

## A LIFT ON THE STATUTORY PROHIBITIONS AGAINST HIV-POSITIVE ORGAN DONATION

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### ABSTRACT

*The climate of the American organ donation pool is bleak. More people are added to the waiting list every year, while the supply of available organs generally remains the same. As modern medicine extends the human lifespan, the need for available organs continues to grow. Of particular salience in this Note is the need to reverse the statutory prohibition on organ donation for HIV-positive organs to willing patients. In an effort to reverse some of the stigma against the use of HIV-positive organs for donation, former President Barack Obama attempted to deregulate some of the landscape by passing the HOPE Act in 2013, which legalized the use of HIV-positive organs in transplantation experiments with other HIV-positive patients. While the HOPE Act was a promising start for using HIV-positive organs, it did not eliminate restrictions on access to these organs in HIV-negative populations. This Note argues that the statutory prohibition on the use of HIV-positive organs needs to be lifted so that medical experimentation and innovation can proceed. If and when medical experimentation demonstrates acceptable patient survival durations, it may be possible to increase the available pool of organs for donation through lifting the ban on HIV-positive organs.*

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## INTRODUCTION

Sally Satel, a forty-eight-year-old psychiatrist and resident scholar at the American Enterprise Institute, thought she was in good health when she went in for her routine annual health appointment in August of 2004.<sup>1</sup> A blood work up, however,

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1. Sally Satel, *Desperately Seeking a Kidney*, N.Y. TIMES MAG. (Dec. 16, 2007), <http://www.nytimes.com/2007/12/16/magazine/16kidney-t.html> [hereinafter *Seeking a Kidney*].

indicated that Sally's kidneys were functioning at 16% of normal capacity and she had limited time before needing dialysis or an organ transplant.<sup>2</sup> Like many who receive this kind of devastating news, Sally immediately began to weigh her options.<sup>3</sup> She added her name to an online organ donation match-up site—MatchingDonors.com—and in desperation gave thought to joining the growing number of “transplant tourists” who travel abroad to seek an organ on the black market<sup>4</sup>—a process that can be as fruitless as idling on the waiting list in the United States. Sally was aware that, in major metropolitan centers, the wait time for an acceptable organ could range from five to eight years and that a patient dies every ninety minutes.<sup>5</sup>

Ultimately, Sally had one of the luckiest and rarest conclusions to an organ donation story. Weeks before her dialysis catheters were to be placed, a voluntary, statutorily permissible<sup>6</sup> donor stepped forward.<sup>7</sup> Most patients awaiting organ donation, however, are not as fortunate as Sally. Statutory prohibitions on organ donation, which limit organ pools, along with strong legal, social, and ethical principles that organs are not to be retrieved as commodities, mean the number of organs available for transplant is extremely limited.

This Note argues the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid (CMS) should amend the language in the National Organ Transplant Act (NOTA) to include the use of suboptimal organ donation. Specifically, language prohibiting donation of organs from human immunodeficiency virus (HIV)-positive do-

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2. *Id.*

3. *Id.*

4. Sally Satel, *Death's Waiting List*, N.Y. TIMES (May 15, 2006), <http://www.nytimes.com/2006/05/15/opinion/15satel.html> [hereinafter *Waiting List*].

5. *Id.*

6. Statutory permissibility will be detailed later in this Note. The significance is that a voluntary donor, who is not statutorily prohibited, is able to donate an organ.

7. *Seeking a Kidney*, *supra* note 1 (noting that a voluntary donor is a living donor who gives informed consent to donate an organ, provided that the donor-patient can survive without the donated organ and is not incentivized with compensation or otherwise bribed).

nors to HIV-negative patients should be removed from the statutes.

There is a massive shortage of viable organs available to patients actively on donation waiting lists. Restrictive federal and state legislation dictating which organs may be donated and which must be discarded contribute, in part, to the long waiting lists. Since the passing of NOTA in 1984, statutory language has prohibited HIV-positive organ donations. In the wake of new medical advancements and effective treatment plans that use anti-retroviral regimens (ARVs),<sup>8</sup> consideration needs to be given to lifting prohibitions on HIV-positive organs donation. In addition to the statutory prohibition in NOTA, the most current legislation, the HIV Organ Policy Equity Act (HOPE Act),<sup>9</sup> should be expanded to include HIV-negative organ recipients for HIV-positive organs.<sup>10</sup>

Recently, Hepatitis C (HCV) positive organs have been used in transplants with HCV-negative patients.<sup>11</sup> The HCV virus was retroactively “cured” in the patient in the sense that the

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8. ARVs have been shown to dramatically slow the disease's progress and to prevent secondary infections and complications. Lin Shen & Richard Siliciano, *Viral Reservoirs, Residual Viremia, and the Potential of Highly Active Antiretroviral Therapy to Eradicate HIV Infection*, 122 J. ALLERGY CLINICAL IMMUNOLOGY 22, 22 (2008).

9. Pub. L. No. 113-51, 127 Stat. 579 (2013) (codified in scattered sections of 18 and 42 U.S.C.).

10. See *People Over Age 50 and Organ Donation/Transplantation*, ORGANDONOR.GOV (Apr. 25, 2014), <https://www.organdonor.gov/minority50plus/minority50plustables.html>. The weight of this conversation rests on a determination of whether a patient is willing to consider consenting to a medical experiment consisting of an organ transplant from an HIV-positive donor, versus waiting for an optimal organ. Of the patients on the organ donation waiting list, approximately 79,867, or 65.3%, are candidates who are over the age of fifty. *Id.* Of the approximate 28,953 transplants performed in 2013, 16,742, or 61.3%, of the recipients were older than fifty. *Id.* The population over fifty years old in need of organ transplants for survival is considerable, and they do command a significant percentage of the organ supply. According to the Centers for Disease Control (CDC), the average life expectancy for an American is 78.8 years old. *Life Expectancy*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 3, 2017), <https://www.cdc.gov/nchs/fastats/deaths.htm>. This means an organ recipient at the age of fifty has twenty-eight or more years of life expectancy should he or she receive a viable organ transplant. Beginning medical trials of the nature proposed in this Note could offer HIV-positive organs to HIV-negative patients in a specified age group of candidates over the age of fifty with the possibility of expanding the trial pool after more research is conducted.

11. *Can Hepatitis C Be Cured?*, AM. LIVER FOUND., <http://hepc.liverfoundation.org/diagnosis/can-hepatitis-c-be-cured/> (last visited Jan. 26, 2018).

“virus is not detected in [the patient’s] blood when measured with a blood test [three] months after treatment is completed.”<sup>12</sup> This procedure not only prevents the discarding of organs otherwise considered suboptimal, but could also relieve the tension on the organ donation waitlist. Applying the HCV organ donation concept, HIV-positive organ donation could be a viable option, with the goal of treating any resulting HIV infection caused by a successful transplant.<sup>13</sup> Moreover, there is merit to lifting statutory bans on HIV-positive organ donation for the sake of medical experimentation and innovation. Such a legislative lift could not only alleviate some burdens of those on the national organ waiting list, but also improve the prospects for those awaiting organ donation. As a matter of public policy, this type of innovative medical treatment could benefit society as a whole.

Due to a large volume of patients who will eventually require a transplant, experiments in this field could help reduce a serious public health problem.<sup>14</sup> Organ transplantation pro-

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12. *Id.* (noting that at this point, the patient is considered to have had a sustained virologic response (SVR) and current data suggests that the virus will not reemerge).

