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**A REASON FOR HOPE? A LEGAL AND ETHICAL  
IMPLEMENTATION OF THE HIV ORGAN POLICY  
EQUITY ACT**

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*“At the beginning of the fourth decade of the HIV epidemic, profound stigma and discrimination is a fact of life for those with the disease— not just socially, but within our legal system.”<sup>1</sup>*

INTRODUCTION

Since the identification of human immunodeficiency virus (“HIV”) in the early 1980s, monumental advances in treatment, including the development

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<sup>1</sup> Sean Strub, *Think Having HIV is Not a Crime? Think Again*, HUFFINGTON POST (Oct. 29, 2012, 1:26 PM), [http://www.huffingtonpost.com/sean-strub/lgbt-hiv-criminalization\\_b\\_2039539.html](http://www.huffingtonpost.com/sean-strub/lgbt-hiv-criminalization_b_2039539.html) [<https://perma.cc/M5D8-U5EH>].

and improvement of antiretroviral therapies, have substantially increased the lifespans of individuals with HIV. As a result, many HIV-positive individuals are developing additional medical conditions that require organ transplants.<sup>2</sup> Although scientific breakthroughs have also led to more organ transplants being performed today than ever before, the growing demand for organs has far outpaced their supply. Due to their unique comorbidities, the effects of this national organ shortage are particularly acute for HIV-positive patients.

In November 2013, Congress enacted the HIV Organ Policy Equity (“HOPE”) Act.<sup>3</sup> The HOPE Act directs the Secretary of the Department of Health and Human Services (“HHS”) and the Organ Procurement and Transplantation Network (“OPTN”) to establish standards for research and transplantation of HIV-positive organs.<sup>4</sup> The HOPE Act has the potential to increase the organ supply for HIV-positive patients and, by reducing the number of HIV-positive patients in need of an HIV-negative organ, to increase the availability of organs for HIV-negative patients as well. The history of discrimination against HIV-positive individuals and the subpopulations most severely affected by the disease requires policymakers to take special precautions to prevent discrimination and unethical treatment of HIV-positive individuals in a transplantation context.

Currently, transplant physicians can list HIV-positive patients on OPTN’s organ registries alongside HIV-negative patients and they can receive HIV-negative organs.<sup>5</sup> Under the HOPE Act, however, only HIV-positive patients will be eligible to receive HIV-positive organs.<sup>6</sup> A question thus arises: Should HIV-positive patients be eligible to receive HIV-positive organs only, or both HIV-positive and HIV-negative organs? The answer to this question will have critical implications for HIV-positive organ recipients.

This Note will argue that HIV-positive patients should be allowed to receive organs from both HIV-positive and HIV-negative donors. Without this provision, the HOPE Act could make it more difficult for HIV-positive patients to receive organ transplants. Part I of this Note provides a brief history of organ transplantation in the United States, reviews current organ allocation policies, and discusses the HOPE Act and its implementation. Part II examines the unique characteristics of the HIV-positive community that make it a

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<sup>2</sup> In fact, “organ failure has replaced opportunistic infections (OI) as the major cause of morbidity and mortality” among the HIV-positive population. D. Sawinski et al., *Factors Associated with Failure to List HIV-Positive Kidney Transplant Candidates*, 9 AM. J. TRANSPLANTATION 1467, 1467 (2009); see also *infra* notes 34-35.

<sup>3</sup> HIV Organ Policy Equity Act, Pub. L. No. 113-51, 127 Stat. 579 (2013) (codified in scattered sections of 18 and 42 U.S.C.).

<sup>4</sup> *Id.*

<sup>5</sup> ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, POLICIES § 15.2 (Mar. 1, 2016), [https://optn.transplant.hrsa.gov/media/1200/optn\\_policies.pdf](https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf) [https://perma.cc/65QZ-37DB] [hereinafter OPTN POLICIES].

<sup>6</sup> 42 U.S.C. § 274(b)(3)(A) (Supp. I 2013).

vulnerable population in need of heightened protection, and elucidates issues of discrimination in the organ transplantation process. Part III presents the legal and ethical doctrines that should frame the implementation of the HOPE Act: autonomy, utility, and justice. Part IV then applies the legal and ethical framework discussed in Part III to the unique issues presented by HIV-positive organ transplantation. After evaluating the arguments for and against allowing HIV-positive patients to receive HIV-positive and HIV-negative organs, Part IV offers a conclusion and raises the question of when, if ever, HIV-negative patients should be able to receive HIV-positive organs.

## I. BACKGROUND

### A. *Organ Transplantation in the United States*

Doctors performed the first kidney transplant in 1954.<sup>7</sup> By 1968, doctors had successfully performed liver, pancreas, and heart transplants.<sup>8</sup> Today, approximately 122,700 patients are waiting for organ transplants,<sup>9</sup> and in 2014, 6,446 patients died while waiting for a transplant.<sup>10</sup> Every day, an average of twenty-two patients die awaiting a transplant.<sup>11</sup>

Prior to 1984, no national system existed to organize the collection and distribution of organs from deceased donors. Among hospitals, this lack of centralization led to unequal access to and competition for donor organs.<sup>12</sup> In 1984, Congress responded by enacting the National Organ Transplant Act (“NOTA”).<sup>13</sup> NOTA established the Organ Procurement and Transplantation Network, a national system designed to facilitate the equitable procurement and allocation of donor organs.<sup>14</sup> OPTN’s primary directives are to increase the

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<sup>7</sup> *History*, UNITED NETWORK FOR ORGAN SHARING, <http://www.unos.org/donation/index.php?topic=history> [<http://perma.cc/MF9A-2VUX>].

<sup>8</sup> *Id.*

<sup>9</sup> ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, <http://optn.transplant.hrsa.gov> [<http://perma.cc/B28N-XX9G>] [hereinafter OPTN WEBSITE].

<sup>10</sup> *Death Removals by Region by Year*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, <http://optn.transplant.hrsa.gov/converge/LatestData/step2.asp> [<http://perma.cc/8LKD-A4DX>] (select report category “Waitlist Removals” and organ category “All” from the drop-down menus; select the “Candidate” count option; then follow the “Death Removals by Region by Year” hyperlink).

<sup>11</sup> OPTN WEBSITE, *supra* note 9.

<sup>12</sup> Gail L. Daubert, Comment, *Politics, Policies, and Problems with Organ Transplantation: Government Regulation Needed to Ration Organs Equitably*, 50 ADMIN. L. REV. 459, 462 (1998).

<sup>13</sup> National Organ Transplant Act, Pub. L. No. 98-507, 98 Stat. 2339, 2344-47 (1984) (codified as amended at 42 U.S.C. §§ 274-274e (2012)).

<sup>14</sup> Among other things, OPTN is responsible for creating and managing: (1) a national list of individuals who need organs, (2) a national system for matching organs and individuals in need of organs, (3) membership criteria for all transplant hospitals and organ

supply of donated organs and to establish standards for the acquisition and allocation of donated organs.<sup>15</sup> NOTA also specifies that OPTN should carry out studies to improve organ procurement and allocation procedures, including projects “to increase transplantation among populations with special needs, including . . . individuals who are members of racial or ethnic minority groups, and among populations with limited access to transportation.”<sup>16</sup> Finally, NOTA expressly prohibits the buying and selling of human organs.<sup>17</sup>

For efficiency reasons, NOTA requires that a private non-profit entity run OPTN.<sup>18</sup> In 1986, HHS awarded the OPTN contract to the United Network for Organ Sharing (“UNOS”).<sup>19</sup> All transplant centers and organ procurement organizations (“OPOs”) are members of OPTN.<sup>20</sup> Specifically, OPOs are non-profit entities that physically acquire and allocate donor organs in their service area.<sup>21</sup> To assist in the geographic distribution of organs, OPTN divides the United States into eleven geographic regions.<sup>22</sup> These regions are further divided into Donation Service Areas (“DSAs”), which are defined as the geographical area served by a single OPO.<sup>23</sup> Each OPO’s DSA varies widely in terms of population size, the number of transplant centers and candidates, and the death rates of suitable organ donors.<sup>24</sup>

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procurement organizations, (4) medical criteria for allocating organs, and (5) standards of quality for the acquisition of organs. 42 U.S.C. § 274(b)(2).

<sup>15</sup> *Id.*

<sup>16</sup> *Id.* § 274(b)(2)(N).

<sup>17</sup> *Id.* § 274e.

<sup>18</sup> *Id.* § 274(b)(1)(A); see Daubert, *supra* note 12, at 463.

<sup>19</sup> *Talking About Transplantation: What Every Patient Needs to Know*, UNITED NETWORK FOR ORGAN SHARING 47 (2013), <http://www.unos.org/docs/WEPNTK.pdf> [<http://perma.cc/76KS-H9E6>] [hereinafter *Talking About Transplantation*]. UNOS is still the sole contractor responsible for operating OPTN. *Id.*

<sup>20</sup> *Id.*; 42 C.F.R. § 121.3(b) (2015). As of February 15, 2016, 248 transplant centers and 58 OPOs were members of OPTN. *Members*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, <http://optn.transplant.hrsa.gov/converge/members/> [<https://perma.cc/93PZ-TF2B>].

<sup>21</sup> See 42 U.S.C. § 273(b)(3).

<sup>22</sup> *Regions*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, <http://optn.transplant.hrsa.gov/converge/members/regions.asp> [<http://perma.cc/GJ8K-GTEC>].

<sup>23</sup> OPTN POLICIES, *supra* note 5, § 1.2.

<sup>24</sup> OPTN/UNOS Liver & Intestinal Organ Transplantation Comm., *Redesigning Liver Distribution to Reduce Variation in Access to Liver Transplantation*, at i (2014) (unpublished concept paper), [http://optn.transplant.hrsa.gov/ContentDocuments/Liver\\_Concepts\\_2014.pdf](http://optn.transplant.hrsa.gov/ContentDocuments/Liver_Concepts_2014.pdf) [<http://perma.cc/D4CH-9W2V>]. OneLegacy, the OPO for Los Angeles, California, serves the largest population with 19,651,750 individuals located in its DSA. SCI. REGISTRY OF TRANSPLANT RECIPIENTS, ONELEGACY OPO-SPECIFIC REPORT 7 (2015), <http://www.srtr.org/csr/current/Centers/201506/pdf/CAOPOP1XX201506P.pdf> [<http://perma.cc/WT33-XGCR>]. Legacy of Life Hawaii, the OPO for all of Hawaii, serves

NOTA also directs OPTN to adopt and use quality standards for the acquisition of donated organs.<sup>25</sup> While OPTN's policies require OPOs to perform various tests on and acquire certain information about deceased donors, OPTN allows OPOs to set their own criteria for accepting deceased donor organs.<sup>26</sup> Additionally, OPTN does not provide any standardized criteria for placing transplant candidates on organ waitlists,<sup>27</sup> though the UNOS ethics committee specifies that health status and psychosocial factors are relevant in determining whether a patient is eligible for a waitlist.<sup>28</sup> Rather, OPTN's

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the smallest population with 1,404,054 individuals located in its DSA. SCI. REGISTRY OF TRANSPLANT RECIPIENTS, LEGACY OF LIFE HAWAII OPO-SPECIFIC REPORT 7 (2015), <http://www.srtr.org/csr/current/Centers/201512/pdf/HIOPOP1XX201512P.pdf> [<http://perma.cc/5PHV-PHDS>].

<sup>25</sup> 42 U.S.C. § 274(b)(2)(E) (Supp. I 2013).

<sup>26</sup> Among other things, OPOs must screen deceased donors' blood for infectious diseases, including HIV, and attempt to obtain their medical and behavioral history. OPTN POLICIES, *supra* note 5, § 2.

<sup>27</sup> *Id.* § 3.4; Danielle Richards, Note, *The Defibrillation of NOTA: How Establishing Federal Regulation of Waitlist Eligibility May Save Organ Transplant Patients with Disabilities from Flat-Lining*, 87 S. CAL. L. REV. 151, 154 (2013). In 1998, HHS promulgated regulations governing OPTN. These regulations, known as the "Final Rule," were implemented in 1999. Neal R. Barshes et al., *Justice, Administrative Law, and the Transplant Clinician: The Ethical and Legislative Basis of a National Policy on Donor Liver Allocation*, 23 J. CONTEMP. HEALTH L. & POL'Y 200, 217, 220 (2007). Although the regulations set out allocation performance goals for OPTN, including "[s]tandardizing the criteria for determining suitable transplant candidates through the use of minimum criteria . . . for adding individuals to . . . organ transplant waiting lists," OPTN has established no such criteria. 42 C.F.R. § 121.8(b)(1) (2015). In fact, UNOS states that "[l]isting practices and requirements may vary among institutions and from one organ type to another." OPTN/UNOS Ethics Comm., *Ethical Principles to Be Considered in the Allocation of Human Organs*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK (June 2, 2015), <http://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/> [[perma.cc/AHV6-MTAW](http://perma.cc/AHV6-MTAW)].

<sup>28</sup> OPTN/UNOS Ethics Comm., *supra* note 27 ("Factors relevant to access to the transplant waiting list . . . include: ethical rules (e.g., honesty, the duty not to harm), clinical indicators (e.g., co-morbidities, cause of organ failure) and psychosocial factors (e.g., financial and social support, patient adherence)."); *see also Talking About Transplantation*, *supra* note 19, at 7 (stating that in determining a patient's eligibility for an organ waitlist, the medical team will consider the patient's medical condition and financial situation, as well as whether the patient has friends and family to care for and support the patient). Decisions made on the basis of such factors do not necessarily constitute "discrimination" under the Americans with Disabilities Act ("ADA") or the Rehabilitation Act of 1973. NANCY LEE JONES, CONG. RESEARCH SERV., RL33381, THE AMERICANS WITH DISABILITIES ACT (ADA): ALLOCATION OF SCARCE MEDICAL RESOURCES DURING A PANDEMIC 13, 15 (2008), <https://www.hsdl.org/?view&did=235752> [<http://perma.cc/7NBL-3JGY>] (discussing the case of *McElroy v. Patient Selection Committee*, No. 4:06CV3162, 2007 WL 4180695 (D. Neb. Nov. 21, 2007), in which the "district court found no ADA violation" where a "hospital refused to provide kidney transplant services due to the plaintiff's mental illness").

policies primarily focus on how the “match system” allocates specific organs among waitlisted candidates.

