under the Civil Code[115] are not met or stipulated, including the right of termination without cause,[116] it appears that the Bureau is right in that the buyer may file a civil action for breach of contract.

This conclusion, however apart from being counterintuitive and contrary to the Iranian juris-culture,[117] necessitates certain assumptions and entails particular consequences that are not justified under the Iranian legal system. Of particular importance here is the possibility of ownership of the human body in general or human organs in particular. The *fatawa* that are permissive of selling human organs are based on the premise that such organs are of value and may therefore be the subject of transactions; but, save for a few, they have not addressed the separate question of ownership of the human body or organs in this context.

The assumption of the possibility of owning a part of another human being, which would be the result of accepting human organ sales by virtue of Article 140 of the Civil Code[118] and relevant provisions cited above, would result in slavery or slavery-like practices which have been illegal in Iran by virtue of international treaties signed[119] and ratified

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[115] *Id.* at arts. 396 *et seq* (Iran).

[116] *Id.* at arts. 399-401 (Iran).

[117] Apart from the ambivalence of the Bureau, the current practice of authorities such as public notaries, courts, and organ procurement centers does not seem to support this conclusion. A widely cited note by the Secretary of the Civil Laws Commission of the Supreme Council for Judicial Development, Dr. Ali Abbas Hayati, also rejects this conclusion. *See* Ali Abbas Hayati, *Mabnaye Hoghooghie Ehda va Paivande A'zaye Badan* [*The Legal Basis of Donation and Transplant of Organs*], 156 Farhango Pajouhesh 12 (2004) (Iran). (The original source and its translation are on file with the *Indiana Health Law Review.*).

[118] Section 2 of this article stipulates that contracts and obligations are a cause of ownership, and one of the most prominent examples of transfer of ownership is the contract of sale, which as discussed above, is a cause of immediate transfer of ownership from seller to buyer under Iranian law. QANUNI MADANI [CIVIL CODE] Tehran 1314 [1935], art. 140 (Iran). (The original source and its translation are on file with the *Indiana Health Law Review.*).

[119] Slavery Convention of 1926, art. 1, Sept. 25, 1926, 60 L.N.T.S. 253. Slavery is defined as "…the status or condition of a person over

by Iran, [120] and Iranian national legislation. [121] The assumption of owning another human being's organ(s) would empower the purchaser to unlimited and unrestricted exploitation and use, and the establishment of a right of ownership and claim to a part of another person.[122]

The consequences of assuming ownership of the human body would also be absurd and would involve numerous questions too detailed and varied to cover in this paper. These include issues such as the possibility of transfer of ownership of the organ by the purchaser to another buyer, possibly for a profit; the matter of inheriting organs by heirs of the purchaser and devolution of ownership rights to third parties by reason of a decedent buyer's will and testament; and the possibility of a criminal charge for crime(s) committed against property, possibly by the organ donor. Taken together, these considerations make it extremely unlikely that a court would uphold a claim for compensation due to breach of contract, the subject of which is the sale of human organs.

On the possibility of requesting specific performance by the donor, it is worthy to note that *lex specialis derogat legi generali*: special laws will have precedence over general legislation where they exist. If in the unlikely scenario, even as a thought experiment, a court were to render a judgment in favor of a claimant and order the surrender of the organ

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whom any or all of the powers attaching to the right of ownership are exercised."

[120] Supplementary Convention on the Abolition of Slavery, the Slave Trade, and Institutions and Practices Similar to Slavery, art. 7, Sept. 7, 1956, 226 U.N.T.S. 3. Article 7(a) of this treaty provides: "Slavery" means, as defined in the Slavery Convention of 1926, the status or condition of a person over whom any or all of the powers attaching to the right of ownership are exercised, and "slave" means a person in such condition or status."

[121] This national legislation includes the prohibition of slavery. Qanuni Man'e Kharido Forooshe Barde dar Khake Iran va Azadi Barde dar Moghe'e Vorood be Mamlekat [Prohibition of the Purchase and Sale of Slaves in Iranian Territory and Freedom of Slaves upon Entry to the Country], Tehran 1307 [1929], Iran. (The original source and its translation are on file with the *Indiana Health Law Review*.).

[122] QANUNI MADANI [CIVIL CODE] Tehran 1314 [1935], art. 30 (Iran). (The original source and its translation are on file with the *Indiana Health Law Review*.).

by the "seller," it is unimaginable how the operation would take place. Iranian criminal laws are replete with provisions on the inviolability of the human body, including post mortem.[123] Particular medical law and regulations[124] are also prohibitive of any surgical procedure without the written authorization of the patient, and the particular requirement for establishing the consent of organ donors for organ transplants procedures has already been covered. It is unimaginable that a transplant center would undertake a transplant operation without the consent of the donor and risk civil action and criminal charges.

In view of the above, it is safe to assume that should a case be brought to court requesting the enforcement of a "sale" of a particular organ, the court will either treat it as an agreement for donating an organ under a contract of reward (*ju'alah*) and respect the will and consent of the donor in revoking the agreement, or reject the submissions of the claimant as violating public order.[125] Until such time that such cases are taken to court however, it will not be absolutely clear what direction the courts or the Supreme Court will take.

VI. CONCLUSION

Any State that decides to provide some form of financial incentive for organ donation should also provide safeguards against the rather dramatic realization of the Shakespearean scene from the Merchant of Venice and fully protect the dignity and consent of donors. The Iranian model of organ transplantation appears to have been somewhat successful in preventing such an outcome. Contrary to popular belief that the Iranian model of organ donation is one of organ sales, by virtue of the particular legal concept of reward or

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[123] QANUNI MOJAZATE ESLAMI [ISLAMIC PENAL CODE] Tehran 1370 [1991], art. 494 (Iran).

[124] *See* Manshoore Hoghughe Bimar dar Iran [Charter on Patients' Rights in Iran] Tehran, 1388 [2009], art. 3 (Iran), *available at* mehr.tums.ac.ir/ShowLaw.aspx?LawID=46 [https://perma.cc/8FNH-K5MU].

[125] AINI DADRASSII MADANI [CIVIL PROCEDURE CODE] Tehran 1379 [2000] art. 6 (Iran). (The original source and its translation are on file with the *Indiana Health Law Review*.).

ju'alah under Iranian law that governs the act of donation and by the establishment of structural safeguards, Iran has managed to provide a compensated incentive to donors without objectifying them or their organs. The prohibition of transplant tourism, ensuring that donors receive free healthcare, provision of free psychological and vocational evaluations and consultations to donors further ensures their welfare. This particular legal regime of organ donations, coupled with the particular provisions of Iranian regulations on live and cadaveric donations, has managed to overcome the organ shortage in Iran and save thousands of lives.

However, much may be said of the fact that many live unrelated donors are undergoing transplant procedures for reason of economic hardship. Such financial distress is a major impediment to the equitable application of the principles of justice and autonomy to donors, but needs to be addressed in the wider context of socio-economic considerations of a nation's healthcare system. The fact of back-alley deals between donors and recipients in Iran is a major concern that needs immediate attention, possibly by adjusting the reward for organ donors to meet the true inflation rate in Iran and tightening the loopholes in current regulations, obviating the need and possibility for donors to conclude transactions with recipients outside the official transplant framework.

Despite these flaws and shortcomings, the fact is that the overall approach of the Iranian model may prove beneficial to reforming the current policy and regulations on human organ transplants in the United States and overcoming the organ shortage that is causing the death of thousands of patients on waiting lists every year. The notion of buying or selling human organs understandably causes pause for most people, if not outright aversion or disgust. However, rewarding the act of saving another person's life is a well-established and welcome approach. The question of compensating organ donors should not be addressed within a discourse of "purchase and sale of human organs," but of "rewarding the act of saving a fellow human being's life," even if such reward may include monetary compensation.

"UNNECESSARY, AVOIDABLE, UNFAIR, AND UNJUST": [EN]GENDERED ACCESS TO CARE IN THE PPACA ERA AND THE CASE FOR A NEW PUBLIC POLICY

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ABSTRACT

Disparities in access to health care are frequently noted along racial lines, but missing from the literature is a robust discussion of the on-the-ground effects of law and policy in creating gender-based disparities outside of the abortion context. This paper seeks to fill that gap by focusing on persons similarly situated but for whom gender results in disparate access. Accepting that neither a robust right to health nor to health care exists in the United States, the paper explores how recent legislative innovations, particularly the Patient Protection and Affordable Care Act, coupled with executive initiatives and trends in the discipline of population health, suggest that a shift in public policy is occurring that could mitigate disparities for all persons if courts and state governments will follow the other federal branches' lead.

I. INTRODUCTION

"Can this same procedure then be done in a pregnancy, swallowing a camera and helping the doctor determine what the situation is?"[1] This question was recently posed by a

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male state representative in Idaho in response to a physician's testimony on medical procedures she considered more dangerous than an elective abortion induced by medication. On that list was colonoscopy via camera pill, which was the procedure that prompted the Republican legislator's question. The ensuing explanation, which differentiated the digestive tract from the reproductive system, was given over the crowd's guffaws.[2] The lawmaker later claimed the question had been "rhetorical."[3] Whether the gentleman indeed failed to demonstrate an elementary understanding of female anatomy or whether he was merely "trying to make the point that equalizing . . . procedure[s] . . . was apples and oranges,"[4] he was successful at identifying at least one issue: the healthcare access needs of women of childbearing age do not necessarily come in parity with those of other sub-populations.

On the one hand, that disparate sex-based legal treatment of health issues arises as a function of the most obvious biophysical differences in men and women is of no surprise. After all, these are distinctions that invoke the most intimate of considerations. To the extent that the medical treatment in question derives from genuine sex-based biophysical variations, so, too, should the legal response vary. As a result, it would seem logical that jurisprudence on access to health care would reflect gender-based distinctions in *need* for care. The testimony described above could be an apt example of state intervention in the

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[1] *Chemical Abortions: Hearing on H.B. 154 Before the H. State Affairs Comm.*, IDAHO LEG. (Feb. 23, 2015), http://lso.legislature.idaho.gov/MediaArchive/ShowCommitteeOrMedia.do (statement of Rep. Vito Barbieri, Member, H. State Affairs Comm.) (63rd Leg., Reg. Sess.).

[2] *Id.*

[3] Kimberlee Kruesi, *Lawmaker Asks if Swallowed Camera Be [sic] Used for Female Exam*, WASHINGTON TIMES (Feb. 23, 2015, 9:16 PM), http://www.washingtontimes.com/news/2015/feb/23/lawmaker-asks-if-swallowed-camera-be-used-for-fema/?page=all [http://perma.cc/4VAA-5AKA].

[4] *Id.* (quoting Idaho Rep. Vito Barbieri).

process of access to health care by certain women—i.e., would-be mothers seeking an abortifacient pill—in the name of protecting those women.

On the other hand, the aforementioned legislature was considering restrictions on the use of telemedicine related only to accessing an otherwise lawful medical procedure.[5] That is, men who sought treatment or diagnosis via the medium of telemedicine would not be similarly restricted. (Neither, of course, would women seeking other types of treatment.) Indeed, the testifying physician was arguing that the remote performance of *riskier* medical procedures would not be proscribed, suggesting that this legislation was targeted at restricting the ability of women to access one particular type of medical care where a provision that expressly sought to interfere with access to that care would not be constitutionally permissible. Nor was it even actually a mere attempt to institute broad protections of health: one of the bill's proponents bluntly stated that the intended effect was a circumscription on the target patient's healthcare options.[6]

This paper theorizes that insofar as law and policy, through such determinations as above, has traditionally created a de facto gendered system of haves and have-nots in terms of access to care, contemporary efforts to remedy disparities in access exist sufficiently to create a public policy that prioritizes access to care and health in general. The paper begins by briefly laying out broad factors that tend to influence access to care and health, noting in particular how the socio-economic environment creates foundational gender-based disparities in access to care. It then provides a broad overview of the current status of access to care from several perspectives, with a focus on new data pertinent to systemic changes to the healthcare financial structure by the Patient Protection and Affordable Care Act. The paper specifically makes note where these disparities are biophysically based

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[5] Physician Physical Presence and Women Protection Act, H.B. 154, 63rd Leg., Reg. Sess. (Idaho 2015) (enacted), http://www.legislature.idaho.gov/legislation/2015/H0154.pdf [http://perma.cc/X4XC-7R53].

[6] Kruesi, *supra* note 3 (quoting Republican representative Linden Bateman's statement that "[i]n my view, this may reduce the number of abortions.").

on different sex-based medical needs, or whether they are the result of social constructs that may better lend themselves to legal remedy. The paper selectively employs both case law and legislative trends to explore the arc of justifications for, and interests that tend to interfere with, health care access according to the patient's gender.

Insofar that remediable disparities in access exist, the paper explores in the next section the limited rights to access to health care, along with other efforts to remedy gender-based disparities in access to care. Finally, the paper concludes by assuming that although health care perhaps cannot be understood as right-like, health is broadly regulated in ways that tend to support individual access. This is a theme that should be incorporated into judicial decisions on issues affecting health, which would tend to rectify disparate results in access to care. Here the paper imports lessons from other pertinent legal perspectives, such as public health law, in the creation of outcomes that are doctrinally consistent, equally protective, and in furtherance of systemic health goals for humans of all genders.

II. GENDER-BASED DISPARITIES IN ACCESS TO HEALTH CARE

What is it to have access to health care? Insofar as it may be conceptualized as the ability to receive care in support of one's health, the 1948 constitution of the World Health Organization (WHO) is instructive: there health is defined as "a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity."[7] It is a definition that has remained unchanged for nearly seventy years,[8] suggesting that access to care for health has long been understood as encompassing access to both holistic

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[7] World Health Organization Constitution [WHO], *Constitution of the World Health Organization*, (signed on Jul. 22, 1946), *available at* http://www.who.int/governance/eb/who_constitution_en.pdf [http://perma.cc/SUD2-U7GF].

[8] WHO, *WHO Definition of Health*, http://www.who.int/about/definition/en/print.html [http://perma.cc/JLZ7-GZL3] (last visited Nov. 1, 2015). *See also WHO: From Small Beginnings*, 9 WORLD HEALTH F. 29 (1988) (discussing background on the wording of the definition).

preventative services and medical treatment targeted at specific conditions. From a gender-equity doctrinal perspective, this means that, barring a pertinent biophysical feature that inheres in one sex or the other, similarly situated men and women alike should have the same access to both wellness care and needed medical treatment.[9]

The evolving definition of health-related disparities accords. WHO defines disparities or inequities as those "differences in health which are not only unnecessary and avoidable but, in addition, are considered unfair and unjust."[10] Nonetheless, our legal understanding of health and health care is not consistent with this proffered tenet, in part, perhaps, because access to health care is in reality a multifactorial inquiry influenced by a variety of laws and policies. In this section, this paper provides a comprehensive overview of health access before turning to law that influences access to care using, predominantly, a "life-cycle" approach rather than focusing on isolated points in time, and highlighting results that are unnecessary, avoidable, unfair, and unjust.[11]

A. Socio-Economic Access to Care: The Role of Social Determinants of Health

"These will be needless deaths—deaths which should shock our conscience and shame our sensibilities. How do we

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[9] This paper does not seek to implicate constitutional arguments regarding gender discrimination in every instance of observed gender disparity in access to health care. Nonetheless, it is not unimportant that "similarly situated" is a term of art within equal protection and many other doctrines. For an extensive treatise on the meaning and treatment of the phrase in jurisprudence, see generally Giovanna Shay, *Similarly Situated*, 18 GEO. MASON L. REV. 581 (2011).

[10] For background on WHO's deliberation on this definition, see Margaret Whitehead, WHO, *The Concepts and Principles of Equity and Health*, 6 HEALTH PROMOTION INT'L 217 (1991).

[11] Because health does not occur in isolation from the rest of one's life, a life-cycle approach is most appropriate in determining access to care. *See generally* Steven Miles, *Gender and Health Insurance*, 23 WM. MITCHELL L. REV. 313, 314-21 (1997) (describing work history and social programs as sources of conflicts and disadvantages by gender that are "magnified because of life cycle effects").

explain that the difference between life and death is a matter of dollars?"[12]

Nearly a half-century after the question was posed, the "how" remains a difficult question. The "why" is not: health care is expensive, and so much so that traditionally the two most widely accepted measures of access to care are the status of healthcare insurance coverage and financial barriers.[13] Yet there is growing appreciation of the importance of the social and physical environment, absent individual constitutional susceptibilities, as the most influential factor on health itself. Thus mitigation or elimination of negative social determinants of health (SDOH) is a foundational mechanism for law and policy to increase access to care—or fail to assuage gender-based disparities in access.

The U.S.'s Healthy People 2020 initiative lists five key areas of SDOH: (1) economic stability; (2) education; (3) social and community context; (4) health and health care; and (5) neighborhood and built environment.[14] While access to care can be considered a mere component of the fourth key area, health and health care, it would present an incomplete picture to not consider briefly how the other four key areas of SDOH underlie access to care.

1. Economic Stability

Because healthcare insurance acts as a proxy for access to care, a tenet explored in greater detail *infra*, lack of or

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[12] EZEKIEL J. EMANUEL, THE ENDS OF HUMAN LIFE: MEDICAL ETHICS IN A LIBERAL POLITY 100 (1994) (quoting Senator Vance Hartke).

[13] *See, e.g.*, KAISER FAMILY FOUND., PUTTING MEN'S HEALTH CARE DISPARITIES ON THE MAP: EXAMINING RACIAL AND ETHNIC DISPARITIES AT THE STATE LEVEL 33 (2012), *available at* https://kaiserfamilyfoundation.files.wordpress.com/2013/01/8344.pdf [http://perma.cc/9AAQ-JEE2] (listing having a regular healthcare provider as the third widely accepted measure of healthcare access).

[14] *Social Determinants of Health*, HEALTHYPEOPLE.GOV, http://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-health [http://perma.cc/6Y2E-67ZL] (last visited Nov. 1, 2015) [hereinafter Healthy People 2020]. Healthy People 2020 is a federal interagency population health workgroup that seeks, inter alia, to achieve heath equity.

insufficient coverage tends to create financial barriers to timely care. Confounding any unequal distribution of insurance between men and women are inequalities in financial resources. Limited resources amongst those of modest income decrease overall health, thereby stimulating a greater need for health care.[15] Unfortunately, limited financial resources also decrease the ability to acquire that care, as does lower overall health.[16] In other words, economic stability is tautologically related to both health and access to care. To the extent that access is about the ability to purchase the goods and services of health care, it is only logical that less money reduces the ability to acquire care. If access to care is understood more broadly, to include adequate transportation, childcare, and ability to miss work, then fewer resources acts as a compounding factor to the access inequity. In terms of both financial ability to purchase care and other resource-related barriers to care, women are more likely to be at disadvantage,[17] suggesting that their access is more significantly reduced by economic instability than that of men.

Further influencing the disparate effect of economics on access to care is that even amongst those with adequate financial resources, women earn less than men across all indicators, including where each is similarly educated, has similar experience, and is in the same occupation.[18] Whether the earnings gap creates unequal access amongst higher earners in reality is improbable, particularly for relatively inexpensive health services; but, as a philosophical matter, men are privileged relative to women in experiencing

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[15] *See* GEORGE A. KAPLAN, THE POOR PAY MORE: POVERTY'S HIGH COST TO HEALTH 8 (2009) ("Most diseases are more common among the poor, and those that are not, such as breast cancer, tend to have worse outcomes for poor people.").

[16] *See id.* at 17 ("Because they often lack health insurance benefits from work, many poor and near-poor families have inadequate access to medical care. Being poor and uninsured means having less access to preventive care, diagnostic services and treatment, and having, overall, poorer care").

[17] *See infra* text accompanying notes 50-51.

[18] *See* Claudia Goldin, *A Grand Gender Convergence: Its Last Chapter*, 104 AM. ECON. REV. 1091, 1093-1103 (2014) (presenting findings in earnings by gender over the life cycle and by occupation).

lessened consequences of profession-based economic instability on access to care.[19]

Law seeks to effect economic stability for those of modest income through federal programs such as the Supplemental Nutrition Access Program; the Women, Infants, and Children program; and the Temporary Assistance to Needy Families program. Concordant with the supposition that women's access to care is disproportionately affected by economic stability, each of these programs has overwhelmingly higher enrollment by women.[20] This suggests either that women's economic misfortune is more likely to be mitigated or, more probable given the low actual value provided by these programs, women are indeed suffering more from economic instability and, thus, in access to care.

2. Education

Educational attainment is a strong indicator of overall health, and lack thereof thus plays a unique role in defeating access to health care across both genders.[21] For example,

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[19] *See* Michael Daly et al., *A Social Rank Explanation of How Money Influences Health*, 34 HEALTH PSYCHOL. 222, 223 (2015) (distinguishing the material and psychosocial health effects of financial resources, and finding that each positively correlates with improved health, including through increased access).

[20] Adult men are not eligible for WIC benefits, though their children may be even in the absence of the mother. *See, e.g.*, U.S. DEP'T OF AGRIC., CHARACTERISTICS OF SUPPLEMENTAL NUTRITION ASSISTANCE PROGRAM HOUSEHOLDS: FISCAL YEAR 2011 xvi (2012), *available at* http://www.fns.usda.gov/sites/default/files/2011Characteristics.pdf [http://perma.cc/3BUX-8SA9] ("In fiscal year 2011, . . . [a]bout 62 percent of [participating] nonelderly adults were women, as were 66 percent of elderly adults."); GENE FALK, TEMPORARY ASSISTANCE FOR NEEDY FAMILIES (TANF): SIZE AND CHARACTERISTICS OF THE CASH ASSISTANCE CASELOAD 5 (2014), *available at* https://www.fas.org/sgp/crs/misc/R43187.pdf [http://perma.cc/GFB5-4VV4] ("In FY2011, 84.7% of adult recipients were women.").

[21] *E.g.*, *Why Does Education Matter So Much to Health?*, ROBERT WOOD JOHNSON FOUND. (Mar. 2013), http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf403347 [http://perma.cc/7XUV-FR32] (giving an overview of studies showing that the better educated live longer, are less likely to have and die from common acute and chronic diseases, are less likely to be overweight or obese, and are less likely to engage in health-harming behaviors).

higher education is correlated with both lower incidence of disease and lower mortality.[22] But how well one does in school can inform access to care on a gendered basis because higher educational performance by women is not associated with higher pay relative to men.[23]

Recent shifts in the college graduation rate norms may result in increases in private healthcare insurance coverage for women and proportional decreases for men. Education positively correlates with healthcare insurance coverage for both genders, regardless of whether or not an employer provides such a plan.[24] That is, individuals with at least a baccalaureate degree are more likely to be insured than those with only a high school education even when employed by a business that does not offer healthcare insurance.[25] Given that women now enroll in college in significantly higher numbers than men,[26] it might expected that the former will experience a growth in healthcare coverage relative to the latter.

3. Social and Community Context

The effects on health of the social and community environment are divided into social cohesion, civic

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[22] *Id.*

[23] Michael T. French et al., *What You Do in High School Matters: High School GPA, Educational Attainment, and Labor Market Earnings as a Young Adult*, 41 EASTERN ECON. J. 370, 376—82 (2015). *See also* Jillian Berman, *Female 'A+' Students End Up Making As Much As Male 'C' Students*, HUFFINGTON POST (May 23, 2014, 7:31 AM), http://www.huffingtonpost.com/2014/05/23/gpa-income_n_5373078.html [http://perma.cc/X84S-CUSM] (providing a sex-based graph of the final results of aforementioned study of earnings relative to high school grade point average).

[24] HUBERT JANICKI, U.S. CENSUS BUREAU, EMPLOYMENT-BASED HEALTH INSURANCE: 2010, at 13 (2013), *available at* https://www.census.gov/prod/2013pubs/p70-134.pdf [http://perma.cc/4HMF-68VP].

[25] *Id.*; Goldin, *supra* note 18, at 1091-92.

[26] *See* Mark Hugo Lopez & Ana Gonzalez-Barrera, *Women's College Enrollment Gains Leave Men Behind*, PEW RESEARCH CENTER (Mar. 6, 2014), http://pewrsr.ch/1qckLFE [http://perma.cc/Z5BX-HFYT] ("By 2012, the share of young women enrolled in college immediately after high school had increased to 71%, but it remained unchanged [since 1994] for young men at 61%.").

participation, perceptions of discrimination and equity, and incarceration and institutionalization.[27] These categories are pertinent to disparities in access to care insofar as social interaction affects a person's ability and willingness to obtain needed health care. Although generally a more social than legal concept, cultural expectations are a significant confounder that affect perception of health and health risks, and that may be formally codified or informally reinforced through legal tolerance of a practice.

For example, culturally bound illnesses—those that "the patient perceives from a sociocultural perspective," as opposed to "what the physician diagnoses from a biomedical understanding"—inform health-seeking behaviors.[28] A subsequent reduction in access to care may occur because legal restrictions override the cultural instinct to seek or avoid care, or they may interfere with the availability of culturally appropriate care. That is, because culturally bound illness generally needs a culturally appropriate healthcare provider, regulation of entry into the practice of medicine can render such care difficult to find.[29] Access to care necessarily suffers when healthcare providers are unavailable. Any effect on access, however, is experienced by all members of the subpopulation regardless of gender.

Dissimilarly, women have a disproportionate limitation on access to care where society tends to place them in a subordinate position.[30] Often this hierarchy is reinforced by

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[27] Healthy People 2020, *supra* note 14.

[28] Juan Carlos Belliard & Johnny Ramírez-Johnson, *Medical Pluralism in the Life of a Mexican Immigrant Woman*, 27 HISP. J. BEHAV. SCI. 267, 269 (2005).

[29] See *id.* at 278 (describing an interviewee's rejection of the idea of going to a traditional clinic for a culturally bound illness because "doctors do not understand those diseases").

[30] *See, e.g.*, Farzaneh Roudi-Fahimi, *Gender and Equity in Access to Health Care Services in the Middle East and North Africa*, POP. REFERENCE BUREAU, http://www.prb.org/Publications/Articles/2006/GenderandEquityinAccesstoHealthCareServicesintheMiddleEastandNorthAfrica.aspx [http://perma.cc/Z6US-JTX3] (last visited Nov. 1, 2015) (describing how a culture with a tradition of strong gender roles affects the perception of health by women); WHO, HEALTH IN ALL POLICIES TRAINING MANUAL 28 (2015) [hereinafter WHO HiAP] ("In some countries, gender can make a significant difference due to social attitudes about the value of men and women. For example, parents might be more

discriminatory law and policy, or through informal mechanisms of intolerance, such as gender bias by providers.[31] The resultant reduction in access to care can be a result of socio-legal control of women's movements and time, or simply a socially ingrained tendency to minimize, or failure to recognize, certain health issues.[32] At the same time, social notions of "machismo" can lessen men's access to care by simultaneously encouraging them to engage in health-harming behaviors and also discouraging them from seeking health care.[33] In both instances, the requisite health care may be otherwise available, and access is reduced merely through social construct.

Additionally, to the extent that incarceration informs the social context of health, institutionalization achieves increases in access to care for the uninsured, though certainly not in an ideal way. On the other hand, the criminal justice system can limit access to care insofar as it may restrict reproductive choices as a condition of probation or parole, which may be a penalty more frequently prescribed for men while more broadly affecting women.[34]

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likely to take a son to get immunized than a daughter because of social customs that value men over women.").

[31] David Gomez et al., *Gender-Associated Differences in Access to Trauma Center Care: A Population-Based Analysis*, 152 SURGERY 179, 184 (2012).

[32] *E.g.*, Roudi-Fahimi, *supra* note 30 (noting that reproductive health is frequently ignored by women in the Middle East and North Africa unless it interferes with childbearing).

[33] *See* Kristen W. Springer & Dawne M. Mouzon, *"Macho Men" and Preventive Health Care: Implications for Older Men in Different Social Classes*, 52 J. HEALTH & SOC. BEHAV. 212 (2011) (comparing the effects of masculinity on men across various socio-economic statuses).

[34] Rachel Roth, *"No New Babies?": Gender Inequality and Reproductive Control in the Criminal Justice and Prison Systems*, 12 AM. U. J. GENDER SOC. POL'Y & L. 391, 392-93 (2004) (noting that "to the small extent that appellate courts have been willing to uphold sex or fertility-related conditions of probation, they have done so with respect to men" but arguing that such orders "can only be carried out on the backs of women.").

4. Neighborhood and Built Environment

The built environment concerns the physical space in which one lives, works, and plays. From an access to care perspective, local availability of a sufficient number and type of healthcare providers is perhaps the most significant indicator of the effect of the built environment. In general, women are less likely than men to have access to outpatient services, specialized inpatient care, and trauma centers.[35] As a normative matter, however, men and women do not seek preventative health care in equal numbers, and men are less likely to receive preventative care than women. How much less likely? A 2001 study by the Centers for Disease Control and Prevention (CDC) found that "[t]he rate of visits by women for non-illness was *100 percent* higher than among men, after controlling for age and removing pregnancy-related visits."[36] A decade later, the results scarcely changed. The most recent such CDC study found a preventative care visit rate for women of 82.9 visits per one hundred persons and a rate for men of 46.8 visits per one hundred persons, a difference still approaching one hundred percent.[37] Men are also significantly less likely to have a dedicated primary care physician.[38] Although gender-based differences in access to care are almost certainly multifactorial, lack of physical proximity to providers, a result of the built environment, necessarily contributes.[39]

B. Financial Access to Care: The Role of Insurance

"In 1900, the average American spent $5 a year on health care ($100 in today's money). No one had health insurance,

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[35] Gomez, et al., *supra* note 31, at 179, 181-84.

[36] KATE M. BRETT & CATHARINE W. BURT, UTILIZATION OF AMBULATORY MEDICAL CARE BY WOMEN: UNITED STATES, 1997-98, 12 (2001), *available at* http://www.cdc.gov/nchs/data/series/sr_13/sr13_149.pdf [http://perma.cc/WH4S-9WRB] (emphasis added).

[37] CHUN-JU HSIAO ET AL., NATIONAL AMBULATORY MEDICAL CARE SURVEY: 2007 SUMMARY 4 (2010), *available at* http://www.cdc.gov/nchs/data/nhsr/nhsr027.pdf [http://perma.cc/RNX8-UUQL].

[38] *Id.* at 15.

[39] Samina T. Syed et al., *Traveling Towards Disease: Transportation Barriers to Health Care Access*, 38 J. CMTY. HEALTH 976, 990 (2013).

because you don't need insurance for something that costs $5 a year."[40]

In general, it might be said that in order to access any service, one must be able to pay for it. Health care in the United States is no exception, as it is currently financed and delivered, but the availability of healthcare insurance, or other health plan, begins to render individual fiscal ability to buy care as unnecessary as it was before such insurance existed. Indeed, in 2014 out-of-pocket contributions constituted only 10.9% of healthcare expenses, including co-payments, deductibles, and other costs not covered by insurance.[41] These statistics do not suggest that insurance always makes all care affordable, but rather to acknowledge health insurance as arguably the most important consideration in access to care, as well as a proxy for the same.[42] Thus, this subsection explores the facilitation of access to health care via insurance.

1. The Prevalence of Employer-Based Group Insurance

The beginnings of healthcare insurance in the United States are well-documented,[43] but it is worth noting that it is

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[40] Alex Blumberg & Adam Davidson, *Accidents of History Created U.S. Health System*, NAT'L PUB. RADIO (Oct. 22, 2009, 3:28 PM ET), http://www.npr.org/templates/story/story.php?storyId=114045132 [http://perma.cc/V226-N4JA].

[41] The percentage given was derived by dividing the federal government's official tally of out-of-pocket expenses ($329,819,000,000), defined in the text, by total expenditures ($3,031,292,000,000). *See* CTR. MEDICARE & MEDICAID SERV., U.S. DEP'T OF HEALTH & HUMAN SERV., NATIONAL HEALTH EXPENDITURES BY TYPE OF SERVICE AND SOURCE OF FUNDS, CY 1960-2014 (2015), *available at* http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html.

[42] This statement is a common understanding. *See, e.g.*, KAISER FAMILY FOUND., WOMEN'S HEALTH INSURANCE COVERAGE (2014) [hereinafter KFF WOMEN'S HEALTH INSURANCE COVERAGE], *available at* http://files.kff.org/attachment/fact-sheet-womens-health-insurance-coverage [http://perma.cc/Z9D8-UXZW] ("Health insurance coverage is a critical factor in making health care affordable and accessible . . . .").

[43] *See generally* Arthur Daemmrich, *U.S. Healthcare Reform and the Pharmaceutical Market: Projections from Institutional History*, 15 PHARMS. POL'Y & L. 137 (2013) (giving an overview of the history of healthcare insurance in the U.S.).

a relatively recent invention—as is the immense cost of health care. Whereas other forms of insurance date to the famous marketplace at Lloyd's in the seventeenth century,[44] the first individual healthcare insurance was a limited, local plan that did not begin until the mid-nineteenth century.[45] Group healthcare insurance, soon called "Blue Cross" and followed by its future partner "Blue Shield," did not commence until 1929.[46] More than a decade later, healthcare insurance began to be provided widely by employers when it became a standard part of the benefits package during the Second World War.[47] Notably, the need to attract women to the workforce catalyzed the availability of insurance for employees.[48] The proliferation was further fed by increasingly business-friendly tax treatment of the benefit.[49]

Today, however, women are less likely than men to have coverage provided by an employer, despite the fact that women work for employers offering healthcare insurance in higher proportion than men.[50] This may be because women—and especially those who are mothers—are more likely than men to be employed on a part-time basis; yet fewer benefits, including healthcare insurance, are typically available for

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[44] *See* Ken Brownlee, *History of Adjusting-Part 3: The Great Fire of London and the "Writing Under" Principle*, CLAIMS MAG., Mar. 2014, at 60 (noting that by February 1688 "both Lloyd's Coffee House and losses covered by insurance had already become synonymous").

[45] Daemmrich, *supra* note 43, at 138.

[46] *Id.* at 139.

[47] *Id.*

[48] *See id.* at 139 (noting that wage controls discouraged higher salaries causing benefits as healthcare insurance to become more generous); Claudia Goldin, *The Role of World War II in the Rise of Women's Work* 3 (Nat'l Bureau of Econ. Research, Working Paper No. 3202, 1989) (describing "a variety of mechanisms" that were used to increase the numbers of women working during World War II), *available at* http://www.nber.org/papers/w3203.pdf. [http://perma.cc/72PZ-GJEF].

[49] *See* Blumberg & Davidson, *supra* note 40 (noting the first changes to the Internal Revenue Code were in 1943); Daemmrich, *supra* note 43, at 139 (describing additional changes in 1954).

[50] Hubert Janicki, *Employment-Based Health Insurance: 2010*, U.S. CENSUS BUREAU 6 (Feb. 2013), https://www.census.gov/ prod/2013pubs/ p70-134.pdf [http:/perma.cc/X49N-LP5L].

part-time work.[51] Women are also more likely to be employed in lower valued jobs with fewer benefits.[52] Indeed, 22% of women with private insurance receive that coverage through a spouse's employer, and 30% are covered as the employee.[53] In contrast, only 13% of men are dependent on their spouse for employer-based healthcare insurance, while 44% are provided coverage as the employee.[54] In total, however, 55% of the U.S. population in 2011 had employment-based healthcare insurance.[55] Amongst those without such coverage, cost is more likely to be cited as a prohibitive factor by men rather than women, but ineligibility for and denials of coverage affect similarly non-elderly adults regardless of gender.[56]

The Patient Protection and Affordable Care Act of 2010[57] (PPACA) sought to remedy some of this disparity through the creation of the Small Business Health Options Program (SHOP) exchange.[58] To participate in a health benefit exchange as a small business, the entity must employ at least one and no more than 100 employees.[59] As with the individual exchanges, discussed immediately *infra*, states had the option to run their own SHOP exchange, to cooperate

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[51] *See* Jeffrey Wenger, *The Continuing Problems with Part-Time Jobs*, ECON. POL'Y INST. 1-12 (Apr. 24, 2001), http://s3.epi.org/files/page/-/old/issuebriefs/ib155/ib155.pdf [http://perma.cc/5KGW-6P7L] (finding that women work two-thirds of all part-time jobs, which are also the lowest paying and often lowest skilled with fewer benefits).

[52] Sabrina Matoff-Stepp, Bethany Applebaum, Jennifer Pooler & Erin Kavanagh, *Women as Health Care Decision-Makers: Implications for Health Care Coverage in the United States*, 25 J. HEALTH CARE POOR & UNDERSERVED 1507, 1509 (2014), *available at* http://muse.jhu.edu/journals/journal_of_health_care_for_the_poor_and_underserved/v025/25.4.matoff-stepp.pdf [http://perma.cc/P26X-F5RV].

[53] KFF WOMEN'S HEALTH INSURANCE COVERAGE, *supra* note 42, at 1.

[54] *Id.*

[55] Janicki, *supra* note 50, at 1.

[56] *Id.* at 13-14.

[57] Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148 [hereinafter PPACA] (codified as amended in scattered sections of 42 U.S.C.).

[58] PPACA § 1311(b)(1)(B) (codified at 42 U.S.C. § 18041 (2015)).

[59] PPACA § 1304(a)(2) (codified at 42 U.S.C. § 19024). For the first three years after enactment, each state was given the option of defining a "small business" to include only those employing fewer than fifty employees. PPACA § 1304(a)(3) (codified at 42 U.S.C. § 18024).

with the federal government to create a SHOP exchange, or to have the federal government create and manage the SHOP exchange.[60] Regardless, they were "designed to assist qualified employers in the State who are small employers in facilitating the enrollment of their employees in qualified health plans offered in the small group market in the State."[61]

However, a November 2014 report by the Government Accountability Office found that after the first six months, SHOP enrollment in the eighteen states that created their own SHOP (instead of using the federal system) included only 76,000 individuals in plans purchased through fewer than 12,000 employers.[62] The low enrollment may be attributed to delays in implementation until 2016.[63] Numbers for enrollment by men versus women are not yet available.[64]

All of these factors together mean the employment-based healthcare insurance market favors men in creating financial access to healthcare providers and access to healthcare overall.[65] Law supports this result through direct regulation of the market, including by not requiring that all employees receive employment-based healthcare coverage. To the extent that legal protections for benefits exist for full-time employees, they extend to part-time employees only in theory.[66] And as noted above, women are significantly more likely than men to work in part-time positions.

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[60] PPACA § 1311(b)(1)(B) (codified at 42 U.S.C. § 18041 (2015)).

[61] *Id.*

[62] U.S. GOV'T ACCOUNTABILITY OFFICE, SMALL BUSINESS HEALTH INSURANCE EXCHANGES: LOW INITIAL ENROLLMENT LIKELY DUE TO MULTIPLE, EVOLVING FACTORS 12 (2014), *available at* http://www.gao.gov/assets/670/666873.pdf [http://perma.cc/XG7B-PTGB].

[63] Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond; Final Rule, 79 Fed. Reg. 30240, 30249-50 (May 27, 2014) (codified at 45 C.F.R. § 155.705(b)(2)-(3) (2015)).

[64] *See generally* U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 62.

[65] *Gender Differences and the ACA*, CTR. HEALTH & ECON. tbl. 5 (Apr. 16, 2014), http://healthandeconomy.org/gender-differences-and-the-aca/ [http://perma.cc/ZDL2-JG6M].

[66] Vai Io Lo, *Atypical Employment: A Comparison of Japan and the United States*, 17 COMP. LAB. L.J. 492, 515-16 (1996) ("[L]egal protections

2. The Contemporary Non-Group Insurance Market

The private healthcare insurance schema was fundamentally altered by PPACA and done deliberately so.[67] The act's insurance exchanges, later rebranded the Health Insurance Marketplace (HIM), have the potential to provide a robust alternative to traditional employer-based insurance through both the individual HIM and the group insurance SHOP exchange. Whereas in 2013, the year before the HIM provisions took effect, equal proportions of men and women purchased insurance on their own,[68] by the end of the second enrollment period in early 2015, fewer men had purchased coverage through the HIM: fifty-four percent of enrollees were women.[69] Total enrollment is expected to grow to include another ten million persons by the end of 2016,

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for regular employees under federal law are theoretically applicable to nonregular employees. [But] nonregular employees . . . receive inferior treatment in various aspects of employment, either because they fail to satisfy certain threshold requirements or because exemptions exist which permit employers to treat nonregular workers differently than regular workers.").

[67] *See, e.g.*, William P. Brandon & Keith Carnes, *Federal Health Insurance Reform and "Exchanges": Recent History*, 25 J. HEALTH CARE FOR THE POOR & UNDERSERVED xxxii, xxxii (2014) (calling the HIMs the "major national innovation" of the legislation).

[68] *See Health Insurance Coverage of Women*, KAISER FAMILY FOUND. 19-64 (2013), http:// kff.org/other/state-indicator/nonelderly-adult-women/ [http://perma.cc/ 696Q-KSVX] [hereinafter KFF *Coverage of Women*] (showing that 8% of women nationwide were enrolled in private insurance that is not employer-sponsored in 2013); *Health Insurance Coverage of Men*, KAISER FAMILY FOUND. 19-64 (2013), http://kff.org/other/state-indicator/nonelderly-adult-men/ [http://perma.cc/H3QU-KRY7] [hereinafter KFF *Coverage of Men*] (showing that 8% of men nationwide were enrolled in private insurance that is not employer-sponsored in 2013).

[69] *Health Insurance Marketplaces 2015 Open Enrollment Period: March Enrollment Report*, DEP'T OF HEALTH & HUMAN SERV. 12 (Mar. 10, 2015), http://aspe.hhs.gov/sites/default/files/pdf/83656/ib_2015mar_enrollment.pdf [http://perma.cc/GAD7-MXCR], *But cf.* Liz Hamel et al., *Survey of Non-Group Health Insurance Enrollees*, KAISER FAMILY FOUND. (Jun. 19, 2014), http://kff.org/health-reform/report/survey-of-non-group-health-insurance-enrollees/ [https://perma.cc/END2-B75K] ("[G]ender distribution is similar for those in ACA-compliant plans purchased inside and outside the Marketplace.").

potentially exacerbating the disparity.[70] However, with the pool of uninsured women shrinking at a faster rate than that of men, those additional enrollees in HIM plans may statistically be more likely to be men.

To assist with the purchase of healthcare insurance in the HIM, a system of subsidies and tax credits was established by PPACA.[71] The monies were designed to benefit those between 100% and 400% of the federal poverty guideline.[72] Those above 400%, or $47,080 for a single adult and $97,000 for a family of four in 2015,[73] were presumed to not require help with the purchase of insurance and/or to be already covered. The subsidies and credits are generally not considered generous for those between 100% and 138%, where coverage was intended to be provided by Medicaid, because the financial assistance is graduated proportionate to income, and the raw dollar amount may be insufficient to purchase coverage.[74] Thus in states that did not expand Medicaid, discussed more fully *infra*, people with incomes under 138% of the federal poverty guidelines are effectively disenfranchised from healthcare coverage, even in the HIM. The cost-reduction assistance in the HIM favors women superficially, with subsidies averaging $9,000 for women and $8, 250 for men.[75] The variation, however, should not have significant effect on access to care for one gender more than the other because the cost-reduction system is based on income proportional to household size.

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[70] *Insurance Coverage Provisions of the Affordable Care Act: CBO's March 2015 Baseline*, CONG. BUDGET OFFICE 4 (Mar. 9, 2015), https://www.cbo.gov/sites/default/files/cbofiles/attachments/43900-2015-03-ACAtables.pdf [http://perma.cc/3ZKN-GELR].

[71] PPACA § 1402(b) (codified at 42 U.S.C. §18071 (2015)).

[72] *Id.*

[73] 80 Fed. Reg. 3236, 3237 (Jan. 22, 2015).

[74] *See, e.g.*, Phil Galewitz, *In States that Don't Expand Medicaid, Some of the Uninsured May Still Get Help*, KAISER HEALTH NEWS (Aug. 11, 2013), http://kaiserhealthnews.org/news/income-projections-low-income-obamacare-state-medicaid-marketplace-exchange/ [http://perma.cc/VQ2X-D7UM] (noting that "even if people with incomes at the poverty level qualify for subsidies for private insurance, the coverage might still be unaffordable . . . because they would owe as much as 2 percent of their income towards the cost of the premium and could still have co-pays and deductibles.").

[75] *Gender Differences and the ACA*, *supra* note 65, at tbl. 3.

The recent case of *King v. Burwell*[76] could have fundamentally altered this analysis, however. At issue was the applicability of the system of subsidies and credits to states who opted not to run their own HIM. The plaintiffs argued that the plain language of PPACA makes the cost-reduction scheme available only in states where the federal government is not a partner or in charge of the HIM.[77] A holding in favor of the plaintiffs would have eliminated the subsidies and tax credits in as many as thirty-four states, causing an estimated $28.8 billion in lost subsidies and credits for over 9 million people.[78] The majority of HIM plan beneficiaries would thus no longer have been able to afford their plans, potentially shrinking the HIM by three-quarters.[79] So while residents of Washington, D.C., and the sixteen states that manage their own HIM would have been unaffected with regard to the subsidies and credits, the resultant increase in premiums caused by the inevitable loss

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[76] King v. Burwell, 759 F.3d 358 (4th Cir. 2014) (U.S. argued Mar. 4, 2015). Companion cases include Halbig v. Burwell, 758 F.3d 390 (D.C. Cir. 2014), *vacated*, and Oklahoma *ex rel.* Pruitt v. Burwell, 51 F. Supp.3d 1080 (E.D. Okla. 2014).