13. *What Are HIV and AIDS?*, Hiv.Gov (May 15, 2017), <https://www.hiv.gov/hiv-basics/overview/about-hiv-and-aids/what-are-hiv-and-aids> (defining “latency” as “a period where a virus is living or developing in a person without producing symptoms”). HIV infection advances in the body in three phases: (1) acute HIV infection, (2) clinical latency; and (3) Acquired Immune Deficiency Syndrome. *Id.* The key factor to selecting HIV positive organs for donation would be to acquire the organ in phase 1 or 2, otherwise ideally when the disease is in the clinical latency phase. Donors should have a low viral load and a low lab test measurement of lymphocytes cells in a blood sample (CD4 count) in order to be considered as a possible organ donor. See *Aids2016: Life Expectancy for People Living with HIV has Increased Again With Analysis*, PROJECT INFORM (Sept. 13, 2016), <http://www.projectinform.org/hiv-news/aids2016-life-expectancy-for-people-living-with-hiv-has-increased-again-with-recent-analysis/> (explaining that data on patients in clinical studies who acquired HIV by age twenty show a life expectancy with early treatment of over 54.9 years post infection). At least one clinical study has found that patients who are newly infected with HIV in their fifties can live until their seventies with appropriate treatment and monitoring. *Id.*

14. Paul W. Eggers, *Medicare’s End Stage Renal Disease Program*, 22(1) HEALTH CARE FIN. R. 55, 56 (2000) (noting that many of these public policy concerns emerged in the 1960s after a social fear of death panels for those on the organ donation waiting list emerged). After the invention of dialysis, due to cost and access restrictions, patients were arbitrarily selected for treatment, leading to the approval of payment from Medicare. *Id.* Many others were denied care and subsequently died as a consequence of lack of treatment. *Id.* Today, as a result, end stage renal disease is the only ailment that Medicare will cover, regardless of the patient’s age. *Id.*; see also *Your Medicare Coverage*, MEDICARE.GOV, <https://www.medicare.gov/coverage/>

grams have historically been given considerable leeway for experimentation and medical innovation.<sup>15</sup>

Due to statutory prohibitions in NOTA, the medical community has not had the legal standing to conduct research on HIV-positive organ donation in HIV-negative patients. A lift of this prohibitive statutory language would allow for medical research and clinical trials to begin. Should these experiments be successful, this form of treatment could be a solution for the long waitlist duration. This Note proposes lifting statutory bans against medical experimentation with HIV-positive organs. Part I of this Note opens with an overview of medical research, including a history of HIV discovery, the Nuremberg Code, patient informed consent, and institutional review board requirements. Part II of this Note discusses federal and state regulation of HIV-positive organ donation. Part III provides an overview of the HCV organ transplant clinical trials and explains how medical experimentation and innovation in other similar fields has resulted in benefits to the public. Finally, Part IV addresses ethical considerations, which impact, at least in part, the legal direction this proposal could take.

#### I. THE PROBLEM DEFINED: A GENERAL OVERVIEW OF THE ORGAN TRANSPLANTATION PROGRAM & ORGAN SHORTAGE PROBLEM

There are currently more than 116,000 men, women, and children on the national organ transplant waiting list.<sup>16</sup> Of these, 74,859 people are on the active waiting list.<sup>17</sup> As the number

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dialysis-services-and-supplies.html (last visited Jan. 26, 2018) (noting that renal failure is given a high importance level and CMS has approved of Medicare funding for treatment until the patient has met the waiting requirements and is stable enough for an organ transplant).

15. Eggers, *supra* note 14.

16. *Organ Donation Statistics*, U.S. DEP'T. HEALTH HUM. SERV., <http://www.organ-donor.gov/statistics-stories/statistics.html> (last visited Jan. 26, 2018).

17. *Organ Procurement and Transplantation Network*, U.S. DEP'T HEALTH HUM. SERV., <https://optn.transplant.hrsa.gov/> (last visited Jan. 26, 2018) [hereinafter *Organ Procurement and Transplantation Network*]; see also *United Network For Organ Sharing*, UNOS, <https://www.unos.org> (last visited Jan. 10, 2018) (noting that in order to be on the active list, a patient must be added by a transplant hospital to the United Network for Organ Sharing

of patients waiting for organ donations grows, the number of organ transplantations grows at a relatively constant rate.<sup>18</sup> In 2015, only 30,975 organ transplants were performed in the United States.<sup>19</sup> Twenty people die each day while waiting for a transplant.<sup>20</sup> Although studies indicate 95% of U.S. adults support organ donation, only 54% are registered donors.<sup>21</sup> Every ten minutes, a new person is added to the waiting list.<sup>22</sup> Due to strict regulation and actual causes of death, only three people per thousand die in a manner that allows for organ donation.<sup>23</sup> The most common cause of death for organ donors results from fatal head injuries, including injuries sustained in car accidents, strokes, and brain aneurysms.<sup>24</sup> All possible life-sustaining measures are attempted before a patient is considered for organ donation.<sup>25</sup> Before organs may be harvested, a patient must be pronounced dead.<sup>26</sup> In addition to the cause and manner of death, restrictions on, and social uncertainty about, organ donation influence how many organs will ulti-

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(UNOS) computer system). When an organ becomes available, "UNOS' computer system generates a ranked list of transplant candidates, or 'matches,' based on blood type, tissue type, medical urgency, waiting time, expected benefit, geography and other medical criteria." *Id.*

18. *Need Continues to Grow*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, <https://optn.transplant.hrsa.gov/need-continues-to-grow/> (last visited Feb. 8, 2018) ("In 2003, there were 83,731 waiting at year end, 25,473 transplants performed . . . [and] [i]n 2015, there were 122,071 waiting at year end [and] 30,975 transplants performed."); see also *Organ Donation Statistics*, *supra* note 16.

19. See *Need Continues to Grow*, *supra* note 18; see also *Data*, UNOS, <https://unos.org/data/> (last visited Jan. 10, 2018).

20. *Id.*

21. See *Organ Donation Statistics*, *supra* note 16.

22. *Id.*

23. *Id.*

24. *Donation Process*, CTR. FOR ORGAN RECOVERY & EDUC., <https://www.core.org/understanding-donation/donation-process> (last visited Jan. 12, 2018).

25. *Id.*

26. *Id.* (noting that according to Pennsylvania Death Law, a patient may be pronounced deceased if they have suffered "(1) irreversible cessation of circulatory and respirator functions; or (2) irreversible cessation of all functions of the entire brain, including the brain stem . . ."). A determination of death is made according to accepted medical standards. *Id.* It is not a subjective decision but rather the result of a number of tests that function to determine an "irreversible loss of brain function." *Id.* Typically, a brain-dead patient has had oxygen deprivation for a significant amount of time, resulting in irreversible damage to the brain, and the patient's heart remains beating through mechanical measures, keeping blood circulating to the organs. *Id.*

mately be available for donation.<sup>27</sup>

## II. BACKGROUND AND OVERVIEW OF MEDICAL RESEARCH

### A. *Discovery of HIV and Human Subject Research*

The first identification of Acquired Immune Deficiency Syndrome (AIDS) was in 1979.<sup>28</sup> Researchers at the Pasteur Institute lab of Luc Montagnier and the National Institutes for Health (NIH) identified the virus in 1983, which they named HIV.<sup>29</sup> This discovery was followed by the emergence of significant AIDS activist groups, prompting Congress to increase available funding for AIDS research.<sup>30</sup> This funding is partially credited for “the development of medications that permit [HIV] victims to live with the [virus] for years as a chronic condition rather than facing an almost certain rapid death.”<sup>31</sup> The NIH continues to grow and receive considerable budgetary allotment from Congress for HIV research.<sup>32</sup>

To date, organs from HIV-positive donors have not been used in donor transplantation experiments to HIV-negative recipients due to statutory prohibition and, presumably, the possible *harm* that could result—HIV infection and, possibly, death. The infection rate remains unknown, however, until

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27. *Id.* It should be noted that statutory and regulatory barriers both exist to obtaining organs. Public fear and myths may contribute to the organ shortage. The common fears include patients fearing that medical staff will not work as hard to save their lives if they are organ donors, families fear that their loved ones will not be able to have open casket funerals, patient fears that they are too old, or not of good enough health, and fears that there may be cost involved to the family of the donor. While these fears may be common: (1) medical staff will not choose to deny treatment to a patient in an attempt to obtain their organs; (2) open caskets are still possible for most organ donors; (3) age and health ailments no longer pose the same obstacles they used to for organ donation; and (4) there is no cost to the families of the organ donor.