OPTN provides separate allocation policies for hearts, intestines, kidneys, livers, lungs, and pancreata.<sup>29</sup> All of the allocation policies take into consideration the location of the transplant recipient, and, except for livers, the first matching criteria for every organ is whether the potential recipient is within the OPO or donor hospital’s DSA.<sup>30</sup> Finally, OPTN policy forbids consideration of a candidate’s citizenship or residency status, political influence, national origin, ethnicity, sex, religion, or financial status in allocating organs.<sup>31</sup>

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If a physician decides that an HIV-positive patient is unable to benefit from a transplant, or that the transplant is unsafe because of the patient’s HIV-positive status, the physician could refuse to list the patient on an OPTN organ waitlist. Such a refusal may be permissible under the ADA or Rehabilitation Act. See David Orentlicher, *Destructuring Disability: Rationing of Health Care and Unfair Discrimination Against the Sick*, 31 HARV. C.R.-C.L. L. REV. 49, 62 & n.66 (1996) (discussing the case of *Glanz v. Vernick*, 750 F. Supp. 39 (D. Mass. 1990), in which the district court found that because “a person’s HIV-related disease decreases the person’s ability to benefit from ear surgery,” the decision to disqualify the patient as a candidate for surgery may be permissible under section 504 of the Rehabilitation Act). For a more in-depth discussion of this issue, see Angela T. Whitehead, *Rejecting Organs: The Organ Allocation Process and the Americans with Disabilities Act*, 24 AM. J.L. & MED. 481 (1998); Richards, *supra* note 27, at 177.

<sup>29</sup> OPTN POLICIES, *supra* note 5, §§ 6-11. The allocation policies prioritize adult transplant candidates based on the following criteria—heart: location, medical urgency, blood type, and waiting time; kidney: location, tissue and blood type, and waiting time; liver: location, medical urgency, blood type, and waiting time; lung: location, blood type, medical urgency, and waiting time; pancreas: location, medical test results and urgency, and waiting time. *Id.*

<sup>30</sup> *Id.* Liver transplant candidates experience significant geographical disparities in accessing liver transplants. OPTN/UNOS Liver & Intestinal Organ Transplantation Comm., *supra* note 24, at 5 (“Candidates in some parts of the country must wait until they are quite ill before they receive a liver transplant, while those in other areas receive transplants when they are much less ill.”). One measure OPTN enacted to reduce these disparities allocates livers to the sickest “Status 1” candidates based on a regional—as opposed to DSA—sharing model. *Id.* at 22. Geographical disparities in access persist, however, and OPTN continues to evaluate new policy changes to improve the liver allocation model. See David Mulligan, *Liver Forum and Committee Update—June 2015*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK (Jun. 30, 2015), <http://optn.transplant.hrsa.gov/news/liver-forum-and-committee-update-june-2015/> [<http://perma.cc/X5UV-QPB5>].

<sup>31</sup> OPTN POLICIES, *supra* note 5, § 5.4.A. Despite its contention that “equitable access to the transplant waiting list is the cornerstone of equitable organ allocation” because it determines “whether ethical principles of allocation are applied in reality,” UNOS allows physicians to consider some of these factors, like financial status, in determining patients’ access to the waitlist. OPTN/UNOS Ethics Comm., *supra* note 27; see *supra* note 28 and accompanying text.

B. *The HOPE Act*

In the 1980s, physicians documented the first transmissions of HIV from infected donor organs to HIV-negative recipients in the United States.<sup>32</sup> Consequently, in 1988, Congress amended NOTA to explicitly prohibit any donation or transplantation of HIV-infected organs.<sup>33</sup>

Today, individuals with HIV are living longer, healthier lives due to advances in HIV treatment and care.<sup>34</sup> However, an increased life expectancy means that HIV-positive individuals are developing other medical conditions that require organ transplants.<sup>35</sup> As a result, the number of HIV-positive individuals in need of an organ transplant is steadily increasing.

In 2001, 15 HIV-positive patients received organ transplants, compared with 137 HIV-positive patients in 2013.<sup>36</sup> Because OPTN does not collect information on the HIV status of patients on the waitlist, the number of HIV-positive patients waiting for an organ is likely much higher.<sup>37</sup> Furthermore, HIV-positive patients are more likely to die while waiting for a transplant than HIV-negative patients.<sup>38</sup> Interested in alleviating this increased need for donor organs through the legalization of HIV-positive organ donation, a group of

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<sup>32</sup> ROBERT M. VEATCH & LAINIE F. ROSS, *TRANSPLANTATION ETHICS* 214 (2d ed. 2015).

<sup>33</sup> Health Omnibus Programs Extension of 1988, Pub. L. No. 100-607, 102 Stat. 3048 (1988).

<sup>34</sup> Frank J. Palella et al., *Declining Morbidity and Mortality Among Patients with Advanced Human Immunodeficiency Virus Infection*, 338 *NEW ENG. J. MED.* 853, 853 (1998) (“The recent declines in morbidity and mortality due to AIDS are attributable to the use of more intensive antiretroviral therapies.”).

<sup>35</sup> B.J. Boyarsky et al., *Estimating the Potential Pool of HIV-Infected Deceased Organ Donors in the United States*, 11 *AM. J. TRANSPLANTATION* 1209, 1213 (2011) (“As life expectancy has dramatically improved in many people living with HIV, [end-stage liver disease] and [end-stage renal disease] account for a considerable amount of morbidity and mortality among HIV-infected patients.”).

<sup>36</sup> *Proposal to Address the Requirements Outlined in the HIV Organ Policy Equality Act*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK 1 (2014), [http://optn.transplant.hrsa.gov/media/1126/13\\_opo\\_hope\\_act.pdf](http://optn.transplant.hrsa.gov/media/1126/13_opo_hope_act.pdf) [<http://perma.cc/G96F-LRWU>] [hereinafter *OPTN Proposal*].

<sup>37</sup> *Id.* at 3.

<sup>38</sup> See Boyarsky et al., *supra* note 35, at 1209. One study conducted on patients with end-stage liver disease found that HIV-positive patients had significantly higher mortality rates while waiting for a liver, though the rates were “unrelated to severity of liver or HIV disease.” Margaret V. Ragni et al., *Pretransplant Survival Is Shorter in HIV-Positive than HIV-Negative Subjects with End-Stage Liver Disease*, 11 *LIVER TRANSPLANTATION* 1425, 1425 (2005). Because the deaths were associated with infection and sepsis, the authors postulated that HIV-positive patients’ compromised immune systems made them more susceptible to infection, though this did not account for the differences in survival among HIV-positive patients. *Id.* at 1429-30 (suggesting that HIV-positive patients be evaluated for transplant earlier than HIV-negative patients due to their higher risk of infection).

researchers estimates that a pool of roughly 500 to 600 HIV-positive deceased donors could contribute organs each year.<sup>39</sup>

In response to the growing shortage of donor organs and new scientific research on HIV-positive-to-HIV-positive transplantation, Congress enacted the HOPE Act on November 21, 2013.<sup>40</sup> The Act repealed the prohibition on the donation of and research on HIV-positive organs for transplantation.<sup>41</sup> Specifically, the HOPE Act directs the Secretary of HHS to develop criteria for the conduct of scientific research on the feasibility of and requirements for HIV-positive-to-HIV-positive transplantation.<sup>42</sup> Following the promulgation of the criteria, transplant hospitals participating in institutional review board (“IRB”) -approved research protocols can begin performing HIV-positive-to-HIV-positive transplants.<sup>43</sup> Before November 21, 2017, and annually thereafter, the Secretary of HHS and OPTN must review the results of the research.<sup>44</sup> If the research demonstrates that HIV-positive-to-HIV-positive transplants are viable, the Secretary shall direct OPTN/UNOS to revise the statutes and regulations governing the acquisition and transplantation of donated organs to allow for HIV-positive-to-HIV-positive transplantation.<sup>45</sup>

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<sup>39</sup> See Boyarsky et al., *supra* note 35, at 1209. The authors point out that the criteria used to identify potentially eligible donors was very selective, and thus, the potential pool of HIV-positive organ donors is likely larger than the authors’ estimate. *Id.* at 1215.

<sup>40</sup> HIV Organ Policy Equity Act, Pub. L. No. 113-51, 127 Stat. 579 (2013) (codified in scattered sections of 18 and 42 U.S.C.); see also Grant Colfax, *HIV Organ Policy Equity (HOPE) Act is Now Law*, WHITEHOUSE.GOV (Nov. 21, 2013, 7:25 PM), <https://www.whitehouse.gov/blog/2013/11/21/hiv-organ-policy-equity-hope-act-now-law> [<https://perma.cc/Q2X2-6ARH>].

<sup>41</sup> See HIV Organ Policy Equity Act § 2. However, 18 U.S.C. § 1122 still provides criminal penalties for donating or attempting to donate HIV-positive organs, “except as determined necessary for medical research or testing or in accordance with all applicable guidelines and regulations made by the Secretary of Health and Human Services under section 377E of the Public Health Service Act . . . .” 18 U.S.C. § 1122 (Supp. I 2013).

<sup>42</sup> 42 U.S.C. § 274f-5(a) (Supp. I 2013). The National Institutes of Health published the final criteria in November 2015. Final Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs Infected with HIV, 80 Fed. Reg. 73,785 (Nov. 25, 2015).

<sup>43</sup> JAMES B. ALCORN, UNITED NETWORK FOR ORGAN SHARING, IMPORTANT POLICY NOTICE: ADDRESSING REQUIREMENTS IN THE HIV ORGAN POLICY EQUITY ACT (July 1, 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) [<https://perma.cc/HV7X-VG4S>]. In January 2016, UNOS approved the first hospital, Johns Hopkins, to perform transplants of HIV-positive organs into HIV-positive recipients. Daniel Victor, *Johns Hopkins to Perform First H.I.V.-Positive Organ Transplants in U.S.*, N.Y. TIMES (Feb. 10, 2016), [http://www.nytimes.com/2016/02/11/health/johns-hopkins-wins-approval-to-perform-hiv-positive-organ-transplants.html?\\_r=0](http://www.nytimes.com/2016/02/11/health/johns-hopkins-wins-approval-to-perform-hiv-positive-organ-transplants.html?_r=0) [<https://perma.cc/GGE2-B9YB>].

<sup>44</sup> 42 U.S.C. § 274f-5(c)(1).

<sup>45</sup> *Id.* § 274f-5(c)(2) (“[I]f the Secretary determines [the results of the scientific research] warrant revision of the standards of quality adopted under . . . this title with respect to



Until recently, OPTN policy prohibited the general recovery and transplantation of HIV-positive organs.<sup>46</sup> In June 2015, OPTN's Board of Directors approved policy amendments intended to conform existing OPTN policies to the requirements of the HOPE Act.<sup>47</sup> Among other things, the amendments established an open variance and the concomitant conditions under which OPTN members may recover and transplant HIV-positive organs.<sup>48</sup> Specifically, OPTN members must verify that the donor and potential recipient are HIV-positive, and determine that the recipient is willing to accept an HIV-positive organ as part of an IRB-approved research protocol.<sup>49</sup>

Recent research from South Africa on HIV-positive-to-HIV-positive kidney transplantation suggests that these transplants are promising.<sup>50</sup> Beginning in 2008, researchers transplanted HIV-positive kidneys into twenty-seven carefully selected HIV-positive recipients and observed the patients' outcomes at three and five years.<sup>51</sup> The patient and organ survival rates were similar to those of HIV-positive patients who received HIV-negative kidneys, and the patients' HIV viral loads did not increase, remaining undetectable following transplantation.<sup>52</sup> Although important differences exist between the HIV-positive patient populations in South Africa and the United States,<sup>53</sup> the

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donated organs infected with HIV and with respect to transplanting an organ with a particular strain of HIV into a recipient with a different strain of HIV, [the Secretary shall] direct [OPTN] to revise such standards . . .”).

<sup>46</sup> ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, POLICIES § 2.7 (Jan. 21, 2016), [https://optn.transplant.hrsa.gov/media/1200/optn\\_policies.pdf](https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf) (“Members [of OPTN] may not participate in the recovery or transplantation of organs from deceased donors known to be infected with HIV.”).

<sup>47</sup> ALCORN, *supra* note 43.

<sup>48</sup> OPTN POLICIES, *supra* note 5, § 15.6. An open variance is an experimental policy in which OPTN members can choose to participate. *Variance Application*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, [http://optn.transplant.hrsa.gov/publiccomment/pubcommentprosurveyexhibit\\_41.pdf](http://optn.transplant.hrsa.gov/publiccomment/pubcommentprosurveyexhibit_41.pdf) [<https://perma.cc/WY64-M28L>].

<sup>49</sup> OPTN POLICIES, *supra* note 5, § 15.6.A.

<sup>50</sup> Elmi Muller et al., *HIV-Positive-to-HIV-Positive Kidney Transplantation—Results at 3 to 5 Years*, 372 NEW ENG. J. MED. 613, 613 (2015).

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

<sup>52</sup> *Id.* at 618. Specifically, the cumulative survival rates were 84% at one year, 84% at three years, and 74% at five years. *Id.* at 613, 616. The graft (organ) survival rates were 93% at one year, 84% at three years, and 84% at five years. *Id.* In fact, the HIV-positive graft survival rates appear better than the graft survival rates for HIV-negative patients in the same transplant unit, which were 88% at one year and 75% at five years. *Id.* at 616-17. The researchers opined that these types of HIV-positive kidney transplants are feasible “with the expectation that the outcome would be similar to that observed in kidney-transplantation programs involving high-risk patients without HIV infection.” *Id.* at 619.

<sup>53</sup> See B.J. Boyarsky et al., *Challenges and Clinical Decision-Making in HIV-to-HIV Transplantation: Insights from the HIV Literature*, 15 AM. J. TRANSPLANTATION 2023, 2025 (2015) (highlighting the difference between South Africa and the United States in terms of the “prevalence of HIV drug resistance”).

research intimates that using controlled donor and recipient populations, HIV-positive-to-HIV-positive transplantation may soon be a reality in the United States. With this reality fast approaching, the medical and legal communities must determine an effective and ethical method for implementing the HOPE Act.

## II. THE HIV POPULATION, DISCRIMINATION, AND ORGAN TRANSPLANTATION

The Centers for Disease Control and Prevention (“CDC”) estimate that over 1.2 million people in the United States are currently living with HIV.<sup>54</sup> Social determinants of health—such as gender, socioeconomic status, race, and ethnicity—play a significant role in determining risk and prevalence of HIV infection.<sup>55</sup> Men who have sex with men (“MSM”) and black people are the largest subpopulations affected by HIV.<sup>56</sup> MSM comprise roughly 4% of the U.S. male population, yet account for 54% of the total HIV-positive population.<sup>57</sup> Similarly, black people comprise approximately 12% of the U.S. population, but 41% of individuals living with HIV in 2011.<sup>58</sup> Although the rates of death among all HIV-positive individuals declined between 2009 and 2012, black people suffered the highest death rate—21.1%.<sup>59</sup> Additionally, the survival rates following a diagnosis of HIV or a stage three classification (AIDS) were lowest among black people and American Indians/Alaska Natives.<sup>60</sup> HIV also disproportionately impacts black women; in 2010, “[t]he rate of new HIV infections among black/African American females . . . was 20.1 times the rate for white females.”<sup>61</sup> Finally, the highest rates of HIV diagnosis occur in the poorest and least educated populations.<sup>62</sup>

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<sup>54</sup> *HIV in the United States: At a Glance*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/hiv/statistics/basics/atagance.html#ref1> [<http://perma.cc/B6E7-GNYL>].