[77] *King*, 759 F.3d. at 364. In an opinion that was vacated, the *Halbig* court held in favor of the similarly situated plaintiffs. *Halbig*, 758 F.3d at 412. The *Pruitt* court held in favor of the similarly situated plaintiffs. *Pruitt*, 51 F.Supp.3d at 1093.

[78] Linda J. Blumberg et al., *Urban Inst., The Implications of a Supreme Court Finding for the Plaintiff in King vs. Burwell: 8.2 Million More Uninsured and 35% Higher Premiums*, ROBERT WOOD JOHNSON FOUND. 2-5 (Jan. 2015), http://www.urban.org/sites/default/files/alfresco/publication-pdfs/2000062-The-Implications-King-vs-Burwell.pdf [http://perma.cc/8UPX-3BX9], *Cf.* Evan Saltzman & Christine Eibner, *The Effect of Eliminating the Affordable Care Act's Tax Credits in Federally Facilitated Marketplaces*, RAND CORP. 3-4 (2015), http://www.rand.org/content/dam/rand/pubs/research_reports/RR900/RR980/RAND_RR980.pdf [http://perma.cc/U8LX-R82T] (predicting a loss of 9.6 million people from the HIM).

[79] *See* Blumberg et al., *supra* note 78, at 5 (75% decrease); Saltzman & Eibner, *supra* note 78, at 5 (70%).

of healthy people in the HIM would have negatively affected participants nationwide.[80]

Had the immediate destabilization of the insurance market oft predicted occur,[81] the rippling effects may have drowned access to care for men and women alike. But such a ruling was more likely to have a disparate effect on the access to care of women for two reasons. First, women are more likely to be uninsured and are also more likely to be poor,[82] and the greatest direct consequence of a plaintiff victory in *King* would have been in states where the highest proportion of uninsured and low-income people live.[83] Second, and as noted *supra*, women enrolled in HIM plans in greater numbers.

Reasons for the disproportionate enrollment are multifactorial. Women are generally the healthcare decision-makers in any given household. The U.S. Department of Labor estimates that women make 80% of such decisions while other studies suggest the rate is as high as 90%.[84] Unsurprisingly, given the overwhelming nature of the disparity, the skewed phenomenon is not new.[85] Presumably, then the generations of greater experience with healthcare decisions translates to a greater likelihood of enrollment in a

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[80] Blumberg et al., *supra* note 78, at 7; Saltzman & Eibner, *supra* note 78, at 5.

[81] *E.g.*, Blumberg et al., *supra* note 78, at 7 (terming such a scenario a "death spiral"); Saltzman & Eibner, *supra* note 78, at 6 ("death spiral"). The Supreme Court itself characterized the potential as a "death spiral," using the term no fewer than twice in the majority opinion. *King*, 135 S. Ct. 2480, 2482 (2015).

[82] *See infra* text accompanying notes 15-20.

[83] Saltzman & Eibner, *supra* note 78, at 5-6. These states typically have conservative governors who are ideologically opposed to PPACA.

[84] *General Facts on Women and Job Based Health*, DEP'T LABOR (Dec. 2013), http://www.dol.gov/ebsa/newsroom/fshlth5.html [http://perma.cc/V3C6-SBZ7]; Matoff-Stepp, Applebaum, Pooler & Kavanagh, *supra* note 52, at 1508.

[85] *See generally, e.g.*, Dana Hostetler, *Women: Health Care's New Decision Makers*, 57 J. AM. MED. REC. ASS'N 18 (1986) (describing the first annual conference of the American College of Healthcare Executives to discuss the role of women as administrators and consumers of health care).

HIM plan where other factors previously prevented insurance coverage.

For instance, as a result of PPACA, insurers are prohibited from denying coverage based on a preexisting illness.[86] While this provision has broad applicability to all persons, women in particular were susceptible to coverage exclusions and increased premiums simply by virtue of having a uterus. One prominent example during the legislative debate over PPACA was the story of one thirty-nine-year-old woman who was expressly advised by her insurance company that only sterilization would make her insurable due to a prior medical history that included a single Caesarean section birth.[87] Another commonly cited example was the insurance declaration of domestic violence, which affects women disproportionately, as a disqualifying preexisting condition.[88] The correlation between womanhood and these kinds of coverage denials was so strong that, once the PPACA preclusion took effect, the then-Secretary of Health and Human Services famously tweeted, "[b]eing a woman is no longer a pre-existing condition."[89]

Similarly, the wide-scale practice of gender rating by insurance companies meant that women were more likely than men to be priced out of the non-group healthcare insurance market. Women between the ages of eighteen and sixty-four were charged as much as 57% more than men, even with maternity coverage excluded.[90] Across the nation, this

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[86] PPACA, Pub. L. No. 111-148, § 2704 (codified as amended at 42 U.S.C. § 300gg (2015)).

[87] Denise Grady, *After Caesareans, Some See Higher Insurance Cost*, N.Y. TIMES (June 1, 2008), http://www.nytimes.com/2008/06/01/health/01insure.html?_r=1&scp=1&sq=Peggy+Robertson&st=nyt [http://perma.cc/8T4X-GYNM].

[88] *E.g.*, Ryan Grim, *When Getting Beaten by Your Husband is a Pre-Existing Condition*, HUFFINGTON POST (May 25, 2011, 2:05 PM), http://www.huffingtonpost.com/2009/09/14/when-getting-beaten-by-yo_n_286029.html [http://perma.cc/WRG2-ZCVC] (noting that eight states allow domestic violence to be considered a preexisting condition).

[89] Kathleen Sebelius, TWITTER (May 10, 2013, 12:10 PM), https://twitter.com/secsebelius/status/333935813069426689 [http://perma.cc/HL6H-VK29].

[90] *Turning to Fairness: Insurance Discrimination Against Women Today and the Affordable Care Act*, NAT'L WOMEN'S L. CTR. 18 (2012),

practice was estimated as costing women an aggregate one billion dollars per year, again expressly excluding maternity benefits.[91] By precluding gender rating and consideration of preexisting conditions,[92] PPACA enhanced the ability of women to afford and qualify for healthcare insurance coverage, suggesting that women's higher enrollment in HIM plans may level off as those previously disenfranchised acquire coverage.

PPACA also increased access to preventative care by requiring that no co-payment be charged for listed services regardless of whether the insured has met his or her deductible. A variety of these provisions are particularly relevant to or expressly designed for women. Eleven preventative health services apply specifically to women: six services for pregnant women; folic acid supplements for women of childbearing age; select sexually transmitted infection screening; breast and cervical cancer screening; domestic violence counseling; and contraception.[93] Only one test—a one-time screening for abdominal aortic aneurysm—applies to men only.[94]

Importantly, several of these gender-restricted services regard preventative care for conditions that are not necessarily gender-specific. Breast cancer, for instance, can and does occur in men; the National Institutes of Health even maintains a website specifically on the subject.[95] Yet denials

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http://www.nwlc.org/sites/default/files/pdfs/nwlc_2012_turningtofairness_report.pdf [http://perma.cc/4G6R-3F6Z].

[91] *Id.* at 7.

[92] PPACA, Pub. L. No. 111-148, § 1557 (2010) (codified as amended at 42 U.S.C. § 18116 (2015)).

[93] *Preventive Health Services for Women*, HEALTHCARE.GOV, https://www.healthcare.gov/preventive-care-women/ [http://perma.cc/98B6-WLAU] (last visited Nov. 1, 2015). Although advertised as twenty-six services for women, eleven of those twenty-six are available to men also without cost-sharing. *Preventive Health Services for Adults*, HEALTHCARE.GOV, https://www.healthcare.gov/ preventive-care-adults/ [http://perma.cc/PE4S-3BDF] (last visited Nov. 1, 2015).

[94] *Preventive Health Services for Adults*, *supra* note 93.

[95] *Male Breast Cancer Treatment*, NAT'L INST. HEALTH (Nov. 25, 2014), http://www.cancer.gov/cancertopics/pdq/treatment/malebreast/patient#_83 [http://perma.cc/YJV8-J4KZ]. Breast cancer accounts for 1% of all cancers in men and male breast cancer is approximately 2% of all breast cancers in the United States, Helmneh M. Sinesha et al.,

of access to breast-cancer-related care for men have been reported since the passage of PPACA. In one self-pay case, a Florida man, whose primary care physician suspected breast cancer, was denied a mammogram by six different facilities, all of whom were offering discounted or free mammograms as part of Breast Cancer Awareness Month campaigns.[96] Apparently the discounts were for females only.

Of the six tests covered for only pregnant women without cost-sharing, only two are irretrievably tied to motherhood—breastfeeding comprehensive support and counseling, and Rh incompatibility screening—though admittedly the effect of the rest on fetal development creates a stronger justification for shifting resources toward greater coverage.[97] But while men may not get cervical cancer, they are subject to other gender-specific cancers, none of which have mandated cost-free coverage for screenings. Indeed, the same virus attributed to cervical cancer also causes penile and testicular cancers, though with less mortality and morbidity.[98] Similarly, men experience domestic violence as

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Black/White Disparities in Receipt of Treatment and Survival Among Men With Early-Stage Breast Cancer, J. CLINICAL ONCOLOGY 1, 1 (2015).

[96] Christy Dimond, *Southwest Florida Man Denied Mammogram Because of Gender*, FOX4 NEWS (Oct. 8, 2013), http://www.scrippsmedia.com/fox4now/news/Southwest-Florida-man-denied-mammogram-because-he-is-a-man-226976931.html [http://perma.cc/EW2B-GTH2].

[97] The cost-free services for pregnant women are: (1) anemia screening; (2) breastfeeding support and counseling; (3) diabetes screening; (4) hepatitis B screening; (5) Rh incompatibility screening; and (6) urinary tract or other infection screening. *Preventive Health Services for Women*, *supra* note 93. As with services for women versus men, the number advertised for expectant mothers—11—is significantly greater than the number actually restricted to the designated group. *See supra* note 93 and accompanying text.

[98] Xiaocheng Wu et al., *Human Papillomavirus-Associated Cancers: United States, 2004-2008*, MORBIDITY & MORTALITY WEEKLY REPORT 258-61 (Apr. 20, 2012), http://www.cdc.gov/mmwr/pdf/wk/mm6115.pdf [http://perma.cc/7MMC-2RGN]. The human papilloma virus can also cause anal and oropharyngeal (base of the throat) cancers in all people regardless of gender, *id.* There are no conclusive methods of screening for oropharyngeal or penile cancers, but there is a test for anal cancer for men and women that is comparable to the test for cervical cancer in women, *see HPV and Cancer*, AM. CANCER SOC'Y 4-5 (Jan. 2015), http://www.cancer.org/acs/groups/content/@editorial/documents/docume

well as women, and they may actually have a reduced access to care relative to women because men tend to be more reticent to seek help for domestic violence.[99] They may also be more likely to be denied services or disbelieved.[100]

Inversely, yet similarly, women as well as men die from abdominal aortic aneurysm, a condition referenced *supra* as the sole cost-share-free benefit PPACA bestows on men. Routine screening has been medically recommended for women at risk, including those over the age of sixty-five who smoke or have heart disease.[101] Yet this screening is not only not free for all women, even women with high risk are subject to co-payment because by law only men are required to be screened without charge.

These sorts of gender-based distinctions in facilitating access to care have failed judicial review on an equal protection basis at least once. In *Woods v. Horton*, several male victims of domestic violence sued the State of California after they were denied specialized health and social services

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nt/acspc-044199.pdf [http://perma.cc/8NMK-LGYP]. Limitations in medical technology that happen to occur along gender lines is not considered a disparity herein, unless some extraneous factor exists, such as funds diverted to research for only one gender.

[99] At least one scholar has found that "women, both generally and in clinical samples, report perpetrating violence against their male intimate partners at rates similar to men." Mary Beth Phelan et al., *Domestic Violence Among Male and Female Patients Seeking Emergency Medical Services*, 20 VIOLENCE & VICTIMS 187, 189 (2005). Additionally, "compared to men, women are more likely to seek health care services for abuse-related injuries than are men." *Id.*

[100] For perspective on the male victim's experience as perceived by the victim, the public, the police, and the female perpetrator, and how each of these can represent a roadblock to services, *see* Caroletta A. Shuler, *Male Victims of Intimate Partner Violence in the United States: An Examination of the Review of Literature through the Critical Theoretical Perspective*, 5 INT'L J. CRIM. JUST. SCI. 163, 164-67 (2010).

[101] *See* Brian G. DeRubertis et al., *Abdominal Aortic Aneurysm in Women: Prevalence, Risk Factors, and Implications for Screening*, 46 J. VASCULAR SURGERY 630, 630 (2007) ("Although the medical literature suggests a low prevalence rate of AAA in women in the general population, . . . subgroups of women can be identified that are at a substantially increased risk of aneurysmal disease. . . . These data support the notion that women with such risk factors should be considered for AAA screening.").

related to their victimization expressly on the basis of their gender.[102] On appeal from a denial of the plaintiff's petition, the court held that there is no compelling state interest in funding a domestic violence program for only women, and thus that the programs fail strict scrutiny analysis.[103] As the court noted in response to the State's assertion that women have a greater need and that insufficient resources require rationing, "equal protection is not concerned with numbers."[104]

Although our healthcare system is ostensibly and fairly concerned with one very important number—cost—what is clear is that only some gender-based access to care determinations are a result of variations in biophysical or sex-based needs.[105] Other access rules, such as the majority of cost-free screening provisions of PPACA, are more like the programs in *Woods*. That is, they are gender-based distinctions that create inequities in access to care that are unnecessary, avoidable, unfair, and unjust, and thus are the epitome of a health disparity. Moreover, they exacerbate the already unequal distribution of limited financial resources for enabling access to care by missing the opportunity to address the most severe, or preempt the most costly, health-related conditions.

With only one such example of cost-free coverage for men, men overall potentially saw a decrease in the affordability of health insurance due to the weighted balance of cost-share-free benefits for women, combined with another PPACA requirement that all insurance plans cover minimum essential health benefits to include obstetrical care.[106] Arguing that men should not have to pay for coverage they would never need, some men—and, curiously, a few women, too—were outraged.[107] Of course, the same argument could

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[102] Woods v. Horton, 84 Cal. Rptr. 3d 332, 337-38 (Cal. Ct. App. 2008).

[103] *Id.* at 346-48.

[104] *Id.* at 347.

[105] The presumed need for rationing with a concrete example in the context of the right to health is discussed *infra* at text accompanying notes 228-240.

[106] *Id.* at § 1302 (codified as amended at 42 U.S.C. § 18022 (2015)).

[107] *See, e.g.*, Garance Franke-Ruta, *Why Is Maternity Care Such an Issue for Obamacare Opponents?*, THE ATLANTIC (Nov. 22, 2013), http://www.theatlantic.com/politics/archive/2013/11/why-is-maternity-

be applied to women who are outside of childbearing age, are infertile, or simply will not have children in the future, all of whom similarly experienced reduced affordability due to the insurance market principle of spreading the risk. This somewhat mitigates the effect on men.

Nonetheless, one study predicted that all men would see an increase of 11% in premiums and women overall would experience a decrease of 9%.[108] In particular, women of childbearing age were anticipated to receive a 13% to 19% decrease in premiums.[109] Another study found that young men would be particularly susceptible to premium increases of up to 75% due to the combination of the prohibition on gender-rating and the separate limitations on age-rating.[110] With only less than two years of HIM existence as of winter 2015, data are not yet available to support or counter these predictions.

Despite the efforts to increase the affordability and availability of healthcare insurance, it has become clear that many of PPACA's mandates of cost-share-free care are religiously and flagrantly violated. The National Women's Law Center recently examined the 2014 and 2015 certificates of coverage of over one hundred insurance companies in fifteen states, focusing on the insurer's compliance with PPACA in facilitating access to health care for women.[111]

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care-such-an-issue-for-obamacare-opponents/281396/ [http://perma.cc/S26N-YCXE] (citing male and female politicians and commentators who complained about the maternity coverage requirement).

[108] JAMES T. O'CONNOR, COMPREHENSIVE ASSESSMENT OF ACA FACTORS THAT WILL AFFECT INDIVIDUAL MARKET PREMIUMS IN 2014, at 21 (2013), *available at* http://ahip.org/Workarea/DownloadAsset.aspx?id=2147491347 [http://perma.cc/3QB6-XN5X].

[109] *Id.*

[110] Gary Claxton, Larry Levitt, Karen Pollitz & Anthony Damico, *Why Premiums Will Change for People Who Now Have Nongroup Insurance*, KAISER FAMILY FOUND. (Feb. 6, 2013), http://kff.org/health-reform/perspective/why-premiums-will-change-for-people-who-now-have-nongroup-insurance/ [http://perma.cc/9WHS-5MVJ].

[111] *State of Women's Coverage: Health Plan Violations of the Affordable Care Act*, NAT'L WOMEN'S L. CTR. (2015), http://www.nwlc.org/sites/default/files/pdfs/stateofcoverage2015final.pdf [http://perma.cc/3VRD-KCAL]. The states examined were those who make the coverage certificates publicly available, and include Alabama,

The violations were broken into multiple bullet points across six categories: (1) maternity coverage, such as the exclusion of maternity coverage for dependent enrollees and the establishment of arbitrary limits on benefits; (2) preventative services coverage, such as the imposition of cost-sharing and the limitation of frequency of wellness visits; (3) abortion coverage, such as the creation of varying coverage based on subsidy status; (4) essential health benefit coverage, such as the establishment of limitations stricter than benchmark coverage and the imposition of waiting periods for certain services; (5) discriminatory benefit design, such as the restriction of coverage based on age and the exclusion of chronic pain treatment; and (6) contraceptive coverage, such as the requirement of cost-sharing or the exclusion of certain methods of birth control.[112]

While the report explored coverage of women's health services pursuant to the requirements of PPACA, the instances of noncompliance are significant here insofar as they are limitations on access to care based on the gender of the patient, as all pertain to the effective insurance coverage of mandatory access to health care. That is, while obstetrical services, for example, may be understood as a gender-specific medical need, the barrier to access to care is not based solely on a legitimate biophysical distinction, but instead is a violation of law that seeks to remedy such disparities in access to health care.

Similarly, the 2014 Supreme Court decision in the case of *Burwell v. Hobby Lobby Stores, Inc.*[113] undermines access to

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California, Colorado, Connecticut, Florida, Maine, Maryland, Minnesota, Nevada, Ohio, Rhode Island, South Dakota, Tennessee, Washington, and Wisconsin, *id.*

[112] *Id.* at 4-6 (maternity), 6-14 (preventative), 15 (abortion), 16-18 (essential health benefits), 18-20 (discriminatory benefit design). The matter of coverage of contraception was more fully addressed in a second, simultaneously released report, *see State of Birth Control Coverage: Health Plan Violations of the Affordable Care Act*, NAT'L WOMEN'S L. CTR. (2015), http://www.nwlc.org/sites/default/files/pdfs/stateofbirthcontrol2015final.pdf [http://perma.cc/N255-X3TQ].

[113] Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751 (2014). Consolidated with this case and ultimately remanded by it were Conestoga Wood Specialties Corp. v. Sec'y of U.S. Dept. of Health and Human Servs., 724 F.3d 377 (3rd Cir. 2013), *rev'd*, 2014 WL 4467879 (3rd

gynecological care, which is admittedly gender-specific, by subjugating health care access vis-à-vis mandatory cost-share-free coverage. At issue were certain forms of contraception that the owners of the plaintiff businesses believe, as a matter of religion, to be abortifacients. These include all types of intrauterine devices and the emergency contraceptive pills Plan B and Ella.[114] Regulations pursuant to PPACA require coverage of twenty forms of contraception, including those to which Hobby Lobby began to object after the act was passed, and it contemplated litigation.[115] Despite the plain meaning of the term "contraception" to expressly exclude actual abortifacients, thereby rendering any burden on religion a legal (and medical) fiction, the Court held in favor of the plaintiffs.[116] That holding and subsequent regulation extended the coverage exception already in place for religiously oriented non-profit entities like charities, hospitals, schools, and colleges to for-profit closely held corporations.[117] Female employees of such entities are still eligible to receive cost-share-free contraceptive coverage through alternative means that do not require cost-sharing by the employer, the insurance plan, or the employee.[118] Nonetheless, the inability to access this type of health care in regular fashion does represent a barrier to care for women

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Cir. 2014) and Autocam Corp. v. Burwell, 730 F.3d 618 (6th Cir. 2013), *vacated*, 134 S. Ct. 2901 (2014).

[114] Hobby Lobby Stores, Inc. v. Sebelius, 723 F.3d 1114, 1125 (10th Cir. 2013), *aff'd*, Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751 (2014).

[115] Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 39870 (July 2, 2013). Hobby Lobby covered emergency contraception for a long time and only discontinued coverage as part of its litigation strategy, which it admitted in its pleadings. Additionally, it invests significantly in the makers of the contraceptives. *See* Molly Redden, *Hobby Lobby's Hypocrisy: The Company's Retirement Plan Invests in Contraception Manufacturers*, MOTHER JONES (Apr. 1, 2014, 6:00 AM EDT), http://www.motherjones.com/politics/2014/04/hobby-lobby-retirement-plan-invested-emergency-contraception-and-abortion-drug-makers [http://perma.cc/BD3A-VNQ8].

[116] Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. at 2759-60.

[117] 79 Fed. Reg. 51092 (2014).

[118] *Id.*

employed by these categories of businesses, the breadth of which is unknown.[119]

In sum, all women are not in fact receiving increased access to preventative care despite the PPACA provisions that expressly sought to remedy gender-based disparities in access. Importantly, however, not all of the decreased access to health care experienced by women occurs around services that are based on biophysical distinctions, though arguably the most egregious examples are. From a gender-parity standpoint, these types of distinctions, while clearly not in alignment with genuine gender-distinct medical needs, are not examples of disparities in access to health care that result from dissimilar legal treatment of similarly situated, but gender-opposed, parties. Other disparities, including cost-share-free coverage of the sole screening available only to men, do unnecessarily represent a greater barrier to access to specific medical treatment by women. Likewise, denials of benefits, such as chronic pain treatment, that have a disparate impact on women further defeat access to care.

On the other hand, the rather overwhelming prejudice toward increased access to care for women in PPACA may effect lack of affordability of healthcare insurance for men. Insofar as insurance is a proxy for access to care, the resulting effect of reduced availability of non-group insurance represents a potential barrier to health care access for men. Arguably, however, leveling the playing field does not create disparity. Confounding this conclusion, however, is one study that suggests that men actually have a slightly greater access to healthcare providers in the non-group insurance market, a trend that has been predicted to hold.[120] Nonetheless, a study similar to one by the National Women's Law Center that considers coverage for all adults would be useful in ascertaining whether the intended increase in

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[119] The opinion left undefined "closely held," which has multiple legal definitions. For the conclusion of one news outlet that as many as 60 million employees would fall into the category, *see* Jillian Berman, *The* Hobby Lobby *Decision Could Affect Millions of Workers*, HUFFINGTON POST, http://www.huffingtonpost.com/2014/06/30/hobby-lobby-closely-held_n_5545064.html [http://perma.cc/9SZS-NV6Y] (last updated Jul. 10, 2014, 9:59 PM).

[120] *Gender Differences and the ACA*, *supra* note 65, at 5.

access to wellness care for men (and also for women on care that is not gender-specific) is indeed being compliantly provided.

3. Medicaid [In]Efficacy in Facilitating Access to Care in the PPACA Era

Fundamental to the functioning of the HIM was expansion of the Medicaid system.[121] Since 1965, Medicaid has provided a limited safety net of healthcare insurance for select poor citizens.[122] A complex system of coverage, Medicaid was, before the PPACA expansion provisions, not available with matching federal funds for non-disabled, childless adults without a waiver.[123] Of the many waivers granted for use of Medicaid dollars, one prominent program is the National Breast and Cervical Cancer Early Detection Program.[124] According to the CDC, over four million women were served by the program in its first twenty years.[125] While the program regulations specify that treatment is available for people of all genders, at least one man was initially denied chemotherapy treatment coverage due to purported state and federal regulations that jointly limited such care to women.[126] Nonetheless, the program's very existence is an

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[121] Brandon & Carnes, *supra* note 121, at xxxiii.

[122] Social Security Amendments of 1965, Pub. L. No. 89-87, 79 Stat. 286 (codified as amended at 42 U.S.C. §§ 1396-1396w (2015)).

[123] *Where are States Today? Medicaid and CHIP Eligibility Levels for Children and Non-Disabled Adults*, KAISER FAMILY FOUND. 2 (Mar. 2013) https:// kaiserfamilyfoundation.files.wordpress.com/2013/04/7993-03.pdf [http:// perma.cc/2T7W-H2PE] [hereinafter KFF *Medicaid 2013*].

[124] 42 U.S.C. §§ 1396a(a)(10)(A)(ii)(XVIII), (aa) (2015).

[125] *Millions of Underserved Women in the U.S. Have Benefited from CDC's Breast and Cervical Screening Program*, CTR. DISEASE CONTROL & PREVENTION (Aug. 6, 2014), http://www.cdc.gov/media/releases/2014/p0806-cancer-screening.html [http://perma.cc/JP4E-FE23].

[126] South Carolina eventually agreed to cover the treatment. Amanda Chan, *Raymond Johnson to Receive Breast Cancer Treatment Coverage, After All*, HUFFINGTON POST, http://www.huffingtonpost.com/2011/08/23/raymond-johnson-breast-cancer-coverage_n_933999.html [http://perma.cc/APN4-6HPG] (last updated Oct. 24, 2011, 5:12 AM). The initial coverage denial may have been wrong, however. The text of the Breast and Cervical Cancer Prevention and Treatment Act of 2000, which allowed States to opt into Medicaid eligibility for "certain breast or

example of increased access to expensive care for women who otherwise would be unable to afford screening and treatment, because there is no equivalent program for any other condition.

Limited waiver programs notwithstanding, the multitude of other requirements for potential parent beneficiaries, such as having a monthly income amount that could literally and easily be counted by the dozen, effectively rendered Medicaid nonexistent for most people.[127] In both Texas and Alabama, for example, the income limit for adult eligibility is currently 18% of the federal poverty guideline, a maximum income of $364 per month for a family of four in 2015.[128] Unsurprisingly, then, only 13% of women and 10% of men were covered by Medicaid in 2013.[129]

PPACA attempted to increase access to care by removing the various restrictions on Medicaid eligibility and raising the upper income limit for all households to an effective 138%

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cervical cancer patients," provides coverage for "individuals," Breast and Cervical Cancer Prevention and Treatment Act of 2000, Pub. L. 106-354, 114 Stat 1381 (2000). Nonetheless, the prefatory language describing the act's intent references only women, as does the CDC's current website on the program, *Breast and Cervical Cancer Prevention and Treatment Act of 2000*, CTR. DISEASE CONTROL & PREVENTION (Nov. 5, 2013), http://www.cdc.gov/cancer/nbccedp/legislation/law106-354.htm [http://perma.cc/5E39-4FS2].

[127] *See* KFF *Medicaid 2013*, *supra* note 123 (noting in 2013 that "[t]he federal minimum level at which states must cover parents through Medicaid today is below poverty in every state and below half of poverty in nearly all states," meaning that expansion would "significantly increase eligibility for parents" and provide even larger coverage gains for other adults). *Cf. Where Are States Today? Medicaid and CHIP Eligibility Levels for Adults, Children, and Pregnant Women*, KAISER FAMILY FOUND. (Apr. 2015), http://files.kff.org/attachment/fact-sheet-where-are-states-today-medicaid-and-chip-2 [http://perma.cc/9WVL-DQVW] [hereinafter KFF *Medicaid in 2015*] (noting in 2015 that in the twenty-two states that have not adopted the Medicaid expansion, the median eligibility limit for parents is 44% [of the federal poverty guideline], and, with only one exception, childless adults are ineligible for Medicaid, which largely reflects the status prior to expansion under PPACA). Forty-four percent of the federal poverty guideline for a four-person household in 2015 is $889.17 per month.

[128] KFF *Medicaid in 2015*, *supra* note 127, at 1.

[129] KFF *Coverage of Women*, *supra* note 68; KFF *Coverage of Men*, *supra* note 68.

of the federal poverty guideline as of January 1, 2014.[130] The purpose of the change was to ensure coverage for those too poor to be sufficiently assisted by the subsidies and tax credits available in the HIM.[131]

However, the Supreme Court ruling in *National Federation of Independent Businesses v. Sebelius*, one of many legal challenges seeking to dismantle PPACA in its entirety, made optional the Medicaid expansion.[132] With seventeen states rejecting the Medicaid expansion option as of fall 2015 and another four merely considering the option,[133] healthcare coverage rates remain low for men and women alike in many states. Texas, for example, has retained its title as the state with the most uninsured citizens—a whopping 24.4%, or over 6.2 million people—by declining to expand Medicaid.[134] The Texas Medicaid roster tracked the national average prior to the enactment of PPACA with men making up only about 40% of enrollees, making Texas a good indicator of the proportionate effect of the lack of Medicaid expansion on access to care by gender.[135]

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[130] PPACA §2001(a), 42 U.S.C. § 1396a (2015) (changing the maximum income to 133% FPL); PPACA § 2002(a), 42 U.S.C. § 1396(a)(e) (2015) (standardizing the system of income disregards to include only a 5% disregard). For a single-person household, 138% is $1,354 per month in 2015. For a family of four, it is $2,789 per month. Annual Update of the HHS Poverty Guidelines, 80 Fed. Reg. 3236, 3237 (Jan. 22, 2015).

[131] Brandon & Carnes, *supra* note 67, at xxxiii. *See also supra* notes 71-75 and accompanying text.

[132] Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566 (2012).

[133] *Status of State Action on the Medicaid Expansion Decision*, KAISER FAMILY FOUND., http://kff.org/health-reform/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act/ [http://perma.cc/7HSK-CUEY] (last updated Sept. 1, 2015).

[134] Dan Witters, *Arkansas, Kentucky See Most Improvement in Uninsured Rates*, GALLUP (Feb. 24, 2015), http://www.gallup.com/poll/181664/arkansas-kentucky-improvement-uninsured-rates.aspx?utm_source=Well-Being&utm_medium=newsfeed&utm_ campaign=tiles [http://perma.cc/5US7-KPDF]; Alexa Ura, *Texas Still Tops Census List of Highest Uninsured Rates*, TEX. TRIB. (Sept. 16, 2014), http://www.texastribune.org/2014/09/16/texas-tops-census-list-highest-uninsured-rate/ [http://perma.cc/JHP4-T7GP].

[135] *See Medicaid Enrollment by Gender*, KAISER FAMILY FOUND., http://kff.org/medicaid/state-indicator/medicaid-enrollment-by-gender/

In expansion states, the uninsured proportion is dramatically different. Combined with the Children's Health Insurance Program, which provides insurance for children through the age of nineteen and some or all services for pregnant women, Medicaid enrollment rose by over 26.1% in the first year since the January 1, 2014, effective date of the expansion.[136] The national uninsured average has since dropped to 11.9%, a figure that includes the twenty-one non-expansion states.[137] Amongst states that have expanded Medicaid are Massachusetts, which has had the lowest uninsured rate since shortly after the enactment of a state version of PPACA, with an uninsured rate of 4.6%, followed by Connecticut and Hawaii at 6%.[138] Thus, Medicaid expansion has had a dramatic effect on financial access to care.

It has in particular increased access to care for men of modest income. Prior to PPACA, the common requirement that an adult be the primary conservator in order to qualify for Medicaid was a factor in inflating the proportion of women receiving Medicaid, largely because women are more likely than men to be the single parent in possession of a child.[139] This is still true in non-expansion states. But, though the data are limited, it appears that in expansion states, men are experiencing a greater increase in access to care through Medicaid enrollment. In Illinois, for instance,

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[http://perma.cc/M5ZJ-N4VU] (last visited Nov. 1, 2015) (listing men as 41% of the national population and 43% of Texans enrolled in Medicaid).

[136] CTR. MEDICARE & MEDICAID SERV., DEP'T HEALTH & HUM. SERV., MEDICAID & CHIP: JANUARY 2015 MONTHLY APPLICATIONS, ELIGIBILITY DETERMINATIONS AND ENROLLMENT REPORT 3 (2015), *available at* http://medicaid.gov/medicaid-chip-program-information/program-information/downloads/medicaid-and-chip-january-2015-application-eligibility-and-enrollment-data.pdf [http://perma.cc/7ZVK-62N5].

[137] Jenna Levy, *In U.S., Uninsured Rate Dips to 11.9% in First Quarter*, GALLUP (Apr. 13, 2015), http://www.gallup.com/poll/182348/uninsured-rate-dips-first-quarter.aspx [http://perma.cc/B9QT-MZDU].

[138] Witters, *supra* note 134.

[139] Rachel Garfield & Anthony Damico, *The Coverage Gap: Uninsured Poor Adults in States that Do Not Expand Medicaid—An Update*, KAISER FAMILY FOUND. 4 (Oct. 2015), http://files.kff.org/attachment/issue-brief-the-coverage-gap-uninsured-poor-adults-in-states-that-do-not-expand-medicaid-an-update [http://perma.cc/7F55-XWL9].

Medicaid enrollees in April 2015 were 55.7% male and only 44.3% female.[140] Given the removal of the conservatorship and other severely limiting eligibility requirements, which favored women, it is logical that Medicaid expansion would cause men to have increased financial access to health care.

Compounding the problem of coverage in non-expansion states is the system of subsidies and tax credits set out by PPACA for insureds in the HIM. As described *supra*, the subsidies and credits available for people between 100% and 138% of the federal poverty guideline are not generous in terms of raw dollar amount relative to the cost of non-group insurance in the HIM.[141] This was not a design flaw, however, as these citizens were intended to be covered by Medicaid; the aforementioned *National Federation of Independent Businesses* ruling interfered with the framework by allowing states to opt out of the expansion, creating a fiscal gap in the availability of healthcare insurance.

While the severity of the problem for the four million people who are estimated to be Medicaid-eligible should not be minimized, men and women are, on the surface, equally affected, with 49% of those in the coverage gap female and 51% male.[142] Nonetheless, in non-expansion states, 85% of men who would be eligible for Medicaid under the expansion schema fall within the gap while only 78% of women do. [143] Thus, this additional barrier to access to health care may be understood as a greater burden for men than women because

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[140] ILL. HEALTHCARE & FAM. SERV., AFFORDABLE CARE ACT ENROLLMENT BY AGE, RACE, AND GENDER AS OF APRIL 2015 (Apr. 2015) (on file with author).

[141] *See supra* notes 71-74 and accompanying text.

[142] Garfield & Damico, *supra* note 139, at 4.

[143] *Id.* Wisconsin represents a partial exception, however, because although the state did not expand the Medicaid maximum permitted income to 138 percent of the federal poverty guideline, it does provide coverage equally for all adults, regardless of gender, whose income is below the federal poverty guideline. For background, *see* Erin Toner, *Wisconsin Chooses its Own Path to Overhaul Medicaid*, NPR (Nov. 19, 2013, 2:56 AM), http://www.npr.org/blogs/health/2013/11/19/246003602/wisconsin-chooses-its-own-path-to-overhaul-medicaid [http://perma.cc/293U-R6K7].

under the current rules in non-expansion states, women are more likely to qualify for Medicaid.

Importantly, the access to care provided by Medicaid is "fairly comparable to that of low-income Americans with employer-sponsored insurance."[144] It is also significantly better than the access of the uninsured: In the first year of the expansion, hospital uncompensated care costs dropped $7.4 billion dollars, a 21% reduction; Medicaid expansion is credited with 68% of that savings.[145] In addition, both proportions and volumes of uninsured or self-pay emergency department visits and hospital admissions fell substantially.[146] While the importance of the reduced cost to the healthcare system cannot be overstated, on both an individual and population level, utilization cost reduction is indicative of the significance of the increased access to primary care that the Medicaid expansion catalyzed. Somewhat surprisingly, however, although the Medicaid expansion seems thus far to have favored men, as discussed *infra*, the decrease in uncompensated care suggests that it is women whose access to primary care has been increased. This is because women are as much as 150% more likely than men to have two or more emergency department visits or hospital admissions in any given twelve-month-period.[147]

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144 DEP'T HEALTH & HUM. SERV., 2014 ANNUAL REPORT ON THE QUALITY OF HEALTH CARE FOR ADULTS ENROLLED IN MEDICAID 10 (2014), *available at* http://www.medicaid.gov/medicaid-chip-program-information/ by-topics/quality-of-care/downloads/2014-adult-sec-rept.pdf [http://perma.cc/6CG2-UEHG].

145 DEP'T HEALTH & HUM. SERV., INSURANCE EXPANSION, HOSPITAL UNCOMPENSATED CARE, AND THE AFFORDABLE CARE ACT (2015), *available at* http://aspe.hhs.gov/health/reports/2015/medicaidexpansion/ib_uncompensatedcare.pdf [http://perma.cc/8K6V-NPPN]. For the full report, which defines "uncompensated care" as the "combined total of bad debt and charity care," *see* Thomas DeLeire et al., *Impact of Insurance Expansion on Hospital Uncompensated Care Costs in 2014*, DEP'T HEALTH & HUM. SERV. (Sept. 24, 2014), http://aspe.hhs.gov/health/reports/2014/UncompensatedCare/ib_UncompensatedCare.pdf [http://perma.cc/N8E8-MGM8].

146 INSURANCE EXPANSION, HOSPITAL UNCOMPENSATED CARE, AND THE AFFORDABLE CARE ACT, *supra* note 145, at 1.

147 *Health, United States, 2014*, CTR. DISEASE CONTROL & PREVENTION 276 (May 2015), http://www.cdc.gov/nchs/data/hus/hus14.pdf [http://perma.cc/2ZZG-WHPW].

That does not, of course, mean that the access to care that Medicaid provides is equivalent to that experienced by people in either the group or non-group markets. Indeed, federal and state reductions in rates of reimbursement have caused fears that the pool of physicians accepting Medicaid would decrease, which is particularly troubling given that an important component of access to care is having a dedicated healthcare provider.[148] Others have predicted that swelling Medicaid rolls would cause the remaining primary care providers to be overwhelmed, decreasing access for all patients as wait-times increased.[149] Neither concern has borne out, but, were they to, women would likely be disproportionately affected in their access to care, because women are more likely to have a dedicated primary care physician.[150] On the other hand, men's reticence to seek medical care may further exacerbate any provider access issues that may develop.[151]

In sum, the restrictions on Medicaid enrollment in non-expansion states represent a barrier to care for the significant proportion of the population that is excluded, which predominantly is men, though low-income men in expansion states have a significantly increased financial access to care that puts them on par with similarly situated women.

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[148] Stephen Zuckerman, et al., *Reversing the Medicaid Fee Bump: How Much Could Medicaid Physician Fees for Primary Care Fall in 2015?*, URBAN INSTITUTE (Dec. 2014), http://www.urban.org/sites/default/files/alfresco/publication-pdfs/2000025-Reversing-the-Medicaid-Fee-Bump.pdf [http://perma.cc/PZF5-P2C4].

[149] *14 Million More Have Coverage, Yet Doctors Aren't Swamped*, UNIV. PITTSBURG MED. CTR. (Apr. 29, 2015), http://www.yourhealthcaresimplified.org/news/14-million-more-have-coverage-yet-doctors-arent-swamped-028new/ [http://perma.cc/C8S3-2FP].

[150] CHUN-JU HSIAO ET AL., *supra* note 37, at 15.

[151] *See, e.g.*, Memorandum from Stacey Zabusky, Harris Interactive on Men's Health Study to Janelle Davis, Am. Acad. Family Physicians 3 (May 9, 2007), *available at* http://www.aafp.org/dam/AAFP/ documents/media_center/men-prevention/final_executive_summary_061307.pdf [http://perma.cc/FCU7-7RYG] ("The majority of U.S. men (92%) indicated they wait at least a few days before seeking medical care or advice, although likelihood to seek care or advice right away increases with age.").

4. Other Third-Party Payors

Medicare covers 93% of adults over the age of sixty-five, largely eliminating disparities in access to care by either gender in that population.[152] Ninety-six percent of Medicare beneficiaries, whether male or female, report having a usual source of care from whom they can receive timely medical attention.[153] Because the program covers two medically needy populations—certain long-term disabled adults along with seniors—regular access to a dedicated healthcare provider is a very important indicator of the efficacy of Medicare in creating access to care.[154] Notably, Medicare beneficiaries' access to care is "comparable to or better than access reported by privately insured individuals."[155] It is also less likely to be financially burdensome.[156]

Fifty-six percent of Medicare beneficiaries are female, a disproportion largely due to the longer lifespans enjoyed by women.[157] Nonetheless, because older women today are less likely to have adequate retirement benefits due to shorter work histories and lower pay,[158] they may be more susceptible than men to other income-based limitations on access to care, as noted *supra*.

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[152] *A Profile of Older Americans: 2012*, ADMIN. ON AGING 14, http://www.aoa.gov/Aging_Statistics/Profile/2012/docs/2012profile.pdf [http://perma.cc/6X37-BU48].

[153] Cristina Boccuti et al., *Medicare Patients' Access to Physicians: A Synthesis of the Evidence*, KAISER FAMILY FOUND. 2-3 (Dec. 2013), https://kaiserfamilyfoundation.files.wordpress.com/2013/12/8526-medicare-patients-access-to-physicians5.pdf [http://perma.cc/V5SF-8ASH].

[154] *Id.* at 2, 15.

[155] ADELE SHARTZER ET AL., ACCESS TO PHYSICIANS' SERVICES FOR MEDICARE BENEFICIARIES 4 (2013), *available at* http://aspe.hhs.gov/health/reports/2013/PhysicianMedicare/ib_physicianmedicare.pdf [http://perma.cc/QX2M-ERFJ].

[156] THE IMPORTANCE OF MEDICARE FOR WOMEN 1 (2012), *available at* http://www.nwlc.org/sites/default/files/pdfs/the_importance_of_medicare_for_women_factsheet_08-29-12.pdf [http://perma.cc/APB2-LUMV].

[157] *Id. See also A Profile of Older Americans: 2012*, *supra* note 152, at 2, 4 (noting that there are 131 older women for every 100 older men, that ratio increase to 203 to 100 at age eighty-five, and that there are four times as many widows as widowers amongst older persons).

[158] *Women and Retirement Savings*, DEP'T OF LABOR 2 (Aug. 2013), http://www.dol.gov/ebsa/pdf/women.pdf [http://perma.cc/U3EC-4762].

Tied to Medicare financial access efficiency is the Tricare system, which provides healthcare insurance coverage to current and former service members and their families, or roughly 4% of the U.S. population.[159] However, because men are much more likely to serve in the military and the women who do serve are typically single,[160] women receive dependent coverage in greater proportions. With a divorce rate amongst military families that exceeds the general population[161] and very restrictive provisions on post-divorce eligibility for Tricare,[162] women's healthcare coverage under Tricare is in general more tenuous than men's. In contrast, men are more likely than women to lose their Tricare coverage due to being discharged at less than honorable status, but this occurs in relatively low numbers.[163] A recent study made clear that changes to the reimbursement mechanism for civilian providers of health care to Tricare beneficiaries, which were unrelated to PPACA but also effective January 1, 2014, did not affect access to care for either gender.[164]

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[159] U.S. GOV'T ACCOUNTABILITY OFFICE, SOLE COMMUNITY HOSPITALS: EARLY INDICATIONS SHOW THAT TRICARE'S REVISED REIMBURSEMENT RULES HAVE NOT AFFECTED ACCESS TO CARE (2015), *available at* http://www.gao.gov/assets/670/669663.pdf [http://perma.cc/G5SE-843N].

[160] EILEEN PATTEN & KIM PARKER, WOMEN IN THE U.S. MILITARY: GROWING SHARE, DISTINCTIVE PROFILE 4-5 (2011), *available at* http://www.pewsocialtrends.org/files/2011/12/women-in-the-military.pdf [http://perma.cc/BFF2-Y895].

[161] Jennifer Hickes Lundquist, *A Comparison of Civilian and Enlisted Divorce Rates During the Early All Volunteer Force Era*, 35 J. POL. & MIL. SOC. 199, 213 (2007) ("When compared to same aged, married civilians in the presence of multiple demographic, religious, socioeconomic, and attitudinal controls, enlistees are still more likely to divorce than comparable civilians.").

[162] *See* 10 U.S.C. § 1072(2)(F)–(I) (delineating the post-divorce Tricare eligibility requirements for former spouses, which include twenty years of marriage contemporaneous with as many years of service).

[163] *See generally* Evan R. Seamone et al., *Moving Upstream: Why Rehabilitative Justice in Military Discharge Proceedings Serves a Public Health Interest*, 104 AM. J. PUB. HEALTH 1805 (2014) (discussing the nexus between less-than-honorable discharges and access to health care through Tricare and the other military health system components, and noting the disproportionate effect on males).

[164] GOV'T ACCOUNTABILITY OFF., *supra* note 159, at 16.

In conclusion, given the current restrictions on gender rating by insurance companies, disparities in access to health care vis-à-vis insurance cannot bear attenuated attribution to biophysical distinctions. Often, social constructs that tend to influence ability to acquire a health plan are driving this aspect of access to care and generally in favor of men. Some of these are also the types of disparities that law is arguably most able to remedy.