28. ROBERT I. FIELD, *HEALTH CARE REGULATION IN AMERICA: COMPLEXITY, CONFRONTATION AND COMPROMISE* 211 (1st ed. 2007).

29. *Id.*

30. *Id.*

31. *Id.* at 212.

32. *Id.* at 212–13 (“[T]he NIH budget rose by 80 percent between 1990 and 1998, in contrast to 48 percent for all other nondefense discretionary spending. However, the years since 2002 have seen a leveling off of this budget growth.”).



proper medical experimentation is conducted and clinical trials ensue. Medical “research has a primary goal [that is] the production of new knowledge for the good of society and requires risk to the individual, although formal ethical principles for medical research require respect for the autonomy and well-being of the individual subject.”<sup>33</sup> Medical research requires a balance of ethical frameworks that “rests on the fulcrum of the prohibition against research without the voluntary consent of the subject.”<sup>34</sup> Research in the United States is heavily regulated and is a dichotomous environment of knowledge gained from the research versus the protection of the individual subject from harm.<sup>35</sup> For medical research to be the most beneficial to society, statutory language should not be prohibitive of medical innovations unless the research itself seems contradictory to public policy.

*B. The Nuremberg Code and the Doctrine of Informed Consent*

The Nuremberg Code (the “Code”) established the legal and moral principles that regulate research using human subjects.<sup>36</sup> It was created in response to the horrendous medical experiments conducted by the National Socialist Party physicians on human subjects without consent during World War II.<sup>37</sup> The perpetrators of these atrocities justified their actions by describing their activities as “legitimate medical research.”<sup>38</sup> Many of the physicians who participated in this “medical re-

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33. BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIAL AND PROBLEMS* 1743 (7th ed. 2013).

34. *Id.* at 1753.

35. *Id.* at 1743.

36. *Id.* at 1744.

37. *Id.*; see also *Nazi Medical Experiments*, U.S. HOLOCAUST MEMORIAL MUSEUM, <https://www.ushmm.org/wlc/en/article.php?ModuleId=10005168> (last visited Jan. 26, 2018) (explaining experiments including submitting human subjects to freezing temperatures, testing immunization compounds and sera in an attempt to combat contagious disease by infecting otherwise healthy subjects with various diseases like typhoid fever and tuberculosis, and conducting other forms of experiments aimed at advancing “the racial and ideological tenets of the Nazi worldview”).

38. FURROW ET AL., *supra* note 33, at 1744.

search" were tried, convicted, and hanged.<sup>39</sup> As a result, the Nuremberg court developed principles for ethical medical experimentation.<sup>40</sup> "In one of the tribunal's most significant judgments, the court sitting in Nuremberg promulgated principles for ethical medical experimentation."<sup>41</sup>

One of the most essential and crucial elements of the Code is the voluntary consent from the human subject to the medical research and experimentation.<sup>42</sup> This involves the patient having the "legal capacity to give consent."<sup>43</sup> Ten elements are required for medical experimentation to be permissible pursuant to the Code:

1. The subject should understand the "nature, duration, method and purpose of the experiment" including all reasonably expected inconveniences, hazards and "effects upon his health which may result from participation in the experiment";<sup>44</sup>
2. The purpose should be of "yield[ing] fruitful results for the good of society . . . and not random and unnecessary in nature;"<sup>45</sup>
3. The experiment design should be "based on the results of animal experimentation;"<sup>46</sup>
4. Unnecessary mental and physical suffering should be avoided;<sup>47</sup>
5. If there is an *a priori* reason to suspect injury or death will occur, the experiment will not be permissible;<sup>48</sup>

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39. *Id.*

40. *Id.*

41. *Id.*

42. *Id.* at 1745.

43. *Id.*

44. *Id.*

45. *Id.*

46. *Id.*

47. *Id.*

48. *Id.*

6. The degree of risk should not exceed the humanitarian "importance of the problem to be solved by the experiment;"<sup>49</sup>
7. Preparations, including facilities provided, are to be available to protect the subjects from injury and death;<sup>50</sup>
8. Only scientifically qualified people may conduct medical experiments;<sup>51</sup>
9. The experiments may be terminated by the subject at any time;<sup>52</sup> and
10. The lead scientist of the study must be prepared to terminate the experiment at any stage if she believes that the study may be causing or is likely to cause serious injury or death.<sup>53</sup>

So long as medical experimentation follows the guidelines of the Code, the experiment will generally be considered within the boundaries of just public policy and the greater good. The Code is an important consideration for this Note, because while clinical data could be acquired within the acceptable parameters established by the Code, statutory restrictions should not be prohibitive of medical experimentation and innovation.

### C. *Regulation of the Doctrine of Informed Consent*

While paving the way for the modern doctrine of informed consent and setting the standards for clinical research, the "Nuremberg Code did not have an immediate impact in the United States."<sup>54</sup> This could be the result of the American medical community viewing the Nazi experimenters as being "apart from ordinary human nature and outside of tradition of

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49. *Id.*

50. *Id.*

51. *Id.* ("The highest degree of skill and care should be required through all stages of the experiment by those who conduct or engage in the experiment.")

52. *Id.* at 1746.

53. *Id.*

54. *Id.* at 1750.

medical ethics.”<sup>55</sup> Therefore, although international communities expressed outrage at the medical atrocities of World War II, regulations governing medical research in the United States did not emerge until decades later.<sup>56</sup> Modern American medical experimentation and innovation regulations involve a combination of congressionally led initiatives and judicially imposed standards.<sup>57</sup>

It was not until Peter Buxtun raised concerns in 1968 about the ethics of the Tuskegee Syphilis Study, which began in 1932, that it became more evident that medical abuse in experimentation was “possible, if not common, in [the United States].”<sup>58</sup> The study denied 399 subjects syphilis treatment for up to forty years and became the “topic of federal administrative and Congressional hearings in 1973.”<sup>59</sup> In 1974, Congress enacted the National Research Act in response to the Tuskegee study.<sup>60</sup> The Act’s purpose was to establish the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research.<sup>61</sup> It also mandated institutions conduct medical research in accordance with the Institutional Review Board (IRB) guidelines, which was to be contracted by HHS.<sup>62</sup> Many modern private organizations have since emerged and set standards for medical experimentation.<sup>63</sup> Perhaps most relevant to this Note, however, is that regulations have not evolved with modern potential of medical experimentation and innovation.<sup>64</sup> Importantly, this may indicate

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55. *Id.* (citing George Annas, *Mengele’s Birthmark: The Nuremberg Code in the United States Courts*, 7 J. CONTEMP. HEALTH L. & POL’Y 17 (1991)).

56. *Id.* at 1751.

57. *Id.* at 1751–52.

58. *Id.* at 1750; see also Derek Kerr & Maria Rivero, *Whistleblower Peter Buxtun and the Tuskegee Syphilis Study*, GOV’T ACCOUNTABILITY PROJECT (Apr. 30, 2014), <https://www.whistleblower.org/blog/04302014-whistleblower-peter-buxtun-and-tuskegee-syphilis-study>.

59. FURROW ET AL., *supra* note 33, at 1750.

60. *Id.* at 1751.

61. *Id.*

62. *Id.*

63. *Id.* at 1752.