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

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

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

<sup>58</sup> *Id.* (indicating that the most recent data available is from 2011).

<sup>59</sup> 25 CTRS. FOR DISEASE CONTROL & PREVENTION, HIV SURVEILLANCE REPORT: DIAGNOSES OF HIV INFECTION IN THE UNITED STATES AND DEPENDENT AREAS, 2013, at 7 (2015), <http://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-vol-25.pdf> [<http://perma.cc/57A7-2YA4>].

<sup>60</sup> *Id.* at 8.

<sup>61</sup> 17 CTRS. FOR DISEASE CONTROL & PREVENTION, HIV SURVEILLANCE SUPPLEMENTAL REPORT: ESTIMATED HIV INCIDENCE IN THE UNITED STATES, 2007-2010, at 6-7 (2012), [http://www.cdc.gov/hiv/pdf/statistics\\_hssr\\_vol\\_17\\_no\\_4.pdf](http://www.cdc.gov/hiv/pdf/statistics_hssr_vol_17_no_4.pdf) [<http://perma.cc/Q56D-BTFR>].

<sup>62</sup> 19 CTRS. FOR DISEASE CONTROL & PREVENTION, HIV SURVEILLANCE SUPPLEMENTAL REPORT: SOCIAL DETERMINANTS OF HEALTH AMONG ADULTS WITH DIAGNOSED HIV INFECTION IN 20 STATES, THE DISTRICT OF COLUMBIA, AND PUERTO RICO, 2010, at 8-9 (2014), [http://www.cdc.gov/hiv/pdf/surveillance\\_Report\\_vol\\_19\\_no\\_2.pdf](http://www.cdc.gov/hiv/pdf/surveillance_Report_vol_19_no_2.pdf) [<http://perma.cc/8HBQ-3M8P>]. For both males and females, the highest rates of HIV diagnosis were among those who lived in areas where at least 19% of the residents lived below the federal poverty level,

A. *The Law and HIV Stigma*

HIV's disproportionate impact on MSM and racial minorities, particularly black people, creates a unique HIV stigma that perpetuates discrimination against these subpopulations. The law impacts the expression of social determinants of health and the structural factors that lead to an increased risk or prevalence of HIV infection and that affect survival.<sup>63</sup> Laws that control access to treatment, that criminalize the possession and distribution of drugs, and that make it illegal to transmit or expose others to HIV are some of the more direct ways in which the law fosters the prevalence of HIV among MSM and black people, particularly those of low socioeconomic status.<sup>64</sup>

For example, laws governing both eligibility for and coverage under Medicaid adversely affect poor racial minorities' ability to access health care as well as the level of HIV care they receive.<sup>65</sup> Moreover, "very limited and ineffective legal remedies are available for claims of unfairness against Medicaid programs (e.g., claims for discrimination due to race)."<sup>66</sup> Specific criminal drug laws that disproportionately impact racial minorities,<sup>67</sup> the discriminatory enforcement of these laws generally,<sup>68</sup> and the increased prevalence of risky drug use and sex in prison<sup>69</sup> all increase minorities' exposure to and contraction of HIV.<sup>70</sup> Finally, criminal laws related to HIV exposure and transmission can create negative gender- and race-related HIV stigmas, which in turn may cause individuals to forgo HIV testing or treatment.<sup>71</sup> In particular, the media's focus on HIV exposure and transmission

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at least 24% or more of the residents had less than a high school diploma, the median household income was less than \$36,000 a year, and at least 7% of the residents were unemployed. *Id.*

<sup>63</sup> Zita Lazzarini & Robert Klitzman, *HIV and the Law: Integrating Law, Policy, and Social Epidemiology*, 30 J.L. MED. & ETHICS 533, 534 (2002) ("Social determinants include poverty, race, and gender, and are expressed as under- or unemployment, homelessness, poor education, racism, discrimination, gender inequality, and stigmatization.").

<sup>64</sup> *Id.* at 535-39.

<sup>65</sup> *Id.* at 535. Racial minorities with HIV are more likely to depend on government-funded health programs and are "less likely to receive antiretroviral treatment than those with private insurance." *Id.*

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

<sup>67</sup> For example, mandatory sentences for drug offenses involving crack cocaine, which "has been sold predominantly in inner cities and marketed . . . in minority neighborhoods," are harsher than penalties for powder cocaine. *Id.* at 536.

<sup>68</sup> Although black people made up only 11% of the estimated 24.5 million Americans who reported using illicit drugs on the National Household Survey on Drug Abuse in 2000, they accounted for 38% of arrests for drug offenses and 59% of convictions. *Id.*

<sup>69</sup> *Id.* ("Incarceration exposes inmates to risky sex and drug use, since condoms and clean needles are largely unavailable in prison and sex may be coerced.").

<sup>70</sup> *Id.*

<sup>71</sup> *Id.* at 537 ("[F]ear of being stigmatized has been associated with individual reluctance to acknowledge risk and to seek testing or other preventive and care-related services.").

cases involving black offenders has fostered a poignant race-related HIV stigma.<sup>72</sup>

Various other social and structural factors<sup>73</sup> exacerbate the unique stigma surrounding HIV-positive individuals. Although public knowledge regarding HIV/AIDS and the perception of those affected has dramatically improved since the discovery of the disease in 1981, substantial stigmatization and a lack of knowledge still exist. Roughly one-third of the U.S. population harbors a misconception about the transmission of HIV.<sup>74</sup> In 2012, many Americans were still uncomfortable working with someone with HIV or AIDS (20%), having a roommate who is HIV-positive (33%), having their food prepared by someone who is HIV-positive (44%), or having their children taught by a teacher who is HIV-positive (26%).<sup>75</sup> Furthermore, 32% of the population believes that “it’s people’s own fault if they get AIDS” and 21% “sometimes think[s] that AIDS is a punishment for the decline in moral standards.”<sup>76</sup>

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<sup>72</sup> *Id.* at 537-38 (“[T]he most notorious case in terms of media coverage involved an African-American man suspected of exposing more than forty white women and infecting thirteen of them. The media coverage of the case revealed many deep-seated stereotypes related to race and sexuality.” (footnote omitted)); *see also* Luke A. Boso, Note, *The Unjust Exclusion of Gay Sperm Donors: Litigation Strategies to End Discrimination in the Gene Pool*, 110 W. VA. L. REV. 843, 848 n.31 (2008) (“[P]op culture . . . has contributed to the creation and perpetuation of the once (and arguably still) common belief that HIV and AIDS are ‘gay diseases’ . . . .” (citation omitted)). This discriminatory portrayal is even more troubling in light of the fact that six in ten Americans report that their primary source of information regarding HIV is the media. KAISER FAMILY FOUND., HIV/AIDS AT 30: A PUBLIC OPINION PERSPECTIVE 2 (2011), [https://kaiserfamilyfoundation.files.wordpress.com/2013/07/8186-hiv-survey-report\\_final.pdf](https://kaiserfamilyfoundation.files.wordpress.com/2013/07/8186-hiv-survey-report_final.pdf) [<https://perma.cc/4XPZ-JVTB>].

<sup>73</sup> Some structural factors include “access to economic resources, policy supports, societal attitudes, and organizational structures and functions; they may be implemented by governments, businesses, faith communities, justice systems, the media, educational systems, and other sectors that form or implement policies or procedures.” Lazzarini & Klitzman, *supra* note 63, at 534.

<sup>74</sup> WASH. POST & KAISER FAMILY FOUND., 2012 SURVEY OF AMERICANS ON HIV/AIDS 13, <https://kaiserfamilyfoundation.files.wordpress.com/2013/01/8334-f.pdf> [<https://perma.cc/8EPC-BFQC>]. Thirty-four percent of the population maintains at least one of the following misconceptions about HIV transmission: that HIV can be transmitted through (1) sharing a drinking glass (27%), (2) touching a toilet seat (17%), (3) swimming in a pool with someone who is HIV-positive (11%). *Id.* (noting that incorrect answers included “yes” and “don’t know” responses). Interestingly, black people were more likely than whites or Latinos to harbor other misconceptions about HIV unrelated to transmission. *Id.* at 15 (finding that more blacks incorrectly responded “yes” or “don’t know” to the following statements: (1) there is a vaccine available to prevent HIV infection, and (2) Magic Johnson has been cured of AIDS).

<sup>75</sup> *Id.* at 16.

<sup>76</sup> *Id.* at 18.

### B. *Donation*

The misconceptions surrounding HIV and the resultant stigma they create<sup>77</sup> engender discrimination against groups associated with the disease, particularly in the context of medical donation. Prior to December 2015, the Food and Drug Administration (“FDA”) banned any man who had had sex with another man since 1977 from donating blood.<sup>78</sup> The implementation of this ban was the direct result of a lack of knowledge regarding HIV/AIDS and the stigmatization of “the homosexual population as the root of the problem.”<sup>79</sup> Even though new technology arose in the early 2000s that allowed HIV to be detected in blood as early as nine days after infection—significantly reducing the risk of HIV transmission through blood donation—the FDA refused to amend the lifetime ban on MSM donation.<sup>80</sup> Although the FDA is finally capitulating to the science and the global acceptance of MSM blood donation,<sup>81</sup> the agency’s longstanding refusal to consider a change in policy evinces how the deep-seated stigma attached to HIV and the subpopulations associated with the disease can maintain outdated, discriminatory policies.<sup>82</sup>

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<sup>77</sup> The Kaiser surveys from 2011 and 2012 show a correlation between mistaken beliefs regarding HIV and discomfort with HIV-positive individuals. *See id.* at 17; KAISER FAMILY FOUND., *supra* note 72, at 7.

<sup>78</sup> U.S. DEP’T OF HEALTH & HUMAN SERVS., REVISED RECOMMENDATIONS FOR THE PREVENTION OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) TRANSMISSION BY BLOOD AND BLOOD PRODUCTS 3 (1992), <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/OtherRecommendationsforManufacturers/MemorandumtoBloodEstablishments/UCM062832.pdf> [<http://perma.cc/N5W8-PVXB>]. The FDA’s new guidance, released in December 2015, still recommends banning donations from men who have had sex with another man within the last year. DEP’T OF HEALTH & HUMAN SERVS., REVISED RECOMMENDATIONS FOR REDUCING THE RISK OF HUMAN IMMUNODEFICIENCY VIRUS TRANSMISSION BY BLOOD AND BLOOD PRODUCTS: GUIDANCE FOR INDUSTRY 14 (2015), <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM446580.pdf> [<https://perma.cc/8ZV6-9ZYR>].

<sup>79</sup> Christopher McAdam & Logan Parker, *An Antiquated Perspective: Lifetime Ban for MSM Blood Donations No Longer Global Norm*, 16 DEPAUL J. HEALTH CARE L. 21, 21 (2014).

<sup>80</sup> *Id.* at 29-30. The Blood Products Advisory Committee (“BPAC”) of the FDA voted down proposed changes to the ban in 2000, 2006, and 2010. *Id.* at 30 n.78.

<sup>81</sup> *Id.* at 31-48 (explaining that by 2014, the following countries had already lifted their lifetime ban on MSM blood donation: the United Kingdom, Australia, Spain, Italy, South Africa, Russia, Mexico, Japan, Canada, Sweden, and Chile); *see supra* note 78 and accompanying text.

<sup>82</sup> “[T]he rationale that MSM donors are all associated with risky behavior and that they are constantly in contact with HIV is no longer valid or supported.” McAdam & Parker, *supra* note 79, at 53. The old FDA policy specifically discriminated against MSM by refusing to include MSM with other high-risk groups, for whom a twelve month deferral period was already in place. *Id.* at 30 n.78. For a discussion of whether this type of

The same discriminatory policy exists in regard to anonymous MSM sperm donation. The FDA's final rule regarding the donation of human cells, tissues, and cellular or tissue-based products specifies that establishments responsible for donor screening must screen a donor for risk factors and "must determine ineligible a donor who is identified as having . . . a risk factor."<sup>83</sup> Although the final rule itself does not enumerate these "risk factors," the FDA's industry guidance document does.<sup>84</sup> The first risk factor listed in the FDA guidance document is "[m]en who have had sex with another man in the preceding 5 years."<sup>85</sup> Like the ban on MSM blood donation, this policy is unsupported by current science,<sup>86</sup> is highly discriminatory,<sup>87</sup> and is a result of (and perpetuates) the HIV stigma associated with the MSM community.<sup>88</sup>

### C. *Organ Transplantation*

Not only do communities stigmatized by HIV face discrimination in a medical donation context, but also, the subgroups most severely impacted by

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discriminatory policy is legal, see *id.* at 56-63 (arguing that "[t]his unfair differentiation between gay and straight donors raises constitutional equal protection concerns").

<sup>83</sup> 21 C.F.R. § 1271.75(a), (d) (2015).

<sup>84</sup> U.S. DEP'T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY: ELIGIBILITY DETERMINATION FOR DONORS OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) 14-21 (2007), <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM091345.pdf> [<http://perma.cc/CH3W-SLSJ>].

<sup>85</sup> *Id.* at 14. The FDA guidance document specifies that it does "not establish legally enforceable responsibilities," "unless specific regulatory or statutory requirements are cited." *Id.* at 1. Before listing the risk factors, the document states that "in accordance with § 1271.75(d), you should determine to be ineligible any potential donor who exhibits one or more of the following conditions or behaviors." *Id.* at 14. The document's citation to § 1271.75(d) effectively establishes the risk factors as legally enforceable requirements.

<sup>86</sup> For semen donations, the FDA requires that donor testing establishments collect specimens within seven days of the original donation, collect specimens again six months later, and test the specimens for communicable diseases. 21 C.F.R. §§ 1271.80(b), 1271.85(d). In addition to the new testing technology that can detect HIV within days of infection, this additional protocol so significantly reduces the risk of HIV transmission through semen donation that there exists no scientific justification for the ban on MSM donation. Boso, *supra* note 72, at 847-48.

<sup>87</sup> Although HIV is almost equally prevalent in the heterosexual community, see *supra* text accompanying note 57, the FDA's guidance document does not include any risk factors related to high-risk behaviors in heterosexuals. U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 84; see also Boso, *supra* note 72, at 844, 849 ("[The FDA policy] continues to classify MSMs as high risk, but refuses to acknowledge the increasing rate of heterosexual HIV transmissions, as well as the reality of today's technology.").

<sup>88</sup> Lacking any scientific rationale to support the policy, the FDA's ban against MSM sperm donation is based on antiquated "notions of HIV as a 'gay disease.'" Boso, *supra* note 72, at 848. "The policy also embodies a moral disapproval of certain kinds of sexual behavior over others . . ." *Id.* at 849.