C. Reproductive Access to Care: The Role of Competing Doctrines

This paper began with an example of a proposed legislative restriction on an otherwise lawful medical procedure for women—medication abortion by telemedicine. That bill passed along party lines.[165] Clearly this represents a gender-specific restriction on access to care, though necessarily along the lines of a biophysical distinction in medical need; but it is problematic and notable because the specific medical service is otherwise a constitutional right, and so a direct proscription would not be lawful. So while Idaho became the sixteenth state with a prohibition on obtaining abortion medication through telemedicine, no state disallows the prescription of any other medication via telemedicine.[166] Relative to the spectrum of medical treatments available by telemedicine, women are disadvantaged by this singular prohibition. Somewhat surprisingly, it appears that only one court has attempted to set aside the abortion issue and addressed a similar law from a gender-conscious access-to-care perspective. In *Planned Parenthood of the Heartland v. Iowa Board of Medicine*, the court acknowledged the potential unequal treatment that inheres in subjecting a single telemedicine procedure to

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[165] *See House Bill 154*, IDAHO LEG., http://www.legislature.idaho.gov/legislation/2015/H0154.htm [http://perma.cc/B6ZU-FRM6] (last visited Jan. 5, 2016) (providing the bill's history to include legislative votes).

[166] LATOYA THOMAS & GARY CAPISTRANT, AM. TELEMED. ASS'N, STATE TELEMEDICINE GAPS ANALYSIS: PHYSICIAN PRACTICE STANDARDS & LICENSURE 81-82 (May 2015), *available at* http:// www.americantelemed.org/docs/default-source/policy/50-state-telemedicine-gaps-analysis-physician-practice-standards-licensure.pdf?sfvrsn=14 [http://perma.cc/7HEH-5NUK].

stricter regulation than other procedures available by telemedicine.[167] But on the matter of the federal and state constitutional equal protection claim, the court essentially held the issue inadequately briefed.[168]

A further limitation for women on access to this time-sensitive need for care is the extension in the Idaho law of a civil remedy against the physician to the female patient's husband, and, in the event of the patient's demise, her mother.[169] Given the marginalization of women in some subpopulations, noted *infra*, this potentially represents a significant mechanism to reduce access to care by women. Moreover, the cause of action is not for loss of consortium, or a derivative claim of harm to the fetus (or something equally pious), or even for prescribing abortion medication via telemedicine; but rather the claim is for the knowing or reckless act of performing or attempting to perform an abortion upon a female.[170] This override of any consent or stated preference of the female body that received the benefit of a lawful medication, albeit through a newly unlawful method, is yet another way that law can be used to create reduced access for women to care.[171]

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[167] Planned Parenthood of the Heartland v. Iowa Bd. Of Med., No. CVCV046429, 2014 WL 7054656, at *21 (Iowa Dist. Jan. 7, 2014) ("[The plaintiff] claims that the board's rule has violated equal protection because telemedicine abortion is treated differently than other telemedicine . . . .") *aff'd,* 865 N.W.2d 252 (Iowa 2015).

[168] *Id.* ("[T]he claim is difficult to evaluate because [the plaintiff] has not precisely defined the groups it claims has been treated differently, a must for an equal protection evaluation . . . There is no evidence indicating to what extent the board allows telemedicine in other contexts, so there is no means to evaluate a broad equal protection claim.").

[169] Physician Physical Presence and Women Protection Act, H.B. 154 § 18-618, 63rd Leg., Reg. Sess. (Idaho 2015) (enacted), http://www.legislature.idaho.gov/legislation/2015/H0154.pdf [http://perma.cc/X4XC-7R53]

[170] *Id.*

[171] In the context of informed consent laws, women are generally not treated as having full capacity. *See* Deborah L. Forman, *When "Bad" Mothers Make Worse Law: A Critique of Legislative Limits on Embryo Transfer,* 14 U. PA. J.L. & SOC. CHANGE 273, 299 (2014) (citing three primary areas of regulation of informed consent: mental health treatment, medical treatment of minors, and treatment related to women's reproduction). *Accord* Dan L. Burk, *DNA Rules: Legal and Conceptual Implications of Biological "Lock-Out" Systems,* 92 CALIF. L.

Examples of selective proscriptions on women's reproductive care services are available elsewhere. Such deliberate prohibitions on accessing a particular medical treatment may even occur through mechanisms designed to effect the opposite. For example, within four years of the U.S. Supreme Court recognizing a right to privacy in all medical care in *Roe v. Wade*,[172] Congress passed the Hyde Amendment, which prohibits the use of federal public dollars for elective abortion with limited exception.[173] A long-standing budget rider, recent efforts to codify the Hyde Amendment have failed,[174] but the Amendment itself was reaffirmed in 2010 by an executive order negotiated alongside PPACA.[175] Expressly prohibited in that order was the use of tax credits and subsidies to pay for healthcare insurance coverage of abortions.[176]

The Hyde Amendment represents a significant restriction on financial access to women's reproductive care because those directly affected include women insured through Medicaid, Medicare, and Tricare, along with all other women whose medical care is provided by or underwritten by the federal government. For this reason, seventeen states use local funds to restore that access, including four that do so voluntarily without judicial intervention.[177] The law and

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REV. 1553, 1580 (2004) ("The historical inclusion of women together with children and mentally handicapped individuals as legal incompetents amply illustrates the danger of judicial preferences not merely to the success of a particular bargain, but to individual autonomy.").

[172] Roe v. Wade, 93 S.Ct. 705 (1972).

[173] Pub. L. No. 94–439 § 209, 90 Stat. 1418, 1434 (1976).

[174] E.g., Hyde Amendment Codification Act, S. 142, 113th Cong. (2013); Hyde Amendment Codification Act, S. 1488, 112th Cong. (2011). The most recent version, Hyde Amendment Codification Act, S. 219, 114th Cong. (2015), has been given a 1% chance of being enacted. *S. 219: Hyde Amendment Codification Act*, GOVTRACK.US, https://www.govtrack.us/congress/bills/114/s219 [https://perma.cc/47NX-TQZ5] (last visited May 29, 2015).

[175] Exec. Order No. 13535 Ensuring Enforcement and Implementation of Abortion Restrictions in the Patient Protection and Affordable Care Act, 75 Fed. Reg. 15599 (Mar. 29, 2010).

[176] *Id.* § 2.

[177] GUTTMACHER INSTITUTE, STATE POLICIES IN BRIEF: STATE FUNDING OF ABORTION UNDER MEDICAID, 1 (2015), *available at* http://www.guttmacher.org/statecenter/spibs/spib_SFAM.pdf [http://perma.cc/KSB8-GUZF].

policy in these states stands in stark contrast to the Hyde Amendment, the constitutionality of which was affirmed in 1980 by the U.S. Supreme Court.[178] Holding that there is no right to the use of public funds to provide for any specific medical treatment under the due process or equal protection clauses because the government does not cause the indigency that makes care unaffordable, the Court nonetheless noted the role of public policy: "[t]he Hyde Amendment . . . encourages alternative activity deemed in the public interest."[179]

Institutional policy may also militate away from access to care in other ways that specifically and derivatively target male and female reproductive medical care. Directives by the Catholic Church turn permissive statutes regarding conscientious objection into mandates for all employees of Catholic institutions[180] and for Catholic providers in secular or other institutions.[181] While the majority of these directives are either gender-neutral toward patients—neither men nor women may be rendered sterile in a Catholic hospital, for example[182]—those that preclude medical attention at or before conception, or during pregnancy, do disproportionately limit women's access to care, and at times where women are most vulnerable.

The effect on access to care is multiplied by at least two factors. First, Catholic hospitals represent a significant portion of the hospital industry in the United States: Every

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[178] Harris v. McRae, 448 U.S. 297 (1980).

[179] *Id.* at 315. While "public interest" does not always equate with the concept of public policy, here it seems it does.

[180] *See* U.S. CONFERENCE OF CATHOLIC BISHOPS, ETHICAL AND RELIGIOUS DIRECTIVES FOR CATHOLIC HEALTH CARE SERVICES, 3 (5th ed. 2009), *available at* http://www.usccb.org/issues-and-action/human-life-and-dignity/health-care/upload/Ethical-Religious-Directives-Catholic-Health-Care-Services-fifth-edition-2009.pdf [http://perma.cc/XDW7-W3Q4] [hereinafter CATHOLIC DIRECTIVES] ("Since they express the Church's moral teaching, these Directives also will be helpful to Catholic professionals engaged in health care services in other settings.").

[181] *See id.* at 125 ("Catholic health care services must adopt these Directives as policy, require adherence to them within the institution as a condition for medical privileges and employment, and provide appropriate instruction regarding the Directives for administration, medical and nursing staff, and other personnel.").

[182] *Id.* at 27.

state has Catholic healthcare facilities that provide acute care, skilled nursing, and other services.[183] With five states lacking a Catholic hospital, one in six patients nationwide nonetheless is admitted to a Catholic bed.[184] One-third of Catholic hospitals are located in rural areas, where they are likely to be the only acute care facility available.[185] Even in urban areas, accessing a non-Catholic institution may be complicated by insurance network rules, poor transportation, inadequate paid time off work, and other socio-economic issues that affect access to care, many of which were explicated above as having a disparate effect on women. The pervasive role of the Catholic Church in health care means that there are areas of the country where men and women alike are without an alternative choice, in turn rendering their effective access to care of lessened value.

Second, in addition to federal law, state laws overwhelmingly sanction these access-restricting policies. For instance, every state permits physicians to refuse to provide abortion services, and thirteen states allow providers to refuse to provide contraception.[186] Additionally, eighteen states have no proscription on providers declining to provide sterilization.[187] Of course, conscience clauses are not restricted to those providing reproductive care, but because the philosophy became legally recognized post-*Roe*, it has continued to be so associated.[188]

But by allowing healthcare providers to opt out of providing *any* health care without regard to the needs of the

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[183] CATHOLIC HEALTH ASS'N OF THE U.S., CATHOLIC HEALTH CARE IN THE UNITED STATES, 2 (Jan. 2013), *available at* https://www.chausa.org/docs/default-source/general-files/mini_profile-pdf.pdf?sfvrsn=0 [http://perma.cc/8Y4H-3F88].

[184] *Id.* at 1-2.

[185] *Id.* at 2.

[186] GUTTMACHER INSTITUTE, STATE POLICIES IN BRIEF: REFUSING TO PROVIDE HEALTH SERVICES, 2 (2015), *available at* http://www.guttmacher.org/statecenter/spibs/spib_RPHS.pdf. [http://perma.cc/M3C9-EAW6]..

[187] *Id.*

[188] The first federal conscience exception to treatment was the Church Amendment, passed in 1973. 42 U.S.C. § 300a-7(b) (1973). *See generally* HOLLY FERNANDEZ LYNCH, CONFLICTS OF CONSCIENCE IN HEALTH CARE: AN INSTITUTIONAL COMPROMISE, 19-24 (2008) (describing the history of conscience clauses).

patient, and especially in ways that can disenfranchise entire subpopulations, access to care begins to become meaningless. After all, increasing access to care is futile if no one will provide the care. Moreover, given the bend toward declining to provide services that broadly affect women, the directives and supporting legislation reduce access disproportionately. Even where the patient is male, restrictions on access to male reproductive care "can only be carried out on the backs of women," because, ultimately, women are physically, emotionally, legally, and financially responsible for pregnancy or lack thereof.[189] Ironically, the resultant increased need for care further concentrates the disproportionality of the burden of the lack of access to care for women.

Religion or other conscientious objection acts as a delimiter on access to reproductive care in other ways, too. As discussed *supra*, the Hobby Lobby case provided a potentially broad expansion of religious liberty to for-profit corporations that are closely held.[190] Unlike the Catholic Church directives, which proscribe effectively all contraception on the basis of interference with sex as having only "unitive and procreative meaning,"[191] the holding in *Hobby Lobby* relies not on consistent religious doctrine, but rather a selective and convenient disbelief of science.[192] Because of the potentially broad applicability of such a holding, it is conceivable that religion may further restrict access to care in the future.[193]

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[189] Roth, *supra* note 34, at 393, 411-13.

[190] *See supra* text accompanying notes 113-119.

[191] CATHOLIC DIRECTIVES, *supra* note 180, at 24.

[192] *See* sources cited *supra* note 69. *See* sources cited *supra* notes 113-119.

[193] *See* Hobby Lobby, 134 S. Ct. at 2787 (Ginsburg, J., dissenting) ("In a decision of startling breadth, the Court holds that commercial enterprises, including corporations, along with partnerships and sole proprietorships, can opt out of any law (saving only tax laws) they judge incompatible with their sincerely held religious beliefs.").

D. Transgendering Access to Care: The Role of the Non-Binary Gender Perspective

As a final consideration of gender-based health and health care disparities, it is worth a brief foray into the access issues of those whose gender falls outside of the Western tradition of a binary gender system. It has been estimated that only 0.3% of American adults are transgender.[194] Difficulties with defining the transgender population have created challenges in solidifying that number,[195] but, nonetheless, it is an increasingly mainstream idea that a not insignificant number of people identify as something other than simply male or female.[196] Exemplifying both the definitional difficulties and pervasiveness of other-genderedness is recent criticism of Facebook: the social networking giant limited its users to one of *fifty-eight* gender identity options, a number that caused such backlash about its insufficiency that the company felt compelled to make the gender identification option an open question.[197]

Thus, any gender-based discussion should at least consider a selective overview of disparities for those who fall outside of the male/female dichotomy, especially, perhaps, in the context of access to health care, which population health research demonstrates is a considerable source of health

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[194] GARY J. GATES, HOW MANY PEOPLE ARE LESBIAN, GAY, BISEXUAL, AND TRANSGENDER?, 6 THE WILLIAMS INSTITUTE (April 2011) (estimating the size of the lesbian, gay, bisexual, and transgender population in the U.S. through review of eleven recent surveys regarding sexual orientation or gender identify questions), *available at* http://williamsinstitute.law.ucla.edu/wp-content/uploads/Gates-How-Many-People-LGBT-Apr-2011.pdf [http://perma.cc/4FBZ-PCW4].

[195] *Id.* at 2.

[196] *See, e.g.,* Katy Steinmetz, *This Is What 'Cisgender' Means*, TIME (Dec. 23, 2014), http://time.com/3636430/cisgender-definition/ [http://perma.cc/RV64-HNWS] (discussing the usefulness of the newly created term "cisgender," included in the Oxford Dictionary only since 2013, to describe those traditionally referred to as "male" or "female").

[197] Jessica Guynn, *Facebook's New Gender Option: Fill in the Blank*, USA TODAY (Feb. 26, 2015, 1:00 PM EST), http://www.usatoday.com/story/tech/2015/02/26/facebook-gender-option-fill-in-the-blank/24059551/ [https://perma.cc/9ZA4-7KMC].

inequality amongst the gender diverse.[198] Nonetheless, this paper does not seek to fully consider the health concerns of other-gendered persons, not because they are wholly irrelevant, but because they are complex and worthy of fuller treatment than would be appropriate here. Additionally, the thesis of this paper is comparative in nature, so the focus here is on a few issues specific to access that mirror the concerns of people gendered as male or female—that is, those who are similarly situated whose access to health care is limited because of, or as a result of, gender.

The medical goals of trans- or other gender persons can create unique issues of access to specialized health care, but access to primary care is often a preliminary barrier.[199] As with the reduced access to primary care by women as against men, the reasons are multifactorial. First, the rate of private and employer-based health insurance amongst transgender persons is lower than the national average, as is the mean income.[200] As noted *supra*, health insurance is a proxy for access to health care, and the more modest a person's income, the less likely that person is to receive preventative care services.[201] The concordant issues of enhanced likelihood of health-harming behaviors and difficulty with prioritizing health are also present.

Second, as much as the marginalization of women in certain communities contributes to lack of primary care, the transgender community is often further on the outskirts of society. As also noted above, marginalization contributes to difficulty accessing care. Transgender people may be more likely, however, to experience outright and express

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[198] Frank Pega & Jaimie F. Veale, *The Case for the World Health Organization's Commission on Social Determinants of Health to Address Gender Identity*, 105(3) AM. J. PUB. HEALTH e58, e59 (2015).

[199] Michael Silverman, *Issues in Access to Healthcare by Transgender Individuals*, 30 WOMEN'S RTS. L. REP. 347, 348 (2009).

[200] Rachel C. Kurzweil, Note, *"Justice is What Love Looks Like in Public": How the Affordable Care Act Falls Short on Transgender Health Care Access*, 21 WASH. & LEE J. CIVIL RTS. & SOC. JUST. 199, 214-215 (2014).

[201] *See supra* notes 40-42 and accompanying text.

discrimination from the healthcare community than either women or men.[202]

Third, the mismatch between a transgender person's appearance and his or her official identification can arouse suspicion, or create inconsistencies that necessitate explanation by the patient and understanding by the healthcare entity representative.[203] That is, insurance or other documents may classify a person as one gender, but hormonal or even lifestyle options may mean that a transgender person's medical needs more closely align with those of the gender opposed to that on the documentation. While that issue is unique to transgender people, it explains why transgender women may be as likely as men to have difficulties accessing preventative health services that are readily available for cisgender women, such as screening for breast cancer.[204] This is particularly concerning because hormone therapy may increase the susceptibility to certain conditions, some of which may typically and legally be associated with primarily one gender.[205]

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[202] Silverman, *supra* note 199, at 348. This status is reinforced by judicial decisions that hesitate in applying to transgender persons the same intermediate scrutiny as is applicable to sex or gender discrimination against those who fall within the Western binary gender perspective. *See, e.g.,* Johnston v. Univ. of Pitt., --- F.Supp.3d---, No. 3:13–213, 2015 WL 1497753, at *8 (W.D. Penn. Mar. 31, 2015) ("[N]either the United States Supreme Court nor the Third Circuit Court of Appeals has recognized transgender as a suspect classification under the Equal Protection Clause. Accordingly, Plaintiff's discrimination claim is reviewed under the rational basis standard. This finding is consistent with numerous other courts that have considered allegations of discrimination by transgender individuals.") *But cf.* Glenn v. Brumby, 663 F.3d 1312, 1317 (11th Cir. 2011) ("[D]iscrimination against a transgender individual because of her gender-nonconformity is sex discrimination, whether it's described as being on the basis of sex or gender.").

[203] Silverman, *supra* note 199, at 348.

[204] Kurzweil, *supra* note 200, at 208. See *also e.g.*, Dani Heffernan, *Colorado Trans Woman Denied Free Breast Cancer Screening by State-Run Program*, GLAAD (Oct. 16, 2013), http://www.glaad.org/blog/colorado-trans-woman-denied-free-breast-cancer-screening-state-run-program. [http://perma.cc/DZ3U-2JXP]. *See also supra* notes 95—126 and accompanying text.

[205] *See* Jamie D. Weinand & Joshua D. Safer, *Hormone Therapy in Transgender Adults is Safe with Provider Supervision; A Review of*

Finally, transgender people may receive greater access to care that is specific to the needs of their gender than do women. Insofar as gender confirming surgery is a medical need unique to transgender persons, and elective abortion is a medical need unique to women, the increasing availability of the former under Medicare and Medicaid stands in contrast to the reduced access to care that women experience under the Hyde Amendment.

In these four ways, transgender people are similarly situated to those traditionally gendered yet have reduced access to care by the realities of the operation of law. Importantly, for these issues and as a normative matter, transgender persons should benefit from efforts to remedy other gender-based disparities in healthcare access.

III. REMEDIATING DISPARITIES IN ACCESS TO CARE THROUGH HEALTH AS A (NONEXISTENT) RIGHT

The previous section explored the results of various laws and judicial decisions that impact access to health care, noting substantial gender-based disparities result from the agglomerated systems that seek to increase access and instances of judicial unwillingness to give weightier consideration to the access issue. In this section, this paper explains how current efforts to promote equitable access to health care by all genders demonstrate that a public policy of prioritizing health in decision-making by courts and states is appropriate. It does this by first acknowledging that although a constitutional right to health would be a clear mandate that favored health, such a right does not exist in the United States. But by juxtaposing the concept of a right to health with the somewhat disjointed efforts that have been undertaken to increase access to care, it becomes clearer that a judicially cognizable health-favoring policy can be viable.

Hormone Therapy Sequelae for Transgender Individuals, 2 J. CLINICAL & TRANSLATIONAL ENDOCRINOLOGY 55 (2015) (providing an overview of current knowledge in transgender medicine as it relates to the safety of hormone therapy for transgender adults and noting that a severe limitation in the field is the lack of large-cohort studies to study the long-term effects of hormone therapy).

A. The International Formulation of a Right to Health and Access to Care

If the United States has not comprehensively created a right to health—and perhaps, as explained below, *cannot* without foundational changes to the healthcare system as it is currently delivered and financed—then we must look to the international community to understand what such a formulation would look like and, moreover, how it defines access to care for similarly situated patients of different genders.[206]

As a preliminary matter, "the denial of health care has often been understood as essentially interfering with the 'right to health,'" from an international perspective."[207] This is evident in both the Universal Declaration on Human Rights (UDHR), which provides the foundation for international human rights,[208] and the International Covenant on Economic, Social and Cultural Rights (ICESCR), which articulates the most important statement of health as a human right.[209]

The UDHR makes only one reference to health, declaring that "[e]veryone has the right to a standard of living adequate for [] health and well-being . . . including food, clothing, housing and medical care and necessary social services, and the right to security in the event of . . . sickness, [and]

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[206] *See generally* Eleanor D. Kinney, *The International Human Right to Health: What Does This Mean for Our Nation and World?*, 34 IND. L. REV. 1457 (2001) (arguing that international law has concrete implications for domestic policy-making regarding health).

[207] Report of the Special Rapporteur on Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, *Rep. of the Special Rapporteur on Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment*, ¶ 11, U.N. Doc. A/HRC/22/53, Feb. 1, 2013.) (by Juan E. Méndez) [hereinafter Special Rapporteur on Torture], *available at* http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session22/A.HRC.22.53_English.pdf [http://perma.cc/RK59-YLJJ]. *Cf.* Manjari Mahajan, *The Right to Health as the Right to Treatment: Shifting Conceptions of Public Health*, 79 SOC. RES. 819 (December (2012) (arguing that the right to health is unnecessarily indistinguishable from a right to health care in the international community).

[208] Kinney, *supra* note 206, at 1459.

[209] *Id.*

disability . . . ."[210] The ICESCR is similar is in mandating that everyone have "the enjoyment of the highest attainable standard of physical and mental health."[211] The ICESCR further requires that four steps be taken to achieve "full realization" of the right, including by (1) reducing infant mortality and childhood morbidity; (2) improving living and work environments; (3) addressing all diseases, regardless of etiology; and (4) "assur[ing] to all medical service and medical attention in the event of sickness."[212] As with the UDHR, the ICESCR contains an acknowledgement of the impact of SDOH and couples it with an express statement that access to care is a component of the right to health.

Complementary for what it contributes to the remediation of gender-based health disparities, the Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW) "devotes major attention to a most vital concern of women, namely their reproductive rights."[213] CEDAW references access to health care no fewer than six times and particular seeks "a basis of equality of men and women."[214] This goal of equalization is consistent with customary international health law, including as expressed by WHO. It is also in much the same vein as U.S. federal efforts that seek equity of men and women's access to health.

Gender-based disparities in access to health care have begun to inform other forms of international human rights law also. For instance, 2013, the U.N. Special Rapporteur sought to complement efforts to combat "violence against women by, inter alia, examining gender-specific forms of

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[210] Universal Declaration of Human Rights, G.A. Res. 217A (III), art. 25.1, U.N. Doc. A/810 at 71 (1948), *available at* http://www.un.org/en/documents/udhr/ [https://perma.cc/C66U-NT5D].

[211] International Covenant on Economic, Social and Cultural Rights, art. 12, Dec. 16, 1966, S. Treaty Doc. No. 95-19, 6 I.L.M. 360 (1967), 993 U.N.T.S. 3, (1976), *available at* http://www.ohchr.org/Documents/ProfessionalInterest/cescr.pdf [https://perma.cc/N2PZ-KWNR].

[212] *Id.*

[213] Convention on the Elimination of All Forms of Discrimination Against Women, Dec. 18, 1979, 1249 U.N.T.S. 13, *available at* http://www.un.org/womenwatch/daw/cedaw/text/econvention.htm#part1 [https://perma.cc/K3SM-HC7P].

[214] *Id.* at art. 1.

torture" in the healthcare setting.[215] Remarkably, on the list of practices found tantamount to torture is the "denial of legally available health services such as abortion and post-abortion care."[216] That report also addresses access to care by those who are transgender, most notably around forced medical procedures designed to rectify gender nonconformity; it concludes that section by noting that both formal and informal mechanisms of discrimination by governments and healthcare providers interfere with access to care.[217]

It is unsurprising that requirements of medically unnecessary surgery that castrate physical functioning would be considered torture, but even describing the inability to access otherwise lawful care as torture is consistent with an international sense of a right to health as a fundamental human right. Additionally, the plain language of the conventions noted above demonstrate that the right to health may be understood as consisting predominantly of a right to health care. However, U.S. courts have failed to recognize the international right to health, finding it "insufficiently definite" to constitute a normative rule of law.[218]

Regardless, in order for the international right to health to be adapted to fit U.S. customs, it must be broad enough as to encompass the negative "right to be let alone" that provides the foundation of U.S. jurisprudence underlying roughly half of individual healthcare access cases.[219] This is important because were U.S. courts to recognize a broad right

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[215] Spécial Rapporteur on Torture, *supra* note 207, ¶ 45.

[216] *Id.* ¶ 46.

[217] *Id.* ¶¶ 76-79.

[218] *E.g.,* Sarei v. Rio Tinto, 650 F.Supp.2d 1004 (C.D. Cal. 2009) (holding that an assertion to a right to health in an environmental pollution action fails because it is based on a norm that has not achieved the status of a matter of universal concern), *vacated* on other grounds, 133 S.Ct. 1995 (2013). *Accord* Flores v. S. Peru Copper Corp., 414 F.3d 233, 254 (2nd Cir. 2003) ("As an initial matter, we hold that the asserted 'right to life' and 'right to health' are insufficiently definite to constitute rules of customary international law."). *See also* Kinney, *supra* note 206, at 1471 (noting that implementation and enforcement of the right to health is difficult where it is predicated on customary international law).

[219] For a treatise on the two legal mechanisms through which individual access to care is funneled, including public health and privacy, see generally B. Jesse Hill, *The Constitutional Right to Make Medical Treatment Decisions: A Tale of Two Doctrines*, 86 TEX. L. REV. 277 (2007).

to health under domestic law, case law suggests that it might be founded on less-than-solid notions of autonomy.[220] However, a significant challenge would exist in the United States in adapting a negative privacy-based right to health to make it a positive right to access to health care without a fundamental shift in law and policy. Thus this paper next considers the existence of positive rights of access to care in the United States.

B. A Right to Health or Health Care Does Not Exist in the United States

American scholars have for years argued that health is akin to other human rights.[221] The concept has even been tied specifically to equalizing disparities in women's health and health care.[222] Yet one might note that healthcare "seems to play second fiddle to other civil rights issues."[223]

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[220] *Id.* *See also* FERNANDEZ LYNCH, *supra* note 188, at 37-42 (discussing the hypothetical right to care of a patient versus a physician's right to refuse to provide that care and describing the legal system as, from the patient perspective, a recognition of a "freedom from" rather than a "freedom to").

[221] *See, e.g.,* Kinney, *supra* note 206, at 1471 ("The human right to health is just a moral right after all."); Aart Hendriks, *The Close Connection Between Classical Rights and the Right to Health, with Special Reference to the Right to Sexual and Reproductive Health*, 18 MED. & L. 225, 226 (1999) (arguing that "[realization] of this right depends necessarily on the protection afforded to certain classical human rights"). *But see* Richard Lamm, *The Case Against Making Healthcare a Right*, 25 HUM. RTS. 8, 9 (1998) ("It is problematic to consider healthcare as a 'right.' . . . Rights are an ineffective way of determining *who* or *what* is covered"). *Cf.* Emanuel, *supra* note 12, at 104-107 (arguing that the most efficient distribution of resources would be through a framework for delineating specific medical services—and only those services—as rights). *See generally* JOHN TOBIN, THE RIGHT TO HEALTH IN INTERNATIONAL LAW (2012) (providing a historical evaluation of the international right to health and seeking to develop a methodology that is implementable in the United States as with other human rights).

[222] *See* Hilary Hammell, *Is the Right to Health a Necessary Precondition for Gender Equality?*, 35 N.Y.U. REV. L. & SOC. CHANGE 131, 172 (2011) ("In the absence of a right to health, women in the United States face numerous barriers that prevent them from realizing their highest attainable standard of health.").

[223] Silverman, *supra* note 199, at 347.

Regardless, these discussions largely occurred before PPACA altered the health care schema in the United States, suggesting that revisiting the matter is timely. The timing is important because, as Erin C. Fuse Brown, for example, argues, PPACA can be understood as having created a "new right to health care for the uninsured."[224] Fuse Brown concluded that the newly established right "will be ephemeral or hollow—a quasi-superstatute rather than a durable superstatute,"[225] which is logical if PPACA is viewed as "health insurance reform, not health care reform."[226] But neither formulation, nor the health-as-human-right discourse, addresses population-wide gender-based disparities in access to health care that result from a tradition of minimizing health in law and policy.

Although this minimization of health may result from a lack of a right to health, in part because such a right is frequently understood as encompassing a right to access needed health care, it is a steadfast status quo. Consider Fuse Brown's summary of the bleak landscape for the creation of such a doctrine:

[T]he U.S. Constitution provides neither a textual nor structural basis for such a right. . . . Despite the limitations of a conceptual dichotomy between positive rights (e.g., entitlements to social goods) or negative rights (e.g., liberties or freedom from interference), this distinction is a useful description of the federal constitutional posture toward a right to health. . . . Nevertheless, the Court has not recognized a generally applicable positive right to health care, and it seems unlikely ever to do so.[227]

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[224] Erin C. Fuse Brown, *Developing a Durable Right to Health Care*, 14 MINN. J.L. SCI. & TECH. 439, 444 (2013).

[225] *Id.* at 490.

[226] Alicia Ely Yamin, *The Right To Health: Assessing How Far The Discourse Has Evolved Internationally and Within the United States*, 104 AM. SOC'Y INT'L L. PROC. 14, 15 (2010).

[227] Fuse Brown, *supra* note 224, at 455. *Accord* Rebecca E. Zietlow, *Democratic Constitutionalism and the Affordable Care Act*, 72 OHIO ST. L.J. 1367, 1382 (2011) ("The U.S. Constitution does not guarantee a right to health care. The U.S. Supreme Court rejected such a right, and held expressly that the government has no obligation to pay the medical expenses of indigents.").

If this formulation is correct—and this paper assumes it is—then an alternative mechanism must be described if we are to look to law to remedy gender-based disparities in access to care. Any such framework need not recreate the wheel, however, and so this paper now turns to the established limited rights to health or health care that promote access in the United States.

C. Legislated Limited Rights of Access to Specific Care in the United States

Statutory rights are those that are grounded not in the Constitution, but rather in a statute. Similar are durable rights, or those that are accepted as fundamental legal norms but do not necessarily have a constitutional foundation. Both are more likely to suffer from ephemerality, as suggested above with regard to PPACA, due to the relative difficulty in entrenching them. In addition, there tend to be a plethora of mechanisms for challenging statutes.

Still, there are several instances of access to health care that have become nearly as embedded in the cultural expectation as a constitutional right. Only two relate to treatment for specific medical conditions for all adults as well as all children: hemodialysis for end-stage renal disease (ESRD)[228] and palliative care for amyotrophic lateral sclerosis (ALS), more colloquially known as Lou Gehrig's disease.[229] Both conditions trigger near-automatic coverage that is not by itself gender-dependent, though men are more likely than women to suffer from the two conditions and thus to need the coverage.[230] Nonetheless, the history of access to

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[228] Social Security Amendments of 1972, Pub. L. No. 92-603, § 299I, 86 Stat. 1329, 1463 (codified at 42 U.S.C. § 426-1).

[229] Consolidated Appropriations Act of 2001, Pub. L. No. 106-554, § 115, 114 Stat. 2763, A-474 (codified at 42 U.S.C. § 426(h)).

[230] *See* CTRS. FOR DISEASE CONTROL & PREVENTION, NATIONAL CHRONIC KIDNEY DISEASE FACT SHEET, 2014, 1 (2014), *available at* http://www.cdc.gov/diabetes/pubs/pdf/kidney_factsheet.pdf [http://perma.cc/MX5N-JAUK] ("Men with [chronic kidney disease] are 50% more likely than women to have kidney failure."); *Who Gets ALS?*, ALS ASS'N (Apr. 2015) ("ALS is 20% more common in men than in women."), http://www.alsa.org/about-als/who-gets-als.html/ [http://perma.cc/4LGM-QNVS].

dialysis in particular is instructive in any discussion of the role of law in enabling access to health care and, especially, in the lack of a right to health care.[231]

As the first effort undertaken by Congress designed to increase access to treatment for a particular diagnosis,[232] dialysis coverage expressly sought to remedy a disparity in access to care—that is, the lacuna between the wealthy and everyone else.[233] Yet the design of the coverage in 1972 is one that, then and now, slightly favors men. This is because dialysis treatment is available only to those who are insured by definition of Title II of the Social Security Act, or the dependents thereof.[234] As suggested *supra*, men are likely to achieve Title II-insured status of their own accord because, traditionally, men worked outside the home in greater numbers. However, when combined with the Social Security Administration's (SSA) treatment of a diagnosis of end-stage renal disease as an automatically disabling condition, coverage becomes effectively universal; Medicaid, which defines eligibility in accordance with the SSA, can then cover dialysis where Medicare does not even in the absence of the schema of expanded eligibility discussed above.[235]

But, as was asked by members of the Senate Finance Committee, "[w]hy favor this treatment . . .over the long-term treatment of cancer," for example?[236] Because it seems disingenuous to accept that end-stage renal disease represented "the one situation . . . where the only thing separating individuals from life and death was money," it is

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[231] *E.g.*, EMANUEL, *supra* note 12, at 100-101 ("In the view of many, the development of the dialysis program typifies the more general 'crisis' in American medical care."); Richard A. Rettig, *Origins of the Medicare Kidney Disease Entitlement: The Social Security Amendments of 1972*, *in* BIOMEDICAL POLITICS 176, 203 (Kathi E. Hanna ed.,1991) ("The kidney disease entitlement remains a focus for debate about the relative benefits and burdens of medical technology.").

[232] Rettig, *supra* note 231, at 177.

[233] Carl W. Gottschalk, Commentary, *in* BIOMEDICAL POLITICS 209, 209-10 (Kathi E. Hanna ed., 1991).

[234] 42 U.S.C. § 426-1(a) (2015).

[235] SOC. SECURITY ADMIN., *POMS DI 45001.001, End-Stage Renal Disease (ESRD) Entitlement Provisions* (2013) *available at* http://policy.ssa.gov/poms.nsf/lnx/0445001001/ [http://perma.cc/9YHQ-F8JV].

[236] Rettig, *supra* note 231, at 191.

noteworthy that creation of a statutory right in this particular chronic disease was likely more a test of the viability of a national catastrophic health insurance program.[237] Nonetheless, in the words of one of the original bill's constructionists, a physician, "[t]he equity issue was agonizing."[238]

Forty years later, the dialysis coverage debate has not made materialize a system of catastrophic health insurance. Another then-senator had predicted why: "[W]e are picking out one particular sector of the whole health care problem, and because it is dramatic, we are trying to push it ahead of everything else. We can only handle so much."[239] Insofar as the right to health may be conflated with the right to health care, it is clear the practical limitations of finite social and fiscal resources make impossible a statutory right to medical treatment for all conditions in the same manner that hemodialysis is available for end-stage renal disease. Indeed, Medicare, which is not the only payer, contributed nearly $29 billion in 2012, or over 5% of its budget, to the care of the 1% of patients with end-stage renal disease.[240]

Dissimilarly, then, are smatterings of other statutory regimes that have in common only a foundational wealth-based inequity that could no longer be stomached. Addressed *infra* were disparities that result from some of these health-related schemas, such as coverage by the HIM, Medicaid, and Medicare, but others create more specific rights.

For instance, the Emergency Medical Treatment and Active Labor Act (EMTALA) created access to a minimum of stabilizing medical treatment where that treatment mitigates a life-threatening condition, but no more.[241] Ostensibly grown out of the same concern for unnecessary suffering by the non-wealthy that informed coverage of

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[237] *Id.* at 191-92.

[238] *Id.* at 210.

[239] EMANUEL, *supra* note 12, at 100 (quoting Senator Wallace Bennett).

[240] U.S. RENAL DATA SYSTEM, 2014 ANNUAL DATA REPORT VOLUME 2: END-STAGE RENAL DISEASE IN THE UNITED STATES 184 (2014), *available at* http://www.usrds.org/2014/download/v2_esrd_full_14.zip/ [http://perma.cc/K2QW-MN8J].

[241] 42 U.S.C. § 1395dd (2011).

dialysis, EMTALA forestalled the somewhat perverse tendency of some physicians to provide emergency care only if payment was guaranteed. Because low-income mothers-to-be were a particularly vulnerable population of patients likely to be "dumped," the act defines active labor as an emergency; the statuses of all other conditions are left to the judgment of the treating provider.[242] The legislative determination that imminent childbirth constituted an emergency arguably conflicted with the medical understanding of labor,[243] but it is consistent with other disparate legal treatment of pregnancy. Furthermore, as noted *supra*, women are greater users of Emergency Departments, suggesting that men's access to emergency care is not equally benefited.[244]

Other areas of law also create specific rights to health and health care. For example, concerns for health have been used to justify entitlements to habitable housing[245] and an unpolluted environment.[246] Occupational regulations limit poor working conditions[247] and intolerably low wages[248] due, inter alia, to their negative influence on health. Public health

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[242] *Id.* § 1395dd (b).

[243] Even post-EMTALA, judicial remedy was necessary to ensure access to emergency care by laboring women. For example, in Burditt v. U.S. Dep't of Health & Human Servs., 934 F.2d 1362 (5th Cir. 1991), the plaintiff was denied stabilizing care and was instead transferred to a hospital 170 miles away. She gave birth in the ambulance. More recent medicalization of pregnancy might have resulted in different treatment even in the absence of EMTALA.

[244] *See supra* text accompanying note 109.

[245] *E.g.*, Conn. Gen. Stat. Ann. § 47a-7(a)(2) (West 2015) ("A landlord shall . . . make all repairs and do whatever is necessary to put and keep the premises in [a] fit and habitable condition.").

[246] *E.g.,* Clean Water Act, Pub., L. No. 95-217, 91 State (1977) (codified at 33 U.S.C. § 1251) ("[I]t is the national goal that the discharge of pollutants into the navigable waters be eliminated . . . ."). *Id.* § 1251(a)(1).

[247] *E.g.*, Occupational Safety and Health Act, Pub. L. No. 91-596, § 2, 84 Stat. 1590 (1970 (codified at 29 U.S.C. § 651) (The "purpose and policy [is] to assure so far as possible every working man and woman in the Nation safe and healthful working conditions . . . .").

[248] *E.g.*, Fair Labor Standards Act, 29 U.S.C. § 202 (finding by Congress of "the existence . . . of labor conditions detrimental to the maintenance of the minimum standard of living necessary for health . . . .").

law even mandates health through provisos requiring inoculation against certain diseases[249] and fluoridation of drinking water.[250]

In all of the above examples, the judiciary has found that the health benefit to the vulnerable masses, without regard for gender, supersedes contrary individual concerns. Although the physician may not get paid for the service provided, the emergent patient's treatment is superior to any takings claim or right to (not) contract.[251] The landlord who would decline to maintain his properties, yet finds a willing tenant, loses as against that tenant whose health or physical safety is at risk.[252] The corporation that may legitimately need to create and thus dump pollutants to produce a product cannot endanger nearby residents or ecosystems.[253] The employer's financial security is less important than the employee's physical workspace[254] and minimum wages.[255] Conversely, there exists a right not to contract a communicable disease[256] nor to have bad teeth.[257]

These varied examples show that there is a pervasive tendency in law to value individual access to health and even to health care. Such a robust history of health-favoring legislation and supportive judicial decision-making suggests that indeed, we as a nation intend to promote the health of all as a policy goal.

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[249] *E.g.*, Va. Code Ann. § 32.1-46(E) (West 2014) (requiring mandatory vaccinations "[f]or the purpose of protecting the public health by ensuring that each child receives age-appropriate immunizations . . .").

[250] *E.g.*, Colo. Rev. Stat. Ann § 25-215.5-102(1)(i) (West 2013) ("Water fluoridation is one of the most researched and cost-effective oral health interventions available . . . .").

[251] Burditt v. U.S. Dep't of Health & Human Servs., 934 F.2d 1362, 1376 (5th Cir. 1991).

[252] Kenyon v. Regan, 826 P.2d 140, 142 (Utah App. 1992).

[253] U.S. v. Hooker Chem. & Plastics (The Love Canal Case), 680 F.Supp. 546, 556 (W.D.N.Y. 1993).

[254] Miller v. Fed. Mine Safety & Health Review Comm'n, 687 F.2d 194, 195 (1982).

[255] W. Coast Hotel Co. v. Parrish, 300 U.S. 379, 394 (1937).

[256] Jacobson v. Mass., 197 U.S. 11, 26 (1905).

[257] Minn. Bd. of Health v. Brainerd, 241 N.W.2d 624 (1976).

D. The Melting Pot Federal Policy on Gender-Based Health Disparities

Similarly suggestive are variations in executive efforts to remedy disparities in access to health care. Federally, there are six offices charged with supporting improvements specifically in women's health. These officers are contained in the National Institutes of Health (NIH), the Department of Health and Human Services (HHS), the Centers for Disease Control (CDC), the Food and Drug Administration (FDA), the Health Resources and Services Administration (HRSA), and the Agency for Healthcare Research and Quality (ARHQ). Four of the six offices were established within a four-year period in the early 1990's.[258] Despite fifteen years of legislative efforts,[259] all but the NIH's Office

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[258] *Office of Research on Women's Health*, NAT'L. INST. OF HEALTH (Dec. 4, 2015) http://orwh.od.nih.gov/about/index.asp [http://perma.cc/R462-E3YS] (giving 1990 as the date of establishment); *Vision, Mission, History*, DEP'T OF HEALTH & HUMAN SERVS. (Oct. 7, 2010), http://www.womenshealth.gov/about-us/mission-history-goals/index.html [http://perma.cc/V7HM-A756] (1991); *About CDC Office of Women's Health*, CTRS. FOR DISEASE CONTROL & PREVENTION http://www.cdc.gov/women/about/index.htm [http://perma.cc/C9BZ-Q6FG] (last updated Jan. 20, 2015) (established in 1994); *About Office of Women's Health*, FOOD & DRUG ADMIN. (Dec. 2, 2014), http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofWomensHealth/default.htm [http://perma.cc/37JK-FBSA] (1994).

[259] Women's Health Office Act of 1994, H.R. 3874, 103rd Cong. (1994); Women's Health Office Act of 1995, H.R. 1736, 104th Cong. (1995); Women's Health Office Act of 1995, S. 427, 104th Cong. (1995); Women's Health Office Act of 1997, H.R. 920, 105th Cong. (1997); Women's Health Office Act of 1997, S. 91, 105th Cong. (1997); Women's Health Office Act of 2000, H.R. 4483, 106th Cong. (2000); Women's Health Office Act of 2000, S. 2675, 106th Cong. (2001); Women's Health Office Act of 2002, H.R. 1784, 107th Cong. (2001); Women's Health Office Act of 2002, S. 946, 107th Cong. (2001); Women's Health Office Act of 2003, S. 1304, 108th Cong. (2005); Women's Health Office Act of 2004, H.R. 4354, 108th Cong. (2004); Women's Health Office Act of 2005 H.R. 949, 109th Cong. (2005); Women's Health Office Act of 2005 S. 569, 109th Cong. (2005); Women's Health Office Act of 2007, H.R. 1072, 110th Cong. (2007); Women's Health Office Act of 2007, S. 612, 110th Cong. (2007); Women's Health Office Act of 2009, H.R. 3242, 111th Cong. (2009)

of Research on Women's Health were formally codified with the enactment of PPACA in 2010.[260]

The focus of each office might be thought of as an express extension to women—and often other demographic groups identified as experiencing significant disparities—of the umbrella agency's health-related priorities. The NIH office seeks to ensure that clinical research includes women and minorities, and that research on women's health and sex differences is expanded.[261] The HHS Office on Women's Health helps women and girls "achieve the best possible health" through policy, education, and model programs, a three-part mission that reflects HHS's broader goals as the top department on all matters related to health.[262] Similarly, the CDC's Office of Women's Health focuses on disease prevention and wellness for women and girls.[263]

In contrast, there is no federal office dedicated solely to men's health. Congress has contemplated mandating such an office thirteen times this century, but these bills have not passed even one house.[264] Instead, men's health is treated as a component of women's health: The CDC website on men's

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[260] PPACA § 2509(e) (codified at 42 U.S.C. 299c (2010) (AHRQ Office of Women's Health and Gender-Based Research); PPACA § 2509(f) (codified at 42 U.S.C. § 914 (2010)) (HRSA Office of Women's Health); PPACA § 2509(g) (codified at 21 U.S.C. 399b (2010) (FDA Office of Women's Health); PPACA § 3509(a) (codified at 42 U.S.C. § 237a) (2010)) (HHS Office on Women's Health); PPACA § 3509(b) (codified at 42 U.S.C. § 242s (2010)) (CDC Office of Women's Health). The NIH Office of Research on Women's Health was codified in the NIH Revitalization Act of 1993, Pub. L. No. 103-43.