64. *Id.* at 1760–61 (Modern potential of medical experimentation and innovation includes “the evolving human research enterprise, the proliferation of multi-site clinical trials and ob-

that the regulations for medical research may limit current experimentation opportunities.<sup>65</sup>

The doctrine of informed consent is one of the most important considerations surrounding the legalization of HIV-positive organ transplant experimentation. Case law has established that patients have a right to self-determination.<sup>66</sup> “True consent to what happens to one’s self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each.”<sup>67</sup> A physician is required to treat her patient skillfully.<sup>68</sup> Due care includes an obligation that the physician has to advise the patient on the desirability and availability of alternative treatments which may promise greater benefit than that being pursued or provided.<sup>69</sup> It requires that “the physician warn the patient of any risks to his well-being which contemplated therapy may involve [and that includes] invariably the occasion for decision as to whether a particular treatment procedure is to be undertaken.”<sup>70</sup>

Informed consent can be broken down “into five components: (1) competence; (2) disclosure; (3) understanding; (4) voluntariness; and (5) consent.”<sup>71</sup> The focus of informed consent has shifted in ethical and medical communities away from what information physicians are “required to disclose and towards the quality of patients’ understanding of the in-

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servational studies, the expansion of health services research, research in the social and behavioral sciences, and research involving databases, the Internet, and biological specimen repositories, and the use of advanced technologies, such as genomics.”).

65. *Id.* at 1761. There may be an argument that the acceptable industry standards and medical research boundaries need to be revisited in order to take into account modern medicine and technological innovation.

66. *See, e.g.,* *Miller v. Kennedy*, 522 P.2d 852, 863 (Wash. Ct. App. 1974); *Wilkinson v. Vesey*, 295 A.2d 676, 688 (R.I. 1972); *see also* *Sard v. Hardy*, 379 A.2d 1014, 1021 (Md. 1977).

67. *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir. 1972).

68. *Id.* at 781 (“[P]roficiency in diagnosis and therapy is not the full measure of [the physician’s] responsibility.”).

69. *Id.*

70. *Id.*

71. Emily K. White, *A Reason for Hope? A Legal and Ethical Implementation of The HIV Organ Policy Equity Act*, 96 B.U. L. REV. 609, 627 (2016); *see also* TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* 266 (7th ed. 2013).

formation disclosed.”<sup>72</sup> Case law, however, continues to focus on a physician’s obligation to disclose specific information prior to treatment.<sup>73</sup> A physician who does not obtain informed consent prior to treatment “can be held criminally liable for battery—an intentional, unconsented touching.”<sup>74</sup>

The IRB requires “that subjects are provided with adequate information and that consent is given voluntarily and without coercion.”<sup>75</sup> It is difficult to establish whether consent meets the federal regulation’s threshold in weighing whether the risks are “reasonable” as defined by the Common Rule:<sup>76</sup>

Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.<sup>77</sup>

#### Federal restrictions regulating medical research and experi-

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72. White, *supra* note 71.

73. *Id.* at 628 n.118 (“[T]he focus of attention is more properly upon the nature and content of the physician’s divulgence than the patient’s understanding or consent.”).

74. *Id.* at 628. Understanding informed consent is important for this Note because it demonstrates that the medical industry is already regulated so as to protect patient safety. Statutory bans beyond those set in this standard may only serve to hinder medical experimentation and innovation.

75. FURROW ET AL., *supra* note 33, at 1783.

76. *Id.* at 1784; *see also* Basic HHS Policy for Protection of Human Research Subjects, 45 C.F.R. § 46C (2017).

77. Criteria for IRB Approval of Research, 45 C.F.R. § 46.111(a)(2).

mentation should not be justified so long as the principles of assuming voluntary consent without coercion are maintained in accordance with the Common Rule.<sup>78</sup> The question remains whether a “competent adult [is] able to participate in research even if it presents a substantial risk to his or her health.”<sup>79</sup> This is partially the responsibility of an IRB, which assesses potential clinical trial patient harm, monitors risk throughout the course of a study, and suspends research under certain circumstances.<sup>80</sup> A study will be suspended when “unanticipated levels of risk or unexpectedly early and strong positive results occur.”<sup>81</sup> In the scenario of transplanting organs from HIV-positive donors into HIV-negative recipients, physicians must take clear, calculated steps to decrease the unanticipated levels of risk as much as possible.

### III. CURRENT REGULATIONS

While current regulations provide a framework to make organ donation as fair and comprehensive as possible, these regulations are outdated and do not maximize solutions to the organ shortage problem. NOTA is the oldest and most comprehensive Act regulating the organ transplant environment.<sup>82</sup> The HOPE Act was the Obama Administration’s attempt at lifting some of the barriers NOTA created.<sup>83</sup> States have fol-

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78. See FURROW ET AL., *supra* note 33, at 1784 (citing Richard A Epstein, *Defanging IRBs: Replacing Coercion with Information*, 101 NW. L. REV. 735 (2007) (“IRBs should assure only that information to the subject about the risks is accurate and understandable, leaving to the individual the decision to enroll or not.”)).

79. See FURROW ET AL., *supra* note 33, at 1785.

80. *Id.*

81. *Id.* This Note will not explore the reasons behind halting a study that yields early unanticipated positive results.

82. See generally *Organ Donation Legislation and Policy*, U.S. GOV’T INFO. ON ORGAN DONATION & TRANSPLANTATION, <https://organdonor.gov/about-dot/laws.html> (last visited Jan. 14, 2018) (“The field of organ donation and transplantation is one of the most regulated areas of health care today.”).

83. See generally *HOPE Act*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, <https://optn.transplant.hrsa.gov/learn/professional-education/hope-act/> (last visited Jan. 11, 2018) (listing the current HOPE Act participating transplant hospitals); see also *HOPE Act Gives Hope to Potential Transplant Patients Living with HIV*, LIFELINK (Sept. 30, 2016), [www.lifelinkfoundation.org/hope-act-gives-hope-patients-living-hiv-waiting-list-organ-](http://www.lifelinkfoundation.org/hope-act-gives-hope-patients-living-hiv-waiting-list-organ-)

lowed the guidelines of NOTA and the HOPE Act and have since expanded them.<sup>84</sup>

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

In 1984, Congress passed NOTA “[t]o address the nation’s critical organ donation shortage and improve the organ matching and placement process.”<sup>85</sup> “The Act requires a private, non-profit organization to operate the network under a federal contract.”<sup>86</sup> The purpose of NOTA is to establish the “Task Force on Organ Transplantation” (“Task Force”) and the “Organ Procurement and Transplantation Network” (OPTN).<sup>87</sup>

The Task Force is responsible for “conduct[ing] comprehensive examinations of the medical, legal, ethical, economic, and social issues presented by human organ procurement and transplantation.”<sup>88</sup> This means it has the ability to control how medical innovators experiment with organ transplantation. The Task Force must generate a report to identify the specific factors that will decrease the number of available organs for transplantation.<sup>89</sup> Congress has delegated the responsibility of defining which organs may be considered as viable for transplant to the Task Force in accordance with statutory language.<sup>90</sup> The Task Force is permitted to make recommenda-

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transplant/ (“The HOPE Act changed federal regulation, recognizing it makes sense—given the very limited number of transplantable organs available for more than 120,000 people who need one – to look at all ways to save as many lives as possible.”).

84. See *infra* Section III.C.

85. *History & NOTA*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, <https://optn.transplant.hrsa.gov/governance/about-the-optn/history-nota/> (last visited Nov. 14, 2017) [hereinafter *History & NOTA*].

86. *Id.*

87. National Organ Transplant Act, Pub. L. No. 98-507, 98 Stat. 2339 (1984).

88. § 101(b)(1)(A).

89. § 101(b)(3).