HIV face more barriers and discrimination in the context of organ transplantation. Racial and ethnic minorities, particularly those of low socioeconomic status, face serious barriers in accessing organ transplants.<sup>89</sup> Some of these barriers are the result of longstanding racial inequalities, perpetuated by a historical tradition of discrimination and maintained through various socio-cultural frameworks. For example, minorities are less likely to have access to preventative medical services or knowledgeable specialists due to a lack of economic resources and an overall paucity of minority transplant physicians.<sup>90</sup> Racial and ethnic minorities are also less likely to have health insurance offered through their jobs, and thus are more likely to be uninsured or covered through Medicaid and other government-sponsored insurance programs.<sup>91</sup>

Uninsured patients are more likely to be excluded from transplant waitlists, and less than 1% of organ-transplant recipients are uninsured.<sup>92</sup> In addition, only certain states' Medicaid programs even fund organ transplants.<sup>93</sup> For renal transplants specifically, high-income patients are more likely to be placed on the waitlist than are middle- and low-income patients.<sup>94</sup>

Other disparities in access to transplantation, however, cannot be so easily attributed to underlying socioeconomic differences. Even when minority patients express a preference for transplantation over other forms of treatment, they receive fewer referrals to transplant centers than white patients and fewer

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<sup>89</sup> R.S.D. Higgins & J.A. Fishman, *Disparities in Solid Organ Transplantation for Ethnic Minorities: Facts and Solutions*, 6 AM. J. TRANSPLANTATION 2556, 2556 (2006).

<sup>90</sup> *Id.* at 2556, 2560 (“African American healthcare providers are significantly more likely to serve minority and medically underserved communities, improving access to care for these individuals. Minorities tend to have greater participation in their care when the patient and the provider are of the same ethnicity.” (footnotes omitted)). Disparities in education also affect minorities’ “ability to understand and to pay for preventive medical care and transplantation.” *Id.* at 2557 (“In the United States, 17% of blacks and 11% of Hispanics have completed 4 or more years of higher education compared to 44% of Asian Americans and 26% of Caucasians.”). Independent of race or ethnicity, educational levels also have an impact on informed consent. Kristina M. Cordasco, *Obtaining Informed Consent from Patients: Brief Update Review*, in MAKING HEALTH CARE SAFER II: AN UPDATED CRITICAL ANALYSIS OF THE EVIDENCE FOR PATIENT SAFETY PRACTICES 461, 463 (2013).

<sup>91</sup> *Eliminating Racial/Ethnic Disparities in Health Care: What are the Options?*, KAISER FAMILY FOUND. 3 (Oct. 2008), <https://kaiserfamilyfoundation.files.wordpress.com/2013/01/7830.pdf> [<https://perma.cc/VNE8-4XC3>]; *see also* Higgins & Fishman, *supra* note 89, at 2557.

<sup>92</sup> Melissa Wong, Note, *Coverage for Kidneys: The Intersection of Insurance and Organ Transplantation*, 16 CONN. INS. L.J. 535, 557 (2010).

<sup>93</sup> For a more in-depth discussion on the circuit split over whether federal law requires state Medicaid programs to fund organ transplants, *see id.* at 546-50, 562.

<sup>94</sup> Higgins & Fishman, *supra* note 89, at 2557.

are listed as transplant candidates.<sup>95</sup> Once placed on a waitlist—and controlling for other factors that may influence receipt of an organ, such as medical criteria, DSA, and insurance type—black people experience an 18% lower transplantation rate compared to non-Hispanic white people.<sup>96</sup> Also, despite the fact that nearly half of the HIV-positive population is black and less than a third of the population is white,<sup>97</sup> “approximately half of the HIV-positive transplant recipients in the US are white.”<sup>98</sup> These data suggest that racial and ethnic minorities, particularly black people, face discrimination specific to accessing and receiving organ transplants.

The stigma associated with HIV-positive status, coupled with existing discrimination against the subpopulations most affected by HIV, unsurprisingly results in increased discrimination against HIV-positive patients seeking organ transplants. For example, one study found that among a set of patients in need of a kidney transplant who were deemed eligible for transplantation, only 20% of the HIV-positive patients were eventually placed on the kidney waitlist compared to 73% of the HIV-negative patients.<sup>99</sup> And of the 242 transplant centers operating in 2011, only 48 performed transplants on HIV-positive patients.<sup>100</sup> Further, a 2005 study found that transplant physicians

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<sup>95</sup> *Id.* (discussing the rates of referral and listing in regards to kidney and liver transplants specifically). One study found that among patients who wanted a renal transplant, black people were about 23% less likely to be referred for an evaluation at a transplant center, and about 28% less likely to be placed on a waitlist or receive a renal transplant within eighteen months of the start of dialysis compared to whites. John Z. Ayanian et al., *The Effect of Patients' Preferences on Racial Differences in Access to Renal Transplantation*, 341 *NEW ENG. J. MED.* 1661, 1663, 1666 (1999). “Evidence suggests that discrimination against blacks, other minorities, women, and the poor occurs leading up to and at the point of referral to transplantation centers and admission to waiting lists.” TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* 266 (7th ed. 2013).

<sup>96</sup> Higgins & Fishman, *supra* note 89, at 2557. Another study found that among patients deemed to be appropriate candidates for renal transplantation, and after correcting for other variables such as patient preference regarding transplantation, education, income, and region, only 17.2% of blacks underwent transplantation, compared to 52.2% of whites. Arnold M. Epstein et al., *Racial Disparities in Access to Renal Transplantation: Clinically Appropriate or Due to Underuse or Overuse?*, 343 *NEW ENG. J. MED.* 1537, 1537 (2000).

<sup>97</sup> *CTRS. FOR DISEASE CONTROL & PREVENTION*, *supra* note 61, at 15.

<sup>98</sup> Sawinski et al., *supra* note 2, at 1470; *see also supra* note 58 and accompanying text.

<sup>99</sup> Sawinski et al., *supra* note 2, at 1467. Another factor that was independently associated with a patient's failure to progress past the initial eligibility determination was “black race.” *Id.* at 1469.

<sup>100</sup> Amy Dockser Marcus, *More HIV-Positive Patients Receive Organ Transplants*, *WALL STREET J.* (Oct. 11, 2012, 8:45 PM), <http://www.wsj.com/articles/SB10000872396390443493304578038812275903232> [<http://perma.cc/2WRG-94MJ>] (explaining that some hospitals' protocols considered HIV-positive status a complete bar to transplantation “along with active substance abuse . . . [and] severe psychiatric disease”). The location of transplant centers willing to perform HIV-positive transplants can also have



were less willing to transplant organs into HIV-positive patients compared to patients with hepatitis C virus (“HCV”), even though the physicians believed that the two groups would have similar post-transplant survival rates.<sup>101</sup>

In addition to discrimination, other risks unique to the HIV-positive population—such as unlawful disclosure of a patient’s HIV-positive status—put the population in a particularly fraught position. Due to these risks and the history of discrimination against and stigma associated with HIV-positive status, any law or policy affecting HIV-positive individuals, particularly in a medical context, needs to be analyzed and administered under the highest legal and ethical standards in order to protect the rights of this vulnerable population.<sup>102</sup>

### III. LEGAL AND ETHICAL FRAMEWORK

The four quintessential principles of biomedical ethics developed by Beauchamp and Childress (two preeminent scholars of bioethical principles) are respect for autonomy, beneficence, non-maleficence, and justice.<sup>103</sup>

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a significant impact on the ability of HIV-positive patients to receive an organ. *See infra* note 252 and accompanying text.

<sup>101</sup> Scott D. Halpern et al., *Determinants of Transplant Surgeons’ Willingness to Provide Organs to Patients Infected with HBV, HCV or HIV*, 5 AM. J. TRANSPLANTATION 1319, 1319, 1323-24 (2005) (“[T]his finding might suggest that surgeons continue to stigmatize HIV-infected patients.”). The study also found that “only for HIV-infected patients were surgeons’ incremental fears of intraoperative viral transmission associated with reduced willingness to consider patients for transplantation.” *Id.* at 1321-22.

<sup>102</sup> *See* BEAUCHAMP & CHILDRESS, *supra* note 95, at 63 (“Often we assert that we owe vulnerable parties more, not fewer protections.”). Beauchamp and Childress take issue with the classification of a population as vulnerable when “some members of the class are not vulnerable in the relevant respects.” *Id.* at 267-68. The use of the phrase “vulnerable population” here recognizes that not every HIV-positive individual is vulnerable to exploitation. Rather, the phrase is used to highlight the historical, pervasive discrimination and potential for exploitation faced by the HIV-positive population and its associated subpopulations.

<sup>103</sup> *Id.* at 13. This Note relies predominantly on Beauchamp and Childress’s articulation of bioethical principles for a number of reasons. First, *Principles of Biomedical Ethics* is generally regarded as one of the canonical texts on bioethics, both in the United States and abroad. *See, e.g.*, Roger Rawbone, *Principles of Biomedical Ethics, 7th Edition*, 65 OCCUPATIONAL MED. 88, 88 (2015) (book review) (“This book has to be one of the most important and influential books in the field of bioethics.”). Second, debates on bioethical principles typically surround the weight and application of various principles. To this end, Beauchamp and Childress present an overarching view of varying ethical perspectives, as well as theories of bioethical principles specifically, and evaluate these competing perspectives, producing a comprehensive analysis of bioethical theories. BEAUCHAMP & CHILDRESS, *supra* note 95, at 13. Finally, Beauchamp and Childress’s articulation of the four fundamental bioethical principles closely parallels the framework set forth by the UNOS ethics committee, allowing for a good foundational comparison. For an application of bioethical principles to organ allocation specifically, see generally TOM KOCH, SCARCE

Similarly, UNOS's ethics committee proposes that the principles of autonomy, utility, and justice should guide organ allocation policy.<sup>104</sup> The ethics committee also incorporates the principles of beneficence and non-maleficence into its utility analysis.<sup>105</sup> These ethical principles are reflected throughout American jurisprudence, and many laws directly enforce these principles for the benefit of society.<sup>106</sup> An understanding of these ethical principles and their legal applications must provide the framework for a proper implementation of the HOPE Act.

A. *Autonomy*

Beauchamp and Childress define autonomy as "self-rule that is free from both controlling interference by others and limitations that prevent meaningful choice, such as inadequate understanding."<sup>107</sup> UNOS's ethics committee states that "[t]he concept of respect for autonomy holds that actions or practices tend to be right insofar as they respect or reflect the exercise of self-determination."<sup>108</sup> However, the UNOS ethics committee places the least importance on the principle of autonomy because of its belief that autonomy will not often conflict with the principles of utility and justice.<sup>109</sup> Two relevant manifestations of autonomy in the organ transplantation context are informed consent (i.e., the right to refuse an organ, and policies and procedures designed to enable informed decision-making) and free exchanges among autonomous individuals (i.e., allocation by directed donation).<sup>110</sup>

Autonomy is a cornerstone of American jurisprudence; "[n]o right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others . . ."<sup>111</sup> To avoid interfering with individuals' autonomy, American courts and legislatures have largely refused to impose positive legal obligations on individuals, such as an affirmative duty

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GOODS: JUSTICE, FAIRNESS, AND ORGAN TRANSPLANTATION (2002); VEATCH & ROSS, *supra* note 32.

<sup>104</sup> OPTN/UNOS Ethics Comm., *supra* note 27.

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

<sup>106</sup> Liam Murphy, *Beneficence, Law, and Liberty: The Case of Required Rescue*, 89 GEO. L.J. 605, 626, 630 (2001) (distinguishing the idea that laws enforce moral duties for the benefit of society from the legal moralism notion that "a legitimate aim of the law is the enforcement of morality for its own sake").

<sup>107</sup> BEAUCHAMP & CHILDRESS, *supra* note 95, at 101.

<sup>108</sup> OPTN/UNOS Ethics Comm., *supra* note 27.

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

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

<sup>111</sup> *Union Pac. Ry. Co. v. Botsford*, 141 U.S. 250, 251 (1891); *see Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 287 (1990) (O'Connor, J., concurring) ("[O]ur notions of liberty are inextricably entwined with our idea of physical freedom and self-determination . . .").

to rescue.<sup>112</sup> Furthermore, tort law, criminal law, and the First Amendment's guarantees of freedom of religion, speech, and the press ensure that citizens can enjoy personal autonomy by prohibiting others from interfering with that enjoyment.<sup>113</sup> Most recently, the Supreme Court has sanctioned states' experimentation with the ultimate grant of decisional autonomy—the right to choose to end one's life through physician aid-in-dying.<sup>114</sup>

Informed consent is an integral part of autonomy.<sup>115</sup> Beauchamp and Childress break informed consent into five components: (1) competence, (2) disclosure, (3) understanding, (4) voluntariness, and (5) consent.<sup>116</sup> In the medical and ethics communities, the focus of informed consent has shifted away from what information doctors are required to disclose and towards the quality of patients' understanding of the information disclosed.<sup>117</sup> The case

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<sup>112</sup> See Murphy, *supra* note 106, at 606 (discussing “English-speaking lawyers’” aversion to positive legal duties because of how they “threaten the common law’s traditional deference to individual liberty”). As of 2009, only ten states had any type of duty-to-rescue or duty-to-report statute. Eugene Volokh, *Duty to Rescue/Report Statutes*, VOLOKH CONSPIRACY (Nov. 3, 2009, 12:24 AM), <http://volokh.com/2009/11/03/duty-to-rescuereport-statutes/> [<http://perma.cc/4FTE-AHMP>].

<sup>113</sup> U.S. CONST. amend. I; see also, e.g., MASS. GEN. LAWS ch. 265 (2014) (setting out “Crimes Against the Person”); RESTATEMENT (SECOND) OF TORTS ch. 2 (AM. LAW INST. 1965) (titled the topics on intentional invasions of interests in personality as “The Interest in Freedom from . . .”).

<sup>114</sup> The Court has held that the right to physician aid-in-dying is not a liberty protected by the Due Process Clause and that statutes banning the practice do not violate the Equal Protection Clause of the Fourteenth Amendment. *Vacco v. Quill*, 521 U.S. 793, 796 (1997); *Washington v. Glucksberg*, 521 U.S. 702, 728 (1997). However, in *Glucksberg*, the Court explicitly sanctioned states' experimentation with laws allowing physician aid-in-dying. 521 U.S. at 735 (“Americans are engaged in an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide. Our holding permits this debate to continue . . .”). The Court has also ruled that the U.S. Attorney General did not have authority under the Controlled Substances Act to promulgate a rule prohibiting doctors from prescribing drugs for use in physician-assisted dying. *Gonzales v. Oregon*, 546 U.S. 243, 248, 259 (2006). Although the Court has not ruled on the constitutionality of laws permitting physician aid-in-dying specifically, its silence demonstrates its deference to the legislative process of the states and may evidence the Court's approbation of individuals' right to self-determination and autonomy. See *Lee v. Oregon*, 107 F.3d 1382, 1391-92 (9th Cir. 1997) (holding that plaintiffs lacked Article III standing to challenge Oregon's Death with Dignity Act), *cert. denied sub nom. Lee v. Harclerod*, 522 U.S. 927 (1997).