[261] *Office of Research on Women's Health*, *supra* note 258.

[262] *Vision, Mission, History*, *supra* note 258.

[263] *About CDC Office of Women's Health*, *supra* note 258.

[264] Men's Health Act of 2000, H.R. 4653, 106th Cong. (2000); Men's Health Act of 2000, S. 2925, 106th Cong. (2000); Men's Health Act of 2001, H.R. 632, 107th Cong. (2001); Men's Health Act of 2002, S. 2616, 107th Cong. (2002); Men's Health Act of 2003, H.R. 1734, 108th Cong. (2003); Men's Health Act of 2003, S. 1028, 108th Cong. (2003); Men's Health Act of 2005, H.R. 457, 109th Cong. (2005); Men's Health Act of 2005, S. 228, 109th Cong. (2005); Men's Health Act of 2006, H.R. 5624, 109th Cong. (2006); Men's Health Act of 2007, H.R. 1440, 110th Cong. (2007); Men's Health Act of 2007, S. 640, 110th Cong. (2007); Office of Men's Health Act of 2007, H.R. 789, 110th Cong. (2007); Men and Families Health Care Act of 2009, H.R. 2115, 111th Cong. (2009).

health, for instance, cites its Office of Women's Health as the source of its content.[265] The HHS site uses the same header for its men's health page as for the women's health page, which, in the span of a few inches, references "women's health" four times.[266] Though one might question the equity of this prioritization, at least one court has decided that there is no equality issue presented for want of any injury.[267]

Despite studies suggesting that gender minorities are "disproportionately affected by adverse health outcomes compared to cisgender (i.e., non-gender minority) people,"[268] federal policy does not prioritize health issues for those who consider themselves gendered in non-traditional fashion. In fact, of the aforementioned six federal offices dedicated to women's health, none lists the health of trans- or other-gendered persons as a priority.

One other questionable consistency exists: as in the international context, women's health is often defined in terms of equity with men. Such formulation suggests that the collective goal is not truly to see that women achieve the highest state of healthy possible, but merely to no longer allow women to be left behind by the medical arts and sciences. As an equality matter, it is perhaps the best that law can do. However, as a matter of true equity and in accordance with the principles that underlie human rights and even population health, it should be understood as insufficient to seek to merely equalize access to health care.

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[265] *Men's Health*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/men/ [http://perma.cc/FA6T-KP83] (last updated Nov. 4, 2015).

[266] *Men's Health*, DEP'T OF HEALTH & HUMAN SERVS. http://www.womenshealth.gov/mens-health/ [http://perma.cc/32VY-8A5X] (last updated Jan. 10, 2011).

[267] Baldwin v. Sebelius, NO. 10CV1033 DMS (WMC), 2010 WL 3418436, at *1, *4 (S.D.Cal. Aug. 27, 2010).

[268] Sari L. Reisner et al., *Monitoring the Health of Transgender and Other Gender Minority Populations: Validity of Natal Sex and Gender Identity Survey Items in a U.S. National Cohort of Young Adults*, 14 BMC PUB. HEALTH 1224, 1224 (2014) (citing eight studies), *available at* http://www.biomedcentral.com/content/pdf/1471-2458-14-1224.pdf [http://perma.cc/WY9K-29BP]. *See also supra* text accompanying notes 199-205.

IV. SHIFTING PUBLIC POLICY IN THE ERA OF PPACA ERA AND HEALTH-IN-ALL-POLICIES

A. The Judiciary and Legislative Support for Prioritizing Health as a Public Policy

There is little doubt that a multitude of reasons can be given as to why we as a nation have not chosen to recognize a constitutional right to health. Moreover, there is little likelihood of a move toward recognizing health or health care as a right in the near future. Not only does the debate on the insurance reforms in PPACA suggest that health or health care as a right is politically untenable,[269] but also the reality of social resources are such that there must be limits to public sponsorship of medical care. Therefore, in this subsection this paper explores how emphasizing the equity of access to health care would tend to rectify the disparities. It does this by substituting, in the areas of disparity laid out *supra*, a public policy that puts a thumb on the scale in favor of health. Such a policy contrasts with the current model of balancing that serves merely to reinforce socio-legal gender biases outside of health care. To be clear, the goal is expressly not "Cadillac" access to care for all, nor even mere adequate access for every conceivable infirmity. After all, "public policy ought to maximize a nation's *health*, not healthcare."[270] Instead, then, the proposal is a specific and positive valuation of health that does not unnecessarily catalyze gender-based disparities, as does the status quo. As noted in the first section, this formulation is consistent with the conception of a health-related disparity as unnecessary, avoidable, unfair, and unjust.

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[269] *E.g.,* Michael McAuliff, *House Passes 56th Anti-Obamacare Measure*, HUFFINGTON POST (Feb. 4, 2015, 12:59 AM), http://www.huffingtonpost.com/2015/02/03/repeal-obamacare_n_6607080.html [http://perma.cc/8J56-6SM8] (describing the fifty-sixth vote by the House of Representatives against all or some of PPACA since 2011). *But see* Erin Merson, *3 Republicans Say No as House Again Votes Obamacare Repeal*, POLITICO (Feb. 3, 2015, 8:09 PM), [http://perma.cc/M94P-3VH6] (noting that the February 2015 vote is the first time any Republicans have ever voted against total repeal).

[270] Lamm, *supra* note 221, at 10.

Politically, such focus is more than tenable for the judicial branch. Though the number of people who dislike but are medically buoyed by PPACA is a startling commentary on the contemporary constituency,[271] and the judicial branch is less subject to political backlash than the legislature. This is not to suggest that public opinion should influence public policy—in fact, the two are unrelated except insofar as the public votes for its representatives and on state constitutional changes.[272] Nor is this a call for much-derided "judicial activism," but rather a shift as a matter of public policy in order to be accordant with the actions of the legislative and executive branches.[273]

It is a doctrinally sound shift also. Although the U.S. Supreme Court has not iterated a precise definition, "public policy" has been defined in the academic literature as "a policy the objective of which is the common good; it is a policy which its maker believes will serve the people well."[274] It has also been described as "the very essence of law":

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[271] For example, polls have shown that while public opinion of PPACA has been middling, Americans overwhelmingly support the provisions within it. *See* Patricia Zengerle, *Most Americans Oppose Health Law But Like Provisions*, REUTERS (June 24, 2012, 1:13 AM), http://www.reuters.com/article/us-usa-campaign-healthcare-idUSBRE85N01M20120625 [http://perma.cc/K7PJ-7T4W] (citing a Reuters/Ipsos poll); MOLLYANN BRODIE ET AL., KAISER HEALTH TRACKING POLL: MARCH 2013 (describing monthly public opinion research on opinions of specific provisions and comparing those to poor awareness that PPACA is the source), *available at* https://kaiserfamilyfoundation.files.wordpress.com/2013/03/8425-t1.pdf [http://perma.cc/5WVE-Q7B2]. Similarly telling is the "viral" nature of a story of an opponent of PPACA who soon found himself needing to access care yet was financially unable to do so. *See* Ann Doss Helms, *Who Should Save Sight of SC Man Who Can't Afford Surgery?*, CHARLOTTE OBSERVER (May 12, 2015 2:00 AM), http:// www.charlotteobserver.com/news/business/health-care/health-care-challenge-blog/article20696283.html [https://perma.cc/Z99Q-4NYZ].

[272] Richard H.W. Maloy, *Public Policy—Who Should Make it in America's Oligarchy?*, 1998 DET. C.L. REV. 1143, 1155 (1998).

[273] Erich Vieth & James P. Lemonds, *Whence Public Policy?* 52 J. Mo. B. 239, 243 (1996) (calling judicial legislating "the most serious and recurrent objection to public policy" yet noting that it is "a legitimate tool of [Judges'] trade").

[274] Maloy, *supra* note 272, at 1145, 1154.

The very considerations which judges most rarely mention, and always with an apology, are the secret root from which the law draws all the juices of life. I mean, of course, considerations of what is expedient for the community concerned. Every important principle which is developed by litigation is in fact and at bottom the result of more or less definitely understood views of public policy; most generally, to be sure, under our practice and traditions, the unconscious result of instinctive preferences and inarticulate convictions, but nonetheless traceable to views of public policy in the last analysis. [275]

Because public policy cannot and should not exist in a judicial vacuum, devoid of any explanation for its occasion,[276] it is worth noting that specifically in regard to PPACA, the Court has noted the individual mandate of healthcare insurance as "Congress's solution to these problems" of financial access to care.[277] Thus, to weigh the congressional determination that remedying disparities in access to care is a worthy goal would require the courts merely to follow what seems an express greater good in the public's interest. This is the essence of good public policy.

Despite the lack of express definition by the Court, it has been relatively consistent in assuming that public policy is to be made by the people through the legislature.[278] Thus insofar as Congress has made a clear statement of public policy, the courts should follow suit absent Constitutional invalidity.[279] Given that statutory rights often form the basis of judicial policy concerns, it would be most consistent with the values set forth by Congress for jurisprudential policy to

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[275] Vieth & Lemonds, *supra* note 273, at 239 (summarizing and then quoting Justice Oliver Wendell Holmes).

[276] *Id.* at 245-46.

[277] Nat'l Fed. Of Indep. Bus. v. Sebelius, 132 S.Ct. 2566, 2585 (2012).

[278] Maloy, *supra* note 272, at 1144-45. *See also* Nat'l Fed. Of Indep. Bus., 132 S.Ct. at 2579 ("[W]e possess neither the expertise nor the prerogative to make policy judgments. Those decisions are entrusted to our Nation's elected leaders, who can be thrown out of office if the people disagree with them. It is not our job to protect the people from the consequences of their political choices.").

[279] *Id.* at 1168-69.

more accurately reflect the increased financial access to care established by PPACA.[280]

Also supporting judicial recognition of a public policy shift is the relatively new Health-in-All-Policies (HiAP) approach of population health. "At its core, Health in All Policies represents an approach to addressing the social determinants of health, which are the key drivers of health outcomes and health inequities."[281] In short, HiAP supplements population health by emphasizing the influence on health of policies that are not traditionally associated with public health.[282] Indeed, "HiAP provides a means to identify and avoid the unintended impacts of public policy that can be detrimental to the health of populations or subgroups of the population."[283] An express goal is remedying health inequities.[284] Because, as delineated above, SDOH also influence access to care, the increasing pervasiveness of HiAP should have implications for judicial interpretation also, and particularly as public policy.

For example, it is known that "today nearly all aspects of the built environment are shaped by law,"[285] suggesting that law has a significant role to play in ensuring that access to care is not defeated by poor civil design. For example,

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[280] Other scholars have also viewed PPACA as changing the public policy of health care in various contexts. *See, e.g.,* Fuse Brown, *supra* note 224 (arguing that PPACA created a durable right to health care); Karen Oehme & Nat Stern, *The Case for Mandatory Training on Screening for Domestic Violence in the Wake of the Affordable Care Act*, 17 U. PA. J. L. & SOC. CHANGE 1, 1, 13 (2014) (calling PPACA a "historic opportunity" to address domestic violence as a public health and criminal matter); Sara Rosenbaum, *Law and the Public's Health*, 126 PUB. HEALTH REP. 130, 130 (2011) (terming PPACA a "watershed" in public health policy), *available at* http://www.ncbi.nlm.nih.gov/pmc/ articles/ PMC3001814/pdf/phr126000130a.pdf [http://perma.cc/FD9X-SYCU].

[281] LINDA RUDOLPH ET AL., AM. PUB. HEALTH ASS'N, HEALTH IN ALL POLICIES: A GUIDE FOR STATE AND LOCAL GOVERNMENTS 8 (2013), *available at* https://www.apha.org/~/media/files/pdf/fact%20sheets/ health_inall_policies_guide_169pages.ashx [https://perma.cc/4BJP-FM96].

[282] For various definitions of Health in All Policies, see *id.* at 138.

[283] WHO HIAP, *supra* note 30, at 4.

[284] *Id.* at 40; RUDOLPH ET AL., *supra* note 281, at 8.

[285] Wendy Collins Perdue, Lesley A. Stone & Lawrence O. Gostin, *The Built Environment and Its Relationship to the Public's Health: The Legal Framework*, 93 AM. J. PUB. HEALTH 1390, 1390 (2003).

Perdue, Stone, and Gostin note that urban areas where constituents are unable to advocate politically are the first places that hospitals and other healthcare clinics close.[286] Not only does such a situation reduce access to those types of medical facilities, but the providers that are left experience greater strain in trying to deliver care, further decreasing access to care.[287] By prioritizing health, the physical environment is built in a way that facilitates access to care. The HiAP approach would ensure that everyone from city councilmen making zoning determinations to civil engineers designing the city structure would consider the impact on access to care in their decision-making. HiAP works as congruently with mitigation of the other SDOH.

B. Access to Care Redux

So how would health as a public policy priority effect equitable access to care by all people regardless of gender?

Justice Oliver Wendell Holmes observed that "[t]he very meaning of public policy is the interest of others than the parties and that interest is not to be at the mercy of the defendant alone."[288] Presumably the Justice would not make it at the mercy of the plaintiff either. Through health as a public policy priority, the judiciary might better balance doctrines that interfere with access to care. In the *Hobby Lobby* case, instead of truly considering only whether cost-free contraceptive coverage by the business's insurer constituted an undue burden on religion, the Court would have to weigh the impact on health and access to care. This analysis would look more like balancing of religious freedom and other governmental initiatives that the Court has undertaken. For instance, theoretically applying the same federal statute at issue in *Hobby Lobby*, the Religious Freedom Restoration Act, to the matter of taxation, the Court in *Hobby Lobby* maintained that the burden to the tax system would be too great.[289] Indeed, the majority predicted "chaos."[290]

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[286] *Id.* at 1391.
[287] *Id.*
[288] Beasley v. Tex. & Pac. Ry. Co., 191 U.S. 492, 498 (1903).
[289] Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751, 2784 (2014).
[290] *Id.*

Although the Court does not acknowledge it, there is a great distinction in the value it places on the benefit of taxes to operations government versus the difficulty of excluding religious objectors, and the benefit of access to prophylactic care to female employees versus the difficulty of excluding the objectors. That is, the "fundamental point" of whether there is a "less restrictive alternative"[291] obscures the counter-claims and renders them of no import. The dissent likens the inadequate weight given by the Court to the access to care claims to a right to swing one's arms, which, as the apologue goes, ends where another's nose begins.[292]

Thus, by applying to health those same concerns of the impracticality of a two-tiered system of taxes, the Court would have to weigh the impairment on access to care presented by the arguments of Hobby Lobby. Rather than dismissively stating that female employees still have access because the general public can absorb their cost-share,[293] as the majority did, the Court would balance, as suggested by the dissent, that there is significant impact on access to care.[294] This is particularly true where precedent may allow a future court to further diminish the importance of the health populace where, for instance, the effect is somewhat more than the "precisely zero" amount that the *Hobby Lobby* Court found.[295] Although having a direct impact on the access to care by women, as it was at issue in the case, this suggested collectivist public policy understanding of health would improve access to care by men and women both and on an individual and population level.[296]

Accordant is *King* and associated cases, wherein the plaintiffs contended that tax credits and subsidies should not be available in exchanges set up by or in partnership with the federal government. Those Courts would be free to disregard the petitioner's claims based not only on legislative history,

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[291] *Id.*

[292] *Id.* at 2791 (Ginsburg, J., dissenting).

[293] *Id.* at 2760.

[294] *Id.*

[295] *Id.* at 2760.

[296] *See* Mahajan, *supra* note 207, at 834 ("A renewed focus on the collectivity in public health might lead to more sustainable and equitable arrangements that appreciate state's responsibilities to the larger public good, which are indispensable to ensuring health to the individual.").

which they collectively found unhelpful,[297] but also on the presumption that Congress intended to increase access to care nationwide and not at the whim of ideologically opposed state governors.[298] Given the attempts to wholesale modify the entire private healthcare insurance market, it is an assumption grounded in logic that efficacious change could not be accomplished by increasing insurance availability for only select citizens.[299] It is also an assumption grounded in a health-prioritizing perspective. That the Kings may thusly genuinely suffer harm because of this proposed public policy is consistent with public health law at large because that doctrine values health—and access to health care—over individual objection.

In some ways the circuit courts in these cases recognized such a value. Both the *Pruitt* and *Halbig* courts supposed that they were "ensuring that policy is made by elected, politically accountable representatives, not by appointed life-tenured judges" by holding in favor of the plaintiffs.[300] Though implicitly tautological in nature due to the courts' notice of both the "high stakes"[301] of the case and PPACA's "lofty goals"[302] while holding in contrary fashion to both, the recognition of the importance of public policy in these decisions suggests that there may be a judicial want for a mechanism for favoring health. The court in *Halbig* noted,

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[297] *Compare* Halbig, 758 F.3d at 407-12 ("[T]he legislative record provides little indication one way or the other of congressional intent"), *and King*, 759 F.3d at 372 ("[N]othing in the legislative history of the Act provides compelling support for either side's position"), *with Pruitt*, 758 F.3d at 1088 nn.15-16 (describing why it found the legislative history irrelevant).

[298] The Fourth Circuit effectively came to this conclusion, catalyzing the *King* petition for certiorari, when it held that Chevron deference meant accepting the plausible determinations of the Internal Revenue Service. *See* King, 759 F.3d at 368-69.

[299] *See, e.g.*, Halbig, 758 F.3d at 406 n.10 (discussing increased access under PPACA of the Children's Health Insurance Program, which uses the same language at issue in the case before the court, and observing that "we recognize the oddity of requiring some states and not others to take this step . . .").

[300] Pruitt, 51 F.Supp.3d at 1092; Halbig, 758 F.3d at 412.

[301] Pruitt at 1091.

[302] Halbig, 758 F.3d at 412.

for instance, that it "reach[ed] [its] conclusion, frankly, with reluctance."[303]

That reluctance was shared by the Supreme Court, but only because it found the text ambiguous and thus sought to "produce[] a substantive effect that is compatible with the rest of the law."[304] Although the Court subscribed to the belief that "Congress passed the Affordable Care Act to improve health insurance markets, not to destroy them[,]"[305] it does not expressly consider that the health of the populace, insofar as access to care is a determinant of health, should be a sufficient catalyst in holding against the plaintiffs.

It seems, then, that there is a trend of courts unwilling to protect access to care by individuals—and often along gender lines—unless there exists an economic harm to the masses. Such harm, of course, would belie the definition of health and misunderstand access to health care. Thus because "the very process of litigation around socioeconomic rights tends to produce a relative sidelining of the public good,"[306] and because, as described above, there is no right to health, there should be broad judicial notice that the discrete issues highlighted by PPACA-related lawsuits are not necessarily actions designed to benefit the masses, though the petitioners may so believe. But "[j]udges must be careful that, by the use of objectivist abstractions, they don't overly distance themselves from the human beings their decisions will effect [sic]."[307] If the courts will not concern themselves with access to care by the population at large, who will?

One need only consider the *Baldwin* case mentioned *supra* to find an example of the clear inequity that results from failure to appreciate the value of health and health care amidst other doctrinal concerns. In that case, the court found that the temporal and financial resources provided to women's health did not create inequality for men, but not as a matter of health and certainly not in terms of the gender

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303 *Id.*

304 King v. Burwell, 135 S.Ct. 2480, 2484 (2015) (quoting United Sav. Ass*'n* of Tex. v. Timbers of Inwood Forest Assocs., 484 U.S. 365, 371 (1988)).

305 *Id.* at 2496.

306 Mahajan, *supra* note 207, at 829.

307 Vieth & Lemonds, *supra* note 273, at 246.

health disparity that was alleged.[308] Rather, the court responded to the plaintiff's claimed harm dismissively with only a conclusory statement that there was insufficient demonstration of any injury.[309]

By putting Baldwin's claim in the context in which it was made—that is, relative to the PPACA provisions that finally codified multiple offices of women's health, all of which expressly seek to improve various forms of access to care by women—one must consider that perhaps men's health is undervalued in this law and policy. Through a public policy lens that emphasizes health, this is clearly a gender-based disparity that is unnecessary, avoidable, unfair, and unjust. After all, the offices were created and funded because research will follow dollars, suggesting that there may be decreased economic incentive to prioritize men's health. And though Congress and the agencies themselves must—and should—mean to improve women's health, they surely do not intend to do so at the expense of men. Disparity cannot be remedied through complete diversion; rather, it is through the affirmative act of prioritizing parity that inequality is resolved.

Yet health as a public policy priority does not require that access always and necessarily be favored. In *National Federation of Independent Businesses*, for example, which challenged, *inter alia*, the mandatory Medicaid expansion, nullification might still have resulted. After all, the Court's opinion effectively rested on antifederalist public policy that precludes the coercion of the states by the federal government.[310] Because the states' entire pool of Medicaid dollars were at risk,[311] finding the expansion unduly coercive was likely.

Nonetheless, through increased prioritization of health the Court at least would have had additional support in noting the legislative goals in mandating—and providing

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[308] Baldwin v. Sebelius, NO. 10CV1033 DMS (WMC), 2010 WL 3418436, at *4 (S.D.Cal. Aug. 27, 2010).

[309] *Id.*

[310] Nat'l Fed. Of Indep. Bus. v. Sebelius, 132 S.Ct. 2566, 2601-07 (2012) ("[T]he financial 'inducement' Congress has chosen is much more than 'relatively mild encouragement'—it is a gun to the head."). *Id.* at 2604.

[311] *Id.*

long-term funding for—the expansion. Consider the plethora of instances of PPACA that assume the Medicaid expansion, including the nonexistence of credits and subsides for those under 100% FPL and the relatively low value of the financial assistance for those covered under the expansion. Had Congress not contemplated a blanket increase in access to care for the indigent, particularly as opposed to the option to forego insurance and pay a penalty for those of less modest income, the body would not have created the dual tiers.

The Court also could then have considered the impact of no expansion on the healthcare system at large. Because uncompensated care costs average $50 billion per year nationally, it would not correct the issue of access to care if whole states were left without coverage for their poor.[312] Compounding the effect is that, as explicated above, the poor are more likely to lack both employment-based and private insurance, and they are also more likely to be medically indigent, suffering greater mortality and morbidity than do those with higher incomes. So while the Medicaid expansion may have still been deemed too coercive to withstand constitutional muster, under the public policy prioritization of health and access to care proposed herein, the Court may have at least considered the effect on health and access to care of making optional the expansion.

Greater gender parity in access to care would result because the Medicaid expansion gave to indigent, childless men an option for coverage that does not otherwise exist. Traditionally, however, although private healthcare insurance is broadly obtained in similar numbers by men and women, but in lesser numbers by the transgender, men have had the greatest independent insurance coverage. This disparity is due to a recent national history that ties healthcare insurance to employment during working years, along with the subsequent availability of Medicare in retirement only for those with a sufficient pattern of work. As noted above, healthcare insurance coverage and financial barriers are widely accepted measures of access to health care.

To the extent that PPACA sought to remedy disparities in financial access to care, a public policy favoring health would

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[312] DELEIRE ET AL., *supra* note 145, at 3.

tend to make enforcement of individual provisions easier, in part by facilitating a joint effort. For instance, the failure of insurers to implement PPACA cost-share preventive provisions implicates state governments, who are tasked with enforcing insurance laws. While legal education of citizens on rights to challenge insurance coverage denials would surely decrease the number of abuses, state department of insurance regulators are well-positioned to create systemic changes by prioritizing the issue. Although law already encourages this enforcement, the federal government could reinforce its commitment and its law through limited grants that might be made available to entice states to prioritize this issue.[313]

With regard to state legislatures, at a minimum and as a matter of federalism, they may not conflict with federal precedent once a public policy on a matter has been established.[314] Examples of the efficacy of health and access to care as a public policy priority might be found in the Illinois legislature's current attempt to create a more patient- and health-friendly balance between the genuine religious objections of Catholic providers and the patients who rely on them for health care.[315] That bill would require that healthcare providers inform patients of their options rather than merely refusing to provide the requested care, in the process under-informing the patient.[316] The text of the bill contains an express statement of impetus: it is "the public policy of the State of Illinois to ensure that patients receive timely access to information and medically appropriate care."[317] Disallowing further expansion of conscience clauses as a matter of public policy increases access to care across the board, particularly for those in rural areas, and especially for women to the extent that their access is disproportionately

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[313] *See* Oehme & Stern, *supra* note 280, at 17-20 (discussing PPACA as creating an "opportunity for cooperative federalism").

[314] *See* Maloy, *supra* note 272, at 1169 (noting that courts may "strike down a state's public policy [if] there is a conflict with federal public policy").

[315] Health Care Right of Conscience Act, S.B. 1564, 99th Leg., Reg. Sess. (Ill. 2015).

[316] *Id.* § 6.1.

[317] *Id.* § 2.

affected by a refusal to provide medical treatment or prescriptions drugs.

V. CONCLUSION

It has been observed that as a nation we "limit healthcare in one of the cruelest ways that any nation can do so–by simply leaving people out of the system."[318] Although limitations in access to health care may be inevitable, it should be unacceptable that law and policy have embedded gender-based disparities into the access equation. These gender-based disparities exist through codified schema generally designed to facilitate access to care, both as an accidental and deliberate by-product of philosophies and doctrines that are granted greater importance than access to care. With regard to the failure of law to increase access to care, remediable areas include those that create disparities in access through a deprioritization of health. Making health a public policy priority is appropriate given that PPACA changed the healthcare landscape; this paper is not the first to suggest that we are now in an era of even more deliberate efforts to erase disparities in access to care. The judiciary and states should follow suit and recognize the emphasis that the other federal branches have placed on health in order to avoid disparities that are unnecessary, avoidable, unfair, and unjust.

[318] Lamm, *supra* note 221, at 9.

SECTION 1557 OF THE AFFORDABLE CARE ACT: AN EFFECTIVE MEANS OF COMBATTING HEALTH INSURERS' DISCRIMINATION AGAINST INDIVIDUALS WITH HIV/AIDS?

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I. INTRODUCTION

Before the passage of the Affordable Care Act ("ACA"), health insurers either completely refused to provide coverage

to individuals with a preexisting condition,[1] or charged such individuals grossly higher rates for coverage than those without a preexisting condition.[2] Because HIV/AIDS qualifies as a preexisting condition,[3] these insurance practices have historically applied to individuals with HIV/AIDS. However, the passage of the ACA changed that landscape. But before proceeding further with an explanation of the current landscape, a brief look at some of the key components of the ACA is necessary.

A. A Quick Breakdown of the ACA

The broad purpose of the ACA is to expand health insurance to make it accessible to more Americans.[4] The ACA accomplishes this goal with five main mechanisms: (1) health insurance exchanges,[5] also referred to as health insurance marketplaces, (2) the individual mandate,[6] (3) premium tax credits,[7] (4) the guaranteed issue requirement,[8] and (5) the community rating requirement.[9]

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1 Mark Bolin, *The Affordable Care Act and People Living with HIV/AIDS: A Roadmap to Better Health Outcomes*, 23 ANNALS HEALTH L. 28, 40-41 (2014); *The Affordable Care Act and HIV/AIDS*, AIDS.GOV, https://aids.gov/federal-resources/policies/health-care-reform/ [http://perma.cc/BG4Y-B69Q] (last revised Mar. 6, 2015).

2 *The Affordable Care Act and HIV/AIDS*, *supra* note 1; Bolin, *supra* note 1; Alan I. Widess, *HIV Infection Among Women of Reproductive Age, Children, and Adolescents: To Insure or Not to Insure Persons Infected with the Virus that Causes AIDS*, 77 IOWA L. REV. 1617, 1680 (1992).

3 *The Affordable Care Act and HIV/AIDS*, *supra* note 1.

4 Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566, 2580 (2012).

5 42 U.S.C. § 18031(b)(1) (2015); 42 U.S.C. § 18041(c)(1) (2015).

6 26 U.S.C. § 5000A (2015).

7 26 U.S.C. § 36B (2015).

8 42 U.S.C. §§ 300gg-300gg–7 (2015).

9 *Id.*

1. Health Insurance Exchanges

The health insurance exchanges are online marketplaces that individuals can utilize to compare and purchase health insurance plans.[10] The exchanges are meant to be a sort of one-stop shop for health insurance.[11] The idea is that each State's exchange will provide people that are looking for health insurance with an opportunity to view and compare plans side-by-side; this format was designed to increase competition between health insurers and thus promote better and cheaper health plans.[12] The ACA also uses the exchanges as a mechanism for regulation. Many of the ACA's regulations apply only to plans that are offered and obtained through the exchanges.[13]

2. The Individual Mandate

The individual mandate, put simply, requires Americans to purchase minimum essential coverage health insurance or else pay a tax penalty.[14] However, the ACA's unaffordability exemption provides that if the cost of the cheapest plan on a State's exchange exceeds 8% of an individual's income, that person is not required to purchase health insurance and is also exempt from the tax penalty that would normally be assessed to persons who do not have health insurance.[15]

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[10] *Health Insurance Marketplace*, HEALTHCARE.GOV, https://www.healthcare.gov/glossary/health-insurance-marketplace-glossary/ [http://perma.cc/F5NW-DWSA] (last visited Sept. 16, 2015).

[11] *Creating a New Competitive Health Insurance Marketplace*, CMS.GOV, http://www.cms.gov/CCIIO/Resources/Marketplace-Grants/ [http://perma.cc/34QW-5VYJ] (last visited Sept. 16, 2015).

[12] *Health Insurance Marketplace*, *supra* note 10.

[13] Bernadette Fernandez, *Health Insurance Exchanges Under the Patient Protection and Affordable Care Act (ACA)*, CONGRESSIONAL RESEARCH SERVICE (Jan. 31, 2013), https://www.fas.org/sgp/crs/misc/R42663.pdf [https://perma.cc/HKW5-3QMC].

[14] 26 U.S.C. § 5000A (2015).

[15] 26 U.S.C. § 5000A(e)(1)(A); *Exemptions from the Fee for Not Having Health Insurance*, HEALTHCARE.GOV, https://www.healthcare.gov/fees-exemptions/exemptions-from-the-fee/ [http://perma.cc/457Y-58T6] (last visited Sept. 16, 2015).

There are also a number of other exemptions that allow individuals to not purchase health insurance and still avoid the tax penalty, most of which involve circumstances in which an individual is under financial stress.[16] However, since the ACA expanded Medicaid to cover all individuals between the ages of 18 and 65 whose income does not exceed 138% of the Federal Poverty Level, many of the individuals that qualify for these exemptions that stem from a low-income will still have access to health insurance.[17]

3. Premium Tax Credits

More relevant here are the premium tax credits that the ACA provides. These tax credits are provided to low- and middle-income Americans to subsidize the premiums of insurance they purchase through the exchanges. Because of this function, they are often referred to as premium subsidies.[18] Premium subsidies are available to individuals and families with an annual income of up to 400% of the Federal Poverty Level.[19] These premium subsidies are paid by the Federal government directly to a qualifying individual's insurance provider in order to subsidize the qualifying individual's premiums under the plan.[20]

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[16] *Exemptions from the Fee for Not Having Health Insurance*, *supra* note 15.

[17] *Medicaid Expansion & What It Means for You*, HEALTHCARE.GOV, https://www.healthcare.gov/medicaid-chip/medicaid-expansion-and-you/ [http://perma.cc/EQ68-UCJ7] (last visited Sept. 16, 2015).

[18] 26 U.S.C. § 36B (2015); *Premium Tax Credit*, HEALTHCARE.GOV, https://www.healthcare.gov/glossary/premium-tax-credit/ [http://perma.cc/6B9U-EPQ4] (last visited Sept. 16, 2014).

[19] *Explaining Health Care Reform: Questions about Health Insurance Subsidies*, KAISER FAMILY FOUND. (Oct. 27, 2014), http://kff.org/ health-reform/issue-brief/explaining-health-care-reform-questions-about-health/ [http://perma.cc/XM22-P7FK].

[20] 42 U.S.C. § 18082 (2015); *Subsidies: Tax Credits for Eligible Consumers*, ASSURANT HEALTH, http://www.assuranthealth.com/corp/ah/HealthCareReform/Premium-Subsidy.htm [http://perma.cc/ D4FZ-TPLJ] (last visited Sept. 16, 2015); *Premium Tax Credit*, *supra* note 18.

4. The Guaranteed Issue Requirement

Also very pertinent to this situation is the ACA's guaranteed issue requirement. This requirement means that health insurers may not deny any individual coverage because that person has a preexisting condition,[21] such as HIV/AIDS.[22]

5. The Community Rating Requirement

The community rating requirement makes it illegal for health insurers to discriminate against individuals with a preexisting condition,[23] such as HIV/AIDS,[24] in terms of the price of coverage. This requirement means that health insurers cannot charge individuals with a preexisting condition a higher rate for coverage than individuals without a preexisting condition.[25] However, there are a few exceptions. Health insurers can still charge higher rates to individuals based on age, tobacco use, and geography.[26] This means that rates may be higher for individuals that are older, use tobacco, or live in a geographic region of the U.S. in which medical costs are higher than average.[27]

B. The Post-ACA Landscape: Three Insurance Practices

As has just been briefly explained, the ACA has many moving parts that together create an environment that is supposed to bring access to affordable, quality health insurance to everyone, regardless of their health status or history. The guaranteed issue and community rating

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[21] 42 U.S.C. §§ 300gg-300gg–7 (2015).

[22] *Health Insurance Market Reforms: Rate Restrictions*, KAISER FAMILY FOUND. (June 2012), http:// kaiserfamilyfoundation. files.wordpress.com/2013/01/8328.pdf [http://perma.cc/27GR-G2Z4]; *The Affordable Care Act and HIV/AIDS*, *supra* note 1.

[23] 42 U.S.C. §§ 300gg-300gg–7 (2015).

[24] *Health Insurance Market Reforms: Rate Restrictions*, *supra* note 22.

[25] *Id.*

[26] 42 U.S.C. §§ 300gg (2015).

[27] *Health Insurance Market Reforms: Rate Restrictions*, *supra* note 22.

requirements are two of the most important of these moving parts. Together, they mean that health insurers can no longer refuse to cover individuals with HIV/AIDS[28] or charge such individuals a higher rate for coverage than those without the disease.[29]

However, some insurers are finding more subtle ways to continue discriminating against individuals with HIV/AIDS in an attempt to discourage them from enrolling in their plans.[30] Specifically, these insurers have continued to discriminate in three main ways. First, many insurers are discriminating via the design of their prescription drug formularies.[31] These insurers design their formularies with

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[28] *The Affordable Care Act and HIV/AIDS*, *supra* note 1.

[29] 42 U.S.C. §§ 300gg, 300gg–2 (2015).

[30] Michelle Andrews, *Some Plans Skew Drug Benefits to Drive Away Patient, Advocates Warn*, KAISER FAMILY FOUND. (July 8, 2014), http://www.kaiserhealthnews.org/stories/2014/july/08/some-plans-skew-drug-benefits-to-drive-away-patients-advocates-warn.aspx [http://perma.cc/V2VU-VBLG].

[31] Letter from Thomas D. Yates, Exec. Dir., AIDS Legal Council of Chi. & John Peller, CEO, AIDS Found. of Chi., to Andrew Boron, Dir., Ill. Dep't of Ins., 13 (Apr. 1, 2014) (on file with AIDS Found. of Chi.), *available at* http://www.afc.01.thirdwaveweb.com/resources/legacy/images/2014/ALCC_AFC_Jenner_letter_re_HIV_meds_marketplace_updated_Apr_1_2014.pdf [http://perma.cc/Q9XY-T6UX]; *See* Press Release, AIDS Found. of Chi., Cost of HIV Medications in the Illinois Health Insurance Marketplace, 1 (Mar. 13, 2014) (on file with AIDS Found. of Chi.), *available at* http://www.hivhealthreform.org/wp-content/uploads/2014/03/IL-HIV-Med-coverage-Marketplace-March-20-2.pdf [http://perma.cc/5W4T-EDZV]; Letter from Robert Greenwald, Dir., Harvard Law Sch. Ctr. for Health Law & Policy Innovation, to Kathleen Sebelius, Sec'y of the Dep't of Health & Human Serv. (Oct. 21, 2013) (on file with Harvard Law School Center for Health Law & Policy Innovation) *available at* http://www.hivhealthreform.org/wp-content/uploads/2013/10/HHS-letter-with-Insurer-letter-and-contacts-enclosed.pdf [https://perma.cc/84N4-RQGN]; Michelle Andrews, *Complaint Says Insurance Plans Discriminate Against HIV Patients*, NPR (July 8, 2014), http://www.npr.org/blogs/health/2014/07/08/329591574/complaint-says-insurance-plans-discriminate-against-hiv-patients [http://perma.cc/8QBJ-4XDY]; Andrews, *supra* note 30; Fair Pricing Coal., *Health Insurance Marketplace Plans and People Living with HIV and/or Viral Hepatitis: The Affordable Care Act Requires Fair Drug Pricing and Access*, FPC, http://fairpricingcoalition.org/wp-content/ uploads/ 2014/02/FPC-QHP-Policy-Guide-Feb-2014-1.pdf [http://perma.cc/R89M-MB68] (last visited Sept. 16, 2014).

all or most of the effective HIV/AIDS medications on the highest tiers.[32] These tiers are characterized by very high cost sharing and deductibles, thus, making the medications placed on these tiers virtually unaffordable.[33] For brevity, I will often refer to this practice as "high tiering." Second, many insurers discriminate against individuals with HIV/AIDS, who take HIV/AIDS medications, by imposing step-therapy requirements.[34] Step-therapy requirements force individuals to use less effective drugs in order to prove them to be ineffective before qualifying for the use of effective medications.[35] And third, these insurers impose pre-authorization requirements for HIV/AIDS medications.[36] Pre-authorization requirements force individuals to obtain permission from their insurer before every refill of their medications.[37] These three insurance practices undermine the broad goal of the ACA and its provisions, that prohibit

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[32] Yates, *supra* note 31, at 16; *See* AIDS Found. of Chi., *supra* note 31; Greenwald, *supra* note 31; Andrews, *supra* note 31; Andrews, *supra* note 30; Fair Pricing Coal., *supra* note 31.

[33] Yates, *supra* note 31, at 16; *See* AIDS Found. of Chi., *supra* note 31; Andrews, *supra* note 30.

[34] Yates, *supra* note 31, at 2; AIDS Found. of Chi., *Illinois Governor's Office Warns ACA Health Insurance Plans Against HIV/AIDS Discrimination*, [hereinafter *Illinois Governor's Office*] AIDSCHICAGO.ORG (May 27, 2014), http://www.aidschicago.org/illinois-news/891-illinois-governors-office-warns-aca-health-insurance-plans-against-hivaids-discrimination [http://perma.cc/L3GC-EBUR]; Letter from the Steering Comm. of the HIV Health Care Access Working Group, to the Office for Civil Rights, U.S. Dep't of Health & Human Servs. (Sept. 30, 2013) (on file with the Steering Comm. of the HIV Health Care Access Working Group), *available at* http://www.nastad.org/Docs/ 123257_ HHCAWG%20Non%20Disc%20RFI%20Response%20FINAL.pdf. [http://perma.cc/CX39-HEKS].

[35] Yates, *supra* note 31, at 2; *see also Illinois Governor's Office*, *supra* note 34; Steering Comm. of the HIV Health Care Access Working Group, *supra* note 34.

[36] Yates, *supra* note 31, at 2; *see* HIV Med. Ass'n. et. al, *Doctors & Advocates Demand Better Health Coverage for HIV & Hepatitis*, HIVANDHEPATITIS.COM (Feb. 7, 2014), http:// www.hivandhepatitis.com/ hiv-policy-advocacy/4514-medical-experts-and-advocates-urge-better-health-coverage-for-people-with-hiv-and-hepatitis [http://perma.cc/ 5EP7-CES4]; *see also Illinois Governor's Office*, *supra* note 34; Steering Comm.of the HIV Health Care Access Working Group, *supra* note 34.

[37] Yates, *supra* note 31, at 2; *see* HIV Med. Ass'n. et. al, *supra* note 36; *see also Illinois Governor's Office*, *supra* note 34; Steering Comm. of the HIV Health Care Access Working Group, *supra* note 34.

discrimination based on preexisting condition, by discriminating against individuals with HIV/AIDS, discouraging such individuals from enrolling in health plans, and making health insurance less accessible to them.

C. Section 1557 of the ACA

Fortunately, § 1557 of the ACA may be an effective weapon in combating these three discriminatory practices. Section 1557 is the ACA's broad nondiscrimination provision. In relevant part, it provides:

> (a) In general. Except as otherwise provided for in this title (or an amendment made by this title), an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments). The enforcement mechanisms provided for and available under such title VI, title IX, section 504, or such Age Discrimination Act shall apply for purposes of violations of this subsection.[38]

Most relevant here is that §1557 prohibits discrimination "on the ground . . . prohibited under section 504 of the

[38] Patient Protection and Affordable Care Act, Pub. L. No. 148, § 1557, 124 Stat. 119 (2010) (codified as amended at 42 U.S.C. § 18116 (2010)).

Rehabilitation Act of 1973,"[39] which prohibits discrimination on the basis of disability.[40] Since HIV/AIDS has been held by the Supreme Court—and other courts—to be a disability,[41] §1557 through § 504 of the Rehabilitation Act prohibits discrimination based on HIV/AIDS. However, the analysis of § 1557 as applied to these three insurance practices does not end there.

D. Roadmap

This note seeks to determine whether § 1557 will be effective at ending, or at least reducing, insurers' discrimination against individuals with HIV/AIDS in the form of high tiering, step-therapy and pre-authorization requirements. To make this determination, this note will adhere to the following itinerary. First, this note will explain in more detail the detrimental effects of the three aforementioned health insurance practices on individuals with HIV/AIDS in order to facilitate an understanding as to why they should be opposed. Next, it will examine what entities § 1557 applies to. Then, this note will discuss whether § 1557 prohibits intentional discrimination, and if so, whether these three insurance practices constitute such prohibited intentional discrimination. Next will be a discussion of whether § 1557 prohibits disparate impact discrimination, and if so, whether such discrimination is present in this case. And finally, a policy consideration for the application of § 1557 will be discussed.

II. THE THREE DISCRIMINATORY HEALTH INSURANCE PRACTICES

Without an understanding of the nature of the HIV/AIDS virus and the standard of care for treating it, the harmful effects these three aforementioned insurance practices have

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[39] 42 U.S.C. § 18116(a) (2015).

[40] 29 U.S.C. § 794(a) (2015).

[41] *E.g.,* Bragdon v. Abbott, 524 U.S. 624, 630-47 (1998) (ADA); Doe v. Cnty. of Ct., PA, 242 F.3d 437, 447 (3d Cir. 2001) (Rehabilitation Act); Chalk v. U.S. Dist. Ct. C.D. Cal., 840 F.2d 701, 705-09 (9th Cir. 1988) (Rehabilitation Act).

on individuals with HIV/AIDS cannot be fully appreciated. Therefore, a brief overview of HIV/AIDS is appropriate.

A. The Nature and Standard of Care for Treating HIV/AIDS

HIV/AIDS is an extremely complex virus that attacks the human immune system.[42] HIV/AIDS can replicate billions of times per day and has a very error-prone replication process; as a result, it has an extremely high mutation rate.[43] Because of this, treating HIV/AIDS is very difficult. In order to effectively manage the virus, multiple HIV/AIDS medications must be used in unison.[44] Furthermore, any cessation in an individual taking medication gives the virus the opportunity to replicate, mutate, and become resistant to that medication.[45] Drug resistant HIV/AIDS is extremely troubling because not all HIV/AIDS medications work for a particular individual,[46] and many HIV/AIDS medications have toxic side effects.[47] So if a person has a lapse in taking his or her effective medication, and their strain of HIV/AIDS becomes resistant to that medication as a result, that person cannot continue to take that drug and may have a limited selection of other

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[42] *What is HIV/AIDS?*, AIDS.GOV, http://www.aids.gov/hiv-aids-basics/hiv-aids-101/what-is-hiv-aids/ [http://perma.cc/X42Q-9MKW] (last revised Apr. 29, 2014).

[43] *Primer on HIV Resistance*, STANFORD UNIVERSITY HIV DRUG RESISTANCE DATABASE, http://hivdb.stanford.edu/pages/documentPage/primer.html [http://perma.cc/5R9U-DHAS] (last updated Sept. 23, 1999).

[44] Panel on Antiretroviral Guidelines for Adults and Adolescents, *GUIDELINES FOR THE USE OF ANTIRETROVIRAL AGENTS IN HIV-1-INFECTED ADULTS AND ADOLESCENTS*, DEP'T OF HEALTH & HUM. SERVICES D-1, http://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf [http://perma.cc/Z8X9-DH5B] (last visited Sept. 17, 2015).

[45] *Id.* at K-1.

[46] *Changing/Stopping Treatment*, AIDS.GOV, https://www.aids.gov/hiv-aids-basics/just-diagnosed-with-hiv-aids/treatment-options/changing-stopping-treatment/ [http://perma.cc/QT4M-V39E] (last revised Aug. 7, 2009).