90. See *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 837 (1984) (noting that the *Chevron* deference test, a principle of administrative law, requires that courts defer to statutory interpretations made by government agencies unless the interpretation is unreasonable). If the statute is ambiguous, deference will be given to the reasonable interpretation of the agency. *Id.*



tions for the continued training and education of health care professionals with respect to organ procurement.<sup>91</sup> Under the language of NOTA, organ procurement organizations (OPOs) are to “conduct and participate in systematic efforts, including professional education, to acquire all useable organs from potential donors.”<sup>92</sup> The standards adopted by the OPTN include “arranging for testing with respect to identifying organs that are infected with . . . (HIV).”<sup>93</sup> Presumably, the reason Congress identified HIV as a precluding factor for organ transplantation was to protect patients from the impacts of an HIV-positive diagnosis.

In 1990, NOTA was amended to include that the “[OPTN] shall . . . adopt and use standards of quality for the acquisition and transportation of donated organs, including standards for preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome (“AIDS”).”<sup>94</sup> This statutory change was another attempt by Congress to protect the public from possible HIV-infection by prohibiting the use of HIV-positive organs in organ donation.

#### B. *HIV Organ Policy Equity Act: The HOPE Act*

Congress passed the HOPE Act “in response to the growing shortage of donor organs and new scientific research on HIV-positive-to-HIV-positive transplantation.”<sup>95</sup> “The HOPE Act [aims to] eliminate the restriction on acquiring HIV-positive organs in order to permit research on transplants between HIV-positive individuals. The legislation [aims to] increase the number of available organs and will help all of those who are awaiting a transplant.”<sup>96</sup> Offering HIV-positive organs to HIV-positive waiting list patients will shorten the organ transplant

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91. National Organ Transplant Act, Pub. L. No. 98-507, §101(b)(3)(C), 98 Stat. 2339.

92. § 371(b)(2)(B), 98 Stat. at 2343.

93. 159 CONG. REC. H6967, 6967 (daily ed. Nov. 12, 2013) (statement of Chairman Upton).

94. H.R. REP. No. 106-429, pt. H, at 30 (1999).

95. White, *supra* note 71, at 616.

96. 159 CONG. REC. H6967, 6968.

waiting list, as HIV-positive patients are able to move forward on the list to receive organs from HIV-positive donors. The HOPE Act took an enormous step in the right direction by creating the possibility of HIV-positive patients receiving HIV-positive organs. The HOPE Act requires organ transplant facilities offering HIV-positive organs to comply with the standards set forth in the Act.<sup>97</sup> It also calls for organ procurement organizations to develop standards for testing organs “with respect to identifying organs that are infected with . . . HIV.”<sup>98</sup> It specified that, within two years of the HOPE Act’s enactment, the Secretary of HHS (the “Secretary”) “shall develop and publish criteria for the conduct of research relating to transplantation of organs from donors infected with [HIV] . . . into individuals who are infected with HIV before receiving such organs.”<sup>99</sup> After the two-year review of the research, OPTN is to “revise the standards of quality” of organ donation.<sup>100</sup> By 2017, the Secretary is to review the scientific research with OPTN in order “to determine whether the results warrant revision of the standards of quality . . . with respect to donated organs infected with HIV and with respect to the safety of transplanting [these] organs.”<sup>101</sup> Three years after the

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97. *Id.*

98. *Id.* at 6967

99. *Id.* at 6968.

100. *Id.*; see *Organ Procurement and Transplantation Network*, U.S. DEP’T HEALTH & HUM. SERVS., <https://optn.transplant.hrsa.gov/governance/about-the-optn/> (last visited Jan. 31, 2018) (stating “[t]he [OPTN] is a unique public-private partnership that links all professionals involved in the U.S. donation and transplantation system,” including “individuals who sign organ donor cards, people who comment on policy proposals and countless volunteers who support donation and transplantation, among many others”); see also JAMES B. ALCORN, UNITES NETWORK FOR ORGAN SHARING, IMPORTANT POLICY NOTICE: ADDRESSING REQUIREMENTS IN THE HIV ORGAN POLICY EQUITY ACT (2015), [https://www.transplantpro.org/wp-content/uploads/sites/3/Policy\\_Notice\\_07-2015.pdf?a3c8d8](https://www.transplantpro.org/wp-content/uploads/sites/3/Policy_Notice_07-2015.pdf?a3c8d8); White, *supra* note 71, at 617 (stating “[i]n June 2015, OPTN’s Board of Directors approved policy amendments intended to conform existing OPTN policies to the requirements of the HOPE Act”) *Organ Procurement & Transplantation Network*, H. RESEARCH & SERV. ADMIN. (Mar. 1, 2016), [https://optn.transplant.hrsa.gov/media/1200/optn\\_policies.pdf](https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf) [hereinafter OPTN Policies] (noting that OPTN members are required to verify that both the donor and potential recipient are HIV-positive and must affirmatively determine that the organ recipient consents to accepting an HIV-positive organ in approval with [IRB] approved research protocol).

101. 159 CONG. REC. H6967, 6968 (daily ed. Nov. 12, 2013) (statement of Chairman Upton)

HOPE Act was passed, and with the approval from the United Network for Organ Sharing (UNOS), “a multidisciplinary team from Johns Hopkins Medicine . . . performed the world’s first-ever HIV-to-HIV liver transplant.”<sup>102</sup>

The HOPE Act broke down a barrier impeding researchers’ ability to experiment on the use of HIV-positive organs. The next step is to advocate that, in 2018, the Secretary review the research accumulated during the four years of allotted time under the HOPE Act, and take legislative steps to allow for medical experimentation of HIV-positive organs into HIV-negative patients.

### C. *California Emergency Organ Transplant of HIV-Positive Organs*

In addition to federal regulation changes, states began enacting legislative changes in an attempt to revamp the organ donation climate and provide greater access to organs for more patients on the donation waiting list. The changes, however, have focused exclusively on the HIV-positive donor recipient pool. California—where it was once considered a felony for an individual aware that he or she was HIV-positive to donate blood or other tissues—is paving the way for change.<sup>103</sup> California’s previous ban excluded voluntary or living donors from donating organs. The ban was another example of legislation that was promoted because HIV infection was considered a life-ending disease that physicians knew little about and was in response to the fact that the virus had been transmitted in a number of patients through organ transplants.<sup>104</sup>

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(focusing research on transplanting organs that are HIV-positive into patients who have a different strain of HIV).

102. *Media Briefing to Announce First-Ever Liver Transplant from HIV-Positive Donor*, JOHNS HOPKINS MED. (Mar. 20, 2016), [https://www.hopkinsmedicine.org/news/media/releases/media\\_briefing\\_to\\_announce\\_first\\_ever\\_liver\\_transplant\\_from\\_hiv\\_positive\\_donor](https://www.hopkinsmedicine.org/news/media/releases/media_briefing_to_announce_first_ever_liver_transplant_from_hiv_positive_donor).

103. CAL. HEALTH & SAFETY CODE § 1621.5 (West 2016), *repealed by* Cal. Legis. Serv., ch. 537, (S.B. 239) (West 2017).

104. D. Johnson, *Organ Transplants in HIV-Positive Patients Now Legal in California*, SCIENCE WORLD REPORT (May 31, 2016), <http://www.scienceworldreport.com/articles/40888/20160531/organ-transplant-in-hiv-positive-patients-now-legal-in-california.htm>.