<sup>115</sup> BEAUCHAMP & CHILDRESS, *supra* note 95, at 121 (explaining that the justification for informed consent is respect for autonomy).

<sup>116</sup> *Id.* at 124.

<sup>117</sup> *Id.* at 121.

law, however, remains focused on doctors' obligation to disclose particular types of information to the patient before treatment.<sup>118</sup>

Physicians must obtain consent from their patients, and those who fail to do so can be held criminally liable for battery—an intentional, unconsented touching. When patients give general consent for the procedure (the touching), physicians are not culpable for intentional crimes, such as battery and assault. Consequently, most informed consent claims are brought under tort law. Although informed consent claims developed under a theory of tortious battery,<sup>119</sup> nowadays, civil liability for battery tends to be limited to unique factual circumstances,<sup>120</sup> and most claims are brought under a theory of negligence (i.e., medical malpractice).

In determining whether a physician committed medical malpractice by failing to obtain informed consent, U.S. states are split between two standards for a physician's duty to disclose: the professional practice standard and the reasonable patient standard.<sup>121</sup> Under the professional practice standard, doctors are required to disclose information that a reasonable doctor would disclose in the same or similar circumstances, i.e., what is customarily disclosed.<sup>122</sup> On the other hand, the reasonable patient standard requires doctors to disclose information that a reasonable person in the patient's position would find material.<sup>123</sup> In addition to doctors' legal disclosure

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<sup>118</sup> See *Canterbury v. Spence*, 464 F.2d 772, 780 n.15 (D.C. Cir. 1972) (“[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.”).

<sup>119</sup> RUTH R. FADEN & TOM L. BEAUCHAMP, *A HISTORY AND THEORY OF INFORMED CONSENT* 26-27 (1986).

<sup>120</sup> MARK A. HALL ET AL., *HEALTH CARE LAW AND ETHICS* 214 (8th ed. 2013) (“In most jurisdictions, battery claims are reserved for those situations in which (1) the patient has not consented to any treatment at all, (2) the health care provider performs a completely different procedure than that for which consent was given, (3) the health care provider performs a procedure on the wrong area of the body, or (4) a different, unconsented-to provider performs the procedure.”).

<sup>121</sup> BEAUCHAMP & CHILDRESS, *supra* note 95, at 125-26; Jaime Staples King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J.L. & MED. 429, 430 (2006). These different legal standards determine what information transplant physicians are required to disclose to HIV-positive patients. See *infra* Part IV.

<sup>122</sup> HALL ET AL., *supra* note 120, at 213; see also FADEN & BEAUCHAMP, *supra* note 119, at 30. In some states the professional practice standard is statutorily imposed, and in others it is a common law standard. HALL ET AL., *supra* note 120, at 212. Compare NEB. REV. STAT. § 44-2816 (2010) (“Informed consent shall mean consent to a procedure based on information which would ordinarily be provided to the patient under like circumstances by health care providers engaged in a similar practice . . .”), with *Culbertson v. Mernitz*, 602 N.E.2d 98, 103 (Ind. 1992) (adopting a physician-based standard).

<sup>123</sup> HALL ET AL., *supra* note 120, at 213. Like the professional practice standard, some states have codified the reasonable patient standard, while others impose it through common law. Compare OR. REV. STAT. § 677.097 (2014), with *Harnish v. Children's Hosp. Med.*

obligations, another important goal of informed consent requirements—particularly in the transplantation context—should be the patient’s understanding of the information disclosed and the voluntariness of the patient’s consent.<sup>124</sup> The voluntariness of a patient’s treatment decision is inextricably linked to competence and consent. The right to voluntarily consent to treatment necessarily implicates patients’ right not to consent, or to voluntarily refuse treatment.<sup>125</sup> Due to its significant implications for autonomy and bodily integrity, the Supreme Court has recognized both competent and incompetent patients’ right to refuse treatment.

Prior to *Cruzan v. Director, Missouri Department of Health*, courts based a patient’s right to refuse treatment on a combination of the common-law doctrine of informed consent and a constitutional privacy right.<sup>126</sup> In *Cruzan*, the Supreme Court stated that under the Due Process Clause of the Fourteenth Amendment, “a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment.”<sup>127</sup> In cases where the patient is not competent, the Court held that states could choose to defer only to the “wishes” of the patient by requiring clear and convincing evidence of what the patient would have chosen if the patient were competent to make the decision.<sup>128</sup> The Court’s ruling demonstrates a substantial respect for individuals’ right to make decisions regarding the treatment of their own body, including the decision to refuse unwanted medical treatment.

Finally, UNOS allows individuals over the age of eighteen to donate their organs while they are alive and to direct those organs to particular recipients.<sup>129</sup> Similarly, under the Uniform Anatomical Gift Act (“UAGA”), adults age eighteen or older have the right to name a particular patient who shall receive their organ(s) upon their death.<sup>130</sup> This ability to direct the donation of one’s

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Ctr., 439 N.E.2d 240, 243 (Mass. 1982) (“[A] physician owes to his patient the duty to disclose in a reasonable manner all significant medical information that the physician possesses . . . that is material to an intelligent decision by the patient . . .”).

<sup>124</sup> See King & Moulton, *supra* note 121, at 431, 477, 480 (discussing improved patient autonomy and comprehension as a positive end).

<sup>125</sup> See *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 270 (1990).

<sup>126</sup> *Id.* at 271.

<sup>127</sup> *Id.* at 278.

<sup>128</sup> *Id.* at 286-87.

<sup>129</sup> OPTN POLICIES, *supra* note 5, § 14.

<sup>130</sup> REVISED UNIF. ANATOMICAL GIFT ACT § 4 (UNIF. LAW COMM’N 2006) (amended 2009). UAGA also allows individuals who are old enough to apply for a driver’s license in their respective states to direct the donation of their organs. *Id.* § 4 cmt. The original version of UAGA was promulgated in 1968 and was enacted by all of the states. *Id.* at intro. note. As of February 15, 2016, forty-six states, the District of Columbia, and the U.S. Virgin Islands have adopted (and one state has proposed a statute to adopt) the most recent version of UAGA. *Anatomical Gift Act (2006)*, UNIF. LAW COMM’N, <http://www.uniformlaws.org/Act.aspx?title=Anatomical%20Gift%20Act%20%282006%29> [http://perma.cc/64FL-DS8A]; S. 180, 2015 Gen. Assemb., Reg. Sess. (Pa. 2015); see O.

organs demonstrates the respect that U.S. laws have for autonomy inasmuch as they allow individuals to make medical decisions regarding what happens to their body while alive and after death. Therefore, a proper implementation of the HOPE Act must afford significant respect to autonomy.

B. *Utility; Beneficence and Non-Maleficence*

The UNOS ethics committee defines utility as the maximization of benefit to the community and states: “The principle of utility holds an action or practice to be right if it promotes as much or more aggregate net good than any alternative action or practice.”<sup>131</sup> In the context of organ transplantation, utility mandates that an organ allocation maximize the net overall good and minimize harm.<sup>132</sup> In this way, the ethics committee incorporates the principles of beneficence—“do good”—and non-maleficence—“do no harm”—into its concept of utility.<sup>133</sup>

In contrast, Beauchamp and Childress view utility as one of two principles of beneficence.<sup>134</sup> While the first principle, positive beneficence, “requires agents to provide benefits to others,” utility “requires that agents balance benefits, risks, and costs to produce the best overall results.”<sup>135</sup> Aside from its consideration of monetary costs, this concept of utility is consonant with the one provided by the UNOS ethics committee.

Beauchamp and Childress distinguish non-maleficence from beneficence, but like the UNOS ethics committee, define non-maleficence as the obligation to do no harm.<sup>136</sup> In contrast to rules of beneficence, the authors explain, rules of non-maleficence “(1) are negative prohibitions of action, (2) must be followed impartially, and (3) provide moral reasons for legal prohibitions of certain forms of conduct.”<sup>137</sup> Consequently, obligations of non-maleficence are more stringent and can override other principles, such as beneficence, even in

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Mgbako et al., *Allowing HIV-Positive Organ Donation: Ethical, Legal and Operational Considerations*, 13 AM J. TRANSPLANTATION 1636, 1640 (2013) (explaining that UAGA “grant[s] adults the right to make an anatomical gift for the purposes of transplant, while granting the recipient of the intended gift the right to accept or reject it. Thus, the law recognizes the autonomy rights of donors and the autonomy rights of transplant candidates.”).

<sup>131</sup> OPTN/UNOS Ethics Comm., *supra* note 27.

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

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

<sup>134</sup> BEAUCHAMP & CHILDRESS, *supra* note 95, at 202.

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

<sup>136</sup> *Id.* at 151-53.

<sup>137</sup> *Id.* at 204 (“By contrast, rules of beneficence (1) present positive requirements of action, (2) need not always be followed impartially, and (3) generally do not provide reasons for legal punishment when agents fail to abide by them.”).

cases where the largest benefit would be realized through beneficence.<sup>138</sup> The authors suggest that the principles of beneficence and non-maleficence must be weighed under the circumstances, just like utility's balancing of benefits and risks.<sup>139</sup>

Taking into account possible benefits and harms to organ transplant candidates,<sup>140</sup> two factors elucidated by the UNOS ethics committee are particularly relevant in applying the principle of utility to HIV-positive organ transplantation policy: (1) patient and graft (organ) survival, and (2) availability of alternative treatments.<sup>141</sup> These factors reflect utility's focus on producing the maximum amount of medical benefit for all transplant patients.<sup>142</sup> The UNOS ethics committee also specifies that an individual's social usefulness and generalized variations in outcome specific to racial, gender, or socioeconomic groups should not be incorporated into the utility calculation.<sup>143</sup> Notwithstanding this statement, the committee explains that doctors may still use objective medical criteria for predicting outcomes, "even if it is known that these [predictors] are not randomly distributed among racial or gender groups."<sup>144</sup>

Although Beauchamp and Childress contend that the principle of non-maleficence will often override the other moral and legal principles, they recognize that the weight given to any one principle depends on the circumstances and that "no rule . . . favors avoiding harm over providing benefit in every circumstance."<sup>145</sup> The UNOS ethics committee also recognizes

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<sup>138</sup> *Id.* at 150-51. The authors illustrate this principle with the following example: "If a surgeon . . . could save two innocent lives by killing a prisoner on death row to retrieve his heart and liver for transplantation, this outcome would have the highest net utility under the circumstances, but the surgeon's action would be morally indefensible." *Id.* at 151.

<sup>139</sup> *See id.* at 152; *see also id.* at 230 ("Physicians routinely base judgments about the most suitable medical treatments on the balance of probable benefits and harms for patients.").

<sup>140</sup> Some of the benefits include "saving life, relieving suffering and debility, removing psychological impairment, and promoting well-being." OPTN/UNOS Ethics Comm., *supra* note 27. Some of the harms include death, rejection, and side effects of medication, among others. *Id.*

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

<sup>142</sup> *Id.*

<sup>143</sup> *Id.* ("For example, even if there is empirical evidence that survival rates of one race, gender, or socioeconomic group exceed those of another, these factors should be excluded from utility models used to justify allocation decisions.").

<sup>144</sup> *Id.* This logic seems to undo the committee's prohibition against using generalized variations in outcome unique to certain social groups in allocation decisions; the committee merely postpones the discriminatory decision and lends credibility to discrimination against certain social groups by justifying these decisions on the basis of "objective medical criteria," rather than solely on a candidate's membership in a particular social group. *See infra* Section IV.B.

<sup>145</sup> BEAUCHAMP & CHILDRESS, *supra* note 95, at 152.

the prominence of the principles of non-maleficence and beneficence, determining that utility, along with the principle of justice, should guide organ allocation policy.<sup>146</sup> Both interpretations highlight the importance of balancing not only the benefits and risks to organ transplant candidates, but also the principle of utility with the principles of autonomy and justice.

Compared with autonomy, the role of utility—the balancing of obligations of beneficence and non-maleficence—in the law is less inherently clear. However, many laws and doctrines effectuate the principles of beneficence and, in particular, non-maleficence.

Due to the fundamental role of autonomy in Western ideology, American citizens have a strong aversion to positive legal obligations, including general obligations of beneficence.<sup>147</sup> A positive legal duty of general beneficence would require the overall promotion of well-being and, more specifically, would require people to benefit others, including strangers.<sup>148</sup> When an individual is actively engaged in a course of conduct, the individual owes a general duty to exercise reasonable care to avoid causing harm to others and may be liable for failing to act affirmatively to exercise such care.<sup>149</sup> Beyond this minimal obligation, however, civil and criminal laws generally do not create any duty to take positive action.<sup>150</sup> Typically, to be liable for a pure failure to act, the actor must be in a special relationship with an individual to whom the actor owes a duty to act.<sup>151</sup> Consequently, individuals do not have a general legal duty to act beneficently towards others.

However, imposing specific obligations of beneficence on those already engaged in conduct or in a special relationship with the beneficiary may be best for society.<sup>152</sup> “[M]any specific obligations of beneficence in health

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<sup>146</sup> OPTN/UNOS Ethics Comm., *supra* note 27.

<sup>147</sup> See *supra* note 112 and accompanying text.

<sup>148</sup> Murphy, *supra* note 106, at 625, 653.

<sup>149</sup> *Id.* at 622 (“A person may be liable in tort for failing to provide aid where that failure is part of a positive course of action already undertaken . . . [because] the failure to act is counted as part of a wider pattern of misfeasance—negligent or otherwise tortious [conduct].”).

<sup>150</sup> 2 DAN B. DOBBS ET AL., THE LAW OF TORTS § 259 (2d ed. 2011); see also Murphy, *supra* note 106, at 611 (explaining that in the United States “liability for any kind of omission or failure to act is exceptional”). The exception would be the duty to rescue. Murphy, *supra* note 106, at 630; see *supra* note 112 and accompanying text.

<sup>151</sup> Murphy, *supra* note 106, at 622 (“[L]andholders, carriers, hosts, and various others may be liable for not taking positive steps to prevent harm or provide aid.”); see also RESTATEMENT (SECOND) OF TORTS §§ 314A-14B, 321-24 (AM. LAW INST. 1965) (enumerating the types of relationships that engender duties to aid and protect); cf. BEAUCHAMP & CHILDRESS, *supra* note 95, at 205 (“By contrast, general beneficence is directed beyond special relationships to all persons.”).