[47] Yates, *supra* note 31, at 5; *Antiretroviral Drugs Side Effects*, AVERT, http://www.avert.org/antiretroviral-drugs-side-effects.htm [http://perma.cc/CRG3-D84A] (last visited Sept. 17, 2015).

drugs to switch to due to side effects and ineffectiveness. Because of this, the medical standard of care for treating HIV/AIDS provides that a person diagnosed with HIV/AIDS begin taking medication as soon as possible after being diagnosed and have no lapses in treatment.[48] In order to facilitate this, the medical standard of care provides that the most effective way to treat HIV/AIDS patients is with a single-tablet regimen (STR) instead of multiple pills per day[49]—this increases adherence to treatment, decreasing dangerous interruptions in treatment.[50] The medically "preferred regimens" of STRs for treating HIV/AIDS include Atripla, Truvada-Reyataz-Norvir, Truvada-Prezista-Norvir, Truvada-Isentress, Stribild, Tivicay-Epzicom, and Tivicay-Truvada.[51]

With a better understanding of how HIV/AIDS works and is treated, a look into how high tiering, step-therapy, and pre-authorization requirements can negatively affect individuals with HIV/AIDS is now appropriate.

B. The Detrimental Effects of These Three Aforementioned Practices on Individuals with HIV/AIDS

The next three subsections will explain how high tiering, step-therapy, and pre-authorization requirements can have harmful consequences for individuals with HIV/AIDS.

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[48] Panel on Antiretroviral Guidelines for Adults and Adolescents, *supra* note 44, at K-1.

[49] Liz Highleyman, *Single-Tablet Regimen Improves Antiretroviral Adherence and Reduces Hospitalization*, AIDSMAP (Sept. 26, 2013), http://www.aidsmap.com/Single-tablet-regimen-improves-antiretroviral-adherence-and-reduces-hospitalisation/page/2763722/ [http://perma.cc/X8YW-95BP].

[50] Yates, *supra* note 31, at 17.

[51] AIDS Found. of Chi., *supra* note 31, at 3-12.

1. High Tiering

HIV/AIDS medications are very expensive.[52] A 30-day supply of Norvir costs $530-$586[53]; a 30-day supply of Prezista costs $1,279-$1,383[54]; a 30-day supply of Reyataz costs $1,288-$1,393[55]; a 30-day supply of Truvada costs $1,309-$1,411[56]; and generic versions of these drugs are not available in the United States.[57] But even drugs that do have generic alternatives available in the United States are expensive.[58] For example, a 30-day supply of generic Combivir is $172-$375, and a 30-day supply of generic Ziagen is $117-$219.[59] And remember, it is necessary for an individual with HIV/AIDS to take not only one of these drugs, but a combination of these drugs in unison.[60] But, one might think, the above numbers are the total costs of the drugs; with insurance the drugs are probably cheap enough that people can afford them, right? Not when these drugs are placed on the highest cost sharing tiers of a health insurers' prescription drug formulary.[61]

In Illinois, Aetna, Coventry, and Humana all place most HIV/AIDS medications, and indeed all of the medically preferred regimens, on the highest tiers of their formularies.[62] For example, under the best plan that Aetna

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[52] *See* Kimberly Holland & Kristeen Cherney, *The Cost of HIV Treatment*, HEALTHLINE (April 2, 2015), http:// www.healthline.com/health/hiv-aids/cost-of-treatment#1 [http://perma.cc/2XEY-SSHL]; Madeline Vann, *Can You Afford Your HIV Treatment?*, EVERYDAY HEALTH, http://www.everydayhealth.com/hiv-aids/can-you-afford-hiv-treatment.aspx [http://perma.cc/RZ8L-UBUF] (last updated May 13, 2009).

[53] Holland, *supra* note 52.

[54] *Id.*

[55] *Id.*

[56] *Id.*

[57] *Id.*

[58] *Id.*

[59] *Id.*

[60] Panel on Antiretroviral Guidelines for Adults and Adolescents, *supra* note 44.

[61] Yates, *supra* note 31, at 16–17; *See* AIDS Found. of Chi., *supra* note 31; Andrews, *supra* note 30.

[62] AIDS Found. of Chi., *supra* note 31.

offers on the Illinois Health Insurance Exchange, the monthly out-of-pocket cost to a plan beneficiary for Atripla is about $1,126; for Truvada-Reyataz-Norvir is about $1,541; for Truvada-Prezista-Norvir is about $1,542; for Truvada-Isentress is about $1,348; for Stribild is about $2,830; for Tivicay-Epzicom is about $654; and for Tivicay-Truvada is about $783.[63]

Under the best plan that Coventry offers on the Illinois Health Insurance Exchange, the monthly out-of-pocket cost to a plan beneficiary for Atripla is about $676; for Truvada-Reyataz-Norvir is about $763; for Truvada-Prezista-Norvir is about $763; for Truvada-Isentress is about $686; for Stribild is about $843; for Tivicay-Epzicom is about $703; and for Tivicay-Truvada is about $792.[64]

And under the best plan that Humana offers on the Illinois Health Insurance Exchange, the monthly out-of-pocket cost to a plan beneficiary for Atripla is about $1,126; for Truvada-Reyataz-Norvir is about $1,541; for Truvada-Prezista-Norvir is about $1,542; for Truvada-Isentress is about $1,348; for Stribild is about $1,405; for Tivicay-Epzicom is about $1,172; and for Tivicay-Truvada is about $1,321.[65]

In 2013, the median household, or combined family, income ranged from about $90,000 to about $45,000 per year.[66] So if someone with a $60,000 yearly salary were to have the best plan that Humana offers through the Illinois marketplace and that person had been prescribed Atripla, he or she would be spending over 22% of their yearly income on their Atripla alone. If someone with a $45,000 yearly salary were to have the best plan that Humana offers through the Illinois marketplace and that person had been prescribed Atripla, he or she would be spending about 30% of their yearly income on their Atripla alone. Thirty percent of a family's income is a substantial amount, to say the least. Thus, it seems safe to say that when these drugs are placed

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[63] *Id.*

[64] *Id.*

[65] *Id.*

[66] Amanda Noss, *Household Income: 2013, American Community Survey Briefs*, U.S. CENSUS BUREAU (Sept. 2014), http:// www.census.gov/content/dam/Census/library/publications/2014/acs/acsbr13-02.pdf [http://perma.cc/KG7D-8898].

in an insurer's highest formulary tiers, they are extremely expensive and virtually unaffordable to most low- and middle-income Americans.

It is apparent that this practice of high tiering by insurers can be financially challenging, or even crippling—depending on an individual's income. This financial burden by itself imposes great harm to individuals with HIV/AIDS. However, the harm does not stop at the pocketbook. Such a high cost for these drugs can mean that many people with HIV/AIDS cannot afford their medication every month. What happens when someone cannot afford to pay for his or her medication for a month? Answer: they do not take it. This is a lapse in treatment, which can lead to a dangerous strain of drug-resistant HIV/AIDS.[67]

In sum, this high tiering practice may not only create an extreme financial burden on beneficiaries with HIV/AIDS, but can also lead to medically dangerous lapses in treatment.

2. Step therapy requirements

Step-therapy requirements force individuals to use less effective drugs in order to prove they are ineffective before qualifying for the use of effective medications.[68] The medical standard of care dictates that an individual should begin treatment as soon as possible after being diagnosed with HIV/AIDS and have no lapses in treatment.[69] This keeps the virus at bay from mutation and thus prevents drug resistance.[70] Step-therapy, by its very nature, violates this standard of care and gives the virus the opportunity to mutate and become drug resistant because either: (1) a person is diagnosed with HIV/AIDS and enrolls in a plan—or is already enrolled in a plan—with a step-therapy requirement that requires them to take less-than-optimally-effective drugs for a period of time, which functionally

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[67] Yates, *supra* note 31, at 4.

[68] Yates, *supra* note 31, at 2; *see Illinois Governor's Office*, *supra* note 34; Steering Comm. of the HIV Health Care Access Working Group, *supra* note 34.

[69] Panel on Antiretroviral Guidelines for Adults and Adolescents, *supra* note 44.

[70] *See id.*

constitutes a delay in initial treatment; or (2) a person who has had HIV/AIDS for some time and has been using an effective drug enrolls in a plan that has a step-therapy requirement and must switch to a less effective drug for a period of time, which functionally constitutes a lapse in treatment. It is in this way that step-therapy requirements harm individuals with HIV/AIDS who are subjected to them.

3. Pre-authorization requirements

Pre-authorization requirements have largely the same effect that step-therapy requirements do: they cause lapses in treatment. This is because pre-authorization requirements mandate that beneficiaries must obtain permission from the insurer before every refill of their medication,[71] and due to the large size and bureaucratic nature of insurance companies, that permission can often take longer to obtain than expected.[72] This delay in permission from the insurance companies can lead to dangerous lapses of treatment. It is in this way that pre-authorization requirements harm individuals with HIV/AIDS who are subjected to them.

It is apparent that these three health insurance practices are acutely detrimental to individuals with HIV/AIDS who are subject to them. However, § 1557 may be able to neutralize these practices and provide such individuals with relief from this discrimination. An analysis of § 1557 and its possible application to such practices follows.

III. COVERED ENTITIES UNDER § 1557

To determine whether § 1557 of the ACA will be effective at ending, or at least reducing, insurers' practices of high tiering and step-therapy and pre-authorization requirements with HIV/AIDS medications, it is necessary to determine what entities the provision actually applies to. To be an effective means of combating these health insurance practices, § 1557 must extend to the vast majority of health

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[71] Yates, *supra* note 31, at 15; *see* HIV Med. Ass'n. et. al, *supra* note 36; *see Illinois Govenor's Office*, *supra* note 34.

[72] Yates, *supra* note 31, at 15.

insurance companies and thus by extension to the health plans they provide.

Section 1557 applies to "any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments)."[73] There are two key pieces at work here: "health program or activity" and "Federal financial assistance." Therefore, to determine whether § 1557 extends to health insurance companies, these two key pieces must be examined. First, it must be determined what "Federal financial assistance" is and whether health insurance companies receive it. And second, it must be determined what a health "program or activity" is and if health insurance companies qualify as such a health "program or activity." If health insurance companies do qualify as health "programs or activities" and receive "Federal financial assistance," section 1557 will apply to such health insurers.

A. "Federal Financial Assistance"

What qualifies as "Federal financial assistance?" There is a vast array of Federal programs that provide various types of assistance. However, the ACA's premium tax credits will be focused on here. This is partly due to the impracticability of exploring every Federal program that provides financial assistance and partly due to the importance and prominence of the premium tax credits. The premium tax credits are especially pertinent in the context of § 1557 covered entities because many people will qualify for them.[74] So if these credits qualify as "Federal financial assistance" then many insurers will receive such federal assistance because they provide coverage to those individuals who qualify for the credits.

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[73] 42 U.S.C. § 18116(a) (2015).

[74] *State-by-State Estimates of the Number of People Eligible for Premium Tax Credits Under the Affordable Care Act*, KAISER FAMILY FOUNDATION (Nov. 5, 2013), http://kff.org/report-section/state-by-state-estimates-of-the-number-of-people-eligible-for-premium-tax-credits-under-the-affordable-care-act-table-1/ [http://perma.cc/X3FM-QZTC].

Section 1557 explicitly provides that "Federal financial assistance" includes "credits, subsidies, or contracts of insurance."[75] The "credits" and "subsidies" referred to by § 1557 seemingly refer to—or at least include—the premium tax credits provided pursuant to the ACA. This makes sense for two reasons. First, it is logical for § 1557 to refer to and use such a key piece of the Act of which it is a part of to effect its specific purpose. As was explained above, the premium tax credits are a key part of the ACA. Without the premium tax credits, the ACA could not stand.[76] It makes sense for the ACA to use such a key component of itself to be the foundation of this nondiscrimination provision. And second, the premium tax credits are both a "credit"—in that they are literally a tax credit—and a "subsidy"—in that they literally subsidize insurance premiums. Furthermore, the premium tax credits are the epitome of "Federal financial assistance;" the federal government is literally assisting in the payment of insurance premiums.

As the analysis above illustrates that it is likely that premium tax subsidies qualify as "Federal financial assistance," the next inquiry to make here is: will most health insurance companies receive these premium tax subsidies? More and more health insurance companies offer, or will offer, health plans through the exchanges.[77] Thus, it is very likely that each insurer offering plans through the exchanges will inevitably receive premium subsidies through beneficiaries of some of those plans. This is because the premium subsidies are available for individuals and families with incomes up to 400% of the federal poverty level, which encompasses an extremely large group of people.[78] With a

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[75] 42 U.S.C. § 18116(a) (2015).

[76] Joel E. Miller, *Healthcare Reform: The "Three-Legged Stool" of Health Insurance Reform Under the ACA*, AMHCA (Oct. 1, 2013), http://www.amhca.org/?page=Advocate20131002 [http://perma.cc/8FA5-M9BV].

[77] Tami Luhby, *More Health Insurers Offer Obamacare Plans*, CNN MONEY (Sept. 23, 2014 3:58 PM), http://money.cnn.com/2014/09/23/news/economy/obamacare-more-health-insurers-on-exchanges/ [http://perma.cc/KD7F-TFFD].

[78] *Explaining Health Care Reform: Questions About Health Insurance Subsidies*, KAISER FAMILY FOUNDATION (Oct. 27, 2014), http://kff.org/health-reform/issue-brief/explaining-health-care-reform-

large, and increasing, number of health insurers offering plans on the exchanges and with a large portion of the population qualifying for premium subsidies, the vast majority of health insurers are likely to receive premium subsidies—"Federal financial assistance"—via the beneficiaries of their plans that are sold on the exchanges.

However, at first blush, there seems to be a wrinkle here. While the premium subsidy is paid directly to the insurer,[79] in actuality it is a premium tax credit of the individual who purchases the plan, and it subsidizes the cost of insurance to the individual. Therefore, one might think, the individuals, not the insurers, are receiving the "Federal financial assistance." However, this argument is not consistent with the law.

In *Moreno v. Consolidated Rail Corp.*, Moreno, a terminated employee of the railroad company Conrail, filed suit under § 504 of the Rehabilitation Act alleging that his termination was due to his disability–diabetes.[80] In response, Conrail maintained that it was not a recipient of federal financial assistance and therefore not subject to § 504 regulation.[81] Conrail received government money for railroad crossing improvements.[82] The improvements were paid to the State of Michigan and then subsequently to Conrail.[83] Conrail argued that while it did receive such government money, it was not the "recipient" of federal financial assistance because the ultimate beneficiary was the traveling public, who benefitted from safe railroad crossings.[84] The court found this argument unpersuasive,

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questions-about-health/ [http://perma.cc/EW37-6632]; *State-by-State Estimates of the Number of People Eligible for Premium Tax Credits Under the Affordable Care Act*, *supra* note 74.

[79] 42 U.S.C. § 18082 (2015); *Subsidies: Available to Eligible Consumers*, ASSURANT HEALTH, http://www.assuranthealth.com/corp/ah/HealthCareReform/Premium-Subsidy.htm [http://perma.cc/CZL5-7RRC] (last visited Sept. 17, 2015); *Premium Tax Credit*, HEALTHCARE.GOV, https://www.healthcare.gov/glossary/premium-tax-credit/ [http://perma.cc/5YT4-PMK3] (last visited Sept. 17, 2015).

[80] Moreno v. Consol. Rail Corp., 99 F.3d 782, 784 (6th Cir. 1996).

[81] *Id.*

[82] *Id.* at 785-786.

[83] *Id.*

[84] *Id.* at 787.

and further found the fact that Conrail received the money from the Federal government through the State of Michigan as a middle-man to be immaterial.[85] The Court held Conrail to be a recipient of "Federal financial assistance."[86]

Similarly, the Supreme Court, in *Grove City College v. Bell*, spoke on the scope of the coverage of antidiscrimination statutes.[87] In *Grove City College*, a college refused to agree to the antidiscrimination terms under Title IX of the Education Amendments of 1972 in order to utilize certain student educational funding.[88] The Court found that although the students were the ultimate beneficiaries of the student educational funding, the college was a "recipient" of federal financial assistance due to such government funding.[89]

In addition, the Department of Health and Human Services ("HHS") has issued a regulation which defines a "recipient" under § 504 as "any state . . . or any person to which Federal financial assistance is extended directly or through another recipient . . . but excluding the ultimate beneficiary of the assistance."[90]

In the current situation, the ultimate beneficiary of the premium subsidies are the individuals who qualify for such premium tax credits. However, the premium subsidies are paid from the Federal government directly to the health insurer.[91] Indeed, this is more direct than in *Moreno* when the State of Michigan acted as a middle-man and the court in that case still found Conrail to be a recipient of "Federal financial assistance." In addition, the health insurers in the current situation are like Conrail in *Moreno* and the college in *Grove City College*: although they are not the true beneficiaries of the federal funds, they still qualify as recipients of "Federal financial assistance." Indeed, individuals who qualify for premium tax credits are equivalent to the students in *Grove City College* who

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[85] Moreno v. Consolidated Rail Corp., 99 F.3d at 787-788.

[86] *Id.*

[87] Grove City College v. Bell, 465 U.S. 555 (1984).

[88] *Id.* at 561.

[89] *Id.* at 569–570.

[90] 45 C.F.R. § 84.3(f) (2015).

[91] 42 U.S.C. § 18082 (2015); *Subsidies: Tax Credits for Eligible Consumers*, *supra* note 79; *Premium Tax Credit*, *supra* note 79.

qualified for student educational funding. They are the ultimate beneficiaries of the funding, but because the money is paid to the institution handling their affairs, the institution is the recipient of "Federal financial assistance" for legal purposes.

Moreover, the HHS regulations have specifically excluded ultimate beneficiaries, such as the students in *Grove City College* or the plan beneficiaries who qualify for premium tax credits in the current situation, from being the legal recipients of "Federal financial assistance" and instead designated the entity that the government money is extended to as the recipient.

Therefore, health insurance companies become the recipients of "Federal financial assistance" when they receive government money in the form of premium tax subsidies. This greatly expands the coverage of § 1557. Also keep in mind that there are many other ways that an insurer can receive "Federal financial assistance" aside from premium tax subsidies. Taking that into consideration, § 1557's coverage is broader still. Therefore, most insurance companies in the United States will likely receive "Federal financial assistance."

B. "Program or Activity"

Since, in this context, discrimination against individuals with HIV/AIDS is prohibited by § 1557 through its invocation of § 504 of the Rehabilitation Act, and because § 1557 does not specifically define "program or activity," it seems appropriate to use the definition of "program or activity" provided by § 504 of the Rehabilitation Act. Section 504 of the Rehabilitation Act provides that, among other things, a "program or activity" means all operations of: (3)(A) an entire corporation, partnership, or other private organization, or an entire sole proprietorship—(i) if assistance is extended to such corporation, partnership, private organization, or sole proprietorship as a whole; or (ii) which is principally engaged in the business of providing education, health care, housing, social services, or parks and recreation[.][92]

[92] 29 U.S.C. § 794(b) (2015).

With this definition, it is now possible to answer the question: do health insurance companies qualify as health "programs or activities?" Insurance companies are corporations. However, there are a great many insurance companies in the United States and not all of their corporate structures are the same. This makes a broad analysis of whether health insurers receive assistance "as a whole" overly cumbersome. This point is also moot due to the second portion of the definition of "program or activity" presented above.

This is because even if a health insurer does not receive the assistance "as a whole," they still qualify as a "health program or activity." The second piece of the definition of health "program or activity" only requires that the corporation be "principally engaged in the business of providing . . . health care." Since insurance companies are "principally engaged in the business of providing" health care, they likely qualify as a "program[] or activit[y]."

C. Putting It Together

Having explored the two key pieces of § 1557 that describe covered entities, it is now appropriate to put those two key pieces together in regard to health insurance companies—and by extension the health plans such insurers provide. Health insurance companies likely qualify as health "programs or activities"; and they will probably receive "federal financial assistance" in one form or another; therefore, they are likely covered entities under § 1557. However, the covered entity analysis does not stop here; there is one important question that must still be answered.

D. A Wrinkle?

If a health insurance company receives federal financial assistance in the form of the ACA's premium subsidies from one plan offered through an exchange, does that company have to make sure that all of the plans it offers, both in and out of the exchanges, comply with § 1557?

The Supreme Court, in *Grove City College v. Bell*, spoke on the scope of the coverage of antidiscrimination statutes.[93] Recall that *Grove City College* was the case in which a college did not want to comply with antidiscrimination regulations in order to be able to utilize federal funds for its students.[94] The Court found that the Department of Education had the authority to withdraw the student educational funding because Grove City College received federal financial assistance through that student funding.[95] However, the Court noted that only the specific funding program that received the Federal financial assistance was subject to regulation and not Grove City College as a whole.[96] Essentially, the court took a very narrow approach to "program or activity." Under this approach, if an institution were to receive "Federal financial assistance," only the specific part of the institution that received that assistance would be subject to antidiscrimination regulations, not the institution as a whole in every aspect of its business.

But this narrow reading by the Court does not negatively affect the current situation being analyzed. Here, a health insurance company receives federal financial assistance through premium subsidies. According to *Grove City College*, the antidiscrimination scrutiny must be "program specific."[97] However, this does not mean scrutiny is extended only to the plan which triggered the premium subsidy but rather that scrutiny is extended to the entire program of the health insurance company which provides health plans. This is so because no case law has taken "program specific" to the extreme of meaning "individually specific." For example, in *U.S. v. Baylor University Medical Center*, the court sought to determine whether and to what extent Medicare and Medicaid payments subjected a hospital to the scrutiny of § 504 of the Rehabilitation Act.[98] The court first determined that Medicare and Medicaid payments qualified as "Federal

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[93] Grove City College v. Bell, 465 U.S. 555 (1984).

[94] *Id.* at 561.

[95] *Id.* at 575-576.

[96] *Id.* at 570-571.

[97] *Id.*

[98] U.S. v. Baylor University Medical Center, 736 F.2d 1039, 1040 (1984).

financial assistance."[99] Then the Court sought to determine whether the antidiscrimination scrutiny applied to the hospital as a whole or to just the inpatient emergency room services that led to the Medicare and Medicaid payments in the first place.[100] The Court held that the hospital's inpatient and emergency room services were subject to antidiscrimination scrutiny, but that the entire hospital as a whole was not because of the "program specific" requirement.[101] Notice that the court did not say that only the specific individuals who caused the Medicare and Medicaid payments to be made to the hospital were subject to scrutiny, but rather all inpatient and emergency room services. In the current situation, it would not just be the specific, individual plan that will be subject to § 504 – and thus § 1557 – scrutiny, but rather the entire program that deals with insurance plans. So while only some plans will trigger the premium subsidies that make the insurance companies recipients of federal financial assistance, all plans which said company provides will likely be subject to § 1557.

E. Other Means of § 1557 Coverage

While the premium tax credits system will likely serve as the broadest means by which a health insurance company can be subject to § 1557 regulation, there are other means. First, Executive Agencies and any other entities established under the ACA are subject to § 1557 regulation.[102] Second, Medicare and Medicaid payments will also trigger § 1557 regulation.[103] And lastly, health insurance companies that do not offer plans through the exchanges can receive "federal financial assistance" in a variety of other ways outside of premium tax subsidy payments, thus making them subject to § 1557 regulation. With all of these various means by which health insurance companies can qualify as covered entities under § 1557, the vast majority of health insurance plans in the United States should be subject to § 1557.

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[99] *Id.* at 1048-1049.

[100] *Id.* at 1049.

[101] *Id.*

[102] 42 U.S.C. § 18116(a) (2015).

[103] U.S. v. Baylor University Medical Center, 736 F.2d 1039, 1048-1049 (1984).

IV. HIGH TIERING AND STEP-THERAPY AND PRE-AUTHORIZATION REQUIREMENTS: DISCRIMINATORY AND PROHIBITED UNDER § 1557?

In order to determine whether § 1557 will be effective at ending health insurers' practices of high tiering and step-therapy and pre-authorization requirements for individuals with HIV/AIDS, it must be determined both what type and what mode of discrimination § 1557 prohibits. The "type" of discrimination will refer to what basis discrimination is prohibited on. The "mode" of discrimination will refer to the method of discrimination: either intentional or disparate impact.[104] Then it must be determined whether high tiering and step-therapy and pre-authorization requirements constitute such prohibited discrimination under § 1557.

Since § 504 of the Rehabilitation Act is the relevant antidiscrimination statute invoked by § 1557 in terms of HIV/AIDS discrimination, this discussion will be based on § 504.

A. What Type of Discrimination is Prohibited by § 1557?

Section 1557 prohibits discrimination "on the ground prohibited under . . . section 504 of the Rehabilitation Act."[105] Section 504 of the Rehabilitation Act prohibits discrimination on the basis of disability.[106] The Supreme Court has held HIV/AIDS to be a disability.[107] Therefore, § 1557 prohibits discrimination on the basis of HIV/AIDS status. But presently, the aforementioned insurance practices are not explicitly based on the forbidden criterion HIV/AIDS. While disability is a forbidden criterion on which

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[104] Disparate impact discrimination occurs when "practices that are facially neutral in their treatment of different groups . . . in fact fall more harshly on one group than another." Smith v. City of Jackson, 544 U.S. 228, 239 (2005).

[105] 42 U.S.C. § 18116(a) (2015).

[106] 29 U.S.C. § 794(a) (1973).

[107] *E.g.,* Bragdon v. Abbott, 524 U.S. 625, 630-647 (1998) (ADA); Doe v. County of Centre, Pa., 242 F.3d 437, 447 (3d Cir. 2001) (Rehabilitation Act); Chalk v. United States Dist. Ct., 840 F.2d 701, 704-709 (9th Cir. 1988) (Rehabilitation Act).

to discriminate and HIV/AIDS is a disability, high tiering and step-therapy and pre-authorization requirements do not technically apply directly to individuals with HIV/AIDS but rather apply to the HIV/AIDS drugs themselves. So the question becomes: is discrimination targeted at HIV/AIDS medications the same as discrimination against individuals with HIV/AIDS?

In *Lawrence v. Texas*, the Supreme Court held that a same-sex sodomy law discriminated against homosexuals because it targeted conduct that was closely tied with being homosexual.[108] The Court concluded "there can hardly be more palpable discrimination against a class than [targeting] the conduct that defines that class."[109] Here, insurance companies have not targeted conduct that technically defines the class, individuals with the disability of HIV/AIDS; however, the insurance companies have targeted conduct that is closely tied to the class. Indeed, the taking of HIV/AIDS medications is absolutely necessary for someone with the disease in order to stay alive. However, same-sex sodomy is not absolutely necessary for homosexual individuals to stay alive. So, same-sex sodomy is actually less linked with being a homosexual than taking HIV/AIDS medications is with being an individual with HIV/AIDS. Therefore, targeting HIV/AIDS medications seems equivalent to targeting individuals with HIV/AIDS.

In sum, § 1557 prohibits discrimination based on HIV/AIDS status, and that prohibition extends to discrimination based on HIV/AIDS medications because of the extremely close link between having HIV/AIDS and the necessity for taking HIV/AIDS drugs.

B. Intentional Discrimination: Prohibited?

In order to determine whether the three aforementioned insurance practices are prohibited by § 1557 as intentional discrimination, it must first be determined whether § 1557 actually prohibits intentional discrimination. The Supreme Court has spoken as to what discrimination qualifies as a

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[108] *See* Lawrence v. Texas, 539 U.S. 558, 583 (2003).

[109] *Id.*

violation of § 504 of the Rehabilitation Act. Indeed, in *Alexander v. Choate*, the Supreme Court interpreted § 504 of the Rehabilitation Act.[110] The Court was not even concerned as to whether § 504 prohibits intentional discrimination; it took that for granted.[111] The Court used intentional discrimination as a starting point, or a floor, for § 504.[112] The issue, in the Court's opinion, was not whether § 504 prohibits intentional discrimination but whether it prohibits disparate impact discrimination.[113] From *Alexander v. Choate*, it is clear that § 504 prohibits intentional discrimination. Indeed, if it did not, the provision would be meaningless. Intentional discrimination is the most blatant and most basic form of discrimination. If intentional discrimination is not prohibited by § 504, then no discrimination is prohibited and the law is useless.

C. High Tiering and Step-Therapy and Pre-Authorization Requirements: Intentional Discrimination?

1. Preliminary Question 1: Are These Three Insurance Practices Discriminatory to Begin With?

Discrimination is not defined in § 1557. However, courts have traditionally found "discrimination" to mean differential treatment based on a forbidden criterion.[114] Since it is apparent that individuals with HIV/AIDS – which is a disability and therefore a forbidden criterion – are being targeted by these practices, it must be determined whether these practices constitute differential treatment. High tiering, step-therapy and pre-authorization requirements seem to constitute differential treatment. These practices deny meaningful coverage to individuals with HIV/AIDS and do not occur with other individuals.

When an insurer places all or most of the effective HIV/AIDS drugs on the highest cost-sharing tiers of their

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[110] Alexander v. Choate, 469 U.S. 287 (1985).

[111] *Id.* at 292.

[112] *Id.*

[113] *Id.* at 292-293.

[114] *See* Jackson v. Birmingham Bd. of Educ., 544 U.S. 167, 174 (2005); Rene v. MGM Grand Hotel, Inc., 305 F.3d 1061, 1067 (9th Cir. 2002).

prescription drug formularies, it makes those drugs virtually unaffordable.[115] This leaves individuals with HIV/AIDS only able to afford either ineffective or toxic generic HIV/AIDS medications. If an individual with HIV/AIDS does still try to go the route of taking the overly expensive HIV/AIDS on the high tiers, they often cannot afford those medications on a monthly basis, causing the extremely dangerous interruptions in treatment the medical standard of care seeks to avoid.[116] Step-therapy and pre-authorization requirements only add to the likelihood of treatment interruption. Step-therapy requirements require individuals to take less effective and potentially toxic generic drugs before moving on to the brand-name drugs that are actually effective.[117] Individuals with HIV/AIDS subjected to step-therapy requirements are really experiencing an interruption in treatment since their HIV/AIDS is not being effectively treated but allowed to replicate and mutate.

Finally, pre-authorization requirements also cause interruptions in treatment. Since an individual subjected to a pre-authorization requirement must obtain permission from his or her insurer before every refill of their medication, there are often delays in obtaining the refill for the medication, leading to dangerous interruptions in treatment. These insurance practices cause effective HIV/AIDS drugs to be virtually unaffordable and cause dangerous interruptions in treatment. Therefore, these insurance practices cause the plans to be effectively useless to individuals with HIV/AIDS, as opposed to individuals without the disease. Since individuals without HIV/AIDS do not need HIV/AIDS medications, these plans would be more favorable for individuals without the disease. This has the effect of discouraging individuals with HIV/AIDS from enrolling in these plans; but since individuals without HIV/AIDS do not require HIV/AIDS medication, these practices have no discouraging effect on individuals without HIV/AIDS. This is the differential treatment constituting discrimination.

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[115] Yates, *supra* note 31, at 16; AIDS Found. of Chi., *supra* note 31; Andrews, *supra* note 31.

[116] Yates, *supra* note 31, at 15.

[117] Yates, *supra* note 31, at 2; *see* AIDS Found. of Chi. *supra* note 31; HIV Health Care Access Working Group, *supra* note 34.

2. Preliminary Question 2: Do Insurance Companies Have Autonomy in Choosing to Adhere to These Practices?

Before moving on to inquire as to whether the discrimination was intentional, another important point must be made. It seems obvious that that portion of insurers that adhere to the aforementioned practices do so intentionally. There is no law requiring these practices, and the practices were not written into the plan by accident. Each company designs its own prescription drug formularies and decides whether to institute step-therapy and pre-authorization requirements for HIV/AIDS drugs. When an insurer places all or most effective HIV/AIDS drugs on the highest tiers of a prescription formulary and institutes step-therapy and pre-authorization requirements, it does so intentionally and not by market force. Note that it is not being said that these practices are intentionally *discriminatory*, but merely that they are intentionally put into place. Basically, insurance companies cannot say that they have no other choice than to implement these practices; they cannot say that there is no discriminatory intent because they simply did not want to implement these practices in the first place. If they did not want to or intend to implement these practices, they simply would not have done so.

3. Are Health Insurance Companies that are Adhering to These Practices Exhibiting Intentional Discrimination?

One can see that these insurance practices are discriminatory and that they are being implemented intentionally, but the big question here is whether this *discrimination* is intentional. How does one define intentional discrimination? In *Lovell v. Chandler*, a group of disabled individuals brought a class action under § 504 of the Rehabilitation Act against the State of Hawaii alleging that they had been declared ineligible for Hawaii's "QUEST"

medical coverage solely based on their disabilities.[118] In 1994, Hawaii developed this "QUEST" program in order to provide health insurance to more of its low-income citizens.[119] Hawaii explicitly and categorically excluded individuals who were over 65 years old, blind, or disabled.[120]

For an award of compensatory damages, the Court needed to determine whether the state of Hawaii had intentionally discriminated against plaintiffs.[121] The Court stated that an entity exhibits discriminatory intent – intentional discrimination – when it is "deliberate[ly] indifferen[t]."[122] The Court went on to say that "[d]eliberate indifference requires both knowledge that a harm to a federally protected right is substantially likely, and a failure to act upon that likelihood."[123] It continued, "The first element is satisfied when the . . . entity has notice that an accommodation is required. The second element is satisfied if the entity's 'failure to act [is] a result of conduct that is more than negligent, and involves an element of deliberateness."[124] Furthermore, an entity "at the very least" exhibits "deliberate indifference" when facial discrimination is present because "by its very terms, facial discrimination is 'intentional.'"[125]

The Court reasoned that because Hawaii had categorically excluded disabled individuals from the program when it knew that doing so would mean some of those individuals would ultimately go without coverage altogether, it did not act with enough care to protect the rights of its disabled citizens.[126] It also stated that Hawaii had facially discriminated against disabled individuals in the QUEST program.[127] For these reasons, the Court found that Hawaii

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[118] Lovell v. Chandler, 303 F.3d 1039, 1044 (9th Cir. 2002), *cert denied*, 537 U.S. 1105 (2003).

[119] *Id.* at 1045.

[120] *Id.*

[121] *Id.* at 1056.

[122] *Id.*

[123] *Id.* (quoting Duvall v. Cnty. of Kitsap, 260 F.3d 1124, 1139 (9th Cir. 2001).

[124] *Id.*

[125] *Id.* at 1057.

[126] *Id.*

[127] *Id.*

had exhibited "deliberate indifference" and therefore intentional discrimination in the design of its QUEST program.[128]

It appears that the insurance companies that adhere to these practices are exhibiting "deliberate indifference" and are therefore intentionally discriminating. As described above, when discrimination is of the type described as facial discrimination, it is *per se* deemed to be intentional discrimination. It seems that is the type of discrimination at play here. It is not the case that there is some other criteria that is being used and these drugs are disproportionately affected by it. The companies that adhere to these practices are explicitly designating HIV/AIDS medications for high tiering and step-therapy and pre-authorization requirements. Therefore, this discrimination seems facial and thus intentional.

On the other hand, this discrimination might be viewed as not being facial simply because it does target the HIV/AIDS drugs and not individuals with HIV/AIDS themselves. However, as was previously explained, targeting HIV/AIDS drugs is the equivalent of targeting individuals with HIV/AIDS themselves. So the argument in favor of these practices constituting facial discrimination—and thus intentional discrimination—seems to remain strong. Indeed, the present situation is much like that in *Lovell*. Just as Hawaii had explicitly and categorically provided in its laws that the QUEST program excluded disabled individuals, some insurance companies are explicitly providing that these overly burdensome practices only apply to HIV/AIDS medications—thus effectively only to individuals with HIV/AIDS.

If these practices are not considered to be intentional discrimination under this sort of *per se* facial discrimination standard, they likely will be under the two-pronged "deliberate indifference" test laid out by the court in *Lovell*. Recall that "[t]he first element [of deliberate indifference] is satisfied when the . . . entity has notice that an accommodation is required.[129] Here, all insurance companies

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[128] *Id.*

[129] *Id.* at 1056.

are undoubtedly aware of the ACA's requirements. Therefore, all insurance companies know that the ACA makes an accommodation for individuals with a preexisting condition—here, HIV/AIDS—such that they may not be denied coverage or charged higher rates for such coverage than individuals without the preexisting condition.[130] All insurance companies in the United States are aware of this ACA requirement. Actually, the mere fact that they are allowing individuals with HIV/AIDS to enroll in their plans and are not charging them higher baseline rates than individuals without a preexisting condition proves they are aware of the accommodation required by the ACA. Before the ACA, insurers would not have let individuals with HIV/AIDS enroll on their plans. If they did, they would charge them grossly higher baselines rates. These companies must be aware that an accommodation is required. Another similarity to *Lovell* arises here. Insurance companies are effectively denying individuals with HIV/AIDS coverage. In *Lovell*, the Court stated that the fact that Hawaii had discriminated against *disabled* individuals meant it was charged with notice that federal protection may apply and an accommodation required.[131] Here, since insurance companies are discriminating against disabled individuals, they are on notice that an accommodation may be required.

Moving on, recall that "[t]he second element [of deliberate indifference] is satisfied if the entity's 'failure to act [is] a result of conduct that is more than negligent, and involves an element of deliberateness.'"[132] Here, the insurance companies adhering to these practices did not fail to act; rather, they acted affirmatively to deny individuals with HIV/AIDS the required accommodation. If a "failure to act" beyond that which is negligent constitutes deliberateness, an affirmative action surely qualifies. Here, one might think that these insurance companies are actually complying with the ACA's required accommodation because said companies are allowing individuals with HIV/AIDS to enroll in their plans and are not charging them higher baseline premiums.

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[130] 42 U.S.C. § 300gg-4 (2015).

[131] Lovell v. Chandler, 303 F.3d at 1057 (emphasis added).

[132] *Id.* at 1056, (quoting Duvall v. County of Kitsap, 260 F.3d 1124 (9th Cir.2001)).

This would be true if the insurers had not gone a step further and implemented these three practices. However, high tiering, step-therapy, and pre-authorization requirements effectively deny enrollment, or, at the very least, deny equivalent cost for the plans to individuals with HIV/AIDS. It is not just the case that these insurance companies' failure to act caused the denial of the required accommodation; it is the case that their affirmative action caused such a denial. Both prongs of the "deliberate indifference" test being fulfilled, and "deliberate indifference" constituting intentional discrimination, insurance companies that adhere to these three practices seem to be exhibiting intentional discrimination as prohibited under § 504 of the Rehabilitation Act – and thus § 1557 of the ACA.

That the health insurance companies adhering to these practices are exhibiting intentional discrimination makes sense intuitively as well. For insurance companies to be most profitable, they seek to insure as many low-risk, low-payout people as possible. However, the ACA, via the guaranteed issue and community rating requirements, keeps insurers from explicitly discriminating against individuals with HIV/AIDS in order to keep their groups low-risk, low-payout. Nonetheless, insurers still have motive to keep their groups low-risk and low-payout. Since HIV/AIDS patients are high-risk and high-payout, insurers want to insure as few of these individuals as possible. With this motive in mind, and such prohibitive and restrictive practices instituted by insurance companies against individuals with HIV/AIDS, the discrimination seems likely to be intentional. What other reason would insurance companies have to institute these practices? It is obvious that these practices go against the medical standard of care for treating HIV/AIDS.

Furthermore, step-therapy and pre-authorization requirements are not always cost-saving methods for insurance companies. This is because of their aptitude to cause interruptions or delays in treatment. These lapses in treatment allow the virus to grow, mutate, and continue to attack the immune system.[133] When this happens, the human immune system is obviously severely weakened; and

[133] DEP'T OF HEALTH & HUMAN SERVS., *supra* note 44, at 188.

when this happens, individuals often have to be hospitalized.[134] Such hospitalizations are extremely costly episodes of care.[135] The insurer ends up paying for these ineffective drugs, and then also pays—an exorbitant amount—for the hospitalization due to the interruption in effective treatment. It is easy to see how these practices could actually end up being more expensive for insurance companies.

The high tiering of HIV/AIDS drugs on prescription drug formularies is not always cost- saving either, for two reasons. First, the interruptions these tierings cost inevitably leads to the proliferation of the HIV/AIDS virus and subsequent costly hospitalization. Second, these formularies often place the individual components of the STR drugs – that are on the highest tiers – on the lower tiers in small doses.[136] If individuals with HIV/AIDS choose to go this medically-unsafe route of purchasing all of the components of the STRs separately and in a large quantity—since each component is only on a lower cost-sharing tier in smaller doses—the cost to the insurance company can actually increase as compared to the STR on the highest tiers.

Insurance companies are just that, companies. Companies want to maximize profit. So why would they institute these practices that would not be cost-saving or even end up costing them more money? The answer is simple. These practices *are* actually cost-saving, although not in the way they are claimed to be. They are cost saving in that they discriminate against individuals with HIV/AIDS. These practices make health plans overly financially burdensome and medically unsafe, which works to discourage individuals with HIV/AIDS from enrolling in

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[134] *See generally* Nancy Crum, *Trends and Causes of Hospitalizations Among HIV-Infected Persons During the Late HAART Era: What is the Impact of CD4 Counts and HAART Use?,* 54(3) J. ACQUIR. IMMUNE DEFIC. SYNDR. 248 (2010).

[135] Michael Carter, *HIV Treatment is Costly, Especially for the Sickest Patients*, AIDSMAP (Sept. 27, 2010), http://www.aidsmap.com/HIV-treatment-is-costly-especially-for-the-sickest-patients/page/1516347, [http://perma.cc/W6V4-ACFZ].

[136] Elizabeth Taylor, *ACA Discrimination Against People with HIV/AIDS Will Not Be Tolerated*, HUFFINGTON POST, (Jun. 6, 2014), [http://www.huffingtonpost.com/elizabeth-taylor/aca-discrimination-against-hiv_b_5511810.html, [http://perma.cc/A5PX-5DC].

them. Thus, the insurance companies get what they want: less people with HIV/AIDS on their plans. They are intentionally discriminating against individuals with HIV/AIDS to keep such individuals off of their plans, which saves money for the insurer.

Overall, it seems that if these insurance practices are not found to be intentionally discriminatory under § 504 of the Rehabilitation Act, and thus § 1557 of the ACA, then intentional discrimination is a breathtakingly narrow and rather useless standard.

D. Disparate Impact Discrimination: Prohibited?

In order to determine whether these insurance practices are prohibited by § 1557 as disparate impact discrimination, it must first be determined whether § 504 of the Rehabilitation Act – which § 1557 invokes – actually prohibits disparate impact discrimination. In *Alexander v. Choate*, the State of Tennessee planned to reduce the number of inpatient hospital days per year that state Medicaid would pay hospitals for a Medicaid beneficiary's hospitalization.[137] A group of Medicaid recipients filed a class action suit seeking declaratory and injunctive relief.[138] Plaintiffs alleged that the reduction in days of coverage violated § 504 of the Rehabilitation Act because it negatively and disproportionately affected the handicapped. The Court opined that "much of the conduct that Congress sought to alter in passing the Rehabilitation Act would be difficult if not impossible to reach were the Act construed to proscribe only [intentional discrimination]."[139] The Court refused to hold that § 504 proscribes disparate impact broadly as a general rule in all cases.[140] The Court's refusal to do so seemed to be fueled by a fear of a "boundless" and overly broad cause of action in § 504.[141] However, the court concluded that § 504 can proscribe disparate impact

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137 Alexander v. Choate, 469 U.S. 287, 289 (1985).

138 *Id.*

139 *Id.* at 296-297.

140 *Id.* at 299.

141 *Id.*

discrimination in some cases,[142] such as when a "[disabled] individual [is not] provided with meaningful access to the benefit that [is] offer[ed]."[143] While "fundamental" or "substantial" modifications to the program or benefit are not required, "reasonable" modifications are required.[144] In fact, "under some circumstances, a refusal to modify an existing program might become unreasonable and discriminatory."[145]

The Court found that Tennessee's reduction in coverage days did not violate § 504.[146] The Court reasoned that the reduction did not disproportionately affect handicapped individuals but affected both handicapped and non-handicapped individuals equally.[147] So although the Court did not find disparate impact discrimination to have been present in *Alexander v. Choate*, it did recognize that § 504 prohibits disparate impact discrimination in certain cases.

E. High Tiering and Step-Therapy and Pre-Authorization Requirements: Disparate Impact Discrimination?

With this legal framework in mind, it can now be determined whether high tiering and step-therapy and pre-authorization requirements qualify as disparate impact of the kind prohibited under § 504 of the Rehabilitation Act – and thus § 1557 of the ACA.

The present situation is different from that in *Alexander v. Choate*. In *Alexander v. Choate*, the reduction in coverage days was not disparate impact discrimination because it affected both handicapped and non-handicapped individuals equally since both groups of people needed equal access to hospitalization. However, in the current situation, only individuals with HIV/AIDS need access to HIV/AIDS medications. Therefore, these aforementioned insurance practices that drastically limit access to HIV/AIDS medications negatively affect individuals with HIV/AIDS whereas it does not negatively affect those without the

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142 *Id.*

143 *Id.* at 301.

144 *Id.* at 300.

145 *Id.* (citing Southeastern Community College v. Davis, 442 U. S. 397 (1979)).

146 *Id.* at 309.

147 *Id.*

disease; in other words, it disproportionately affects individuals with HIV/AIDS. This is disparate impact discrimination.