The debate was recently sparked among California legislators when an HIV-positive patient in need of an emergency liver transplant was barred from the procedure even though there was a voluntary HIV-positive donor available.<sup>105</sup> The matter was imminent and medically necessary as failure to perform transplantation as soon as possible would jeopardize the patient's ability to have the surgical procedure.<sup>106</sup> The patient's husband, who was also HIV-positive, had volunteered to be a living donor for his spouse and was a biological match.<sup>107</sup> The patient was unable to have this life-saving procedure, however, because the Code's language banned the donation of "HIV-infected organs, blood and semen."<sup>108</sup>

Senate Bill 1408 eliminated the California Code language preventing the donation of potentially HIV-positive blood or other tissue by willing donors who are aware of their HIV-positive status.<sup>109</sup> The Bill was proposed as an urgency statute.<sup>110</sup> On May 27, 2016, California Governor Jerry Brown signed the Bill that protects HIV-positive living donor patients from facing felony charges for knowingly donating organs or other biological tissue.<sup>111</sup> Because of the new law, "[t]he University of California San Francisco Medical Center is [now] one of four U.S. hospitals authorized to transplant HIV-infected organs."<sup>112</sup>

In the wake of California's progressive stance on HIV-

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105. Jonathan J. Cooper, *California Rushes to Allow HIV-Infected Organ Transplants*, U.S.NEWS.COM (May 27, 2016 6:15 P.M.) <http://health.usnews.com/health-news/news/articles/2016-05-27/california-rushes-to-allow-hiv-infected-organ-transplant>.

106. *Id.*

107. *Id.*

108. *California Rushes to Allow HIV-Positive Organ Transplant – To Save the Life of a Man in Desperate Need of a Liver*, DAILYMAIL.COM (May 27, 2016 01:09 EST), <http://www.dailymail.co.uk/health/article-3613139/California-rushes-allow-HIV-infected-organ-transplant.html>.

109. S.B. 1408 (Cal. 2016).

110. *Id.*

111. Johnson, *supra* note 104 (stating the Bill "protects [and] ensures the protection of surgeons who transplant organs from HIV-positive donors to HIV-positive patients from being punished by the state's medical board").

112. Cooper, *supra* note 105.

positive organs, other states may also introduce legislation that will make research on HIV-positive organ use more available to a limited number of patients. The Delaware Senate, for example, has recently approved a bill that would “allow . . . people who are HIV-positive to donate organs for research or transplantation.”<sup>113</sup> The legislation, which was unanimously approved without debate, will now proceed to the House.<sup>114</sup> “The Bill provides for research or transplantation of organs and other anatomical gifts as authorized under federal law among donors who have tested positive for exposure to HIV and intended recipients who also have tested positive for exposure to HIV.”<sup>115</sup> Until recently, Delaware was “the only state with laws entirely prohibiting the use of HIV-positive organs for HIV-positive recipients, including the use of organs as part of a research protocol.”<sup>116</sup> While these types of state legislation aim to lift bans on the use of HIV-positive organs, they fall short by not granting access to include patients who are HIV-negative. Legislation that affirmatively lifts bans on HIV-positive organ use and simultaneously includes organ access for HIV-negative patients is needed to improve the organ shortage problem.

#### IV. ANALYSIS: SHOULD ORGANS FROM HIV-INFECTED DONORS BE TRANSPLANTED TO UNINFECTED PATIENTS?

##### A. *Argument for a Lift on Prohibitory Statutory Language on the Use of HIV-Positive Research with HIV-Negative Patients*

It should not be illegal to transplant an HIV-infected organ to an uninfected recipient. Rather, if an HIV-positive organ becomes available for donation, the patient “first on the list”

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113. Randall Chase, *Bill Allows Research, Transplants with HIV-Positive Organs*, WASH. TIMES (Jan. 26, 2017), [https://www.washingtontimes.com/national/bill-allows-research-transplants-with-hiv-positive-organs/2017/01/26/b53f67f6-e417-11e6-a419-eefe8eff0835\\_story.html?utm\\_term=.c604990976b7](https://www.washingtontimes.com/national/bill-allows-research-transplants-with-hiv-positive-organs/2017/01/26/b53f67f6-e417-11e6-a419-eefe8eff0835_story.html?utm_term=.c604990976b7).

114. *Id.*

115. *Id.*

116. *Id.*

awaiting the donation should be able to accept the organ.<sup>117</sup> Statutory language should not prevent this form of medical experimentation and innovation from occurring. As long as the treatment is consistent with the standards of medical experimentation and the patient has given informed consent, physicians should be permitted to test this new approach.

Should the legislation allow for the transplantation of HIV-positive organs to HIV-negative patients, the role of the physician will remain one of the most crucial aspects.<sup>118</sup> The actual risks of HIV-positive organ donation are relatively unknown.<sup>119</sup> Transplanting organs from stable, virally suppressed HIV-infected donors into stable, virally suppressed HIV-infected recipients, however, is likely safe based on what is known about disease transmission risk in other settings.<sup>120</sup> In addition, the potential risks of the procedure must be weighed against the risk of the patient dying while waiting for an uninfected organ.<sup>121</sup>

If statutory bans are lifted, HIV-positive organ donation to HIV-negative recipients should only be considered as a last-resort medical option for the purpose of this medical experimentation and innovation proposal. "HIV-positive to HIV-negative transplantation would be appropriate only in rare cases where the risks of transmitting HIV infection are clearly outweighed by the risks of continuing to wait for a transplant and with the recipient's informed consent."<sup>122</sup> An example of

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117. This Note does not argue that patients should be forced to take the organ from the HIV-positive donor, or forfeit their placement on the list. Rather, this Note asserts that the patient awaiting the donation should at least have the option of accepting the organ from the HIV-positive donor. Should the patient deny the organ, the patient would maintain his or her placement at the top of the list for the next optimal (HIV-negative) organ to become available.

118. The physician communicates the risks of the procedure and the prognosis to the patient. As such, the physician is the first line of defense against possible medical malpractice suits involving non-consenting patients.

119. *See infra* Section III.C.

120. Shen & Siliciano, *supra* note 8, at 27 (noting that a particular concern could be a "risk of super infection").

121. O. Mgbako et al., *Allowing HIV-Positive Organ Donation: Ethical, Legal, and Operational Considerations*, 2013 AM. J. TRANSPLANT. 1636, 1638 (2013).

122. *Id.*

such a scenario would be when “a recipient’s medical urgency for transplant is so severe that the risks of waiting include imminent death.”<sup>123</sup> “[T]ransplantation using HIV-positive organs should first take place using organs from donors with well controlled HIV and no history of opportunistic infections.”<sup>124</sup> In an effort to avoid organ death while awaiting transplantation, “[p]atients should be prospectively consented for HIV+ organ transplant eligibility . . . (similar to existing practice for transplantation with HCV-positive organs).”<sup>125</sup>

The organ donation waiting list will predictably increase as the population continues to age, medical innovations advance, and life expectancies rise. This will potentially result in an even greater organ shortage, especially if statutory language continues to force suboptimal organs to be discarded and fails to consider lifting the barriers on the medical experimentation of organ transplantation from HIV-positive donors.<sup>126</sup> The organ donation pool “consists of organs from donors who die of causes unrelated to their HIV infection, but also of organs currently being discarded due to false positive serologic testing for HIV in the donor.”<sup>127</sup> It is “estimated that 534 potential HIV+ deceased organ donors would be available per year using [National Inpatient Sample (NIS)] data and 494 donors using [HIV Research Network (HIVRN)] data.”<sup>128</sup> It is also “estimated that approximately 20 potential deceased donors per year are determined to have HIV infection that was not anticipated until medical screening for donation was undertak-

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123. *Id.*

124. *Id.* (noting that of significant importance is “the first HIV-positive donors accepted would have had stable and well-characterized HIV infection for a substantial period . . . so that transplant teams could obtain important information on the donor virus, such as historical genotype patterns and current viral load”).

125. *Id.* at 1639.

126. *Id.* at 1637.