<sup>152</sup> Murphy, *supra* note 106, at 653 (“[O]verall well-being is best promoted through the organized and coordinated efforts of well-trained people. This holds true for most



care—often referred to as duties—rest on a health professional’s assumption of obligations through entering a profession and taking on professional roles.”<sup>153</sup> Thus, the law imposes certain types of beneficent obligations on physicians towards their patients.<sup>154</sup>

In contrast to the limited role of beneficence in the law, the principle of non-maleficence forms a large part of the foundation for both civil and criminal liability in the United States.<sup>155</sup> For example, all intentional torts and their criminal counterparts prohibit individuals from intentionally causing harm to others.<sup>156</sup> The principle of non-maleficence not only requires that individuals abstain from inflicting harm, but also from imposing risks of harm.<sup>157</sup> From this idea derives the legal doctrine of negligence. Individuals are negligent when they fail to exercise the level of care that a reasonable or prudent person would exercise in the same or similar circumstances.<sup>158</sup> This is not to say that an individual who imposes *any* risk of harm on another is negligent per se. The hypothetical reasonable or prudent person may impose risks of harm on others,

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emergency situations as well—that is why we have police forces and fire departments.” (footnote omitted)).

<sup>153</sup> BEAUCHAMP & CHILDRESS, *supra* note 95, at 205.

<sup>154</sup> Duties to treat, to protect confidential information, and to obtain informed consent are examples of such obligations. Beauchamp and Childress contend that patients should also owe beneficent obligations to their health care providers based on a theory of reciprocity. *Id.* at 213. They argue that a “reciprocity-based approach to beneficence” could be beneficial in overcoming the current shortage of donated organs. *Id.* at 214. “A reciprocity-based system would give preferential access to patients in need who previously agreed, some years earlier, to donate their own organs after their deaths.” *Id.* (“Some private organizations, including LifeSharers, have taken this approach, and in 2012 Israel became the first country to implement a reciprocity-based system.”). However, this model introduces issues of justice and fairness. *Id.* (explaining that this model introduces concerns about fairness in regards to transplant candidates who are not eligible to be donors or who are uninformed about organ donation, and raises questions about how much weight should be given to donor status versus medical need); *see infra* Part IV. Regardless, patients in the United States currently have no legal obligations of beneficence towards their physicians, and OPTN does not utilize a reciprocity-based system of organ allocation.

<sup>155</sup> The principle of non-maleficence directly correlates with an individual’s right to autonomy—the right to be free from unlawful interference with one’s person.

<sup>156</sup> *See, e.g.*, RESTATEMENT (SECOND) OF TORTS § 13 (AM. LAW INST. 1965) (“An actor is subject to liability to another for battery if . . . he acts intending to cause a harmful or offensive contact . . . .”); MODEL PENAL CODE § 211.1 (AM. LAW INST. 1985) (defining simple assault to include purposely or knowingly causing bodily injury to another).

<sup>157</sup> BEAUCHAMP & CHILDRESS, *supra* note 95, at 154.

<sup>158</sup> Generally, medical practitioners are liable for negligence if they fail to follow the customary standard of care in their field. *See* Philip G. Peters, Jr., *The Role of the Jury in Modern Malpractice Law*, 87 IOWA L. REV. 909, 911-13 (2002). However, some jurisdictions adopt a reasonable doctor standard. *Id.* (explaining that in reasonable physician jurisdictions “the jury decides whether the physician behaved reasonably, not whether she complied with custom”).

but only if “the goals pursued justify the risks that must be imposed to achieve those goals.”<sup>159</sup>

Applied to organ transplantation, the principle of non-maleficence manifested through negligence law may sanction the imposition of more serious risks of harm on patients depending on the gravity of the emergency and/or the goals to be achieved.<sup>160</sup> Balancing obligations of beneficence and non-maleficence is necessary to apply the HOPE Act to HIV-positive individuals in the most beneficial, utilitarian way possible.

### C. *Justice*

At its most fundamental level, the principal aim of the law is to bring about justice for a nation’s citizens, though this aim is not always achieved. According to the UNOS ethics committee, “justice refers to the fair pattern of distribution of benefits.”<sup>161</sup> In the context of organ transplantation, the principle of justice seeks to ensure “fairness in the . . . distribution of the benefits and burdens of an organ procurement and allocation program” by providing equitable access to organ transplants and equitable distribution of donated organs.<sup>162</sup> However, the ethics committee states that justice does not require treating all patients the same, but simply requires giving all patients equal respect and concern.<sup>163</sup>

In contrast to the principle of utility, justice requires that an organ allocation policy consider both medical benefit *and* medical need, even if sicker patients with worse outcomes receive priority.<sup>164</sup> To ensure the fair treatment of potential organ recipients, the ethics committee specifies five factors that should be included in a just organ allocation policy: “1) medical urgency; 2) likelihood of finding a suitable organ in the future; 3) waiting time; 4) first versus repeat transplants; and 5) age.”<sup>165</sup>

Beauchamp and Childress address the principle of justice primarily in terms of distributive justice, or the “fair, equitable, and appropriate distribution of

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<sup>159</sup> BEAUCHAMP & CHILDRESS, *supra* note 95, at 154-55 (“Serious emergencies justify risks that many nonemergency situations do not justify. For example, attempting to save lives after a major accident justifies . . . the dangers created by rapidly moving emergency vehicles.”).

<sup>160</sup> In the context of HIV-positive organ transplantation, such a theory may sanction the transplantation of HIV-positive organs into individuals who are HIV-negative in extreme emergency situations. For a more in-depth discussion of this idea, see *infra* Section IV.D.

<sup>161</sup> OPTN/UNOS Ethics Comm., *supra* note 27.

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

<sup>163</sup> *Id.*

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

<sup>165</sup> *Id.* Notably, the ethics committee does not place significant weight on whether a patient is a first-time or repeat transplant candidate. See VEATCH & ROSS, *supra* note 32, at 327-28.

benefits and burdens.”<sup>166</sup> This formal principle of justice rests on the notion that equals must be treated equally, but provides no mechanism for determining which individuals are equals or in what manner they are to be treated equally.<sup>167</sup> To fill in this gap, Beauchamp and Childress present six general theories of distributive justice, focusing primarily on egalitarian as well as utilitarian theories.<sup>168</sup>

Like the principle of utility, utilitarian theories propound that the aim of justice is to “produce the maximal balance of positive value over disvalue,” otherwise known as the maximization of public utility or welfare.<sup>169</sup> Although utilitarian theories of justice are problematic, they are particularly useful in forming public health policies founded on risk-benefit comparisons.<sup>170</sup> Arguably the most important theory of justice, egalitarianism prioritizes “equal access to the goods in life that every rational person values, often invoking material criteria of need and equality.”<sup>171</sup> Interestingly, egalitarianism still supports the existence of inequalities so long as the inequalities benefit everyone, and everyone has a “fair equality of opportunity.”<sup>172</sup> This egalitarian idea of fair opportunity forms an important basis for thinking about principles of justice and antidiscrimination.

A fundamental tenet of justice and the rule of fair opportunity is that individuals generally cannot be discriminated against on the basis of “gender, race, IQ, linguistic accent, ethnicity, national origin, and social status.”<sup>173</sup> Because individuals are not responsible for these characteristics, basing any general theory of distribution on them is unjust and discriminatory.<sup>174</sup> The rule of fair opportunity can also be used as a means of redress, mandating that individuals who non-voluntarily possess disadvantageous properties, whether acquired through the “natural lottery” or the “social lottery,” receive

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<sup>166</sup> BEAUCHAMP & CHILDRESS, *supra* note 95, at 250.

<sup>167</sup> *Id.*

<sup>168</sup> *Id.* at 252-54, 262, 292 (utilitarian, libertarian, communitarian, egalitarian, capabilities, and well-being). There are many different approaches to and theories of justice, such as social justice, racial justice, environmental justice, etc. For a brief introduction to different conceptions of justice in a health policy context see MADISON POWERS & RUTH FADEN, *SOCIAL JUSTICE: THE MORAL FOUNDATIONS OF PUBLIC HEALTH AND HEALTH POLICY* 3-6 (2006).

<sup>169</sup> BEAUCHAMP & CHILDRESS, *supra* note 95, at 254.

<sup>170</sup> *See id.* at 254-55 (explaining that utilitarian theories of justice are problematic because they ground individuals’ rights on social arrangements whose purpose is to maximize an ever-changing balance of social utility).

<sup>171</sup> *Id.* at 252, 254, 256-57.

<sup>172</sup> *Id.* at 256-57.

<sup>173</sup> *Id.* at 262; *see infra* note 199. Notably absent from this list are sexual orientation, gender identity, and class, though the authors’ inclusion of gender and social status may suggest that their conception of morally irrelevant properties includes these characteristics as well.

<sup>174</sup> BEAUCHAMP & CHILDRESS, *supra* note 95, at 252.

compensation to overcome these disadvantages.<sup>175</sup> In the context of health care, this theory maintains that “[i]nstead of permitting broad inequalities in access to health care and quality of care—based on employer contributions, wealth, and the like—justice is achieved only if opportunity-reducing inequalities are first addressed.”<sup>176</sup> Because Beauchamp and Childress maintain that society cannot endlessly compensate individuals for these inequalities, however, they provide the principle of utility as a counter against which the rule of fair opportunity can be weighed.<sup>177</sup>

When rationing scarce health care resources such as organs, Beauchamp and Childress advocate policies that combine utilitarian and egalitarian theories of justice.<sup>178</sup> The authors recommend a two-tiered system of standards for distribution: “(1) criteria and procedures to determine a qualifying pool of potential recipients, such as patients eligible for heart transplantation; and (2) criteria and procedures for final selection of recipients, such as the patient to receive a particular heart.”<sup>179</sup>

The two relevant factors for determining a qualifying pool of potential organ recipients are constituency and prospect of success. Constituency criteria determine eligibility based on controversial social factors, including clientele boundaries, geographic or jurisdictional boundaries, and ability to pay.<sup>180</sup> Society often endorses these criteria as a means to promote justice—for example, Veterans Affairs centers can justly exclude non-veterans.<sup>181</sup> The second factor, prospect of success, utilizes medical criteria and utilitarian theory to conclude that only patients who have a reasonable chance of benefiting from a scarce medical resource should be eligible to receive that resource.<sup>182</sup> Although consideration of a transplant’s prospect of success may result in organs going to patients with less medical urgency, the authors contend that allocating organs to patients who are “virtually certain to die” even if they receive an organ is unjust, wasteful, and inefficient.<sup>183</sup>

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<sup>175</sup> *Id.* at 263-64 (“‘Natural lottery’ refers to the distribution of advantageous and disadvantageous genetic properties, and ‘social lottery’ refers to the distribution of assets or deficits through family property, school systems, tribal affiliation, government agencies, and the like.”).

<sup>176</sup> *Id.* at 264.

<sup>177</sup> *Id.* at 254, 264 (stating that “a strict fair-opportunity rule is overly demanding” and that “limited resources will constrain the implementation of this rule”).

<sup>178</sup> *Id.* at 288.

<sup>179</sup> *Id.*

<sup>180</sup> *Id.* at 288-93 (“These criteria are entirely nonmedical, and they involve moral judgments that often are not impartial, such as excluding noncitizens or including only veterans.”).

<sup>181</sup> *Id.* at 288. In addition to the jurisdictional boundary of citizenship, the use of geographical boundaries in organ allocation policy can sometimes be just if permitting allocation outside a specified geographic area would unjustly waste the organ.

<sup>182</sup> *Id.* at 289.

<sup>183</sup> *Id.*

The three relevant factors for final selection of recipients are medical utility, impersonal mechanisms of queuing, and social utility.<sup>184</sup> Again, medical utility derives from a utilitarian theory of justice and attempts to maximize the number of lives saved through consideration of patients' prospects of success.<sup>185</sup> Even though the authors state that allocation policies must consider medical utility, they recognize that prospect of success may come into conflict with medical need/urgency and, consequently, that medical utility is not the only relevant consideration.<sup>186</sup>

In conjunction with considerations of medical utility, acceptable organ allocation policies may also use impersonal mechanisms of queuing.<sup>187</sup> If the medical utility is the same for all patients in need of an organ transplant, "then considerations of fair opportunity and equal respect may justify . . . queuing."<sup>188</sup> However, problems arise with queuing, or "first come, first served" systems, when certain individuals' access to the queue is inhibited due to low-quality medical care, delayed referrals, discrimination, or differences in education and resources.<sup>189</sup>

The last and arguably most controversial factor in selecting final organ recipients is social utility—the value an individual contributes to society. "An argument in favor of social-utilitarian selection is that medical institutions and personnel are trustees of society and must consider the probable future contributions of patients."<sup>190</sup> Beauchamp and Childress do not accept this argument, and instead maintain that allowing considerations of social utility would impermissibly threaten the patient-physician relationship.<sup>191</sup> The authors argue that specific considerations of social value are acceptable "in rare and exceptional cases involving persons of critical social importance."<sup>192</sup> For example, in the case of a disaster affecting both medical personnel and lay individuals, it would be justifiable to treat the medical personnel first because they could then help the others.<sup>193</sup> Such narrow considerations of social worth

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<sup>184</sup> *Id.* at 289-91.

<sup>185</sup> *Id.* at 289.

<sup>186</sup> *Id.* at 290.

<sup>187</sup> *Id.* at 290-91.

<sup>188</sup> *Id.*

<sup>189</sup> *Id.* at 291 ("A system is unfair if some people gain an advantage in access over others because they are better educated, are better connected, or have more money for frequent visits to physicians."). For a discussion of how these factors affect the access of racial minorities and individuals with HIV to transplant waitlists, see *supra* notes 89-95, 99 and accompanying text.

<sup>190</sup> BEAUCHAMP & CHILDRESS, *supra* note 95, at 291.

<sup>191</sup> *Id.* ("[I]n general we need to protect the relationship of personal care and trust between patients and physicians, and it would be threatened if physicians were trained to look beyond their patients' need to society's need.")

<sup>192</sup> *Id.*

<sup>193</sup> *Id.* at 292.

must be limited to these unique situations in which the social criteria prioritize individuals whose “contribution[s] [are] indispensable to attaining a major social goal.”<sup>194</sup>

Although Beauchamp and Childress incorporate utilitarian theory within their conception of justice, their approach is still consonant with the UNOS ethics committee’s overall consideration of both utility and justice, of medical benefit and medical need, in setting allocation policy. However, the two approaches to justice differ most significantly in their willingness to consider social worth. While Beauchamp and Childress concede that allocations based on social utility may be permissible, albeit narrowly and presumably in emergency situations only,<sup>195</sup> the UNOS ethics committee states that an individual’s social usefulness should never be considered.<sup>196</sup>

In its broadest sense, the principle of justice can be found in the Fourteenth Amendment, which entitles all persons to due process of law and equal protection of the laws of the United States.<sup>197</sup> By attempting to guarantee that all persons receive equal treatment and protection under the law, the Due Process Clause and the Equal Protection Clause reflect egalitarian notions of fairness and equality. However, these broad rights do little to develop more specific principles of distributive justice, such as fair equality of opportunity. The laws that best reflect the principles of distributive justice are those that prohibit discrimination and provide benefits in an attempt to reduce social and economic inequalities.<sup>198</sup>

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<sup>194</sup> *Id.*

<sup>195</sup> I say “presumably” because of the absence of a reference to an emergency situation in the following quote: “It is also legitimate to invoke narrow considerations of social utility to give priority to individuals who fill social roles that are essential in achieving a better overall outcome.” *Id.*

<sup>196</sup> OPTN/UNOS Ethics Comm., *supra* note 27.