So it is clear that disparate impact discrimination is at play here. However, recall that § 1557, through § 504 of the Rehabilitation Act, does not extend to all disparate impact discrimination, but only such discrimination that denies individuals with a disability "meaningful access" to the benefit offered.[148] In this case, that is exactly what is happening. Insurance companies are offering the benefit of health insurance coverage for medications. However, because high tiering and step-therapy and pre-authorization requirements cause HIV/AIDS medications to be unaffordable and cause dangerous interruptions in treatment, they effectively deny individuals with HIV/AIDS the benefit of insurance coverage for their medications. These practices are such that an individual with HIV/AIDS cannot effectively manage and treat their condition, causing the plans that subscribe to such practices to be inaccessible to those with HIV/AIDS. So individuals with HIV/AIDS are being denied the very benefit that is being offered to them – health insurance coverage for their medications and treatment. Such individuals are being denied meaningful access to the benefit at issue. This is precisely the form of disparate impact discrimination that the Court in *Alexander v. Choate* explained that the law prohibits.

Furthermore, insurance companies that subscribe to these practices need only modify their plans to a "reasonable" degree; a "substantial" or "fundamental" change in the program is not necessary.[149] HIV/AIDS medications need only be dropped down to lower tiers. While these insurers may argue that this would cost too much money, it is obviously not financially debilitating considering that some insurance companies already have such medications on lower, more affordable tiers.[150] Surely these other companies

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[148] *Id.* at 301.

[149] *Id.* at 300.

[150] *See* AIDS Found. of Chi., Cost of HIV Medications in the Illinois Health Insurance Marketplace (March 13, 2014) (on file with the AIDS Found. of Chi.), *available at* http://www.aidschicago.org/resources/content/1/4/documents/afc-il-marketplace-hiv-med-coverage-2015.pdf/ [http://perma.cc/T4PK-3L78].

are not operating at a loss by putting these HIV/AIDS mediations on lower tiers; if such a formulary structure were to cause a loss, these companies would not have such formularies. The step-therapy and pre-authorization requirements would need to be completely abolished. While at first blush this may seem to be a "substantial" or "fundamental" modification, it is not. Again, this is because other companies do not impose these requirements and they are not operating at a loss. Operating without these requirements is feasible and reasonable. Furthermore, it is not an unreasonable modification for insurers to alter or even completely dispose of practices whose sole purpose is to discriminate and discourage qualified individuals from enrolling. Overall, high tiering, step-therapy, and pre-authorization requirements seem to constitute the very sort of disparate impact discrimination that § 504 of the Rehabilitation Act – and thus § 1557 of the ACA – was interpreted by the Supreme Court to prohibit.

V. A POLICY CONSIDERATION

With such a new, expansive, and unprecedented law as the ACA, it is wise to take a step back and at least briefly look at some of the policy considerations that may affect this situation and that courts may factor in to a decision. Section 1557 does not exist *in vacuo* but lives within the broader context of the entire ACA and indeed the entire health insurance market. In the introduction to this Note the key pieces of the ACA were briefly explained. The following is an explanation about how some of those pieces interact to keep the ACA afloat.

The guaranteed issue and the community rating requirements ensure that everyone, regardless of their health status or history, is functionally able to obtain health insurance at relatively similar rates.[151] However, if this were all the ACA did, health insurance rates overall would skyrocket because of all of the high-risk people entering the

[151] Joel E. Miller, *Healthcare Reform: The "Three-Legged Stool" of Health Insurance Reform Under the ACA*, AMHCA (Oct. 1, 2013), http://www.amhca.org/news/detail.aspx?ArticleId=717 [http://perma.cc/U66C-ZJN4].

market.[152] However, the individual mandate, in a sense, forces most Americans to buy insurance and thus participate in the health insurance market.[153] This brings low-risk individuals into the market to counterbalance the high-risk individuals and thus reduces the cost of insurance.[154] Finally, the premium tax credits subsidize the cost of the insurance from low- and middle-income individuals so that it is actually feasible for them to afford the health insurance the individual mandate requires them to buy.[155] This is the "three-legged stool" of the ACA; abolish or damage any one of these provisions and the ACA cannot stand.[156]

We have seen that insurance companies are trying to find ways to keep out high-risk individuals —individuals with a preexisting condition—even though the ACA prohibits such practices.[157] If these practices, such as high tiering, step-therapy, and pre-authorization requirements, go unchecked, it will functionally undo the key provisions of the ACA that provide for the guaranteed issue and the community requirements. Without that leg of the stool, the ACA will fall.[158] One of the ACA's largest purposes will go unfulfilled. Therefore, it is imperative that § 1557 be given broad scope and considerable teeth to combat these discriminatory practices and close the back door the health insurance companies have been using to elude the guaranteed issue and community rating requirements. The Supreme Court has already seemed willing to interpret portions of the ACA so that they may stand and have effect, even if not as originally intended, as opposed to completely gutting them.[159] So there is some hope that the Courts will interpret § 1557 favorably in upcoming cases in order to keep the ACA intact and thus keep millions of people insured.

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[152] *Id.*
[153] *Id.*
[154] *Id.*
[155] *Id.*
[156] *Id.*
[157] Andrews, *supra* note 30.
[158] Miller, *supra* note 151.
[159] *See* Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S.Ct. 2566, 2580 (2012).

VI. CONCLUSION

Most of the health insurance companies in the United States will be covered entities under, and thus be subject to, the regulation of § 1557. Section 1557 prohibits intentional and certain forms of disparate impact discrimination against individuals with HIV/AIDS. The three health insurance practices described in this note likely qualify as the intentional discrimination prohibited by § 1557 and even more likely qualify as the disparate impact discrimination prohibited by § 1557. Policy also weighs in favor of § 1557 prohibiting these insurance practices. Therefore, § 1557 should serve as an effective means to combat discrimination by health insurance companies against individuals with HIV/AIDS in the form of the high tiering of HIV/AIDS medications on prescription drug formularies and step-therapy and pre-authorization requirements.

YES, THE FDA CAN MAKE YOU SAY THAT: WHY THE FDA'S PROPOSED NUTRITION FACTS LABEL CHANGES WILL WITHSTAND FIRST AMENDMENT CHALLENGES FROM FOOD INDUSTRY MEMBERS

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I. INTRODUCTION

In recent years, consumers have become increasingly concerned about the ingredients and overall nutritional content of foods they are eating. Such concerns often stem from weight-loss programs, food allergies, and environmental concerns. The nation has seen a number of movements in this direction ranging from calorie counting via mobile apps,[1] and "gluten free"[2] diets to the overall "clean eating"[3] concept.

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[1] Kathy Niedler, *Self Tracking Fitness, Review of Popular MyFitnessPal App*, iMEDICAL APPS: MEDPAGE TODAY, (Nov. 12, 2012) http://www.imedicalapps.com/2012/11/review-popular-myfitnesspal-app-fitness/ [http://perma.cc/WFP7-T4TZ] MyFitnessPal is a mobile app that allows users to track daily intake of calories and nutrients by selecting foods from a database or by manually entering the information from the Nutrition Facts label.

[2] Mayo Clinic Staff, *Gluten-Free Diet*, THE MAYO CLINIC http://www.mayoclinic.org/healthy-living/nutrition-and-healthy-eating/in-depth/gluten-free-diet/art-20048530 [http://perma.cc/B7C9-QWDR] (last updated Nov. 25, 2014). A gluten free diet is a diet that excludes the protein gluten and is typically followed by those with Celiac disease, although the diet has more recently become popular among non-Celiac disease sufferers. *Id.*

[3] Lauren Torrisi, *What the Heck is Clean Eating?* ABC NEWS (Apr. 5, 2013), http://abcnews.go.com/blogs/lifestyle/2013/04/what-the-heck-is-clean-eating [http://perma.cc/N4EL-JWY9]. (stating that "clean eating" is the concept that the shorter the ingredient list of a food, the better. The

The FDA has stepped in with an attempt to assist consumers with understanding the nutritional content of foods in response to consumer interest to learn more about the nutrients in common foods. The FDA made such an attempt by a proposal to add more detailed nutrition information to Nutrition Facts labels, as well as a proposal for a restructured label to make the label easier for consumers to read and understand.[4]

In addition to assisting the individuals who are following strict diets, the FDA recognized the need to improve the accessibility of nutrition information for all consumers due to the current obesity epidemic throughout the United States.[5] To address various health concerns, such as obesity and the chronic conditions associated with obesity, the FDA proposed updates to the Nutrition Facts labels of packaged food products to provide consumers with the necessary and important information to make healthy food choices.[6]

Among the updated information, the FDA hopes to implement a requirement of the disclosure of the amount of added sugar on the Nutrition Facts label as part of a major overhaul to the Nutrition Facts label.[7] As support for the added sugar disclosure, the FDA asserted all the proposed changes to the Nutrition Facts label are necessary and impactful because recent studies have shown that the number of consumers that use the information on the Nutrition Facts label has grown since 2002,[8] which is not surprising due to calorie counting, clean eating and gluten free trends.[9] Further, the FDA concluded the new added

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idea focuses on eating whole foods that lack artificial preservatives, sugars, and other additives.).

[4] *Proposed Changes to the Nutrition Facts Label*, FDA, http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm [http://perma.cc/9VPE-3AEP] (last updated July 27, 2015) [hereinafter "*Proposed Changes*"].

[5] *Id.*

[6] *Id.*

[7] *Id.*

[8] *Id.*

[9] *Gluten-Free Diet Appeals to 30Percent of Adults, Survey Says*, HUFFINGTON POST (Mar. 6, 2013), http://www.huffingtonpost.com/2013/03/06/gluten-free-diet_n_2818954.html [http://perma.cc/7V4P-GCTR]

sugar disclosure requirement will encourage food manufacturers to reformulate products to include less overall added sugar.[10]

The necessity of such updates to the Nutrition Facts label was identified before the FDA stepped in with the proposed rule in 2014. In 2010, the Center for Science in the Public Interest ("CSPI") released a report that called for the reform of food labeling legislation.[11] CSPI called for eight specific updates to the Nutrition Facts label in its report, largely because the label has not been updated since the passage of the Nutrition Labeling and Education Act of 1990 ("NLEA").[12] Further, CSPI asserted the updates to the label are essential because the current label from NLEA was not designed to prevent or reduce obesity.[13]

The FDA included some form of most of the changes recommended by CPSI in the proposed rule.[14] CSPI recommended an update to the design of the Nutrition Facts label by increasing the font size of the word "calories," as well as changing the "amount per serving" statement.[15] The organization also recommended a modification to the serving size for foods that are reasonably likely to be consumed by one person in a single sitting.[16] Additionally, CSPI recommended an update to the serving size of foods to more closely reflect the larger portion sizes consumed today.[17]

(reporting that "[t]hirty percent of adults are interested in avoiding or cutting down in gluten in their diets."); *Announcing 75 Million MyFitnessPal Users*, HELLO HEALTHY, MYFITNESSPAL UPDATES (Dec. 9, 2014), http://blog.myfitnesspal.com/announcing-75-million-myfitnesspal-users/ [http://perma.cc/EPQ6-8FR9]. MyFitnessPal claims to have 75 million registered users of the app worldwide as of 2014.

[10] *Proposed Changes, supra* note 4.

[11] Bruce Silverglade & Ilene Ringel Heller, *Food Labeling Chaos: The Case for Reform*, THE CTR. FOR SCIENCE IN THE PUB. INTEREST 1 (Mar. 2010), http://www.cspinet.org/new/pdf/food_labeling_chaos_report.pdf. [http://perma.cc/L7N6-NB3X].

[12] *Id.* at I-1.

[13] *Id.*

[14] *See generally,* Food Labeling: Revision of the Nutrition and Supplement Facts Label, 79 Fed. Reg. 11880 (Mar. 3, 2014) (to be codified at 21 C.F.R. 101) [hereinafter "Food Labeling"]

[15] *Id.* at I-2.

[16] *Id.*

[17] Silverglade & Ringel Heller, *supra* note 11, at II-3.

CSPI also proposed including the amount of added sugar to the label, as well as the creation of a recommended daily value for added sugar.[18]

Nearly four years after CSPI published the report highlighting the recommended updates to the Nutrition Facts label, the FDA published the proposed rule, "Food Labeling: Revision of the Nutrition and Supplement Facts Label" in the Federal Register on March 3, 2014.[19] Additionally, the FDA published revisions to the 2014 Proposed Rule on July 17, 2015.[20]

First Lady Michelle Obama also expressed her support for an updated Nutrition Facts label with an endorsement of the FDA's proposed rule during an event for her "Let's Move!" campaign.[21] During the event she emphasized the importance of labels that are easier for consumers, who have little or no nutrition knowledge to understand.[22] She noted that consumer-friendly labels would help consumers make informed and healthy decisions based on the information provided in the new label.[23] The First Lady also specifically applauded the added sugar disclosure by stating "[y]ou'll also learn where sugar in food comes from—if sugar in yogurt is added during processing or comes from fruits. This is a huge deal."[24]

The campaign for the updated Nutrition Facts label also follows the passage of the front of package label requirements.[25] Once food manufacturers started using front

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[18] *Id.* at II-1.

[19]. Food Labeling, *supra* note 14.

[20] Food Labeling: Revision of the Nutrition and Supplement Facts Label: Supplemental Proposed Rule to Solicit Comment on Limited Additional Provisions, 80 Fed. Reg. 44303 (July 17, 2015) (to be codified at 21 C.F.R. 101) [hereinafter "Supplemental Proposed Rule"].

[21] Sabrina Tavernise, *New FDA Nutrition Labels Would Make Serving Sizes Reflect Actual Servings*, N.Y. TIMES (Feb. 27, 2014), http://www.nytimes.com/2014/02/27/health/new-fda-nutrition-labels would-make-serving-sizes-reflect-actual-servings.html?_r=1., [http://perma.cc/7ZNW-EBBT].

[22] *Id.*

[23] *Id.*

[24] *Id.*

[25] Kathryn E. Hayes, *Front of Package Nutrition Claims: Trustworthy Facts or Deceptive Marketing? Closing the Loopholes in Labeling*, 19 CARDOZO J.L. & GENDER 545, 550 (2013); *See also Background*

of package labels, the government recognized a need for easier to understand Nutrition Facts labels because many consumers could not properly understand the Nutrition Facts labels and therefore relied on sometimes misleading front of package labels.[26] Fruit snacks often appear to be a healthy snack choice for children based on the front of package label that boasts, "made with real fruit."[27] However, after a proper examination of the ingredients label, these seemingly healthy fruit snacks are filled with corn syrup—a form of added sugar that increases the calories in the snack.[28] If the consumer had been able to find the high amount of added sugar conveniently located on the Nutrition Facts label, the mistake of consuming a snack high in added sugar that claims to be "made with real fruit" could have been avoided.[29]

A. The Issues

Despite the urgent need for updated Nutrition Facts labels with an added sugar disclosure, the FDA faces pushback from food manufacturers. The FDA was required by law to allow time for comments from the public after the 2014 proposed rule was published, and must consider and evaluate all comments before promulgating a final rule.[30]

Information on Point of Purchase Labeling, FDA (Oct. 2009) http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm187320.htm [http://perma.cc/S9UJ-4ECQ] [hereinafter *Point of Purchase Labeling*]. (Front of package ("FOP") labels often include nutritional information in addition to health or nutrient content claims and the FOP labels may also be in the form of graphics that indicate the food is a "healthy choice," although evidence suggests that the graphics can give the products an "overrated" view of healthiness).

[26] Hayes, *supra* note 25, at 550.

[27] *Id.* at 564.

[28] *Id.* at 565.

[29] *Id.*

[30] Administrative Procedures Act, 5 U.S.C §553 (2015) ("…the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments"). Food Labeling, *supra* note 14 at 11880 (Initially, the comment period was open for 90 days after the proposed rule was published on March 3, 2014). Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Extension of Comment Period, 79 Fed. Reg. 30055 (May 27, 2014). (The FDA extended the comment period to August 1, 2014 in response to many

Further, the 2015 supplemental proposed rule reopened the comment period in order to solicit additional comments for a limited number of provisions that were revised based on new evidence and some of the public comments.[31]

In many of the public comments that opposed the 2014 proposed rule, there was an assertion that the mandatory disclosure of added sugar infringes on First Amendment rights to free speech, specifically the right to "refrain from speaking."[32] Ocean Spray Cranberries, Inc. asserted in their comment that the added sugar disclosure will fail First Amendment scrutiny.[33] In addition to alleging First Amendment violations, food industry members also claimed the disclosure is unwarranted and misleading.[34] Based on such comments, it seems fair to assume challenges may be brought against the disclosure because some food industry members consider it controversial.[35] The food industry had similar comments and concerns when the mandatory disclosure of trans fats was introduced in 2003.[36] The

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requests for the extension because the 90-day period was not sufficient time to develop thoughtful comments and suggestions).

[31] Supplemental Proposed Rule *supra* note 20, at 44311.

[32] Glenn G. Lammi, *FDA's "Added Sugar" Labeling Proposal: More Information Isn't Always Better (Or Legal)*, FORBES (Sept. 8, 2014), http://www.forbes.com/sites/wlf/2014/09/08/fdas-added-sugar-labeling-proposal-more-information-isnt-always-better-or-legal/ [http://perma.cc/U3KT-ZAUJ].

[33] Public Comment from Ocean Spray Cranberries, Inc. on Proposed Rule: Food Labeling: Revision of the Nutrition and Supplement Facts Labels (Aug. 1, 2014), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2012-N-1210-0388 [http://perma.cc/7S77-2YK7].

[34] Public Comment from Decas Cranberry Products on Proposed Rule: Food Labeling: Revision of the Nutrition and Supplement Facts Labels (Aug. 1, 2014), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2012-N-1210-0085 [http://perma.cc/7ZPA-36MP] ("…the inclusion of 'added sugar' as a separate item within the nutrition facts panel, is scientifically unwarranted, and will create confusion with consumers as to the healthful properties of cranberry products.").

[35] Tavernise, *supra* note 21.

[36] Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, 68 Fed. Reg. 41434, 41439 (July 11, 2003) [hereinafter "Trans Fatty Acids"]. ("Several general comments

previous comments on the trans fat disclosure support the likelihood of formal First Amendment challenges to the added sugar disclosure.

The first issue with respect to the added sugar disclosure that must be resolved is whether it would survive such First Amendment challenges. The resolution of such a challenge requires that a court first determine whether the labeling disclosure is commercial speech[37]. Once the disclosure is regarded as commercial speech, the court must determine the appropriate standard to apply in analyzing the disclosure.[38] Similar commercial speech challenges, such as warning labels on tobacco products, were held under the standard created in *Central Hudson Gas & Electric Corp. v. Public Service Commissioner*.

However, recent litigation regarding meat product labeling was held to the more lenient standard created in *Zauderer v. Office of Disciplinary Counsel of Supreme Court*. In the 2014 D.C. Circuit case, *American Meat Institute v. USDA*, the challenged country-of-origin disclosure on meat products was held to the reasonable relationship *Zauderer* standard, discussed in further detail later in this Note.[39] The decision was declared to be a "win for public health" because it opened the possibility of holding future food labeling challenges to the same standard.[40]

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were received asserting that the agency's action to mandate labeling is subject to review under the First Amendment").

[37] *See* Lucien J. Dhooge, *The First Amendment and Disclosure Regulations: Compelled Speech or Corporate Opportunism?*, 51 AM. BUS. L.J. 599 (2014).

[38] Courts have historically analyzed commercial speech First Amendment challenges under the standard created in *Central Hudson* or *Zauderer*, discussed in further detail later in this Note.

[39] Jonathan H. Adler, *En banc D.C. Circuit Upholds USDA Country-of-Origin Labeling Rule*, VOLOKH CONSPIRACY (July 30, 2014), http://www.washingtonpost.com/news/volokh-conspiracy/wp/2014/07/30/en-banc-d-c-circuit-upholds-usda-country-of-origin-labeling-rule/ [http://perma.cc/8MAN-MMVD].

[40] Kerry Cork, *Court Decision on "Mandatory Disclosure" Could be a Big Win for Public Health*, NETWORK FOR PUBLIC HEALTH LAW BLOG (Aug. 6, 2014, 11:40 AM), https://www.networkforphl.org/the_network_blog/2014/08/06/480/court_decision_on_mandatory_disclosure_could_be_a_big_win_for_public_health, [http://perma.cc/W2UV-7H5G].

Even though some food industry members asserted the added sugar disclosure should be held to the *Central Hudson* standard,[41] a court would likely hold the FDA's proposed added sugar disclosure to the *Zauderer* standard because of the *American Meat Institute* analysis. Through the application of the reasonable relationship test from *Zauderer*, a court would likely find the added sugar disclosure to survive First Amendment challenges due to the many legitimate government interests for providing information about the amount of added sugar in a product for consumers.

B. Roadmap

This Note will begin by exploring the FDA's proposed rule, "Food Labeling: Revision of the Nutrition and Supplement Facts Labels,"[42] with an emphasis on the added sugar disclosure. Next, the Note will transition into an examination of First Amendment standards in the context of commercial speech and an evaluation of the standards that courts have used when examining such disclosures.

As a continuation of the First Amendment evaluation, the Note will also discuss some of the most recent food labeling litigation and provide an analysis of the court's review under the respective standard applied by the court. After evaluating recent case law regarding food labeling, a determination of whether the *Central Hudson* or *Zauderer* standard should apply to the disclosure will be made.

Finally, the Note will analyze the added sugar disclosure requirement under the five-prong reasonable relationship test from *Zauderer* and explain the reasons why the disclosure will withstand First Amendment challenges under this standard. The final section will also provide a few supporting policy reasons for the proposed rule and explain

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[41] Public Comment from The Corn Refiner's Association on Proposed Rule: Food Labeling: Revision of the Nutrition and Supplement Facts Labels (Aug. 1, 2014),) *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2012-N-1210-0455 [http://perma.cc/RZ4G-RBYB] (asserting the added sugar disclosure would fail First Amendment scrutiny under the four prong test from *Central Hudson*).

[42] Food Labeling, *supra* note 14, at 11880.

why the FDA should move forward with a final rule, regardless of potential First Amendment challenges.

II. BACKGROUND

The FDA published an initial proposed rule, "Food Labeling: Revision of the Nutrition and Supplement Facts Label" in the Federal Register on March 3, 2014 and published revisions to the initial proposed rule on July 17, 2015.[43] The FDA's main goal of the proposed rule was to update the regulations to better assist consumers in maintaining healthy eating practices by improving "how the information is presented to consumers."[44] The FDA aimed to achieve such a goal with three major categories of proposed changes to the Nutrition Facts label.

A. The FDA's Proposed Changes to the Nutrition Facts Label

The first major category of changes is designed to create a "greater understanding of nutrition science[45] by adding the amount of added sugar to the label, an update to the "percentage of daily value" for some nutrients, and removal of the line "calories from fat."[46] By modifying the label, the FDA hopes to provide consumers with the necessary information to understand the link between the nutrients and calories consumed and obesity.[47] In addition, the update to the percentage of daily values for some nutrients, such as sodium, dietary fiber, and vitamin D, will help consumers understand the role the nutrients play in their overall daily diet.[48]

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[43] *Id.*; Supplemental Proposed Rule, *supra* note 20, at 44303.

[44] Food Labeling, *supra* note 14, at 11880.

[45] *Proposed Changes*, *supra* note 4.

[46] *See id.; Nutrition Facts Label: Proposed Changes Aim to Better Inform Food Choices* FDA (Feb. 2014), http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM395422.pdf [http://perma.cc/TK6P-ELRN].2X3X-PAK5]. (The FDA has proposed the removal of "calories from fat" because evidence shows the type of fat is more important than the total amount of fat).

[47] *Proposed Changes, supra* note 4.

[48] *Id.*

The second major category of changes to the Nutrition Facts label is intended to update the "serving size requirements."[49] One update calls for "new labeling requirements for certain package sizes,"[50] including modifying serving sizes for food and drinks typically consumed in one sitting.[51] Currently, a twenty-ounce bottle of soda is labeled as more than one serving.[52] With the proposed changes to the Nutrition Facts label, the soda would be labeled as one single serving because it is most often consumed in one sitting, by one consumer.[53]

Additionally, the serving sizes of certain foods and drinks will be updated to reflect the larger portions Americans consume today.[54] For example, a pint of ice cream is currently labeled as four servings—about half a cup per serving.[55] The FDA proposed a change to the number of servings in a pint of ice cream to two servings in order to more accurately represent the larger portions consumed by Americans.[56]

Finally, the last category of proposed changes to the Nutrition Facts label is intended to create a "refreshed design"[57] with more emphasis on the serving size and calorie content of the label.[58] Serving size and calorie content are essential pieces of information for consumers to understand in order to make healthy choices to prevent obesity and other chronic conditions.[59] The new label would also relocate the percentage of daily value, another important piece of information used to make healthy choices, to the left of the nutrients so that it will also quickly attract consumer attention.[60]

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49 *Id.*
50 *Id.*
51 *Id.*
52 *Id.*
53 *Id.*
54 *Id.*
55 *Id.*
56 *Id.*
57 *Id.* at 4.
58 *Id.*
59 *Id.*
60 *Id.*

B. Added Sugar Disclosure

Based on a review of the public comments to the 2014 proposed rule, it appears the added sugar disclosure sparked the most conversation and will therefore be reviewed with the most detail in this Note. The FDA proposed the amount of added sugar in a food should be included in the Nutrition Facts label, indented under the line where "sugar" is currently listed.[61] The FDA proposed the disclosure based on the updated recommendation to reduce the number of calories consumed from excess solid fat and added sugars,[62] as well as a recommendation of the amount of energy intake that should come from added sugars.[63] Currently, the Institute of Medicine ("IOM") Dietary Reference Intake Report recommends a maximum of twenty-five percent of energy intake from added sugars,[64] based on evidence that a high intake of added sugars decreases the intake of other more important nutrient dense foods.[65]

Along with the updated dietary recommendations, the FDA also cited consumer awareness as a major support for the added sugar disclosure.[66] The FDA asserted that without the declaration of added sugars, consumers are unable to compare the amount of non-naturally occurring sugar in foods, such as fruit juices and yogurt.[67] Forms of added sugar are often listed in the ingredients section of food labels under complex chemical names that many consumers do not understand or recognize as a form of sugar.[68]

Finally, the FDA provided four additional reasons to include the disclosure of added sugars on the Nutrition Facts label to improve consumer awareness, including:

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[61] *Id.*

[62] Food Labeling, *supra* note 14, at 11903. ("…to meet nutrient needs within an individual's calorie limits, a key recommendation of the 2010 DGA is to reduce the intake of calories from solid fats and added sugars").

[63] *Id.* at 11902.

[64] *Id.*

[65] *Id.*

[66] *Id.* at 11904.

[67] *Id.*

[68] *I d.*

> (1) The variability in ingredients used, (2) the need for consumers to have a consistent basis on which to compare products, (3) the need for consumers to identify the presence or absence of added sugars, and (4) when added sugars are present, the need for consumers to identify the amount of added sugars added to the food.[69]

Additionally, one of the revisions contained in the 2015 Supplemental Rule would also require a daily recommended value ("DRV") for added sugars to be displayed on the Nutrition Facts label.[70] The FDA initially rejected this idea in the 2014 proposed rule based on a lack of evidence for the establishment of a DRV.[71] However, the 2015 Dietary Guidelines Advisory Committee performed additional updated research and suggested the label should include a declaration of a percent of daily value for added sugars.[72]

C. First Amendment Protected Speech

After establishing a foundation for why the FDA believes the added sugar disclosure on the Nutrition Facts label is necessary, it is essential to establish the foundation of the challenges that may be brought against the disclosure. A discussion of the types of First Amendment protected speech and how they are distinguished is necessary to understand why the food industry opposes the disclosure.

A First Amendment challenge brought by the food industry to protect its right to not speak or right to not disclose information would fall under the context of commercial speech. The Supreme Court classifies commercial speech as "speech which does no more than propose a commercial transaction,"[73] and later extended the definition to include speech "related solely to the economic

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[69] *Id.*

[70] Supplemental Proposed Rule, *supra* note 20, at 44308.

[71] Food Labeling, *supra* note 14, at 11902.

[72] Supplemental Proposed Rule, *supra* note 20, at 44307.

[73] Dhooge, *supra* note 37, at 606-07 (quoting Pittsburgh Press Co. v. Pittsburg Comm'n on Human Relations, 413 U.S. 376, 386 (1973)).

interests of the speaker and its audience."[74] The Court also included speech in which the transaction was "the core notion of commercial speech."[75]

Commercial speech is afforded a different type of protection than individual speech and can be restricted in ways that individual speech cannot be restricted.[76] Such restriction may be in the form of a disclosure of additional information, warnings and any disclaimers that would be helpful in preventing deception in consumers.[77]

The idea of different restrictions for commercial speech is based on the theory that the government has an interest in ensuring "the flow of truthful and legitimate commercial information is unimpaired."[78] Commercial speech can also be considered compelled speech, subject to government restrictions and requirements.[79] In a corporate or commercial context, compelled speech can be generally categorized as speech the government requires of the corporation.[80]

Two standards developed by the Supreme Court are typically used for evaluating whether commercial speech is protected under the First Amendment. In recent years, courts appear to be split in deciding the standard to apply to the different types of commercial speech, which has led to controversy over the issue. Both standards, the stricter from the 1980 case, *Central Hudson Gas & Electric Corporation v. Public Service Commissioner*, and the more lenient from the 1985 case, *Zauderer v. Office of the Disciplinary Counsel of Supreme Court*, may be applied to speech restrictions or compelled speech.

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[74] *Id.* at 607 (quoting Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 561 (1980)).

[75] *Id.* (quoting Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60, 66 (1983)).

[76] *Id.* at 606.

[77] *Id.*

[78] *Id.* (quoting Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 771 n.24 (1976)).

[79] *Id.* at 611.

[80] *Id.* at 609–611.

D. Central Hudson Standard Introduction

The standard from *Central Hudson* has been used for commercial speech cases related to compelled speech in the form of labeling, however there is concern as to whether it is the appropriate standard to apply in such a situation.[81] The standard was most recently and notably applied to the compelled speech of graphic warning labels on cigarette packaging in *R.J. Reynolds Tobacco Company v. FDA*, discussed further in this section.[82] Additionally, the FDA also included a brief First Amendment analysis of the mandatory trans fat disclosure on the Nutrition Facts label under the *Central Hudson* standard when it published the final rule in 2003.[83]

In the *Central Hudson* decision, the Supreme Court developed a four-part intermediate scrutiny test used to analyze commercial speech.[84] The four-part test begins with a determination of whether the speech concerns "lawful activity" that "must not be misleading."[85] Next, the government interest in restricting the speech must be substantial.[86] Third, the means used to restrict or compel the speech must directly advance the substantial government interest, and finally, the means must not be "more extensive than necessary to serve that interest."[87]

E. R.J. Reynolds Tobacco Co. Under Central Hudson

The proposed graphic warning labels for tobacco products in *R.J. Reynolds Tobacco* failed the First Amendment intermediate scrutiny test under the *Central Hudson*

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[81] *Id.* at 618–619.

[82] R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d. 1205, 1209 (D.C. Cir. 2012) (the graphic warnings contained a graphic photo depicting the negative effects of tobacco use, as well as the phone number for the "National Cancer Institute's Network of Tobacco Cessation Quitlines").

[83] Trans Fatty Acids, *supra* note 36, at 41439.

[84] Dhooge, *supra* note 37, at 616.

[85] Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 566 (1980).

[86] *Id.*

[87] *Id.*

standard.[88] In 2012, the Family Smoking and Tobacco Prevention Act directed new regulations to be issued by the FDA that required new textual, as well as graphic warnings on all tobacco product packaging.[89] The graphic warning labels contained "color graphics depicting the negative health consequences of smoking."[90] The FDA's primary goal in implementing such graphic warnings was "to effectively convey the negative health consequences of smoking on cigarette packages and in advertisements."[91]

Once the FDA implemented a final rule, "Big Tobacco" filed suit, alleging First Amendment violations.[92] Before addressing the specific First Amendment challenges, the court determined that the *Central Hudson* standard was the appropriate level of scrutiny to apply to the graphic warnings.[93] The court's determination rested on the finding that the warnings were not purely factual and uncontroversial, nor were the warnings intended to correct false or misleading claims made by the tobacco companies.[94]

The court evaluated the warnings under the *Central Hudson* standard and found the FDA was able to show the purported interest of the graphic labels in reducing smoking rates was substantial.[95] However, the analysis ended at the next prong because the FDA was unable to produce a "shred of evidence" that the graphic warnings would directly advance the substantial interest.[96] Upon failing to provide substantial evidence that the graphic warnings would directly advance the substantial interest as required by the Administrative Procedure Act, the FDA's graphic warnings failed intermediate scrutiny under *Central Hudson*.[97]

In the dissenting opinion of the decision, Circuit Judge Rodgers argued the warnings should have been held to the lesser standard from *Zauderer* because the court failed to

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88 Dhooge, *supra* note 37, at 620.
89 R.J. Reynolds, 696 F.3d. at 1208 (D.C. Cir. 2012).
90 *Id.*
91 *Id.* at 1210.
92 *Id.* at 1211.
93 *Id.* at 1216.
94 *Id.*
95 *Id.* at 1218.
96 *Id.* at 1219.
97 Dhooge, *supra* note 37, at 621.

consider the tobacco companies' history of deceptive marketing.[98] Judge Rodgers also asserted the warnings should have been held to the *Zauderer* standard because they contained "factually accurate information and addressed misleading speech."[99]

F. Trans Fatty Acids Under Central Hudson

Although there was no litigation regarding the mandatory disclosure of trans fatty acids on the Nutrition Facts label, the FDA still engaged in a brief First Amendment analysis under the intermediate scrutiny standard from *Central Hudson* in the final rule, published on July 11, 2003.

The FDA issued a proposed rule on November 17, 1999 that called for the amount of trans fats to be disclosed on the Nutrition Facts label.[100] The FDA based the proposal for the trans fats disclosure on the label on recent evidence that showed the "consumption of diets containing *trans* fatty acids…resulted in increased serum low-density lipoprotein cholesterol, [LDL-C] a major risk factor for [coronary heart disease]."[101]

In response to the many comments claiming the mandatory disclosure of trans fat on the Nutrition Facts label violated the First Amendment, the FDA included a brief analysis of how the disclosure would pass a First Amendment challenge under the *Central Hudson* standard in the final rule. The disclosure was related to lawful activity and not misleading and therefore passed the first prong of the standard.[102] According to the FDA, the disclosure also satisfied the second prong because the FDA's interest in requiring the amount of trans fat on the label was clearly substantial.[103]

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[98] *R.J. Reynolds Tobacco*, 696 F.3d. at 1222 (Rodgers, J., dissenting).

[99] *Id.*

[100] Trans Fatty Acids, *supra* note 36, at 41435.

[101] *Id.*

[102] *Id.* at 41439.

[103] *Id.* ("[The] FDA's interest is substantial for at least two reasons….substantial interest in protecting and promoting public health and in preventing consumer deception by ensuring accuracy and completeness of trans fat information in labeling.").

The FDA asserted the mandatory disclosure would pass the third prong as well because it directly advanced the government interest when consumers relied on the information in the Nutrition Facts label in order to maintain healthy dietary practices.[104] Finally, the trans fat disclosure passed the fourth prong of *Central Hudson* because it was not more extensive than necessary to serve the FDA's interest.[105] The FDA asserted the disclosure was not extensive because it contained "truthful, factual, noncontroversial information about the presence or absence and amount of *trans* fat in food" that would assist consumers with choosing foods that will lower their risk of coronary heart disease.[106]

The FDA claimed that the trans fat disclosure would pass intermediate scrutiny under *Central Hudson*, but also stated that it was likely not even necessary for the disclosure to satisfy the test.[107] The FDA claimed the trans fat disclosure should not have to pass the *Central Hudson* standard because it is compelled commercial speech rather than a prohibition on speech in which *Central Hudson* typically applies.[108] The FDA's assertion that the mandatory disclosure should not be held to the strict standard of *Central Hudson* may provide insight into which standard will apply to the FDA's proposed added sugar disclosure.

G. Zauderer Standard Introduction

In addition to the *Central Hudson* standard, courts have also used the more lenient standard from *Zauderer* to analyze commercial speech cases. *Zauderer* was decided after *Central Hudson* and provides an easier path for the government to pass when requiring a disclosure of additional information.[109] The Supreme Court developed a reasonable relationship test in *Zauderer* based on the theory that "rights are adequately protected as long as [the] disclosure requirements are reasonably related to the State's interest in

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104 *Id.* at 41440.
105 *Id.*
106 *Id.*
107 *Id.*
108 *Id.*
109 *See* Dhooge, *supra* note 37, at 621.

preventing deception of consumers."[110] The reasonable relationship test consists of five prongs used to determine whether government compelled speech violates First Amendment protection for commercial speech.[111]

The first two prongs of the reasonable relationship test require the compelled speech to be "purely factual" and "uncontroversial."[112] Speech that contains "accurate factual information" has been found to satisfy the first two prongs.[113] The third prong mandates a "legitimate government interest" for requiring the speech or disclosure.[114] The fourth prong requires the compelled speech or disclosure to also be "reasonably related" to the legitimate interests, and finally, the compelled speech or disclosure must not be "unjustified or unduly burdensome" in order to satisfy the fifth prong.[115]

H. International Dairy Foods Association Under Zauderer

International Dairy Foods v. Boggs is a 2010 Sixth Circuit case involving composition claims and label disclosures on dairy products. The Ohio Department of Agriculture developed regulations to address the claims of "rbST Free" used on dairy products that contained milk from cows not treated with rbST. [116] The Department required a disclosure that addressed the FDA's findings of no significant difference between milk from cows treated with rbST and milk from cows not treated with the hormone.[117] While the court

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[110] Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985).

[111] Dhooge, *supra* note 37, at 624.

[112] *Id.*

[113] *Id.*

[114] *Id.*

[115] *Id.*

[116] Int'l Dairy Foods Ass'n v. Boggs, 622 F.3d. 628, 640 (6th Cir. 2010) (rbST is a genetically engineered hormone sometimes given to cows to increase milk production. Dairy producers were using the phrase "rbST Free" on labels and the FDA required them to disclose that there has been no evidence that shows a compositional difference between milk from treated and untreated cows).

[117] *Id.* at 632. (The department recommended a disclosure that stated, "the FDA has determined that no significant difference has been

evaluated the compensation claim under the *Central Hudson* standard, it evaluated the disclosure claim under the *Zauderer* standard.[118]

The court determined the disclosure was reasonably related to the agency's interest in preventing consumer deception because some commentators pointed out that consumers were confused about what substances are or are not in the dairy products they purchased.[119] Although the court concluded the actual disclosure was reasonably related to the interest, it found that the required placement and format of the disclosure lacked rational basis.[120]

The court also addressed whether the disclosure was unduly burdensome. In addressing the last prong of *Zauderer*, the court found the disclosure was not unduly burdensome because it would be identical to disclosures used by other states once the ban on the use of asterisks in the disclosure was lifted.[121] Although the disclosure from *International Dairy Foods* does not explicitly pass the *Zauderer* standard, it serves as an excellent example of how courts apply this standard to government compelled speech.

I. American Meat Institute Under Zauderer

American Meat Institute v. USDA is the most recent food labeling case that could serve as a guide for any future litigation related to the FDA's required disclosure of added sugar on the Nutrition Facts label. *American Meat Institute* involved a First Amendment challenge by members of the American Meat Institute ("AMI") against the USDA for the implementation of a rule that required the country-of-origin

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shown between milk derived from rbST-supplemented and non-rbST-supplemented cows.").

[118] *Id.* at 641. ("there are material differences between purely factual and uncontroversial disclosure requirements and outright prohibitions on speech").

[119] *Id.* at 642.

[120] *Id.* at 643. (The disclosure was required to be in the exact font, case, style, color and at least half the size as the production claim and not linked to an asterisk after the claim).

[121] *Id.*

of certain meat products to be disclosed on the label.[122] The District Court applied the *Zauderer* reasonable relationship test to the country-of-origin disclosure and the D.C. Circuit affirmed the use of *Zauderer* for the disclosure.[123]

In an attempt to reject the standard applied by the District Court, plaintiffs asserted that *Zauderer* could not apply outside of government interests to prevent consumer deception.[124] The plaintiffs instead asserted the stricter standard of *Central Hudson* should have applied to the mandatory disclosure.[125] The D.C. Circuit rejected the plaintiffs' contention and instead held "[t]o the extent that other cases in this circuit may be read as holding to the contrary and limiting *Zauderer* to cases in which the government points to an interest in correcting deception, we now overrule them."[126]

When applying the reasonable relationship test from *Zauderer*, the court first evaluated whether the government had a substantial interest in requiring the country-of-origin disclosure.[127] Throughout the evaluation, the court found several substantial government interests, even though *Zauderer* only requires legitimate interests based on consumer choice, consumer interest, and consumer health concerns; therefore, the disclosure was reasonably related to such legitimate interests.[128]

The court then added that the country-of-origin disclosure was purely factual and uncontroversial.[129] Absent any allegations by AMI that the disclosure would be unduly burdensome, the court held the disclosure was not unduly

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[122] Am. Meat Inst. v. United States Dep't of Agric., 760 F.3d. 18, 20 (D.C. Cir. 2014).

[123] *Id.*

[124] *Id.*

[125] *Id.*

[126] *Id.*

[127] *Id.* at 23.

[128] *Id.*

[129] *Id.* at 27. (AMI did not contest that the disclosure was not purely factual, but did assert it was controversial. The court rejected AMI's controversial assertion because it is not of the category of facts that are so one-sided or incomplete that they could not be uncontroversial).

burdensome.[130] The country of origin disclosure therefore survived First Amendment challenges under *Zauderer*.

To demonstrate how *American Meat Institute* would serve as a guide for any litigation involving the added sugar disclosure, it is important to note the government interests for requiring the country-of-origin disclosure are similar to the government interests for requiring the added sugar disclosure. The two interests will be compared later in the Note, but a brief introduction to the government interests of country of origin labeling appropriately follows.

As noted above, the government interests in requiring country of origin labeling were based on consumer choice, interest and health concerns. First, the more detailed label with the disclosure gives consumers the power to choose American made products.[131] The government has an interest in providing consumers with the necessary information to be aware of where the food came from, especially when this expectation has been long required of other non-food products.[132] Finally, the government has an interest in providing consumers with the information necessary to choose meat from countries of their choice, based on individual health concerns and concerns related to food-borne illness.[133]

The *Central Hudson* and *Zauderer* standards developed by the Supreme Court are still used by courts for compelled speech cases today as shown by *R.J. Reynolds Tobacco, International Dairy* and *American Meat Institute*.[134] Although *R.J. Reynolds* used the *Central Hudson* standard, *American Meat Institute* is evidence that courts are moving toward applying the more lenient *Zauderer* standard to government compelled speech situations, possibly changing the outcome of commercial speech cases.

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[130] *Id.* at 23.

[131] *Id.* at 23.

[132] Am. Meat Inst., 760 F.3d. at 23. ("…country-of-origin label mandates indeed have a long history. Congress has been imposing similar mandates since 1890, giving such rules a run just short of 125 years.").

[133] *Id.*

[134] Dhooge, *supra* note 37, at 620.

III. ANALYSIS

In order to determine whether the FDA's proposed added sugar disclosure would survive a First Amendment challenge brought by food industry members, it is essential to first determine how a court would analyze such a challenge. However, the analysis of whether the *Central Hudson* or *Zauderer* standard would apply to the added sugar disclosure cannot begin without first determining whether the disclosure is considered commercial speech.

A. Commercial Speech Analysis

To determine if speech is commercial speech, a court will consider three factors: "(1) whether the speech is an advertisement; (2) whether it refers to a specific product; and (3) whether the speaker has an economic motivation for speaking."[135] The three factors do not only apply to situations that involve actual speech.[136] The Sixth Circuit found disclosures on food labels to be commercial speech in the 2010 *International Dairy* decision.[137] Food labels typically present a commercial transaction for purchase and even when the label contains a disclosure, courts have considered them to be commercial speech.[138] The Nutrition Facts label presents a commercial transaction for purchase; therefore even if it contains the added sugar disclosure, it is likely commercial speech.

B. Zauderer or Central Hudson

After the determination that the added sugar disclosure is commercial speech, the next step is to evaluate whether the test from *Zauderer* or *Central Hudson* should apply to a

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[135] Melissa M. Card, *America, You are Digging Your Grave with Your Spoon—Should the FDA Tell You That on Food Labels?*, 68 FOOD & DRUG L.J. 309, 313 (2013).

[136] *Id.*

[137] *See* Int'l Dairy Foods Ass'n v. Boggs, 622 F.3d. 628, 635 (6th Cir. 2010); *See also* Card, *supra* note 135, at 314.

[138] Card, *supra* note 135, at 314.

First Amendment challenge in this context. The determination is best made after quickly reviewing the recent case law involving commercial speech litigation discussed earlier. Currently, courts are split as to which standard should be applied to commercial speech cases that involve labels of products regulated by the FDA.[139]

1. Central Hudson Standard Analysis

The *Central Hudson* standard was the most widely used standard for commercial speech cases in the past, but appears to have been used less often in recent cases. As previously discussed, the D.C. Circuit applied the intermediate scrutiny test from *Central Hudson* to *R.J. Reynolds Tobacco Co.* in 2012 to evaluate the FDA's proposed use of graphic warnings on the labels of tobacco products.[140] Under the *Central Hudson* standard, the D.C. Circuit found the FDA could not require this compelled speech in the form of graphic warnings on the labels.[141] Further, the court rejected using the *Zauderer* standard because the graphic warnings were not "purely factual and uncontroversial."[142]

When the FDA promulgated the final rule for adding the disclosure of trans fats to the Nutrition Facts label, it included a brief *Central Hudson* analysis in response to many public comments that asserted the disclosure would not pass the intermediate scrutiny test.[143] In the analysis, the FDA claimed the disclosure would pass the first prong because the disclosure of trans fats is related to lawful activity and is not misleading.[144] The disclosure also passed the second and third prongs because the mandatory trans fat disclosure directly advanced the substantial interests of protecting and promoting public health, as well as preventing consumer deception.[145]

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[139] *Id.*

[140] *See generally* R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d. 1205 (D.C. Cir. 2012).