127. *Id.*

128. *Id.*; see Brian J. Boyarsky et al., *Estimating the Potential Pool of HIV-Infected Deceased Organ Donors in the United States*, 2011 AM. J. TRANSPLANT. 1209, 1209–17 (2011) (quantifying the number of potentially eligible HIV-positive donors using three sources: the Nationwide Inpatient Sample (NIS), the HIV Research Network (HIVRN), and UNOS).

en.”<sup>129</sup>

Not only would legalizing HIV-positive organ donation partially alleviate the organ shortage, but “allowing transplantation of organs from HIV+ donors might reduce the discard of organs due to false positive results from viral antibody and nucleic acid testing.”<sup>130</sup> Indeed, “[a]lthough limited data quantify the number of lost organs due to unconfirmed testing for HIV, it is plausible that some centers would be willing to accept high quality organs with possible HIV infection particularly for their HIV+ candidates.”<sup>131</sup>

*B. Modern Use of Suboptimal Organs: An Analysis of Hepatitis C Organ Donors into HCV Negative Recipients in the United States*

The harm and treatment potential “of an anticipated transmission with HIV+ to HIV-negative transplant are in some ways analogous to existing circumstances involving recipients of organs from donors who have known HCV infections or other serious infections.”<sup>132</sup> Unlike HIV-positive organs, which are federally proscribed from being included in the organ donor pool, HCV-positive organs have not faced the same legislative restrictions.<sup>133</sup> HCV is a long term and chronic infection that can destroy an individual’s liver if left untreated for “over two or three decades.”<sup>134</sup> “At least 2.7 million people in the U.S. have chronic hepatitis.”<sup>135</sup> “Until recently, HCV was only treatable by medications that had severe side effects and poor cure rates.”<sup>136</sup> Modern medicine, however, has generated breakthrough drugs that “promise to cure 95 percent of HCV

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129. Mgbako et al., *supra* note 121, at 1637.

130. *Id.*

131. *Id.*

132. *Id.* at 1638.

133. *Id.* at 1639.

134. Associated Press, *Bid to Speed Transplants with HCV-Infected Kidneys*, PBS, (Oct. 27, 2016) <https://www.pbs.org/newshour/health/bid-speed-transplants-hepatitis-c-infected-kidneys> [hereinafter *Speed Transplants*].

135. *Id.*

136. *Id.*



cases with fewer side effects.”<sup>137</sup> Previously, HCV antibody positive donor organs were only available to HCV-positive recipients.<sup>138</sup> This meant that patients who were HCV-negative would not be considered candidates for organs from HCV-positive donors, and if a HCV recipient was not on the HCV donor list the organ would be discarded.<sup>139</sup> As a solution to the vast number of patients on organ donation waiting lists and advancements in modern medicine, physicians at the University of Pennsylvania have utilized clinical research programs to explore the possibility of using organs from HCV-positive donors in HCV-negative recipients.<sup>140</sup> The research showed that if the patient tests positive for HCV after the transplantation, the patient can be treated for and possibly cured of the HCV.<sup>141</sup>

In July 2016, the first HCV-negative study participant received a HCV-positive organ from a positively diagnosed donor.<sup>142</sup> The patient has subsequently been treated for HCV and “there is no evidence of the virus in her blood.”<sup>143</sup> The research concluded that “if the new approach works, for patients who do not have HCV, there is the potential to provide a chance at a lifesaving kidney transplant for hundreds more patients each year.”<sup>144</sup> The clinical trial, referred to as THINKER (Zepatier For Treatment Of HCV-Negative Patients Who Receive Kidney Transplants From HCV-Positive Donors) and is led by Assistant Professors of Medicine and Epidemiology David S. Goldberg and Peter Reese.<sup>145</sup> THINKER “aims to determine the

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137. *Id.*

138. *Hepatitis C Antibody Positive Donors*, UC DAVIS HEALTH, [http://www.ucdmc.ucdavis.edu/transplant/nonlivingdonors/nonliving\\_hepc\\_donors.html](http://www.ucdmc.ucdavis.edu/transplant/nonlivingdonors/nonliving_hepc_donors.html) (last visited Mar. 18, 2018).

139. Abbey Hunton, *Expanding Access: First Clinical Trial Transplants HCV-infected Kidneys as Penn Medicine*, PENN MED. NEWS (Sep. 13, 2016), <https://www.pennmedicine.org/news/news-releases/2016/september/expanding-access-first-clinica>.

140. *Id.*

141. *Id.*

142. *Id.*

143. *Id.*

144. *Id.*

145. *Id.*

safety and efficacy of transplanting kidneys from [HCV] positive donors into patients currently on the kidney transplant waitlist who do not have the [HCV].”<sup>146</sup> According to Reese, “If we can demonstrate that it’s possible to eradicate HCV from patients who contract the virus from a transplant, this approach could open up access to an entirely new pool of donor organs that are currently being discarded.”<sup>147</sup>

The informed consent component of the clinical trial is described by the researchers as extensive, and includes information on how HCV transmission is possible and may not be cured post-transplant.<sup>148</sup> According to the University of California Davis Transplant Center, “Patients who receive organs from a [HCV] positive donor have a superior survival when compared to remaining on dialysis[,] . . . [and] research suggests that transplantation of [HCV] positive kidneys into [HCV] positive recipients does not affect patient or transplant survival up to ten years after transplant.”<sup>149</sup>

The pilot studies are currently active at both the University of Pennsylvania and Johns Hopkins University as researchers continue “to test transplanting kidneys from deceased donors with [HCV] into recipients who don’t already have [the] virus.”<sup>150</sup> If the studies are successful, hundreds “more kidneys—and maybe some hearts and lungs . . . could be transplanted each year.”<sup>151</sup> Using this study as a model for HIV-positive organs, lifting the statutory prohibition of HIV-positive organ donation to HIV-negative patients could achieve beneficial clinical results with the goal of treating the possible HIV-infection post-transplant.

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146. *Id.*

147. *Id.*

148. *Id.*

149. *Hepatitis C Antibody Positive Donors*, *supra* note 138.

150. *Speed Transplants*, *supra* note 134.

151. *Id.*

C. *Ethical and Legal Considerations for the Approval of HIV Positive Organs for Organ Donation in HIV-Negative Patients*

A proposal for lifting the statutory prohibitions against using HIV-positive organs requires the analysis of several ethical considerations: (1) whether the patient is able to offer informed consent while under duress; (2) whether an HIV super infection will likely result; and (3) if so, whether physicians performing the transplants would be violating the Hippocratic Oath and the potential legal consequences.

The first ethical consideration asks whether informed consent can possibly be obtained from an HIV-negative patient on an organ waiting list who is offered a potentially HIV-positive organ. The doctrine of informed consent is a legal standard recognized in health law to assess the understanding of a participating patient.<sup>152</sup> To assess this ethical concern, therefore, it is important to consider the perspective of an HIV-negative patient in the United States on an organ waiting list.

In general, patients on organ waiting lists have a shortened life expectancy.<sup>153</sup> Therefore, being offered any organ may be considered favorably by the patient, as potentially the last attempt at prolonging the patient's life. This is not an easy decision to make, and the patient may end up deciding to receive the organ under duress or fear of death. Gaining true informed consent from vulnerable patient pools may prove to be difficult and could be subject to a strict level of both medical and ethical scrutiny.

An additional component to the informed consent consideration is whether a patient is able to make a rational and coherent decision about the receipt of a suboptimal organ. A patient may feel pressure to consent to the transplant based on the worry that another organ may not become available prior to

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152. See *supra* Section II.C.