<sup>197</sup> U.S. CONST. amend. XIV, § 1. The principle of justice can also be seen in the Fifth Amendment’s Due Process Clause, inasmuch as it has been interpreted to incorporate the Fourteenth Amendment’s equal protection obligation. *See id.* amend. V.

<sup>198</sup> This Note focuses on how the distributive justice principle is embodied in antidiscrimination laws specifically, and their role in producing the best ethical and legal implementation of the HOPE Act. For a general discussion of how one philosopher’s theory of distributive justice bears on the recognition of legal “welfare rights,” see Frank I. Michelman, *In Pursuit of Constitutional Welfare Rights: One View of Rawl’s Theory of Justice*, 121 U. PA. L. REV. 962 (1973). Aside from Medicare’s End-Stage Renal Disease (“ESRD”) program—which covers dialysis treatments and transplants for individuals with kidney failure—no other government program is required to provide benefits specific to organ transplantation. *See Wong, supra* note 92, at 546-48. This Note does not explore whether government-sponsored health insurance programs’ coverage of organ transplants is adequate. For a discussion of the intersection of insurance and organ transplantation, see *id.* Finally, a general discussion of whether additional government benefits should be provided in the organ transplantation context is beyond the scope of this Note.

Antidiscrimination laws attempt to effectuate the principles of distributive justice and fair opportunity by making discrimination against people on the basis of “morally irrelevant propert[ies]” unlawful.<sup>199</sup> In various contexts, such as employment, education, health care, and public accommodations, numerous federal and state laws prohibit discrimination on the basis of race, gender, age, and disability status, among other categories. In regards to organ transplantation, the two most relevant antidiscrimination statutes are the Americans with Disabilities Act of 1990<sup>200</sup> (“ADA”) and the Affordable Care Act<sup>201</sup> (“ACA”).

The ADA defines disability as a “physical or mental impairment that substantially limits one or more major life activities,” including major bodily functions such as functions of the immune system.<sup>202</sup> This definition of disability covers HIV-positive individuals, whether symptomatic or asymptomatic.<sup>203</sup> Under the ADA, transplant hospitals and OPOs are prohibited from discriminating against disabled individuals by denying them participation, affording them unequal participation, or providing them with a different or separate benefit “unless such action is necessary to provide the individual . . . with a good, service, facility, privilege, advantage, or accommodation, or other opportunity that is as effective as that provided to others.”<sup>204</sup> More specifically, the ADA prohibits “the imposition or application

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<sup>199</sup> BEAUCHAMP & CHILDRESS, *supra* note 95, at 252. In *UAW v. Johnson Controls, Inc.*, 499 U.S. 187 (1991), Johnson Controls had adopted a fetal protection policy, which excluded fertile women from jobs involving lead exposure because of the risk to the women’s potential unborn children. *Id.* at 192. Johnson Controls did not extend the policy to its male employees despite scientific evidence that lead exposure also damaged male reproduction. *Id.* at 198. The Supreme Court held that Johnson Controls’s fetal-protection policy was facially discriminatory and constituted unlawful sex discrimination under Title VII of the Civil Rights Act because sex was not a bona fide occupational qualification. *Id.* at 199-200, 206; *see also* BEAUCHAMP & CHILDRESS, *supra* note 95, at 252 (explaining that the Supreme Court in *Johnson* “revise[d] entrenched notions about morally relevant properties” by finding that Johnson Controls’s policy “unfairly discriminate[d] based on the morally irrelevant property of gender”).

<sup>200</sup> Pub. L. No. 101-336, 104 Stat. 327 (codified as amended in scattered sections of 42 and 47 U.S.C.).

<sup>201</sup> Pub. L. No. 111-148, 124 Stat. 199 (2010) (codified as amended in scattered sections of the U.S.C.).

<sup>202</sup> 42 U.S.C. § 12102(1) (2012); U.S. DEP’T OF JUSTICE, QUESTIONS AND ANSWERS: THE AMERICANS WITH DISABILITIES ACT AND PERSONS WITH HIV/AIDS 1 (2012), [http://www.ada.gov/aids/ada\\_q&a\\_aids.pdf](http://www.ada.gov/aids/ada_q&a_aids.pdf) [<http://perma.cc/V6ST-W2RT>] [hereinafter *ADA Questions and Answers*].

<sup>203</sup> *ADA Questions and Answers*, *supra* note 202.

<sup>204</sup> 42 U.S.C. § 12182 (governing discrimination in public accommodations and services operated by private entities). Hospitals that are associated with a state government or university may also be subject to Title II of the ADA, governing public entities. *See id.* §§ 12131-34. UNOS, as a recipient of federal financial assistance, would also be subject to these same prohibitions under section 504 of the Rehabilitation Act of 1973. *See* 29 U.S.C.

of eligibility criteria that screen out or tend to screen out an individual with a disability . . . unless such criteria can be shown to be necessary.”<sup>205</sup> However, the ADA does not prohibit hospitals from classifying or administering risk—e.g., assessing the risk that a transplant candidate will not substantially benefit from an organ and using that assessment in the transplant determination.<sup>206</sup>

In addition to the ADA, the ACA makes it illegal for any health program that receives federal financial assistance to discriminate against individuals on the basis of race, color, national origin, sex, sex stereotypes, gender identity, age, or disability.<sup>207</sup> An organ allocation system under the HOPE Act must comply with these antidiscrimination statutes by law, but also, in doing so, the system has the potential to combat broader issues of distributive justice by reducing the discrimination faced by HIV-positive patients.

#### IV. IMPLEMENTING THE HOPE ACT

During the initial research phase of the HOPE Act, HIV-positive patients will have to consent to participation in a research protocol and the receipt of an HIV-positive organ.<sup>208</sup> If HIV-positive-to-HIV-positive transplantation is implemented following the research phase, some scholars presuppose that

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§ 794 (2012); JONES, *supra* note 28, at 17 (“Title II of the ADA would apply to policies implemented by states and localities and . . . ADA Title III would apply to private entities, such as hospitals, whereas Section 504 would cover recipients of federal financial assistance, federal executive agencies, and the U.S. Postal Service.”); *see also Facts and Figures*, UNITED NETWORK FOR ORGAN SHARING 1 (2015), [https://www.unos.org/wp-content/uploads/unos/UNOS\\_FactsFigures.pdf](https://www.unos.org/wp-content/uploads/unos/UNOS_FactsFigures.pdf) [<https://perma.cc/57CE-AYQW>] (“About six percent of UNOS’ funding is derived directly from its federal contract.”).

<sup>205</sup> 42 U.S.C. § 12182(b)(2)(A)(i).

<sup>206</sup> *Id.* § 12201(c)(1); *see Orentlicher, supra* note 28, at 57.

<sup>207</sup> 42 U.S.C. § 18116(a) (“[A]n individual shall not . . . 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 . . . .”); *Nondiscrimination Protection in the Affordable Care Act: Section 1557*, NAT’L WOMEN’S LAW CTR. (Sept. 3, 2015), <http://www.nwlc.org/resource/nondiscrimination-protection-affordable-care-act-section-1557> [<http://perma.cc/UB69-APWB>]. Hospitals receive substantial federal financial assistance, most notably in the form of Medicare and Medicaid payments, UNOS receives federal funding to run OPTN, *see supra* note 204, and NOTA provides for federal grants to OPOs, 42 U.S.C. § 273. The ACA’s prohibition of discrimination on the basis of disability derives from section 504 of the Rehabilitation Act of 1973, under which HIV and AIDS qualify as disabilities. Office for Civil Rights, *Know the Rights that Protect Individuals with Disabilities from Discrimination*, U.S. DEP’T OF HEALTH & HUMAN SERVS., <http://www.hhs.gov/sites/default/files/knownyourrights504adafactsheet.pdf> [<http://perma.cc/7T7S-6RVT>]. Furthermore, HHS recently proposed a rule that would require the standards under the ACA to provide, at minimum, the same level of protection as the standards under section 504. *Nondiscrimination in Health Programs and Activities*, 80 Fed. Reg. 54,172 (proposed Sept. 8, 2015).

<sup>208</sup> *See supra* note 49 and accompanying text.



HIV-positive patients will still have access to HIV-negative organs and will have the choice to accept HIV-positive organs as well.<sup>209</sup> While an analogous situation exists for organ transplant candidates with HCV—they can receive HCV-negative organs and have the option to accept HCV-positive organs as well<sup>210</sup>—nothing in the HOPE Act or accompanying regulations mandates this conclusion in the case of HIV-positive patients. Before assuming that this choice will exist, we must examine the legal and ethical prescriptions surrounding HIV-positive patients' access to both types of organs. Without such an inquiry, the scholarship fails to engage in a critical conversation about the endemic discrimination faced by the HIV-positive population and risks overlooking the concerns of HIV-positive patients (at the potential cost of creating a regulatory scheme antithetical to their interests).

After applying the legal and ethical framework laid out above, I conclude that HIV-positive patients must be given the choice to accept HIV-positive and/or HIV-negative organs, and explore whether, in unique circumstances, HIV-negative patients should be allowed to receive HIV-positive organs.

#### A. *Autonomy*

The principle of autonomy mandates that HIV-positive patients have access to both HIV-positive and HIV-negative organs. Individuals have freedom to make medical decisions regarding their own body. Accordingly, HIV-positive patients ought to have the right to make autonomous, informed medical decisions regarding whether they are willing to accept HIV-negative organs only, or both HIV-positive and HIV-negative organs.<sup>211</sup> Because HIV-positive patients can currently receive HIV-negative organs from OPTN's organ registries, and because there may be additional risks associated with accepting an HIV-positive organ,<sup>212</sup> it would violate HIV-positive patients' right of autonomous choice if UNOS attempted to prohibit them from receiving HIV-negative organs.<sup>213</sup> An integral part of patients' right to autonomous choice is

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<sup>209</sup> *E.g.*, Mgbako et al., *supra* note 130, at 1638.

<sup>210</sup> *See* VEATCH & ROSS, *supra* note 32, at 216.

<sup>211</sup> In the spirit of autonomous medical decision-making, HIV-positive patients could potentially *choose* to accept HIV-positive organs only. This Note does not analyze the availability or implications of this choice, however.

<sup>212</sup> Some potential risks of HIV-positive-to-HIV-positive transplantation include the possibility of acquiring an antiviral-resistant HIV strain or opportunistic infection, and a potentially higher rate of organ rejection. Mgbako et al., *supra* note 130, at 1639 tbl.2. Acquisition of an antiviral-resistant HIV strain could accelerate the progression of a patient's HIV to AIDS. Boyarsky et al., *supra* note 35, at 1213-14.

<sup>213</sup> Because the risks associated with accepting an HIV-positive organ will vary from patient to patient and from organ to organ, it is particularly necessary that UNOS give HIV-positive patients the right to choose between HIV-positive and HIV-negative organs. *See* Mgbako et al., *supra* note 130, at 1637, 1641. This is consistent with the UNOS ethics committee's requirement that each patient "be assessed individually." OPTN/UNOS Ethics Comm., *supra* note 27.

their right to refuse treatment.<sup>214</sup> Therefore, because HIV-positive patients must have the option to refuse HIV-positive organs, they must retain their right to receive transplants of HIV-negative organs.<sup>215</sup>

Currently, physicians recommending transplantation to HIV-positive patients have a duty to inform them of the option to be listed on an OPTN organ registry and receive HIV-negative organs. Consequently, if physicians attempted to deny HIV-positive patients access to HIV-negative organs following the legalization of HIV-positive-to-HIV-positive transplantation, they could be liable in tort for failing to disclose that HIV-negative organs are available and potentially safer for transplantation. A physician could be tortiously liable for this type of failure to disclose regardless of whether the physician is in a jurisdiction that employs a professional practice standard or a reasonable patient standard.<sup>216</sup> Although the law does not focus on the nature of patients' understanding in determining whether a doctor violated informed consent requirements, it is particularly essential that doctors ensure that HIV-positive patients understand the risks attendant to accepting an HIV-positive organ due to the unique vulnerability of the HIV-positive community.<sup>217</sup>

Further, HIV-negative individuals should have the right to direct the donation of their organs to HIV-positive transplant candidates. The UNOS

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<sup>214</sup> See *supra* notes 125-28 and accompanying text.

<sup>215</sup> See *supra* note 110 and accompanying text.

<sup>216</sup> In a reasonable patient jurisdiction, doctors would most certainly be required to inform HIV-positive patients about the availability of HIV-negative organs because a reasonable patient would find this information material. See *supra* note 123 and accompanying text. Further, because the current custom is for physicians to inform HIV-positive patients of the option to be listed on OPTN's HIV-negative organ waitlists, physicians would likely be required to disclose this information to HIV-positive transplant candidates in professional practice jurisdictions as well. See *supra* note 122 and accompanying text. However, if transplant physicians at large chose not to inform HIV-positive patients about the availability of HIV-negative organs following the legalization of HIV-positive-to-HIV-positive transplantation, then physicians in professional practice jurisdictions might not be liable for failing to disclose this information.

<sup>217</sup> See BEAUCHAMP & CHILDRESS, *supra* note 95, at 138 (“[D]ebilitating disease, psychiatric disorders, and drug addiction can also diminish or destroy voluntariness, thereby precluding autonomous choice and action.”). HIV can be a debilitating disease, and psychiatric disorders and drug addiction are prevalent among the HIV-positive population. See *HIV/AIDS and Drug Abuse: Intertwined Epidemics*, NAT’L INST. ON DRUG ABUSE: DRUG FACTS, <http://www.drugabuse.gov/publications/drugfacts/hivaids-drug-abuse-intertwined-epidemics> [https://perma.cc/6FNQ-DDJU]. The fact that HIV-positive patients generally have lower levels of education compared to the HIV-negative population, see Sawinski et al., *supra* note 2, at 1470, coupled with the fact that education plays a role in comprehension during the informed consent process, Cordasco, *supra* note 90, at 463, also adds to the concerns surrounding voluntariness and informed consent when it comes to the HIV-positive population. Furthermore, independent of education, age, and health literacy, “minority race or ethnicity may be an independent risk factor for having lower levels of comprehension in the informed consent process.” Cordasco, *supra* note 90, at 464.

ethics committee's prescription that autonomy as applied to organ transplantation requires free exchanges among autonomous individuals contemplates these types of directed donations in the HIV-positive transplantation context.<sup>218</sup> A policy whereby HIV-positive patients could only receive HIV-positive organs would interfere with the right of HIV-negative individuals to donate their organs to a person of their choosing and could potentially violate UAGA.<sup>219</sup> Likewise, such a restriction would contradict UNOS's living donation policy.<sup>220</sup> Therefore, the principle of autonomy supports HIV-positive patients having access to both HIV-positive and HIV-negative organs.