[141] *Id.*

[142] *Id.*

[143] Trans Fatty Acids, *supra* note 36, at 41439.

[144] *Id.*

[145] *Id.* at 41439-41440.

2. Zauderer Standard

Contrary to *R.J. Reynolds Tobacco*, the D.C. Circuit held *American Meat Institute v. USDA* to the *Zauderer* standard in the summer of 2014.[146] The court's decision shifted from the use of *Central Hudson* by finding that *Zauderer* can apply to speech beyond situations of deception.[147] The court also found that *Zauderer* could be extended to disclosures that are required to serve government interests other than preventing deception.[148] Finally, the D.C. Circuit made a point to state that it now overrules the cases where *Zauderer* is read to only apply to disclosures where the government's interest is correcting deception.[149]

The Sixth Circuit also applied *Zauderer* to commercial speech cases that involve compelled speech through label disclosures. In *International Dairy*, the court evaluated a disclosure requirement on dairy products that claimed to be "rbST free" under *Zauderer* in 2010.[150] The Sixth Circuit found *Zauderer* to be the appropriate standard because it is applicable to disclosures that are required based on the government's interest to correct potentially misleading speech and not just inherently misleading speech.[151]

Because litigation arising from compelled disclosures on food labels has most recently been decided under *Zauderer*, it appears that a court would hold the added sugar disclosure to the same standard. The court's effort in *American Meat Institute* that overruled the cases that only apply *Zauderer* to cases to correct deception is dispositive in the determination of which standard a court would apply to the added sugar disclosure, even though the FDA previously used the Central Hudson standard to self evaluate a mandatory disclosure. Further, the FDA even stated in their self-evaluation of the trans fat disclosure that the disclosure

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146 Am. Meat Inst., v. United States Dep't of Agric., 760 F.3d. 18, at 20 (D.C. Cir. 2014).

147 *Id.*

148 *Id.* at 21.

149 *Id.* at 22.

150 Int'l Dairy Foods Ass'n v. Boggs, 622 F.3d. 628, 640 (6th Cir. 2010).

151 *Id.* at 641.

likely did not need to be analyzed under the intermediate scrutiny test from *Central Hudson*.[152]

Additionally, Judge Rodgers expressed his dissatisfaction with the use of *Central Hudson* in his dissent in *R.J. Reynolds Tobacco*, stating that *Zauderer* should have applied instead.[153] Rodgers' assertion that *Central Hudson* was not appropriate to evaluate the graphic warning labels supports a finding that *Zauderer* is the correct standard for analyzing the less dramatic added sugar disclosure proposed by the FDA.

Further, the fact that the public comments asserted *Central Hudson* as the standard to be applied to the disclosure does not weigh on the analysis in this Note.[154] The added sugar disclosure is purely factual and uncontroversial and even though the government's interest in the disclosure may be beyond correcting deception, *American Meat Institute* opened the door for *Zauderer* to be extended to government interests beyond correcting deception.

C. Zauderer First Amendment Analysis

After establishing *Zauderer* as the appropriate standard to evaluate the added sugar disclosure, each of the five factors of the reasonable relationship test should be applied to the added sugar disclosure.

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[152] Trans Fatty Acids, *supra* note 36, at 41440.

[153] R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d. 1205, 1222 (D.C. Cir. 2012) (Rodgers, J., dissenting) ("[i]n affirming the grant of summary judgment to the tobacco companies, the court applies the wrong level of scrutiny").

[154] Public Comment from the Corn Refiner's Association on Proposed Rule: Food Labeling: Revision of the Nutrition and Supplement Facts Labels (Aug. 1, 2014), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2012-N-1210-0455 [http://perma.cc/8LK6-Y3H2]V9L2-XQ6Y]. The association attempts to claim that the added sugar disclosure would fail on all four prongs of the *Central Hudson* test and *Zauderer* cannot apply because the FDA has failed to show any value the disclosure of added sugar would provide for consumers.

1. Purely Factual

The first prong of the *Zauderer* test is to determine whether the disclosure is purely factual.[155] *Zauderer* demonstrates that disclosures or speech that contain accurate, factual information are considered to be purely factual.[156] Based on this description of purely factual, it appears the added sugar disclosure passes the first prong. The FDA's proposed disclosure requires a statement of the amount of sugar the food manufacturer has contributed to the product, which is simple, factual information.[157]

A comparison of the added sugar disclosure with the country-of-origin disclosure provides further support for the FDA's purely factual argument. The two disclosures appear to be comparable because of the similar basic structure of each disclosure. The country-of-origin disclosure was an undisputed simple, accurate statement regarding the location of origin of a meat product, held by the court to be purely factual.[158]

The added sugar disclosure is the same type of simple, accurate information as the country-of-origin disclosure and should therefore also be considered purely factual. The added sugar disclosure should also be considered purely factual when compared to the graphic warning labels on tobacco products that Judge Rodgers claimed to be factual in his dissent.[159]

2. Uncontroversial

The second prong in the *Zauderer* reasonable relationship test is to determine whether the disclosure or speech is uncontroversial.[160] The FDA may have the most difficultly

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[155] Dhooge, *supra* note 37, at 624.

[156] *Id.*

[157] Food Labeling, *supra* note 14, at 11884.

[158] Am. Meat Inst. v. United States Dep't of Agric., 760 F.3d. at 18, 20 (D.C. Cir. 2014).

[159] R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d. 1205, 1222 (D.C. Cir. 2012) (Rodgers, J., dissenting).

[160] Dhooge, *supra* note 37, at 624.

passing this prong because many food industry members strongly oppose the added sugar disclosure as highly controversial in the public comments.

The FDA relied on scientific evidence that "many foods and beverages that are major sources of added sugars have low levels of nutrients, such as vitamins" to support its assertion that the added sugar disclosure is uncontroversial.[161] The FDA asserted the added sugar disclosure is uncontroversial because consumers may incorrectly believe foods to be full of vitamins and nutrients that are in fact diminished when the sugar was added to the food.[162]

Although the FDA relied on scientific evidence to support the disclosure as uncontroversial, the opponents argue there is a lack of evidence to support the added sugar disclosure. The Sugar Association, one of the major opponents of the disclosure, claimed that when the Dietary Guidelines for Americans Council made their determination that added sugars contribute to obesity, weight gain, and heart disease in 2010, there was no strong or conclusive evidence to support the findings.[163] However, a 2015 scientific report released by the Dietary Guidelines Advisory Committee provided evidence "suggesting a strong association between a dietary pattern of intake characterized, in part, by a reduced intake of added sugars and a reduced risk of cardiovascular disease."[164]

Further, some opponents claimed there was a lack of evidence to show the body processes added sugar any differently than natural sugars—an assertion the FDA did

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[161] *Proposed Nutrition Facts Label Changes Are Based On Science And Research*, U.S. FOOD AND DRUG ADMINISTRATION, *available at* http://www.fda.gov/forconsumers/consumerupdates/ucm387164.htm [http://perma.cc/Q4PK-BCL7] (last updated Sept. 1, 2015) [hereinafter "*Science and Research*"].

[162] *Id.*

[163] *The Sugar Association Calls for Withdrawal of 'Added Sugars' Labeling Proposal in Comments Filed to FDA*, THE SUGAR ASSOCIATION (Jul. 31, 2014), http://www.sugar.org/sugar-association-calls-withdrawal-added-sugars-labeling-proposal-comments-filed-fda/ [http://perma.cc/9LC8-CBUE] [hereinafter "*Sugar Association*"].

[164] Supplemental Proposed Rule, *supra* note 20, at 44303.

not dispute when it published the proposed rule.[165] Although the FDA conceded on this issue, supporters of the added sugar disclosure countered the argument with an assertion that even if there is "no differing physiological effect for added versus naturally present sugar," lack of differing effects is not a relevant point to the required disclosure.[166] Instead, supporters asserted the main point of the disclosure is to bring attention to the overconsumption of sugar among consumers.[167] If such an assertion is accepted as true, the disclosure is not controversial when used to encourage consumer awareness.[168]

The similar country-of-origin disclosure was considered uncontroversial because there was no dispute over the truth of the facts contained in the disclosure. [169] It does not appear that the opposition to the added sugar disclosure disputes the truthfulness of the amount of added sugar in a product; therefore the added sugar disclosure is uncontroversial as well. Further, the added sugar disclosure is much less radical than the proposed graphic warning label that tobacco companies found to be very controversial.

3. Legitimate Government Interest

The third prong of the reasonable relationship test from *Zauderer* requires a legitimate government interest for compelling the disclosure.[170] The FDA asserted several interests to support the added sugar disclosure, but perhaps the most legitimate was to improve consumer health and

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[165] Food Labeling, *supra* note 14, at 11905 (Noting "[w]e continue to recognize the lack of a physiological distinction between added and naturally occurring sugars.").

[166] Gretchen Goldman, *Five Things Sugar Interests Get Wrong About FDA Added Sugars Labeling*, FOOD SAFETY NEWS (Jul. 3, 2014), http://www.foodsafetynews.com/2014/07/goldman-contributed/#.VFPkY_nF-nF [http://perma.cc/3WXD-JPPU].

[167] *Id.*

[168] *Id.*

[169] *See* Am. Meat Inst., v. United States Dep't of Agric., 760 F.3d. at 27 (D.C. Cir. 2014).

[170] Dhooge, *supra* note 37, at 624.

access to healthy food choices.[171] Americans are facing a health crisis with the rise of the obesity epidemic, despite the government's efforts to alleviate the crisis. Current data reveals about sixty-eight percent of adults are overweight or obese[172]—which in turns leads to high rates of other chronic diseases, such as heart disease, type II diabetes and even some types of cancer.[173] The chronic diseases typically caused as a result of obesity are currently the leading causes of death in the United States.[174]

Society as a whole has an interest in reducing the obesity rate. The FDA has set out to take part in reducing the obesity rate through the update of a Nutrition Facts label to "help consumers make informed food choices to consume a nutritionally adequate diet while monitoring calorie intake and lowering their risk of some chronic diseases."[175]

Consumers are in need of additional information in order to efficiently make healthy choices for a healthy lifestyle. The additional information is most efficient if it is available to consumers on the labels, and therefore the government has a legitimate interest in requiring the disclosure of added sugar.[176] The interest of improving consumer health through availability of necessary information on added sugar is supported by evidence from the Dietary Guidelines for Americans Council that revealed "added sugars . . . make[s] up a significant percentage of the American diet and are a source of excess calories."[177]

The government asserted a similar interest in providing the necessary tools for consumers to make informed and healthy choices by implementing the country-of-origin disclosure. There was a legitimate government interest to provide consumers with information that would give them

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171 Food Labeling, *supra* note 14, at 11881.

172 *Id.* at 11885.

173 *Id.* ("An estimated 37 percent of Americans suffer from cardiovascular disease (CVD), 11.3 percent of the population 20 years and older has diabetes, 35 percent of adults has pre-diabetes, and 41 percent of the population is predicted to be diagnosed with cancer during their lifetime.").

174 *Id.*

175 *Id.*

176 *Id.*

177 *Id.* at 11904.

the opportunity to choose to purchase American raised meat through a disclosure similar to the added sugar disclosure.[178]

In addition to improving consumer health and increasing access to healthier food choices, the government has an interest in encouraging changes in food processing, a change endorsed by supporters such as the Obesity Society.[179] The food industry has continually made changes to the way food is produced and manufactured since the introduction of the Nutrition Facts label through the NLEA.[180] With the rise in the obesity epidemic, it is important to continue to make the necessary changes to the make-up of food, and as the past has shown, disclosure of unhealthy ingredients is a good motivator of change for the food industry.[181]

The FDA has an additional legitimate interest for requiring the disclosure of added sugars; the improvement of consumer awareness. As consumers become interested in reducing caloric intake and increasing the amount of nutrient dense foods, the government has a legitimate interest in supporting consumer interest through the added sugar disclosure.[182] Without including added sugar on the Nutrition Facts label, many consumers are unable to determine which foods are high in unnatural sugars and which are not—a consideration that strengthens the FDA's interest in promoting awareness.[183]

Finally, the FDA may have a legitimate government interest in preventing consumer deception. Although

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[178] Am. Meat Inst., v. United States Dep't of Agric., 760 F.3d. at 18, 23 (D.C. Cir. 2014) (The "context and long history of country of origin disclosures to enable consumers to choose American made products.").

[179] *The Obesity Society Supports all Proposed Changes to Food Nutrition Facts Labels and Commends the U.S. Food & Drug Administration for the Much-Needed Update*, THE OBESITY SOCIETY (May 15, 2014), http://www.obesity.org/proposed-major-revision-to-food-nutrition-facts-labels.htm [http://perma.cc/7WRG-HGHN] [hereinafter *Obesity Society*].

[180] *Proposed Changes*, *supra* note 4.

[181] *Id.* An example of a disclosure that led to an improved formulation of food products is when the FDA began requiring the amount of trans fats on the Nutrition Facts label, the amount food manufacturers used decreased.

[182] Food Labeling, *supra* note 14, at 11905.

[183] *Id.* at 11904.

American Meat Institute allows disclosures that are not aimed at preventing or correcting deception to be held to the *Zauderer* standard,[184] it may still be one of the FDA's purposes for requiring the added sugar disclosure. As discussed earlier, consumers may incorrectly assume that a food does not contain added sugar because of a front of package label that categorizes the food as healthy.[185] The added sugar disclosure allows consumers to correctly identify foods that contain added sugar versus natural sugar, and avoid mistaking a food as healthy when it actually contains a high amount of added sugar.

In summary, there is a legitimate government interest in requiring the disclosure of added sugar on the Nutrition Facts label because of the need to improve consumer health and access to healthier food choices. Additionally, there is a legitimate interest in improving the way food is manufactured, as well as improving consumer awareness of the ingredients in food through the disclosure of added sugar. Finally, the FDA has an interest in preventing potential consumer deception.

4. Disclosure Must Be Reasonably Related

The fourth prong of the reasonable relationship test from *Zauderer* requires the added sugar disclosure to be reasonably related to the legitimate government interests asserted in the third prong.[186] First, the added sugar disclosure is reasonably related to the government interest of improving consumer awareness because evidence reveals that many consumers actually read and use the Nutrition Facts label.[187] In fact, the number of consumers that report reading the Nutrition Facts labels increased ten percent in

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[184] Am. Meat Inst. v. United States Dep't of Agric., 760 F.3d. 18, 20 (D.C. Cir. 2014).

[185] *Point of Package Labeling*, *supra* note 25.

[186] Dhooge, *supra* note 37, at 624.

[187] *See* Food Labeling, *supra* note 14, at 11887.

six years.[188] The increase is confirmation that the disclosure will affect more consumers than the food industry believes.[189]

Further, the added sugar disclosure on the Nutrition Facts label is reasonably related to the government interest of improving consumer awareness because the flow of information is an important method of creating awareness. Without the amount of added sugar on the Nutrition Facts label, the consumer would not be able to discern between naturally and unnaturally occurring sugars in a food product, thus hindering their ability to make informed decisions when searching for healthy food choices.[190]

The added sugar disclosure is reasonably related to the government interest of changing the way food is processed. By improving the way food is processed, more healthy food options with less added sugar will be available for consumers. The increased availability of healthy foods will improve access to healthy choices, as well as improve overall consumer health.[191] In addition to improving access and health, history has shown that requiring the disclosure of an unhealthy ingredient is related to altering the way some foods are produced. When the FDA began requiring the disclosure of trans fats in 2003, the amount of trans fats that food manufacturers used lowered dramatically and in some cases was completely removed from foods.[192]

Before declaring the disclosure reasonably related to the legitimate interests, it is important to consider the opposition's reasoning for why the disclosure is not reasonably related to the government interest. The opposition attacks the FDA's main interest of improving consumer health because the disclosure is not reasonably related to improving health through a reduction of excess calorie consumption due to added sugar intake.[193] The Sugar

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[188] *See id.* ("The percentage of consumers reporting that they often read a food label the first time they purchase a food product rose from 44 percent in 2002 to 54 percent in 2008.").

[189] *Id.*

[190] Food Labeling, *supra* note 14, at 11904.

[191] *Proposed Changes, supra* note 4.

[192] Goldman, *supra* note 166.

[193] *Sugar Association, supra* note 163.

Association highlights there is no official recommendation for the amount of added sugar individuals should consume.[194] Further, they assert the "average American consumes 300 calories of added sugar per day"[195] and therefore the disclosure will only affect a small number of consumers and is not reasonably related to the government interests.[196] However, the 2015 Scientific Report of the Dietary Guidelines Advisory Committee made a recommendation to limit added sugar intake to less than ten percent of overall caloric intake.[197]

Although the opposition provides valid arguments to consider, the arguments do not outweigh the support that the disclosure is reasonably related to the government interests. The FDA also has support for their argument from the D.C. Circuit's finding that the country-of-origin disclosure was reasonably related to the legitimate government interests.[198] The D.C. Circuit pointed out the disclosures were reasonably related to legitimate interests when they provided "purely factual and uncontroversial information about attributes of the product or service being offered."[199] Because the added sugar disclosure is similar to the country of origin disclosure and has already been determined to be purely factual and uncontroversial, the added sugar disclosure is reasonably related to the FDA's legitimate interests.

The added sugar disclosure is reasonably related to the legitimate interests of improving consumer health through enhancing awareness of food content and access to healthy food options, as well as encouraging change in the way food is produced and manufactured. Accordingly, the disclosure will move on to the fifth and final prong of the reasonable relationship test.

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194 *Id.*

195 Tavernise, *supra* note 21.

196 *Id.*

197 Supplemental Proposed Rule *supra* note 20, at 44308.

198 *See* Am. Meat Inst. v. United States Dep't of Agric., 760 F.3d. 18, 26 (D.C. Cir. 2014).

199 *Id.* (The court also stated that a disclosure will usually be reasonably related to the government interests, "absent a showing that the disclosure is 'unduly burdensome' in a way that 'chill[s] protected commercial speech,'") (quoting Edenfeld v. Fane, 507 U.S. 761, 651 (1993)).

5. Disclosure Is Not Unjustified or Unduly Burdensome

The fifth and final prong of the reasonable relationship test from *Zauderer* requires that the disclosure is not unjustified or unduly burdensome. To determine whether or not the added sugar disclosure is unjustified or unduly burdensome, the analysis begins by examining some of the reasons why opponents argue the disclosure is unjustified or unduly burdensome. First, opponents asserted there is no analytical method to distinguish between added and naturally occurring sugars in a food.[200] The same opponents also raised the argument that there is no analytical method to distinguish between the two types of sugars, therefore disclosure would require "unprecedented record keeping," that would be unduly burdensome on food manufacturers.[201]

The FDA and supporters of the added sugar disclosure reject the Sugar Association's claims with several points. First, the FDA and supporters assert that since manufacturers are responsible for adding the extra sugar to the food products, they should have an idea of how much sugar is added during processing.[202] If manufacturers have knowledge of the amount of added sugar they are adding during processing, there is no need for analytical methods that would lead to burdensome record keeping.[203] The FDA also asserted that the alleged lack of analytical methods should not preclude the promulgation of a final rule because the FDA could achieve the record keeping through maintenance and record review.[204] Further, the FDA has required similar record keeping in the past for food products,

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[200] *Sugar Association, supra* note 163.

[201] *Id.* The Sugar Association asserts the disclosure cannot be enforced without such "unprecedented record keeping and inspection requirements."

[202] Goldman, *supra* note 166.

[203] *Id.*

[204] Food Labeling, *supra* note 14 at 11905. (The FDA has requested the review of records for values of dietary fiber, folate, and vitamin E under certain circumstances, implying the records will not be used solely for review of added sugars.)

which rejects the opponents' idea that the record keeping would be unprecedented.[205]

In addition to the Sugar Association's burdensome record keeping argument, other opponents of the disclosure claimed it is unjustified because it may deceive consumers into purchasing foods that may be lower in added sugar but are actually higher in calories and fat.[206] The opponents also alleged that the extra line for added sugar on the label would confuse consumers because they may add the two lines of sugar together.[207] If consumers add both sugar lines together, they may be misled into believing a product contains more sugar than it actually does.[208]

The FDA conceded on the issue of initial confusion, but instead asserted the lack of consumer understanding about how to read the two sugar lines will be resolved with consumer education over time.[209] The FDA's idea for such education is through consumer studies in the form of questionnaires on the understanding of the use of the added sugar disclosure.[210] The FDA maintained that the consumer studies would be referred to for future actions related to the added sugar disclosure.[211] As support for resolving the consumer confusion, the FDA's consumer studies were completed before the publishing of the 2015 revisions and revealed that the majority of consumers were able to correctly identify the amount of total sugar and added sugar when both were listed separately on the label.[212]

Finally, the FDA asserted the disclosure is not unjustified or unduly burdensome because of the generous amount of

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[205] *Id.* (requiring record keeping with respect to the aeration to reduce fat in foods).

[206] *Sugar Association, supra* note 163.

[207] Lammi, *supra* note 32.

[208] *Id.*

[209] Food Labeling, *supra* note 14, at 11905. (The FDA has previously used explanatory footnotes on labels, such as describing the amount of calories the daily value percentage is based on. Additionally, the FDA emphasizes that the two sugar lines are independent of each other and are necessary for consumers to compare the amount of added sugar in different foods.).

[210] *Id.* at 11905.

[211] *Id.*

[212] Supplemental Proposed Rule *supra* note 20, at 44306.

time being allotted for food industry members to become compliant with a final rule.[213] The time for implementation for the proposed rule, including the added sugar disclosure is two years from the date of the implementation of a final rule.[214]

The disclosure of added sugar on the Nutrition Facts label passes the final prong of the reasonable relationship test because it is not unjustified or unduly burdensome. Food manufacturers should be able to record the amount of added sugar included in food products during processing because the FDA has required similar record keeping requirements in the past related to food labeling.

Additionally, the disclosure is not unjustified or unduly burdensome because the FDA plans to address the possible consumer confusion with educational pieces to describe how to read the new Nutrition Facts label. Finally, the FDA has granted a generous amount of time for food manufacturers to become compliant with the final rule.[215] In conclusion, the disclosure is not unjustified or unduly burdensome.

D. Final Policy Reasons for Implementing the Proposed Rule

Despite the threat of First Amendment litigation from food industry members and regardless of the standard used to analyze the added sugar mandatory disclosure in anticipation litigation, there are a number of policy reasons for why the FDA should promulgate a final rule. The need for updated Nutrition Facts labels is essential to public health. Commentators point out that Americans have the "sweetest diet in the world" and the added sugar disclosure is necessary to make consumers aware of this diet.[216]

Additionally, one of the FDA's goals behind the updated label is to empower consumers to make healthy choices,

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[213] *Id.* at 11882.

[214] *Id.*

[215] Food Labeling, *supra* note 14, at 11959 (Manufacturers have two years from the effective date of a Final Rule to be in compliance with the regulations.).

[216] Tavernise, *supra* note 21.

rather than explicitly telling consumers what they should eat.[217] In a society that is constantly seeking transparency from the government, consumers should have the opportunity to make an educated decision on whether or not to consume a glass of apple juice if it contains ten grams of added sugar.

Further, consumers should be able to make such educated decisions without a complex educational background in nutrition science.[218] The update to the Nutrition Facts label provides a simplified label that allows consumers to determine whether the sugar in fruit juice came from the fruit itself, without having to interpret scientific names for sugar in the ingredients list.

Finally, food labeling practices and policies should be updated every so often in order to remain effective. As technology changes and more is learned about the way certain foods affect individual health, the information that is presented to consumers must also be updated.[219] As consumer lifestyles and food consumption trends change, the information provided to the consumer must reflect these changes.[220]

The policy reasons for including the added sugar disclosure provide further support for the FDA to march on with a final rule implementing the disclosure, along with the rest of the proposed changes to the Nutrition Facts label.

IV. CONCLUSION

The added sugar disclosure on the Nutrition Facts label, as proposed in "Food Labeling: Revision of the Nutrition and Supplement Facts Label," will be analyzed under the more lenient reasonable relationship test created in *Zauderer*.[221] *American Meat Institute* frames the standard so that it can

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[217] *Obesity Society, supra* note 179.

[218] Tavernise, *supra* note 21. (First Lady Michelle Obama emphasized the importance of enabling consumers to be able to look at products at the grocery store and quickly determine whether it is a healthy choice).

[219] *See Science and Research supra* note 161.

[220] *Id.*

[221] *See Id.*

be applied in cases where the government has an interest beyond preventing consumer deception through purely factual information,[222] such as the added sugar disclosure.

While the opponents of the added sugar disclosure may have some compelling arguments, the FDA's proposed rule will still withstand First Amendment challenges because it passes the five prongs of the reasonable relationship test from *Zauderer*. The disclosure is purely factual and uncontroversial and the government has a legitimate interest in mandating the disclosure. The added sugar disclosure is reasonably related to the legitimate interests and finally, the disclosure is not unjustified or unduly burdensome.

In addition to passing the *Zauderer* test, it is apparent the updated Nutrition Facts label is necessary as one of many steps to help combat the obesity crisis the United States is currently facing. Even without a First Amendment analysis under either standard, the FDA should press on with a final rule, based on the strong policy reasons. With such a frightening obesity crisis, even the slightest chance that the updated Nutrition Facts label will motivate consumer change should be enough to move forward with the rule.

Finally, the FDA could take the same cautious step it took when promulgating the trans fat disclosure by including a *Zauderer* analysis in the published final rule. Such an analysis would be in response to the public comments that assert First Amendment violations. However, even without such an analysis in the final rule, the added sugar disclosure will likely withstand First Amendment challenges because of the legitimate public health need for the disclosure.[223]

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[222] Am. Meat Inst., v. United States Dep't of Agric., 760 F.3d. 18, at 22 (D.C. Cir. 2014).

[223] Tavernise, *supra* note 21 (referring to President George Bush's statement that the proposed changes are "one of the most important public health upgrades in this decade").

JUSTICE FOR JAILBIRDS: SUMMONING BIOETHICAL LIBERATION FOR DEATH ROW AND REINVENTING INDIANA'S HOUSE BILL 41

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I. INTRODUCTION

Somewhere in our country a young child is dying in a hospital bed. Wires cover her body and the monotonous pang of a heart monitor fills the air. Next door, a young man hobbles out of bed. He makes it far enough to look out of his room's window. Each day, for each of these patients, is a gift– for each day is not a given. Each patient faces a similar fate. Living on the organ waiting list has its travails. It is unlikely that either patient will ever be a recipient.

And yet still, somewhere else in our country, two men are exact biological matches for these two patients. They want to donate. They have the medical requisites. However, they are disallowed from doing so. They cannot save the lives of these two patients. This story's conclusion is an unfortunate one, for at the end, both the patients and the willing donors die.

Should the patients' lives have been saved? Should the men have been allowed to donate? This cold injustice has happened and will continue to happen. However, what if you were told that these two men, the potential donors, were death row inmates? Would that change the injustice of the story? Would that change the weight of the patients' needs? Would that change the value of a decision to donate?

This is the battle that Indiana's legislative system needs to fight. We need to change the ending to this story. And we can. We can allow death row inmates to donate their organs. By allowing this, not only could we proactively combat the organ shortage but we could also preserve the biological autonomy of those condemned to die.

A. The History of Organ Donation

Organ donation may seem like a phenomenon brought on only by the recent breakthroughs of the medical community within the last few decades. However, organ donation and transplantation date back to the 18th century when researchers experimented with transplantation on both

humans and animals.[1] Since then, the evolution of medicine has come a long way. Now more and more tissues and organs are available to be recycled to save lives.

Anatomically, the organs and tissues available to be used in transplantations are numerous. Currently, "[t]he human body has approximately twenty-five transplantable parts, including the heart, nerves, skin, bone marrow, the liver, kidneys, corneas, glands, blood vessels, and tendons."[2] And yet, just because the body has so many different parts that can be donated, does not necessarily mean that, by default, these organs are in fact given to those in need. Nonetheless, science has progressed to allow for this possibility. As such, the organ donation process has become quite simplistic. Transplantation surgeries are now more common than ever before.

In 1869 the first skin transplant was performed.[3] Years later, doctors were able to successfully transplant a cornea.[4] Even later, the first successful transplant of a kidney was performed in 1954.[5] This was an immense breakthrough. The transplantation of an entire organ, like a kidney, meant that more vital and complex parts of the human body had the potential to be recycled as long as they remained functional.

Biological science was making leaps and bounds in the mid 1900s with these new technologies that allowed people to both donate and to receive life-saving organs and parts.

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[1] *History*, *Organ Procurement and Transplantation Network*, U.S. DEPT. OF HEALTH AND HUMAN SERV., http://optn.transplant.hrsa.gov/learn/about-transplantation/history/ [http://perma.cc/7B44-9Q5X](last visited Nov. 20, 2015).

[2] Laura-Hill M. Patton, *A Call for Common Sense: Organ Donation and the Executed Prisoner,* 3 VA. J. SOC. POL'Y & L. 387, 388 (1996) (citing to Lloyd R. Cohen, *Increasing the Supply of Transplant Organs: The Virtues of a Futures Market*, 58 GEO. WASH. L. REV. 1, 3 (1989)).

[3] *Timeline of Historical Events Significant Milestones in Organ Donation and Transplantation*, ORGANDONOR.GOV, http://www.organdonor.gov/legislation/timeline.html [http://perma.cc/9CHV-MLHA] (last visited Oct. 7, 2015).

[4] *Id.*

[5] *History*, UNITED NETWORK FOR ORGAN SHARING, https://www.unos.org/transplantation/history/ [http://perma.cc/48KJ-QA8H] (last visited Oct. 7, 2015).

Thus, due to the increase in the use of these procedures, "the National Organ Transplant Association (NOTA) [in 1984], called for an Organ Procurement and Transplantation Network (OPTN)."[6] OPTN was to be managed by a private, non-profit group.[7] Doctors and patients alike could rely on this independent governing body to facilitate each of their needs. Organ donation, in practice and in procedure, was rapidly evolving and becoming a highly regulated and structured endeavor.

Nearly forty years after the first organ transplantation surgery, the first living-donor and living-recipient organ donation procedure was performed in 1998.[8] By 2001, there were more living donors than deceased: 6,5281living donors as compared to 6,081 deceased donors.[9] This accomplishment allowed the surplus living donors to achieve a valuable position in the organ donation hierarchy.

After successes in dead-donor operations, doctors began conducting procedures involving more essential, non-self-renewing organs.[10] In one documented case involving a living donor, "Dr. Joseph E. Murray successfully transplanted a healthy kidney from Ronald Herrick to Mr. Herrick's identical twin Richard, who had been diagnosed with end-stage kidney failure."[11] Richard lived many years longer following the life-saving transplant, before suffering a heart attack and dying.[12]

After Dr. Murray's successful kidney transplant procedure, the realm of biological science and operative medicine had been forever changed. To keep pace with the growing evolution of organ transplantation, even more regulation was needed. Today, the Uniform Anatomical Gift

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[6] *Id.*

[7] *Id.*

[8] *Id.*

[9] *Id.*

[10] 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, 865-66 (2003).

[11] *Id.*

[12] *Id.*

Act (UAGA), the United Network for Organ Sharing (UNOS), and the National Organ Transplant Act (NOTA) all serve as entities that regulate various transplant and donation procedures, established to coordinate and regulate organ transplantation.

The UAGA was established in 1968. [13] This Act established protocol that allowed for donation via documented gifts. [14] The Act "deemed a person's legal consent to donate before death sufficient under the law . . . ."[15] Thus, UAGA allowed the law to catch up with science.

However, despite the breakthroughs in science and the legal underpinnings that proved to be quite simple, a deficit was created. As of January 31, 2016, there were 121,579 individuals waiting for an organ transplant.[16]

Someone is added to the organ wait list every 10 minutes.[17] And, although seventy-nine people receive organ transplants each day, [18] on average, it is estimated that twenty-two people die waiting for an organ everyday.[19]

For those lucky enough to be placed on a waiting list, the process is highly and thoroughly systematic. Through the UNOS Organ Center, organ donors are matched to waiting recipients all day, every day throughout the year.[20] "When an organ becomes available, the local organ procurement

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[13] *Selected Statutory and Regulatory History of Organ Transplantation*, ORGANDONOR.GOV, http://www.organdonor.gov/legislation/legislationhistory.html [http://perma.cc/5Q2M-9PJ2] (last visited Nov. 16, 2015).

[14] *Id.*

[15] *Id.*

[16] *Data*, ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, http://optn.transplant.hrsa.gov/converge/data/ [https://perma.cc/RX7E-NLLS] (last visited Jan. 31, 2016).

[17] *The Need is Real: Data*, ORGANDONOR.GOV, http://www.organdonor.gov/about/data.html [http://perma.cc/8PDC-2NDB] (last visited Nov. 16, 2015).

[18] *Id.*

[19] *Id.*

[20] UNITED NETWORK FOR ORGAN SHARING, https://www.unos.org [http://perma.cc/P359-AMZA] (last visited Oct. 8, 2015).

organization (OPO) sends medical and genetic information to UNOS." [21] UNOS then generates a list of potential recipients.[22] The organ is first offered to the candidate who is the best match.[23] Organs are distributed locally first, and if no match is found, they are offered regionally and then nationally.[24]

Though there are thousands on the waiting list, many of those people could be helped or saved by just a few donors. "Experts say that the organs from one [person] can save or help as many as [fifty] people."[25] With a few simple steps, it's easy to become a donor. All it takes is signing up for a state's donor registry. Even when updating one's identification at the DMV, a simple "yes" answer would allow an individual to become a donor. However, despite the seemingly simple processes, not all people are given the right to donate in its entirety.

II. ORGAN DONATION IN PRISON SYSTEMS

A. Rights of Regular Inmates

Many are unaware that even in light of the huge demand for organs and tissues, not all people are afforded the right to donate. Many cannot participate in live donations and even more striking, others may not be allowed to donate upon death. These people are our nation's death-row prisoners.

Many states oppose the idea of allowing condemned prisoner organ donation considering the high-risk population

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[21] *Organ Transplantation*, CLEVELAND CLINIC: TREATMENT AND PROCEDURES, https://my.clevelandclinic.org/health/treatments_and_procedures/hic_Organ_Donation_and_Transplantation [https://perma.cc/5KVP-BT5V] (last visited Nov. 24, 2015).

[22] *Id.*

[23] *How Organs Are Matched*, UNITED NETWORK FOR ORGAN SHARING, https://www.unos.org/transplantation/matching-organs/ [http://perma.cc/3URR-F84Y] (last visited Oct. 8, 2015).

[24] *Id.*

[25] *Organ Donation*, U.S. NAT'L LIBR. OF MED., http://www.nlm.nih.gov/medlineplus/organdonation.html [http://perma.cc/UG3Z-7KGK] (last updated Oct. 2, 2015).

that comprises prisons in the United States.[26] Since the 1990s, health-related risks have prevented inmates from being able to donate their organs.[27]

However, in Arizona's Maricopa County, as of 2007, there is a program to allow inmates to donate only certain organs.[28] Nevertheless, for death row inmates, the official position of UNOS currently is that until the ethical and legal barriers of condemned prisoner organ donation are overcome, no support can be lent to the movement.[29]

And yet, in spite of UNOS's stance, Arizona's prison organ donation program has proven to be quite effective.[30] In Arizona, when criminals are booked into prison, they are given the opportunity to register to be an organ donor.[31]

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[26] *See* Lawrence O. Gostin, *Prisoners Shouldn't Be Allowed to Donate Their Organs*, N.Y. TIMES (April 26, 2013, 1:18 PM), http://www.nytimes.com/roomfordebate/2013/04/25/should-prisoners-be-allowed-to-donate-their-organs/prisoners-shouldnt-be-allowed-to-donate-their-organs [https://perma.cc/JPE3-DHRY].

[27] Martha F. Rogers et al., *Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs*, CDC (May 20, 1994), http://www.cdc.gov/mmwr/preview/mmwrhtml/00031670.htm [http://perma.cc/W2CY-HJTA].

[28] Shannon Ross, *With Organ Donations, Let Prisoners Give Life to Others*, N.Y. TIMES (Apr. 25, 2013), http://www.nytimes.com/roomfordebate/2013/04/25/should-prisoners-be-allowed-to-donate-their-organs/with-organ-donations-let-prisoners-give-life-to-others [http://perma.cc/38BK-4TUG]. *See also* Joe Arpaio, *Arpaio's 'I Do' Program (Inmates Willing to Donate Their Organs) Has Them Joining National Drive,* MARICOPA COUNTY NEWS RELEASE (Apr. 29, 2015) *available at* http://www.mcso.org/MultiMedia/PressRelease/Organ%20Donor.pdf [https://perma.cc/78VH-9G34].

[29] *The Ethics of Organ Donation from Condemned Prisoners*, U.S. DEP'T OF HEALTH & HUMAN SERV., http://optn.transplant.hrsa.gov/resources/ethics/the-ethics-of-organ-donation-from-condemned-prisoners/ [http://perma.cc/5GWH-3VG5] (last visited Oct. 8, 2015).

[30] Arpaio, *supra* note 28.

[31] Kate Bennion, *Kidneys from Felons? Prisoner Organ Donation Spurs Debate*, DESERET NEWS (April 24, 2013, 11:05 AM), http://www.deseretnews.com/article/865578852/Kidneys-from-felons-Prisoner-organ-donation-spurs-debate.html?pg=all [http://perma.cc/B2N4-4QHM].

Somewhere between frisking and fingerprinting, those who opt in are given access to the state donor registry site . . . . As of [January] 28 of [2013], the office has registered 14,124 inmates for the state organ donor program. Those booked into the county jail are pre-sentence and pre-trial detainees or sentenced to a year or less. If they [a]re released, they are no longer considered by the organ registry to be at high risk for health complications – and remain on the state organ donor registry.[32]

One must keep in mind though, that the various programs that are offered to allow inmates to donate their organs are conditioned upon death within the prison system. Many politicians, lawmakers, and ethicists struggle in grappling with the idea of allowing *living* prisoners to donate non-vital organs like kidneys. The potential risks of coercion, undue persuasion, or even compensation for a decreased prison sentence are worrisome.

As an example, "[i]n January 2011, Mississippi Governor Haley Barbour freed two sisters from life sentences . . . on the condition that one donate a kidney to the other."[33] Governor Barbour granted parole to Gladys Scott on the condition that she become a donor for her sister, Jamie Scott, who needed a kidney transplant in order to survive without the imposition of dialysis treatment.[34] Barbour claimed that his reasoning was based in part on the financial burden of Jamie Scott's kidney dialysis treatment on the state.[35] Despite the arguably unethical underpinnings of these orders, one must ask how this can be tolerated over death row organ donation, where there may be no coercion or unethical persuasion at play.

Similar to Governor Barbour's order, other state legislators have proposed bills that would shorten sentences

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[32] *Id.*

[33] Arthur Caplan, *The Use of Prisoners as Sources of Organs – An Ethically Dubious Practice*, 11 AM. J. OF BIOETHICS 1, 1 (2011), *available at* http://ldihealtheconomist.com/media/caplan_prisoners_organs.pdf [https://perma.cc/TP72-XUZB].

[34] *Id.*

[35] *Id.*

for inmates who choose to donate organs.[36] In 2007, a law was proposed in South Carolina that would shorten prison sentences in exchange for kidney or bone marrow donation.[37] Further, South Carolina "State Senator Ralph Anderson proposed bills that would release prisoners [sixty] days early . . . ."[38] One bill gave early release for those who donated bone marrow and the other gave "good-behavior credit of up to 180 days, 'to any inmate who perform[ed] a particularly meritorious or humanitarian act [] includ[ing] living kidney donation.'"[39]

Regulations such as these are completely unethical because they function as bribes. These ethical pitfalls are not givens, and they are not necessarily fundamental to how death row inmate donation could work. Realistically, for condemned prisoners, unlike regular inmates, there is no incentive to be had. And so, without any indication of incentivized conditions, even those who wish to be wholly and truly altruistic nonetheless cannot.

B. Rights of Death Row Inmates

Utah, in 2013, became the first state to allow any inmate to donate his organs if he were to die while incarcerated.[40] This law, while a major breakthrough in the realm of bioethics and the law, still leaves much to be done in other states to follow suit. Although strides such as Utah's law have been made to allow prisoners to donate, death row inmates in Indiana, and across the nation, are still disallowed access to one of life's most noble deeds. They are denied the right to donate organs, whether during their lives or upon their deaths.

This issue has spurred debate over what rights death row inmates actually possess. Some believe that due to their incarceration, prisoners have no rights–not even to their

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[36] *Id.*
[37] *Id.* at 1-2.
[38] *Id.* at 1.
[39] *Id.* at 2 (citation omitted).
[40] Utah Code Ann. 1953 § 64-13-44 (2013).

bodies. Others believe that allowing our nation's worst criminals to become organ donors, would detract from the retributive nature of the death penalty itself. In other words, if death is the punishment, any act of altruism or act of purification (in this case organ donation) would seemingly purge the sentence of its inherent severity.

Others may believe the stigma of inmate-donated organs cannot be overcome, or that organs acquired from prisoners are too risky. That is, there may be too many health concerns. And yet, despite these concerns, many states have proposed legislation to allow death row inmates to donate their organs. However, these bills have not survived the wide criticism they encounter.

In 2000, Florida State Representative William F. Andrews introduced Florida House Bill 999 entitled "An Act Relating to Anatomical Gifts by Capital Defendants."[41] This bill, like many of its predecessors and progeny, would have permitted condemned prisoners to donate their organs following their executions. [42] However, this bill saw huge opposition from all facets of the community.[43]

In 1984, California tried to pass a similar bill, which would have provided for organ donation from death row inmates.[44] However, this bill failed to be introduced due to huge opposition and distaste for the idea.[45]

Arizona also tried to allow death row inmates to donate their organs. [46] There, Representative Bill McGibbon proposed a system that would allow inmates to have a choice in the method of execution–one where their organs could be harvested and another where a lethal injection was used.[47] However, like the others, the bill did not pass.[48]

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[41] Whitney Hinkle, *Giving Until It Hurts: Prisoners Are Not the Answer to the National Organ Shortage*, IND. L. REV. 593, 599 (2002).

[42] *Id.*

[43] *Id.*

[44] Patton, *supra* note 2, at 432.

[45] *Id.*

[46] *Id.*

[47] Hinkle, *supra* note 41, at 600.

[48] *Id.*

Concerning Indiana most, though, is the case that began the state's legislative drive to allow death row inmates to donate their organs.[49] Gregory Scott Johnson, a death row inmate who catalyzed the controversy, was sent to prison and sentenced to death for the murder of an 82-year-old woman.[50] On May 25, 2005, the headline of an article in the *Indianapolis Star* read: "[s]tate executes killer who wanted to donate liver."[51] Johnson had fervently petitioned for clemency in order to become an organ donor.[52] On the Tuesday before Johnson's execution, Governor Mitch Daniels rejected Johnson's plea for clemency, which was to determine if he could donate a portion of his liver to his dying sister.[53] The Indiana Parole Board did not believe that Johnson truly wanted to help his sister.[54] Then, just twelve hours before Johnson was scheduled to die, Governor Mitch Daniels denied a final clemency plea stating that he "found no reasonable grounds to spare Johnson's life."[55]

One of the reasons that the Indiana Parole Board denied Johnson's request was due in part to the response from the greater Indiana physician network.[56] The network advised the Parole Board "that they did not want to jeopardize [the transplant center's] compliance with guidelines set by the United Network for Organ Sharing, which has a 'clear position against allowing condemned prisoners to donate organs.'"[57]

Further, Governor Daniels was informed by the medical community that Johnson, regardless of his status as a

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[49] Johnson v. State, 584 N.E.2d 1092 (Ind. 1992).

[50] *Id.* at 1096-97.

[51] Vic Ryckaert & Kevin Corcoran, *State Executes Killer Who Wanted to Donate Liver; Gregory Scott Johnson is 3rd Inmate Indiana Has Put to Death This Year*, INDIANAPOLIS STAR (May 25, 2005) *available at* http://www.clarkprosecutor.org/html/death/US/johnson970.htm [http://perma.cc/HWM8-8EVN].

[52] *Id.*

[53] *Id.*

[54] *Id.*

[55] *Id.*

[56] *Id.*

[57] *Id.*

condemned prisoner, was an unsuitable donor.[58] The doctors stated that there was "the presence of a hepatitis B antibody in Johnson's system." [59] This antibody, in addition to Johnson's obesity, rendered him an unsuitable donor.[60]

Despite its setbacks and final result, this case raised the question in Indiana concerning the morality of condemned prisoner organ donation. Had Johnson been a suitable candidate, would it have been likely that he would have been granted a stay in order to harvest a portion of his liver to save his dying sister? Based on the medical community's outcry and their strict deference to the standards set by UNOS, it is unlikely. Further, judging from other states' failures in their bill passage initiatives, it is unlikely that a stay for Johnson would have been granted.