153. See *The Kidney Transplant Waiting List*, LIVINGKIDNEY DONORS NETWORK, [www.lkdn.org/kidney\\_tx\\_waiting\\_list.html](http://www.lkdn.org/kidney_tx_waiting_list.html) (last visited Jan. 16, 2018) ("The longer a person is on dialysis and has to wait for a transplant, the short and long term success rates are negatively affected. On average, receiving a kidney transplant can double someone's life expectancy.").

death. The patient may also suffer from anxiety and depression at the prospect of accepting an organ from an HIV-positive donor. "Patients who require transplantation face serious illness, stressful medical evaluations, and a severe curtailing of their usual lives."<sup>154</sup> This makes it especially vital for a patient awaiting an organ transplant and considering an HIV-positive donor organ to receive psychiatric evaluation and care.<sup>155</sup> Mental health professionals can "assist . . . with the selection process and managing psychiatric disorders that predate the transplant, as well as those that may develop thereafter."<sup>156</sup> Carefully evaluating patients pre-transplant is crucial to successful organ transplantations. "The psychosocial portion of the evaluation serves to ensure that patients are prepared to be successful stewards of their new organs."<sup>157</sup> "Although many patients adapt to the limitations that their illnesses create, [the organ failure and the ensuing chronic disease state] remains a major challenge and source of stress for the majority of transplant patients."<sup>158</sup>

The second major ethical concern is the potential transmission of new and/or possibly resistant strains of HIV from the donor to the recipient.<sup>159</sup> "Infecting [a patient] with a new strain of HIV could lead to uncontrolled viral replication, immune deregulation, and opportunistic infections."<sup>160</sup> Additionally, organ "[r]ejection rates . . . have been reported to be approximately 3 times as high as those among HIV-negative organ recipients."<sup>161</sup> There are two hypotheses for this out-

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154. Thomas W. Heinrich & Michael Marcangelo, *Psychiatric Issues in Solid Organ Transplantation*, 17 HARV. REV. PSYCHIATRY 398, 398 (2009).

155. *Id.* at 399-400.

156. *Id.* at 398.

157. *Id.*

158. *Id.* at 399.

159. This is especially the case when transmitting HIV-positive organs into HIV-positive recipients. Since medical communities have not yet experimented with HIV-positive organs being transplanted into HIV-negative recipients, it is difficult to predict how, if at all, the virus will evolve or react to medical treatment.

160. Mgbako, et al., *supra* note 121.

161. Elmi Muller et al., *HIV-Positive-to-HIV-Positive Kidney Transplantation – Results at 3 to 5 Years*, 372(7) NEW ENG. J. MED. 613, 620 (2015).

come: “The first is immune dysregulation, and the second is the challenge of managing the drug interactions between the antiretroviral agents and immunosuppressants.”<sup>162</sup> Creating new HIV positive diagnoses through medical treatment could “run counter to extensive public health efforts to minimize HIV transmission and could also put intimate partners of an organ recipient at risk.”<sup>163</sup> Additionally “the medical workup of organ donors is time-limited.”<sup>164</sup> For example, transplant and OPO teams will not necessarily have time to ascertain HIV genotype or other relevant features of HIV infection (such as history of opportunistic infections) for many donors.<sup>165</sup> Bioethical and medical considerations are therefore dichotomous and need to be carefully considered in this type of research.

The third ethical consideration involves the Hippocratic Oath of doing no harm, and the principles of medical experimentations, which require physicians to work closely with legal teams to navigate potential lawsuits that could arise with recipients’ family members. “Infecting an HIV-negative organ recipient also puts the recipient’s intimate partner(s) at risk.”<sup>166</sup> By knowingly infecting these patients, “physicians could be liable for more than mere negligence, perhaps even involuntary manslaughter.”<sup>167</sup>

Physicians have some leeway with regards to treatment of their patients. With the expanding scientific and medical possibilities, many once-impossible procedures are now available, with some level of risk. So long as the notions of complete patient autonomy are upheld, inherently dangerous procedures,

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162. *Id.* (citing S. Iordanskiy et al., *Nature, Nurture and HIV: The Effect of Producer Cell on Viral Physiology*, 443 *VIROLOGY J.* 208, 208-13 (2013)).

163. Mgbako et al., *supra* note 121, at 1638.

164. *Id.*

165. *Id.*

166. White, *supra* note 71, at 652.

167. *Id.* (noting that it has been hypothesized that physicians could potentially face battery charges for knowingly infecting their patients with HIV, even with consent and contracts to treat). The legal ramifications of this kind of medical innovation require medical research teams to work closely with legal departments to ensure total compliance with regulatory, ethical, and clinical practices. *Id.*

such as bilateral lung and heart transplants are now possibilities for patients with grim prognoses.<sup>168</sup> “One of the main concerns with infecting HIV-negative patients through the use of HIV-positive organs is non-maleficence.”<sup>169</sup> The customary Hippocratic Oath language to “do no harm”<sup>170</sup> may give some physicians pause when considering the possibility of infecting an HIV-negative patient with HIV via organ donation. The idea of intentionally infecting patients with a virus may bring about memories of the unethical Tuskegee experiments.<sup>171</sup>

The counterargument to this ethical and legal concern is that the experimental use of HCV-positive organs into HCV-negative recipients is already being conducted.<sup>172</sup> The purpose of the experimentation would not be to infect the patient with HIV, but rather to save the patient from organ failure and treat the HIV post transplant using the most current medical treatment available. Fortunately, “the efficacy of current antiretroviral treatments could minimize potential harms resulting from HIV infection.”<sup>173</sup> This may give the patient a longer or more favorable prognosis than waiting for an organ on the ever-expanding transplant list. The principle of utility requires that these harms be balanced against the benefits of receiving an HIV-positive organ.<sup>174</sup> For many patients, “accepting an HIV-positive organ could mean the difference between life and death.”<sup>175</sup>

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168. See generally Clemens Aigner & Walter Klepetko, *Bilateral Lung Transplantation*, 17 J. THORACIC CARDIOVASCULAR SURGERY 181 (2012) (stating that bilateral procedures are the most common type of lung transplant today); Michael C. Fishbein & Jay W. Marks, *Heart Transplant*, MEDICINENET.COM, [https://www.medicinenet.com/heart\\_transplant/article.htm](https://www.medicinenet.com/heart_transplant/article.htm) (last visited Mar. 12, 2018) (explaining that heart transplants are reserved for the most critical cases).

169. White, *supra* note 71, at 652.

170. *Bioethics Oaths and Codes*, JOHNS HOPKINS SHERIDAN & LIBR. (Nov. 20, 2017 11:29 AM), <http://guides.library.jhu.edu/c.php?g=202502&p=1335752>.

171. FURROW, *supra* note 33, at 1750-51.

172. Hunton, *supra* note 139.

173. White, *supra* note 71, at 652-53.

174. *Id.* at 652.

175. *Id.*

## CONCLUSION

The HHS and CMS should amend the language in NOTA to include the use of suboptimal organ donation including organs that come from donors who are HIV-positive to patients who are HIV-negative. Given the need for organs suitable for transplant, coupled with medical advances and treatment options for HIV, statutory language should not proscribe medical experimentation and innovation in this field. Ethical considerations should be reviewed and updated as studies progress. While clinical experiments might demonstrate that HIV-positive organ donation is not a suitable treatment option, it would behoove the medical society to research this possibility more thoroughly. The law does not proscribe other fields of medical research to the extent it does in fields surrounding HIV. A clinical trial to use as an example of this research is the University of Pennsylvania's use of HCV-positive organs in HCV-negative patients. HIV has played a unique role in recent American history stemming from the uncertainty that it produced in the 1980s, when relevant legislation was written. By lifting these bans, medical research can be conducted, and many lives may be saved.

LIST OF ABBREVIATIONS

Acquired Immune Deficiency Syndrome	AIDS
Anti-Retroviral Regimens	ARVs
Centers for Medicare and Medicaid	CMS
Centers for Disease Control	CDC
Department of Health and Human Services	HHS
Hepatitis C Virus	HCV
Human Immunodeficiency Virus	HIV
HIV Organ Policy Equity Act	the HOPE Act
HIV Research Network	HIVRN
Institutional Review Board	IRB
National Inpatient Sample	NIS
National Institutes of Health	NIH
National Organ Transplant Act	NOTA
Organ Procurement and Transplantation Network	OPTN
Organ Procurement Organization	OPO
Sustained Virologic Response	SVR
THINKER	(“Zepatier For Treatment of HCV-Negative Patients Who Receive Kidney Transplants from HCV-Positive Donors”)
United Network for Organ Sharing	UNOS