In fact, prior to Johnson's execution, a bill was proposed by Indiana State Representative Jon Padfield that would have allowed Johnson to donate. [61] "[R]epresentative Padfield introduced a resolution in 1995 urging Indiana's Legislative Council to [create a committee to] consider organ [extraction] from condemned prisoners."[62] The bill called "for a study of execution methods that do not destroy human organs."[63] The bill did not pass.[64]

Since then, no bill in Indiana has had full support from the legal, political, or medical community–the kind of support required to prevail. It would appear then that Indiana's status is much like that of other states across the country. It will not be until key bioethical dilemmas and legal hurdles are overcome that the state will be able to pursue a bill like this again. Until a Padfield-like bill is passed, our nation's organ shortage may only grow larger as this population of willing donors is continually denied access to saving lives.

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[58] *Id.*

[59] *Id.*

[60] *Id.*

[61] H. Res. 41, 109th Leg., 1st Sess. (Ind. 1995) *reprinted in* State of Indiana, JOURNAL OF THE HOUSE OF REPRESENTATIVES, 109TH GENERAL ASSEMBLY, FIRST REGULAR SESSION, at 1111 (1995).

[62] Hinkle, *supra* note 41 at 599-600 (citation omitted).

[63] *Id.* at 600 n.44.

[64] *Id.* at 599.

III. CHALLENGES OF PASSING A BILL

A. Stigma

The first place to start in gaining speed with a bill allowing for condemned prisoner organ donation would be to overcome the stigma attached to prisoners–and even more so, to death row prisoners. There is no question that incarcerated individuals are stigmatized, that is, they are stereotyped and deemed to be members of an overall distasteful group. Studies have shown that the public's thoughts and perceptions regarding inmates are generally quite negative.[65] It is not hard to imagine then, given that inmates exist as reflections of society's stigma, that there would be some hesitation with combining a part of an inmate's body with the body of a non-criminal member of society. This is all to say that some individuals may not like the idea of having a criminal's organs used within the organ transplantation network. It could be that many do not value the lives of inmates and view organ donation as a perversion of the qualities of retributive justice.[66] Given the past acts of these condemned prisoners, most of whom are guilty of society's most heinous crimes, many may feel repulsed by the idea of the potential to somehow be biologically "linked" to them. As Dr. David Orentlicher, professor of law at Robert H. McKinney School of Law states in a piece done by the New York Times, "People might say, 'Gosh I'm walking around with the organ of a murderer," – that is, some individuals

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[65] Kelly Moore, et. al., *Jail Inmates' Perceived and Anticipated Stigma: Implication for Post-release Functioning*, 12 SELF AND IDENTITY: THE J. OF THE INT'L SOC'Y FOR SELF AND IDENTTY, 527-28 (2013) *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/ PMC4103667/pdf/nihms-596010.pdf [https://perma.cc/5QFW-PAGK].

[66] Rabbi Geoffrey A. Mitelman, *Retributive Justice and Restorative Justice*, HUFFINGTON POST (May 4, 2011) http://www.huffingtonpost.com/rabbi-geoffrey-a-mitelman/retributive-justice-and-r_b_857219.html [perma.cc/RW3F-A93Q].

may be wary of such a connection, no matter how attenuated, to a condemned prisoner. [67] However, this hypothetical associative stigma should not stand in the way of saving other lives.

Instead, stigma should be bypassed entirely. Christian Longo, a man serving his sentence on death row claims, "to be able to save so many lives, that means a lot to me [],"[68] For many, this outlook is difficult to understand in light of Longo's history.[69] Longo was sentenced to die after being found guilty of killing his wife and children and throwing their bodies into an Oregon waterway in December 2011.[70] In an article discussing Longo's drive to donate, the author acknowledges that this sentiment is

> hard to hear from a man who went back to work at his job at a local Starbucks outlet in the days after the murders before fleeing to Mexico, where he told people he was a New York Times reporter, went swimming and snorkeling, and struck up a brief romance with a woman, according to court records. When he was caught, he denied the killings.[71]

But what if this man's organs could save more lives than he took? Perhaps then, justice would still have been served. The horrible histories of condemned prisoners like Longo surely can be cast aside when it comes to donating valuable

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[67] Brandi Grissom, *Considering Death Row for Organs*, THE N. Y. TIMES (SEPT. 8, 2012), http://www.nytimes.com/2012/09/09/us/considering-the-ethics-of-organ-donations-from-death-row.html [perma:perma.cc/B9RD-7L7U].

[68] JoNel Aleccia, *Killer's Quest: Allow Organ Donation After Execution*, NBCNEWS.COM (April 21, 2011, 9:33 AM), http://www.nbcnews.com/id/42667886/ns/health-health_care/t/killers-quest-allow-organ-donation-after-execution/#.VFJMnYvF91Y [http://perma.cc//4YQW-P4DQ].

[69] *Id.*

[70] *Id.*

[71] *Id.*

and necessary organs. It is not about the pasts of the donors, but rather, the futures of the recipients.

While the criminal histories of these potential donors may be a huge stigma to overcome, others may believe that prisoners are "dirty"–that their organs would not be as good as another person's organs, due to illness or disease.[72] This particular sentiment is not without merit. In 2011-12, about 4 in 10 prisoners (41%) . . . reported having a current chronic condition."[73]

However, other populations around the nation have much higher rates of conditions including infectious diseases in relation to size. These populations include New York City, Miami, and Washington D.C.[74] And yet, these populations are not scrutinized or barred from organ donation. Furthering this logic, the difference between receiving an organ from a young man who had been a methamphetamine addict for ten years versus an inmate who has no access to drugs and is in a more controlled environment is politically negligible, but medically immense. How can a meth addict be allowed to donate his corneas, skin, and bone marrow, while the prisoner cannot? The reason likely does not rest purely with stigma but with the concerns held by the medical community.

Therefore, the hurdles posed by the medical community are the biggest obstacles to overcome if Indiana is ever going to be able to pass a bill like House Bill 41, as Padfield tried to do. First, we must start with the role of physicians in executions and organ extraction.

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[72] Marcus Berzofsky, et. al, *Medical Problems of State and Federal Prisoners and Jail Inmates, 2011-2012*, BUREAU OF JUSTICE STATISTICS, http://www.bjs.gov/index.cfm?ty=pbdetail&iid=5219 [http://perma.cc/CX28-ZRYK] (last revised Feb. 5, 2015).

[73] *Id.* at 11.

[74] *HIV Surveillance Report, 2008*, CTRS. FOR DISEASE CONTROL AND PREVENTION (June 2010), http://www.cdc.gov/hiv/pdf/statistics_2008_hiv_surveillance_report_vol_20.pdf [perma.cc/82R8-NZP5].

B. A Physician's Role

The tangled web that is the death penalty, and a physician's role within it, must be unraveled if organ donation from condemned prisoners is ever to be allowed. Physicians paired with the lethal injection process equates to a huge ethical challenge.

Historically, Dr. Jack Kevorkian favored the lethal injection because he initially believed that it would allow inmates to donate their organs.[75] He would later champion the idea of physician-assisted suicide. He believed that "only the highest degree of technical competence should be relied upon to insure trouble-free lethal injection, to avert unnecessary suffering, and, even more important, to minimize the potential danger of inadvertent suffocation of the condemned."[76] In other words, he believed that lethal injections should be performed by medical professionals.

Politicians must have the support from the medical community, and the legal community must have the authority from those medical boards that stand to make and analyze policy in order to gain any ground in passing a bill. However, the American Medical Association's Medical Code of Ethics states that physicians should not participate in capital punishment and executions.[77]

Physician involvement in capital punishment is ethically banned because it violates the ethical foundations of the profession as a whole. The World Medical Association has condemned physician participation in prison executions. [78]

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[75] Deborah W. Denno, *The Lethal Injection Quandary: How Medicine Has Dismantled the Death Penalty*, 76 FORDHAM L. REV. 49, 84 (2007).

[76] *Id.*, at 85 (quoting JACK KEVORKIAN, PRESCRIPTION: MEDICINE, THE GOODNESS OF PLANNED DEATH 17-99 (1991))

[77] Opinion 2.06-Capital Punishment, AM. MED. ASS'N, *available at* http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion206.page? [http://perma.cc/A6XB-B3UX].

[78] *WMA Resolution to Reaffirm the WMA's Prohibition of Physician Participation in Capital Punishment,* WORLD MED. ASS'N (Oct. 2012), http://www.wma.net/en/30publications/10policies/c23/ [https://perma.cc/GX5M-9H66] [hereinafter *WMA Resolution*].

Further, it has been said that, "[d]octors are not executioners. Inflicting death is antithetical to their ancient creed."[79]

Although physician participation in some instances may arguably reduce pain in the execution procedure, there are other reasons some may cite to disallow physician participation. For example, physicians' presence during executions may serve only to "feign the appearance of humanity."[80] The presence of a physician could be a way of showing compassion during a gruesome act. Second, the physician may provide a false showing of medical legitimacy.[81] Third, the physician would act on behalf of the state as an executioner.[82] "In return for possible reduction of pain, the physician, in effect, acts under the control of the state, doing harm," a seemingly deliberate violation of the World Medical Association's prohibition.[83]

Mirroring those three reasons to disallow physician participation, the medical ethics community blatantly condemns physician participation in lethal injection execution; further, two states even statutorily forbid doctors from participating in such executions.[84]

Despite the numerous concerns, ethicists must understand that, "since the inception of capital punishment, physicians have aided in the execution process."[85] Still today, doctors may be used to ensure adequate measures are taken, and that the execution procedures go according to plan. Ultimately it may be determined "that a physician's

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[79] *Medical Ethics and Physician Involvement,* HUMAN RIGHTS WATCH (2014) *available at* https://www.hrw.org/reports/1994/usdp/8.htm [perma.cc/ S9FS-HFHD] (quoting Kim Thorburn, *Doctors and Executions*, 7 AM. J. OF DERMATOPATHOLOGY (1985)).

[80] *Id.*

[81] *Id.*

[82] *Id.*

[83] *WMA Resolution, supra* note 78.

[84] KY. REV. STAT. ANN. § 431.220(3) (2015); 725 ILL. COMP. STAT. 5/119-5(d-5) (2015).

[85] Stacy Ragnon, *A Doctor's Dilemma: Resolving the Conflict Between Physician Participation in Execution and the AMA's Code of Medical Ethics*, 20 U. DAYTON L. REV. 975, 976 (1995).

presence is necessary [for] a responsible execution, [so] physician participation will not be barred."[86]

However, physicians who decide to participate in the lethal injection process face harsh consequences like license revocation or other severe consequences.[87] Despite these consequences, those physicians who choose to violate the creed and the call to the profession should not face legal consequences if those actions were to ensure that an execution was performed responsibly and successfully.

C. The Lethal Injection Process

Lethal injection is the primary method of execution used in all United States jurisdictions that still retain the death penalty. Indiana is among those states.[88] However, that was not always the case. The United States Supreme Court held in *Furman v. Georgia* that the statutory imposition of the death penalty in sentencing was unconstitutional because it violated the cruel and unusual punishment clauses of the Eighth and Fourteenth Amendments.[89] However, Indiana, only one year later, in 1973, "enacted a new death penalty sentencing statute to replace the statute struck down by the U.S. Supreme Court in *Furman.*" [90]

In *Baze v. Rees*, the United States Supreme Court upheld the protocol of injecting the three drug cocktail (the lethal injection) in executions as used by the State of Kentucky.[91] The Court held that there was no evidence to show that Kentucky's lethal injection procedure was "objectively intolerable" and therefore the procedure did not violate the Eighth Amendment. [92]

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[86] *Id.* (quoting 58 Fed. Reg. 4898 (Jan. 19, 1993)).

[87] *Id.*

[88] IND. CODE § 35-38-6-1-(1) (2015); IND. CODE § 35-50-2-9 (2015).

[89] Furman v. Georgia, 408 U.S. 238, 286 (1972).

[90] *Death Penalty Facts*, INDIANA PUBLIC DEFENDER COUNCIL 1, http://www.in.gov/ipdc/public/dp_links/indianadpfactsheet.pdf [http://perma.cc/6MDY-GDUB] (last updated July 8, 2015).

[91] Baze v. Rees, 553 U.S. 35 (2008).

[92] *Id.*, at 62-63.

Today in Indiana, the condemned are imprisoned until their execution day arrives. Upon execution, the lethal injection is the method used. [93]

Of the states that use lethal injection as the primary means for execution, the overwhelming majority of them "essentially [use] the same three-drug cocktail: 1) sodium thiopental; 2) pancuronium bromide; and 3) potassium chloride." [94] Sodium thiopental is used to anesthetize patients, inducing an unconscious state. [95] Once unconscious, mechanical ventilation is required.[96] In clinical doses sodium thiopental acts quickly and lasts for a short time only; "however, when used in a massive or superclinical dose, as is the case in an execution, it is capable of reliably produc[ing] prolonged and deep unconsciousness."[97]

Pancuronium bromide is the next drug injected. Pancuronium bromide is a neuromuscular blocking agent.[98] In effect, pancuronium bromide stops respiration and ceases involuntary muscle movement. Because these drugs have such severe effects, ensuring appropriate dosages, standards, and methods are of the utmost importance One mistake could have disastrous effects.

The final drug injected is potassium chloride which is used to stop the heart from beating. [99] This is the most important step in the procedure. Not only does this drug lead to cardiac failure, but this is the point at which donation from prisoners becomes much harder. Most organ procurement is

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[93] Ind. Code § 35-38-6-1.

[94] Jerry Merrill, *The Past, Present, & Future of Lethal Injection: Baze v. Rees' Effect on the Death Penalty*, 77 UMKC L. Rev. 161, 162 (2008).

[95] *Id.* at 162; *See also* Brief of American Society of Anesthesiologists as Amicus Curiae Supporting Neither Party, Baze v. Rees, 128 S. Ct. 1520 (2008) (No. 07-5439), *available at* https://www.law.berkeley.edu/clinics/dpclinic/LethalInjection/LI/documents/bazebriefs/ASA.pdf [https://perma.cc/59DR-8RH5].

[96] Merrill, *supra* note 94, at 162.

[97] *Id.* at 163 (citing Brief of American Society of Anesthesiologists as Amicus Curiae Supporting Neither Party, *supra* note 95, at 5).

[98] *Id.*

[99] *Id.*

performed following brain death, not cardiac death. Therefore, "donation from death row inmates will not be like a typical brain-death donation and thus will have to be a case of controlled DCD (donation after cardiac death)."[100] Because the heart has stopped beating in cases of DCD, the organs do not get oxygen, meaning there may be a shorter period of time for procurement before the organs become unusable.

As such, the procedure to procure organs becomes exceedingly more challenging in the execution setting due to the execution methods used. However, just because the setting is different, does not mean that the tissues sought are somehow different. Procedures and methods can change.

D. Jury Deliberations

Another substantial hurdle in gaining support for a bill to allow for death row organ donation is the risk that juries and judges may be more inclined to hand out death sentences. That is, jurors may believe that criminals should pay back society for their wrongs by giving up their organs (or so the logic would go). Juries do not always make decisions based purely on the evidence presented; other variables and stereotypes interfere with jury verdicts as it is. Concerns regarding higher incidences of death sentences rest on this basic assumption.

Furman v. Georgia originally addressed the issue of inappropriate death sentences due to bias and prejudice.[101] There, the Court was concerned that death sentences could be imposed at the unfettered discretion of judges and of jurors – that "people die dependent on the whim of one man or of [twelve]."[102] Sometimes jury decision-making may not focus entirely on the evidence presented at trial. Jurors are not immune from internal psychological impulses no matter how

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[100] Shu Lin, Lauren Rich, Jay Pal & Robert Sade, *Prisoners on Death Row Should be Accepted as Organ Donors* (July 3, 2012), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3388804/ [http://perma.cc/S4MN-TFHQ].

[101] Furman v. Georgia, 408 U.S. 238 (1972).

[102] *Id.* at 253.

obviously prejudicial these impulses are. It is hard to determine whether organ donation would be analogous to considerations of race, previous convictions, or confidence of a defendant, in jury decision-making paradigms, but it is a genuine concern held by the legal community.[103]

Before the year 2002, a jury's sentence in death penalty cases in Indiana was nothing more than a nonbinding recommendation to the court. In *Ring v. Arizona,* the United States Supreme Court held that a judge, even in determining appropriate sentencing, could not conduct a factual inquiry to find for the presence or absence of aggravating factors that would lead to the imposition of the death penalty; a jury, by the mandate of the Sixth Amendment must engage in that type of determination. [104] Because of the Supreme Court's holding in that case, "the 2002 General Assembly amended our death penalty statute to provide that if a jury unanimously reaches a recommendation, the trial court must 'sentence accordingly.'" [105]

Though the standard for the death penalty is set quite high, unanimous decisions can still be born of both conscious and unconscious bias. Stereotypes of groups of people necessarily inform these biases because they "operate as source[s] of expectancies about what a group as a whole is like . . . as well as about what attributes individual group members are likely to possess. . . ." [106] That is, jurors may see a defendant as a member of a group and then apply characteristics to that defendant based on that group's purported stereotype. Stereotypes can affect a "perceiver's attention to, encoding of, inferences about, and judgments

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[103] Dennis J. Devine, et al., *Jury Decision Making: 45 Years of Empirical Research on Deliberating Groups*, 7 PSYCHOLOGY, PUB. POL. & L. 622 (2001).

[104] Ring v. Arizona, 536 U.S. 584, 609 (2002).

[105] *Death Penalty Facts*, *supra* note 90, at 3.

[106] Nancy King, *Postconviction Review of Jury Discrimination: Measuring the Effects of Juror Race on Jury Decisions*, 92 MICH. L. REV. 63, 77 (1993); David Hamilton et al., *Stereotype-Based Expectancies: Effects on Information-Processing and Social Behavior*, 46 J. SOC. ISSUES, 35, 43 (1990).

based on that information."[107] Resulting cognitions reflect the previous patterns of information received.[108] In other words, confirmation bias acts to bring what people see and hear (i.e. what the jurors would see and hear) in line with what people believe or what society has conditioned them to believe about something or someone. This opens the door to bias.

In *Turner v. Murray*, the United States Supreme Court determined that juror latitude mixed with prejudice may prove to be too risky a combination to leave unbridled.[109] In its opinion, the Court stated that "the range of discretion entrusted to a jury in a capital sentencing hearing [poses] a unique opportunity for racial prejudice to operate but remain undetected . . . ."[110] Thus, the Court determined that "a capital defendant accused of an interracial crime is entitled to have prospective jurors informed of the race of the victim and questioned on the issue of racial bias."[111] Theoretically, this line of questioning would serve to detect hidden biases present within the juror pool.

Though evidence points to several accounts of juror decision-making that seem hardly ethical—decisions and sentences based on faulty cognition, racial prejudice, and psychological pull,—we may be able to rule out this hurdle in the realm of death row organ procurement fairly quickly. Just as our legislature should not make laws that seek to pierce through unconscious motives—mostly because this would be impossible and because it would be difficult to exact within a statute—laws surrounding the death penalty and organ donation would be unable to circumvent any prejudice that already exists in relation to the death penalty overall.

It is not the same to say that jurors are more likely to hand down the death penalty for African American men as it is to say that if someone *does not* believe in the death penalty suddenly he or she *will* if death row prisoners were allowed to donate their organs. Further, it is not as if the government would force these inmates to donate. Moreover, if juror

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[107] King, *supra* note 106, at 77.
[108] *Id.*
[109] Turner v. Murray, 476 U.S. 28 (1986).
[110] *Id.* at 35.
[111] *Id.* at 36-37.

prejudice were a true concern in death penalty cases (where statutorily an inmate could donate), those jurors that would foreseeably pose problems to the defendant's case could be weeded out just like any other.

IV. PADFIELD AND HOUSE BILL 41 – A HISTORY OF PUSHING FOR PROCUREMENT

All legal, ethical, and medical reasons aside, Indiana's Representative Padfield had the right idea. Condemned prisoner donation, while not the end of the organ shortage, is surely a step in the right direction. A bill like House Bill 41, would not be without at least some support from constituents of the state. As an example, in an ongoing internet poll on a webpage seeking to gauge opinions on controversial and popular issues, (as of November 17, 2015), 60% of web participants agreed with Padfield; that is, that prisoners should be allowed to donate organs.[112] As stated by a condemned prisoner, mimicking one side of the spectrum of sentiments felt by the community, "[w]hy go out and waste your organs when you have the potential to go out and save six to [twelve] lives?"[113]

A. What Happened?

The Padfield Bill did not pass. It was likely due to the immense stigma (yet likely undisclosed and unvoiced) attached to this topic, the distaste for subtracting from retributive justice, and the impossible battle lawmakers and the medical community would face in establishing protocol. The fight to get these kinds of bills passed is still alive as is the fervor with which proponents of it fight. Christian Longo still fights for his right to donate, and, similarly, up until his execution, Gregory Johnson fought for his ability to donate as well.

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[112] *Should Death Row Inmates Donate Their Organs,* DEBATE.ORG, http://www.debate.org/opinions/should-death-row-inmates-donate-their-organs [http://perma.cc/QZ32-FD5P] (last visited Nov. 17, 2015).

[113] Aleccia, *supra* note 68.

B. No Legislation Since Bill 41 in Indiana

Legislation of this kind will likely not be brought back to the table in Indiana until there is clear evidence that a number of things can change. The method of execution would have to change. Though, as aforementioned, donation after cardiac death can be a viable way to harvest healthy organs, the lethal injection process and the hurdles regarding its implementation are too strong to overcome. It is likely that in order for organs to be viable following execution, procedures must preserve the integrity of the organs. Tackling a method of execution, however, should not be the first order of business. Rather, the role of physicians would have to change.

V. OVERCOMING CHALLENGES

A. Changing the Role of Physicians in Executions

In order to procure organs from executed prisoners, a physician must be present. Though it may see macabre and somewhat voodoo, physicians and death are not strangers. In fact, Dr. Joseph Guillotin was a French physician who developed a method of execution – the guillotine.[114] He believed executions by this method would relieve pain in death; he later faced many critical responses following this invention.[115] Further, by 1982, there was clear evidence of physician involvement in executions within the United States.[116] Condemned prisoner Charles Brooks was set to be executed in 1982 by lethal injection.[117] Dr. Ralph Gray participated in the injection in a limited capacity. "He []

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[114] *Medical Ethics and Physician Involvement, supra* note 79.

[115] *Id.* at 5.

[116] *Id.*

[117] *Id.*; *See also* Robert Reinhold, *Technician Executes Murderer in Texas by Lethal Injection*, N.Y. TIMES (Dec. 7, 1982), http://www.nytimes.com/1982/12/07/us/technician-executes-murderer-in-texas-by-lethal-injection.html [https://perma.cc/5KJF-56UF].

examine[d] the prisoner to make sure his veins were large enough to accept the needle . . . ."[118] After the injection, Dr. Gray was ultimately the one to pronounce Brooks dead.[119]

In that case, the physician, Dr. Gray, did everything but inject the drugs. Dr. Gray monitored the inmate, assisted the executioner, pronounced death, and oversaw the general sequence of events. This, by some standards, could be seen as a physician-assisted execution.

It is hard to grasp that there is room for physician-assisted suicide, but not physician-assisted organ procurement in executions. Is there really a difference? Many U.S. physicians get requests for assisted death and assisted suicide, and of these physicians receiving requests, roughly six percent have accepted on at least one occasion.[120]

1. Exploring the Case of Brittany Maynard

Recently in the news was the case of Brittany Maynard, a woman diagnosed with a terminal form of brain cancer.[121] At only twenty-nine years of age, Brittany made the decision to end her life.[122] Facing the prospect of terrible side effects from radiation, and the symptoms of the brain cancer itself, Maynard and her husband journeyed to Oregon in search of the death with dignity law.[123]

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[118] Tamar Lewin, *Execution by Injection: A Dilemma for Prison Doctors*, N.Y. TIMES (Dec. 12, 1982), http://www.nytimes.com/1982/12/12/weekinreview/execution-by-injection-a-dilemma-for-prison-doctors.html [https://perma.cc/L47N-UWJ7].

[119] Patton, *supra* note 2, at 392.

[120] Diane E. Meier, et al., *A National Survey of Physician-Assisted Suicide and Euthanasia in the United States*, 338 NEW ENG. J. MED. 1193 (1998), *available at* http://www.nejm.org/doi/full/10.1056/NEJM199804233381706 [http://perma.cc/BFG9-YDDU].

[121] Brittany Maynard, *My Right to Death With Dignity at 29*, CNN NEWS, http://www.cnn.com/2014/10/07/opinion/maynard-assisted-suicide-cancer-dignity/ [http://perma.cc/U98C-BTKB] (last updated Nov. 2, 2014 10:44 PM).

[122] *Id.*

[123] *Id.*

Oregon, in 1994 passed a one-of-a-kind law that allowed terminally ill patients to access physician assisted suicide.[124] In effect, the law allowed competent, adult patients to receive a physician-authorized prescription for drugs that would result in death.[125] The law was greeted with scorn and apprehension from many across the nation and especially in Oregon. The law barely passed: "[t]he statewide vote was 51% in favor and 49% opposed [in 1994]."[126] Even after its initial passage, the bill's enforcement was enjoined, only later to wind up as a hot topic in the United States Supreme Court. The Court held that there was a distinction "between 'physician-assisted suicide' and withdrawal of life support or the 'double effect' of aggressive palliative care."[127] In essence, the Court did not see Oregon's law as a constitutional issue, but rather one of politics. Thus, the law took full effect in 1997.[128]

Maynard took advantage of the passage of this law and moved from California to Oregon to seek death with dignity.[129] She passed away after taking her prescribed medication in late 2014.[130]

Many, like Maynard, have done the same since Oregon's law has gone into effect. "More than 750 people in Oregon used the law to die as of Dec[ember] 31, 2013 . . . Only six were younger than 35, like Maynard."[131]

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[124] OR. REV. STAT. §§ 127.800-127.897 (2015); *see also* PATRICK DUNN ET AL., THE OREGON DEATH WITH DIGNITY ACT: A GUIDEBOOK FOR HEALTHCARE PROFESSIONALS 4 (2008), *available at* https://www.ohsu.edu/xd/education/continuing-education/center-for-ethics/ethics-outreach/upload/Oregon-Death-with-Dignity-Act-Guidebook.pdf [http://perma.cc/R8PT-RW7E].

[125] DUNN ET AL., *supra* note 124.

[126] *Id.* at Appendix A.

[127] *Id.* Appendix A, at 113.

[128] *Id.*

[129] *Death With Dignity Advocate Brittany Maynard Ends Her Life*, CBS NEWS (Nov. 2, 2014, 10:22 PM), http://www.cbsnews.com/ news/ death-with-dignity-advocate-brittany-maynard-ends-her-life/ [http://perma.cc/88FA-JUZP].

[130] *Id.*

[131] *Id.*

2. Oregon's Death with Dignity Act and the Hippocratic Oath

Following the widespread recognition of Maynard's case, a documentary, that was unveiled in 2011, rose in popularity. It was entitled: "How to Die in Oregon."[132]

> This documentary explores real life responses to Oregon's 'Death with Dignity Act,' the first law in the U.S. to allow physicians to prescribe lethal doses of drugs to the terminally ill. A middle-aged woman with terminal liver cancer, prepares to take her own life, while another cancer patient decides to suffer through his illness even though death is just as certain for him. Others grapple with choosing their own course of action, and one man decides to hold a 'death party.'[133]

The film explores the problems patients encounter when their decision ultimately is to die. For the most part, the film highlights the relief each patient feels for having the opportunity to assert his or her "right to die" under the Oregon law. While it is most difficult for the family members who must sit idly by and watch helplessly, the film truly hones in on the power the patient holds in determining his fate.

There are two interesting components of the film that must be addressed, especially in relation to the issue of death row organ procurement and the involvement of the medical community. There is no doubt that Oregon's medical community has established many protocols, rules, and guidelines to traverse the confusing realm of its law. As such,

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[132] HOW TO DIE IN OREGON (2011), *available at* http://www.imdb.com/title/tt1715802/ [http:/perma.cc/AY9Y-LCY4] (last visited Oct. 11, 2015).

[133] *How to Die in Oregon,* MOVIE FONE, http://www.moviefone.com/movie/how-to-die-in-oregon/10054198/main [http://perma.cc/V7PW-MRMZ] (last visited Nov. 17, 2015).

medical ethicists and legal scholars are especially interested in the safeguards and methods employed in carrying out this law. However, though the statute was passed, and though the procedures have been tried, verified, and found to be adequate, there are potential problems with the processes instituted before the patient ingests the lethal medication.

Indiana residents, as viewers and as members of a population somewhat detached from this Oregon law, must assume that the real-life accounts portrayed in the film are the actual and true ways that the right to die law is carried out. Building on this assumption, the analysis of risk can begin.

In the film, a volunteer arrives at the patient's home and speaks with him before the medication is taken.[134] The volunteer tells the patient how to crush the pills, how much water to mix in, what it will taste like, and how long it will take for him to die.[135] Additionally, the volunteer asks the patient two questions: first, the patient is informed that he has the right to change his mind and if he would like to presently do so; second, the patient is asked if he knows what the medication will do.[136]

To a politician and to a potential patient, these questions may seem adequate–they probe competency and underscore the possibility for liability. However, once in the position of comparing this process with that of the potential criteria for death row organ procurement, one must employ a deeper, more microscopic analysis.

A large potential problem with this procedure is that a volunteer, not a physician or a nurse, is present during the ingestion of the drugs and is present for the death. A volunteer is the one who asks these questions in an effort to categorically determine understanding and competency. Why is a volunteer the judge of the mental health and competency of a patient prior to the time of death? Why is a volunteer the one overseeing the process? Granted, the volunteers are likely adequately trained before engaging in this process, but the risk is ultimately too high regarding

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[134] HOW TO DIE IN OREGON (Peter D. Richardson, 2011).

[135] *Id.*

[136] *Id.*

liability and bioethics to allow anyone other than a medically trained and licensed professional to oversee this process. The potential for mistakes, the questions that could be posed and then incorrectly or ignorantly answered, and the way in which the patient takes the drug, are all potentially catastrophically harmful situations. What would happen if two gulps into the drug cocktail the patient changes his or her mind? How would a volunteer be equipped to handle such a hazardous situation? Realistically, the patient's physician should be there.

Secondly, that there are so few questions posed moments before the medication is to be ingested raises serious concerns regarding willingness, competency, safety, and liability. These questions only seek to uncover whether the person knows he will die upon taking the drug, and whether he wants to change his mind. This could be troublesome. Would the fact that others (for example, family members and friends of the patient) are present for these questions change the answer? Would the patient feel compelled to say that he did not want to change his mind? How could a person asking these questions gauge competency invariably? There is no battery of questions, no history of psychological screenings, and no tests – it is just too easy.

The process of end-of-life decision-making does not square with that of the lethal injection. Each offers the same result: death. And yet, one offers physician-prescriptive help to achieve the result while the other doesn't. One is established with relatively relaxed bioethical safeguards while the other has heightened ones. As such, Oregon's death with dignity law ties a close knot to the ethics behind organ donation of death row inmates and parallels some key concerns, especially regarding physician involvement.

The same concerns held by the medical community when physicians participate in the lethal injection process are highlighted in right to die laws. Doctors may not inflict death–to do so would be "antithetical to their ancient creed."[137] This argument is used to prevent physicians from

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[137] *Medical Ethics and Physician Involvement, supra* note 79 (quoting Kim Thorburn, *Doctors and Executions*, 7 AM. J. OF DERMATOPATHOLOGY (1985)).

meddling in the lethal injection process. It is used to prevent physicians from developing ways to procure organs during the "death process," and it is used to disallow a method of execution that would necessarily entail organ harvest. And yet, this argument is cast aside when it comes to Oregon's death with dignity law.

It seems contrived that our medical community and political infrastructure could pick and choose when to employ this reasoning. Many may view the difference between physician involvement in lethal injections versus their involvement with right to die patients as an informed consent issue. Right to die patients must be deemed competent, and must jump through several hoops before being able to be prescribed the lethal medication. On the other hand, those inmates who must face death do not get the luxury of informed consent for any portion of the process. The State decides.

The physician involvement distinction is negligible. Despite the fact that there is finer print and more safeguards to acquire informed consent in right to die cases, there could never, ever be such a strict and humanitarian standard for executions. Courts, juries, politics, and state governments, in essence, act as the informed consent counselors.

Just because one form of doctor-induced death operates on a different set of standards does not mean that by default medical rules and ethics apply more so to that one. The Hippocratic oath and a doctor's involvement in death in the most general sense must be a level platform if a medical ethics argument is to be used to prevent incarcerated organ donations. To apply the oath in only some cases would take the vigor out of the standards themselves.

In addition to the informed consent and medical standards parallel, residents of Indiana should consider right to die laws and ask what the true difference is between physician-prescribed death and physician-assisted death.

As stated before, one of the ways to overcome challenges in passing a bill to allow for organ procurement from death row inmates would be to rewrite the role of physician involvement in executions–to either write them out of the process completely, or more effectively, to allow them to participate in organ extraction during a brain death execution as opposed to a cardiac death execution. Here,

dissidents claim that to allow a doctor to do this allows him to be the executioner himself. One would have to ask then, what was the role of the physician who prescribed Brittany Maynard her lethal prescription? Using that logic, is he not the executioner as well? A key question as posed by Dr. David Waisel, an anesthesiologist with the Mayo Clinic is: "whether the physician is acting as a tool of the individual to minimize suffering and to further the individual's goals or whether the physician is acting as a tool of the government to ensure a successful execution."[138] If an inmate wishes to donate his organs, in theory, a physician conducting the procurement would be ensuring that this inmate's wishes are carried out and that his goals are attained, rather than acting as the "hand of death" on behalf of the State. In other words, the goal of the doctor providing comfort and the goal of the State in executing a criminal have aligned[139] in a seemingly perverse way.

It is hard to draw the line that physician participation in death is fine for patients in Oregon, but is inexcusable in the eyes of the medical community for condemned inmates.

First, patients who seek Oregon's death with dignity law are invoking their right to their own health autonomy. Physicians who assist these patients, in effect are respecting the patient's autonomy. The argument put forth by proponents of the right to die is that, "[c]ompetent people should have the right to choose the timing and manner of death."[140] Physicians tout the importance of respecting this right; competent individuals must never be deprived of their personal and patient autonomy. [141] However, condemned

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[138] David Waisel, *Physician Participation in Capital Punishment*, 82 MAYO CLINIC

PROCEEDINGS 1073, 1076-77 (2007) (discussing the nature of physician involvement in executions).

[139] *Id.* at 1077

[140] Helene Starks et al., *Physician Aid-in-Dying*, ETHICS IN MED. U. WASH. SCH. MED. (2013), https://depts.washington.edu/bioethx/topics pad.html [http://perma.cc/V7JY-C88V].

[141] *Declaration of Lisbon on the Rights of the Patient*, WORLD MED. ASS'N., (reaffirmed April 2015) *available at* http://www.wma.net/en/ 30publications/10policies/l4/ [perma.cc/YMV5-ZLBL]. The third patient

inmates are denied the right to autonomy in their end of life choices altogether. The denial of this right is stretched to bar choices about the fate of their own organs. Nonetheless, respect for autonomy cannot be the end-all be-all of physician involvement arguments.

Second, there is no distinction between active and passive death either in executions or in physician-prescriptive death.[142] Brittany Maynard's doctor in Oregon prescribed her medication to take.[143] There is nothing passive about this kind of death. The medication was deliberately requested and prescribed. Similarly, in executions, the method is not passive; it is active. The injections are deliberately administered. Therefore, in a very crass sense, an active "killing" exists on both sides of the spectrum; yet, one is tolerated, and the other is not.

In *Washington v. Glucksberg*, the United States Supreme Court found that the right to assisted suicide was "not a fundamental liberty interest that is protected by the Due Process Clause."[144] Further, the Supreme Court in *Vacco v. Quill*, held that a New York law prohibiting "assist[ed] suicide [did] not violate the Equal Protection Clause."[145] This in effect left it up to each state to decide whether or not to legalize physician-assisted suicide.[146] Thus, courts have continually recognized both liberal interpretations of right to die laws while still limiting the enforceability of such broad life-ending rights.

Oregon's right to die law raises serious questions about the integrity of medical ethics. While many may not want to agree, the circumstances facing the physicians who choose to participate in patients' right to die plans, are the same

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right listed, "right to self-determination," states: "the patient has the right to self determination, to make free decisions regarding himself/herself."

[142] *Id.*

[143] Lindsey Bever, *Cancer Patient Brittany Maynard, 29, Has Scheduled Her Death for Nov. 1,* WASH. POST (Oct. 8, 2014), https://www.washingtonpost.com/news/morning-mix/wp/2014/10/08/terminally-ill-brittany-maynard-29-has-scheduled-her-death-for-nov-1/ [https://perma.cc/3REF-YUQC].

[144] Washington v. Glucksberg, 521 U.S. 702 (1997).

[145] *Vacco v. Quill,* 521 U.S. 793 (1997).

[146] *Id.*

circumstances that physicians would be facing in organ extraction executions. The point is this: wavering medical ethics provide no true guiding light to overcoming serious challenges in not only condemned prisoner organ procurement, but in all facets of medical decision-making. Therefore, physicians can and should be involved in the execution process.

If the legal and medical community cannot come together as they did in establishing Oregon's death with dignity law, perhaps the Indiana community can still achieve medical reform to allow for death row organ procurement nonetheless. Physicians may not even need to be the ones to do the lethal injection at all. In turn, this would purge them of any ties to the actual death, rendering them capable of procuring the inmate's organs thereafter.

Prisons commonly hold required trainings prior to the execution date where participants are educated regarding the process and their responsibilities. As an example highlighted by the state of Kentucky, there, the prison implements training sessions regarding the lethal injection process to those individuals who play integral roles.[147] Among those involved in the training are EMT'S.[148] Allowing EMTs or any other health professional to administer an IV (the channel for lethal injection drugs) would overcome the ethical dilemma raised by physician participation. The physician may be in attendance to pronounce death but not to administer the process that ultimately results in death. The physician could then extract organs. Here physicians would be fulfilling their roles as caregivers as they would be extracting and procuring organs on behalf of the transplant recipients.

B. Changing the Nature of Lethal Injection

In addition to renegotiating the role of physicians and the staff used for executions, the method of execution could be

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147 Baze v. Rees, 553 U.S. 35, 118 (2008).

148 *Id.*

altered. The lethal injection may not be the best model for organ procurement purposes. In the clinical setting, organ transplantation surgeries are typically performed on patients whose hearts are still beating, but who have reached brain dead status.[149] The goal in harvesting organs from executed prisoners would in theory be to mimic a clinical transplantation as much as possible. Therefore, achieving brain death would be ideal in order to procure organs while the person's heart still beats. To this end, the introduction of anesthesia in "excessive amounts" would lead to death with a still-beating heart in a seemingly simpler process.[150]

This could be the new lethal injection process. Doctors perform organ procurement operations on brain dead, yet heart-beating patients all the time. Unlike donation upon cardiac death, brain death donations may yield far greater results due to the fact that the heart is still beating and is still able to provide oxygenated blood to all tissues.

Changing the lethal injection would not destroy a flawless process. The injection has faced its fair share of problems. Botched executions are not entirely uncommon. On January 9, 2014, Michael Wilson was executed in Oklahoma by lethal injection.[151] As the drugs were introduced, Wilson remarked, "I feel my whole body burning."[152] He was dead shortly after uttering this sentiment.[153] The pain he felt during the lethal

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[149] D.W. McKeown, et. al., *Management of the Heartbeating Brain – Dead Organ Donor*, 108 BRITISH J. ANAESTHESIA 96 (2012) *available at* http://bja.oxfordjournals.org/content/108/suppl_1/i96.full.pdf+html [https://perma.cc/6BCV-2QM9].

[150] Paul Kempen, *Lethal Injection, Anesthesia, Medicine and Organ Donation – Ethical and Clinical Consideration Regarding the Pending Supreme Court Case: Baze v. Rees*, 2 OPEN ANESTHESIOLOGY J. 7-9 (2008) http://benthamopen.com/contents/pdf/TOATJ/TOATJ-2-7.pdf [http://perma.cc/YHK7-XMR8].

[151] Graham Lee Brewer, *Condemned Man's Last Words Lead to Questions About Lethal Injection 'Cocktail' in Oklahoma, U.S.,* THE OKLAHOMAN (Feb. 9, 2014), http://newsok.com/article/3932043 [http://perma.cc/V3AP-GUVH].

[152] *Id.*

[153] *Id.*

injection raised serious concerns regarding the safety and effectiveness of the chemicals used in the process.[154]

In a separate instance, Clayton Lockett, after the drug cocktail was administered, moaned and jerked on the gurney.[155] Edith Shoals, who was present as a victim advocate described the scene as "like a horror movie . . . he kept trying to talk."[156] Debate spurred on whether to take Lockett to a hospital or not, but Lockett died soon after.[157] Nothing went according to plan.

Additionally, in 2009, Ohio attempted to execute a man named Romell Broom.[158] Officials could not find a vein to insert the IV; instead records indicate that officials stuck him eighteen times until the governor finally terminated their efforts.[159]

Other instances perpetuate the need for change in lethal injection procedure. In light of the need for organs, and in light of the rights denied to death row inmates, this change could and should incorporate medical techniques that not only allow for a more humane death, but also for a death that would be conducive to organ procurement.

The problems with lethal injection procedure will not fix themselves. And, like any medical complication, medical adjustments, not political ones, will be the best corrective action. The lethal injection is dangerous as it is. If the process of death went from cardiac death to brain death,

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[154] *Id.*

[155] *Scene at Botched Oklahoma Execution of Clayton Lockett Was a 'Bloody Mess,'* THEGUARDIAN.COM, http://www.theguardian.com/world/2014/dec/13/botched-oklahoma-execution-clayton-lockett-bloody-mess [http://perma.cc/H4MH-6JJT] (last visited Nov. 18, 2015).

[156] *Id.*

[157] *Id.*

[158] Tracy Connor, *Top Court Will Hear Rommell Broom's Execution Do-Over Appeal*, NBC NEWS (June 3, 2014), http://www.nbcnews.com/storyline/lethal-injection/top-court-will-hear-romell-brooms-execution-do-over-appeal-n121366 [http://perma.cc/4J5D-656P].

[159] *Id.*

many of these botched injections would not have happened. Rather, the patients would have eventually "overdosed" on anesthesia[160]–a relatively peaceful and pain free process.

Further, allowing for physician involvement would accomplish two things. First, if a medical complication were to arise during the execution, the physician would be there to make the right call. There would be no lengthy debate on whether hospitalization was or was not necessary as was the case for Lockett's execution.

Second, the physician could be there to do the organ procurement. This would not only ensure that the organ extraction was done in a timely manner, but that it was done with the kind of precision that is required.

Adjusting simple techniques and restructuring the staffing procedure for executions may provide room to overcome bioethical challenges. Performing organ procurement as a means of execution—that is, brain death executions versus cardiac death executions—would not only overcome problems associated with the adverse biological effects of the lethal injection, but would also allow other trained personnel (other than licensed physicians) to be a part of the execution process, circumventing any potential issues that may arise from medical ethics communities regarding physician-involved executions.

C. Bill Reintroduction is a Necessity

Indiana has the potential to turn the dial in advancing the evolution of the field of bioethics and to set precedent in the law. Just as Oregon made waves in instituting the Death with Dignity Act, so too can the state of Indiana make waves. Passing a bill to allow for organ procurement from death row inmates will not cure the organ deficit, nor will it change stigma and opposition from certain members of society, but just as Oregon's Act was intended to grant justice to those who had no other recourse, a bill to allow death row inmates

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[160] Kempen, *supra* note 150.

to donate organs would grant justice to those also without recourse. Those inmates condemned to die would have the opportunity to reach for atonement and reveal their humanity – a final act of selflessness and autonomy while incarcerated.

Ultimately, in truth, the number of organs that would end up viable and transplantable may be miniscule. Nonetheless, there is something much greater at play. Denying these people—because yes, inmates are people—the right to donate, infringes on a basic tenant of personal autonomy that not even a death sentence can remove. These prisoners seek, in their final hour, to have one last attempt to overcome their pasts. Whether to atone or to demonstrate a manifestation of their own humanity, these prisoners continue to pursue organ donation.

In light of Oregon's new law, in light of the measures attainable to overcome bioethical barriers, and in light of the methods with which organ procurement within the execution process are possible, there is no reason why another bill like House Bill 41 could not be reintroduced and passed.

Stigma will not perish, nor will resentment from victims' families and other members of the community. Yet, despite trepidation from all fronts of opposition, a new bill should and must be reintroduced. To continue to deny organ transplants to the dying and to deny organ donation to the almost dead seems too great a burden for our state to bear–killing two by denying rights to one.

It is time to re-think the system. It is broken and it can be reworked. In his concurrence in *Cruzan v. Director, Missouri Department of Health*, Justice Scalia highlighted the liberty interests at stake in end-of-life decision-making, writing that "[t]he text of the Due Process Clause does not protect individuals against deprivations of liberty . . . . [i]t protects them against deprivations of liberty 'without due process of law.'"[161] While the *Cruzan* case does not delve into the realm of incarcerated individuals, the holding marks an important concept that must be actualized. All people hold the biological

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[161] Cruzan v. Director, Mo. Dep't of Health, 497 U.S. 261, 293 (1990).

rights to do with their bodies what they wish. Under the strength and steadfastness of the law, due process should adequately protect this right, because all people deserve, at the end of their lives, to be the apex of authority for the liberties of their bodies–for in death, everyone is a vulnerable prisoner.