B. *Utility; Beneficence and Non-Maleficence*

Although there exists no legal obligation of general beneficence, allowing HIV-positive patients to receive both HIV-positive and HIV-negative organs would benefit all organ transplant recipients and could maximize utility in that regard. First, allowing HIV-positive patients to access both types of organs would reduce their waiting time and consequently increase their survival rates.<sup>221</sup> Second, HIV-positive patients' acceptance of HIV-positive organs would shorten the wait time for HIV-negative transplant candidates as well because those patients who accepted HIV-positive organs would be removed from HIV-negative organ waitlists.<sup>222</sup> Therefore, allowing HIV-positive patients to receive both HIV-positive and HIV-negative organs would create a great amount of good for all organ transplant candidates and would help physicians "do good" for their patients.

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<sup>218</sup> See *supra* note 110 and accompanying text.

<sup>219</sup> See *supra* note 130 and accompanying text. By itself, the principle of autonomy would also likely support allowing HIV-positive patients to direct the donation of their organs to HIV-negative patients. See *infra* Section IV.D. Whether prohibiting this type of directed donation would violate UAGA is a question for future scholarship.

<sup>220</sup> See *supra* note 129 and accompanying text.

<sup>221</sup> See *supra* note 38 and accompanying text; cf. Boyarsky et al., *supra* note 35, at 1214 ("This practice [of transplanting HCV-positive organs into HCV-positive recipients] has substantially shortened time on the waiting list for these recipients without significantly compromising patient or graft survival."); Mgbako et al., *supra* note 130, at 1640 ("The use of HCV+ organs has enabled HCV+ renal transplant candidates to shorten waiting time and to improve survival compared to waiting longer for an HCV-negative organ . . ."). This is true for all HIV-positive patients, regardless of whether they are willing to receive HIV-positive organs. If an HIV-positive patient is willing to accept HIV-positive organs in addition to HIV-negative organs, her wait time will likely be shortened because she will have access to more organs. Boyarsky et al., *supra* note 35, at 1214-15. Even if an HIV-positive patient is not willing to accept HIV-positive organs, her wait time will likely still be shortened because those HIV-positive patients who do accept HIV-positive organs will be taken off the HIV-negative organ waitlist.

<sup>222</sup> Boyarsky et al., *supra* note 35, at 1215.

If the benefits of shortened wait times outweigh any potential harms from providing HIV-positive patients access to both types of organs, the principle of utility would support such dual access. However, utilitarian theories of medical benefit and prospect of success could favor restricting HIV-positive patients to HIV-positive organs only. Although many physicians believed that compared to HIV-negative recipients, HIV-positive patients would have poorer life expectancy after transplantation with HIV-negative organs,<sup>223</sup> this has not proven to be the case.<sup>224</sup> Yet, several studies have found that organ transplant recipients who are HIV-positive experience higher organ rejection rates than HIV-negative recipients.<sup>225</sup> Furthermore, black transplant recipients generally experience worse outcomes than recipients of any other race.<sup>226</sup> Based on these statistics, utilitarians might argue that allowing HIV-positive patients, particularly black HIV-positive patients, to receive HIV-negative organs is wasteful, inefficient, and not in the best interests of society.

Additionally, even though the UNOS ethics committee specifies that a utilitarian allocation policy should not consider generalized variations in outcome among social groups, the committee explains that physicians may consider objective medical criteria in making allocation decisions, even if these criteria are not evenly distributed among social groups.<sup>227</sup> This statement

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<sup>223</sup> One study conducted in 1997 found that the majority of kidney transplant centers in the United States “would not transplant a kidney . . . into an asymptomatic HIV-infected patient who is otherwise a good candidate for transplantation” based on concerns about poor outcomes in HIV-infected transplant candidates. Aaron Spital, *Should All Human Immunodeficiency Virus-Infected Patients with End-Stage Renal Disease Be Excluded from Transplantation?: The Views of U.S. Transplant Centers*, 65 *TRANSPLANTATION* 1187, 1187 (1998).

<sup>224</sup> Mgbako et al., *supra* note 130, at 1636 (describing various studies findings that HIV-positive kidney and liver transplant recipients had survival rates similar to those of HIV-negative patients).

<sup>225</sup> Peter G. Stock et al., *Outcomes of Kidney Transplantation in HIV-Infected Recipients*, 363 *NEW ENG. J. MED.* 2004, 2012 (2010) (explaining that HIV-positive kidney recipients experienced “unexpectedly higher rejection rates (by a factor of 2 to 3) . . . as compared with recipients who did not have HIV infection”); Alan Taege, *Organ Transplantation and HIV Progress or Success? A Review of Current Status*, 15 *CURRENT INFECTIOUS DISEASE REPS.* 67, 70, 72-73 (2013) (finding that “[o]ne-year graft survival was lower (87.9% vs. 94.6%)” for HIV-positive recipients compared to HIV-negative recipients).

<sup>226</sup> Satheesh Nair et al., *Effect of Race on Outcome of Orthotopic Liver Transplantation: A Cohort Study*, 359 *LANCET* 287, 287, 292 (2002) (explaining that black liver transplant recipients have worse survival rates and higher rates of chronic rejection than whites and Hispanics); Carlton J. Young & Robert S. Gaston, *Renal Transplantation in Black Americans*, 343 *NEW ENG. J. MED.* 1545, 1549 (2000) (“After receiving renal transplants, black patients with end-stage renal disease fare substantially worse than whites or members of other minority groups . . .”).

<sup>227</sup> The committee mandates that patients be assessed “individually rather than merely by group membership in an attempt to reduce healthcare disparities related to social inequities.” OPTN/UNOS Ethics Comm., *supra* note 27. Although this “rule[s] out excluding individual

seems to allow physicians to couch decisions that are based on a person's membership in a certain social group, such as the HIV-positive, black, or MSM community, in a determination of "medical" utility. So long as physicians purported to exclude individual patients from HIV-negative organ registries due to "medical" characteristics that lead to higher organ rejection rates, the UNOS ethics committee's policy could favor allowing physicians to exclude HIV-positive patients from HIV-negative organ registries.

However, this conception of utility incorrectly excludes considerations of autonomy, beneficence, and justice. Utility is not the only relevant principle, and utilitarian considerations must be weighed against the harms to the other principles that would result if HIV-positive patients could not receive HIV-negative organs, particularly the harms to justice.<sup>228</sup> Also, while determining the allocation of organs based on prospect of success may seem inherently fair, often these "objective medical criteria" reflect discriminatory social biases, as demonstrated above.<sup>229</sup>

The principle of non-maleficence could also be seen as favoring the provision of HIV-negative organs to HIV-negative patients only. One could argue that because of HIV-positive patients' higher rates of organ rejection, giving HIV-negative organs to HIV-positive patients wastes vital organs and harms HIV-negative patients in need of an organ. However, providing an HIV-negative organ to an HIV-positive patient could only potentially harm HIV-negative patients indirectly by "wasting" the organ.

Because physicians certainly would not intend to cause this type of indirect harm to HIV-negative patients, their transplanting of HIV-negative organs into HIV-positive patients would not rise to the level of intentionally tortious conduct. Nonetheless, an HIV-negative plaintiff could argue that this type of conduct is negligent because a reasonable physician would ensure that no organs are wasted and, thus, would not provide HIV-negative organs to HIV-positive patients. Because of the indirect nature of the harm, however, it would be difficult for an HIV-negative plaintiff to prove causation absent a showing that the specific organ would have gone to the HIV-negative patient had the physician not transplanted it into the HIV-positive patient. Further, if the jurisdiction employed a custom-based standard, and if most transplant physicians provide HIV-negative organs to HIV-positive patients, the plaintiff may also have issues proving that the physician breached her duty of care.<sup>230</sup>

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members of a social group or giving them low priority simply because the group has statistically poorer outcomes," it does not "rule out the use of objective medical predictors of outcome . . . even if it is known that these factors are not randomly distributed among racial or gender groups." *Id.*; see *supra* notes 143-44 and accompanying text.

<sup>228</sup> See Orentlicher, *supra* note 28, at 53 ("[A] rationing system that allocates care on the basis of degree of benefit will often result in unfair discrimination against sicker patients or patients with more disabling conditions."); *supra* note 146 and accompanying text.

<sup>229</sup> See Orentlicher, *supra* note 28, at 51.

<sup>230</sup> See HALL ET AL., *supra* note 120, at 316; see also Sawinski et al., *supra* note 2, at 1470 ("[K]idney transplantation is likely to become standard of care in HIV-positive ESRD

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Ultimately, providing HIV-positive patients with an equal opportunity to receive organs and the choice of whether to accept potentially riskier HIV-positive organs is a goal that justifies the “harm” imposed on HIV-negative patients.

Similarly, non-maleficence would not condone forcing HIV-positive patients to accept the possible risks associated with HIV-positive organs if potentially safer HIV-negative organs are available. Because non-maleficence and negligence law may sanction the imposition of insubstantial and justifiable risks, however, one could argue that imposing this uncertain risk is justified based on the emergency shortage of donated organs. By limiting HIV-positive patients to HIV-positive organs, the argument would go, HIV-negative patients would have access to a larger supply of HIV-negative organs because they would no longer be competing with HIV-positive patients for these organs. Nonetheless, when viewed in conjunction with the principles of autonomy and justice, as well as with the vulnerable status of the HIV-positive population, this justification is not strong enough to impose *any* risk on HIV-positive patients without their consent. Therefore, the ethical principle of utility and its legal counterparts do not favor eliminating HIV-positive patients’ access to HIV-negative organs.

### C. *Justice*

The principle of justice favors allowing HIV-positive patients to receive HIV-positive and HIV-negative organs. Because HIV-positive patients face discrimination in accessing and receiving transplants,<sup>231</sup> giving them access to both types of organs has the potential to reduce the inequalities present in the current system by increasing the chances that they will receive an organ. Such a system will increase the availability of organs for HIV-positive patients and could thereby increase the speed with which they receive an organ, which, ultimately, would increase the likelihood that they actually receive an organ before they die awaiting a transplant.<sup>232</sup>

However, one aspect of justice that could favor restricting HIV-positive patients’ access is social value. Based on the stigma and misconceptions surrounding HIV—particularly the view that individuals are personally responsible for contracting AIDS—one might argue that HIV-positive patients are less socially valuable and should be restricted to receiving HIV-positive

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patients . . .”). The physician may also have an affirmative defense if he or she acted in accordance with OPTN allocation policies.

<sup>231</sup> See *supra* notes 99-101 and accompanying text.

<sup>232</sup> The comparable practice of allowing HCV-positive patients to accept both HCV-positive and HCV-negative organs has shortened their waiting times without adversely affecting their post-operative outcomes. See Boyarsky et al., *supra* note 35, at 1214.

organs only. However, the principle of justice and the UNOS ethics committee forbid such broad types of social status and value considerations.<sup>233</sup>

Further, such considerations may explicitly violate provisions of the ADA and ACA. If transplant hospitals only allowed HIV-positive patients to register for HIV-positive organs, they could be said to afford these patients unequal participation or a different and separate benefit in violation of the ADA, or to be discriminating against them on the basis of their disability in violation of the ACA. Likewise, the ADA and section 504 of the Rehabilitation Act prohibit transplant hospitals and UNOS, respectively, from imposing eligibility criteria that screen out individuals with HIV.<sup>234</sup> However, hospitals are allowed to assess and administer risk—i.e., determine the risk that an HIV-positive patient would receive less benefit from an HIV-negative organ than an HIV-negative patient.<sup>235</sup> Therefore, if HIV-positive organs were shown to be “as effective” as HIV-negative organs in treating HIV-positive patients, transplant hospitals could argue that restricting HIV-positive patients to HIV-positive organs is a necessary “separate benefit.”<sup>236</sup> Even though requiring a patient to be HIV-negative to receive an HIV-negative organ is an eligibility criterion that screens out HIV-positive patients, the hospital could argue that it is an allocation of risk necessary to the provision of HIV-negative organs.<sup>237</sup> However, these arguments may be seen as pretext to evade the ADA’s requirements, and thus may still violate the Act.<sup>238</sup>

A justice-based prospect of success argument could also be made in favor of limiting HIV-positive patients’ access to organs. However, this argument

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<sup>233</sup> See *supra* notes 190-94 and accompanying text. For another perspective, see VEATCH & ROSS, *supra* note 32, at 306-19 (“[I]f justice requires opportunities for equality, then those who voluntarily choose to engage in health-risky behaviors should be seen as having had an opportunity and should be placed in a somewhat subordinate position when it comes to allocating organs.”). Even under this perspective, the behaviors associated with the contraction of HIV may not qualify as voluntary health-risky behaviors that should be considered in organ allocation policy. See *id.* at 312-15 (explaining that the theory depends “upon whether there are significantly truly voluntary behaviors in which those who choose to participate can reasonably expect to understand the organ-threatening consequences of their behavior”).

<sup>234</sup> See Office for Civil Rights, *supra* note 207 (“[T]hose receiving HHS funding may not: . . . [a]pply eligibility criteria for participation in programs . . . that screen out or tend to screen out individuals with disabilities . . . .”); *supra* note 205.

<sup>235</sup> See *supra* note 206 and accompanying text; see also Whitehead, *supra* note 28, at 484.

<sup>236</sup> 42 U.S.C. § 12182 (2012); see Orentlicher, *supra* note 28, at 56-58.

<sup>237</sup> See Orentlicher, *supra* note 28, at 56-58.

<sup>238</sup> 42 U.S.C. § 12201(c). HIV-positive patients may easily be able to show that such risk allocations are merely pretext by pointing to the fact that post-transplant survival rates are generally lower among diabetics and HCV-positive patients, and that transplant hospitals have never restricted the access of these groups to HIV-negative organs. Halpern et al., *supra* note 101, at 1324.

suffers from the same flaws as the medical utility argument.<sup>239</sup> In addition, the UNOS ethics committee explicitly states that a just organ allocation system must consider both medical benefit and medical need.<sup>240</sup> While HIV-positive patients may have a slightly lower prospect of success in terms of higher organ rejection rates, they still have more than a reasonable chance of benefitting from the transplant. Because HIV-positive transplant candidates are more likely to die while waiting for an organ, their situation is also more medically urgent. Their increased need outweighs any minor decrease in medical benefit they may experience compared to HIV-negative patients. Therefore, justice supports granting HIV-positive patients access to both HIV-positive and HIV-negative organs in order to increase their chances of receiving an organ faster. This requirement of justice is consonant with the UNOS ethics committee's recognition that sicker patients with worse prognoses may receive priority.<sup>241</sup>

Three additional justice factors UNOS considers, however, are likelihood of finding a suitable organ in the future, waiting time, and whether a patient has already received a transplant.<sup>242</sup> In regard to the first factor, one could argue that with the implementation of HIV-positive donation, HIV-positive candidates are more likely to find a suitable organ in the future because they have more organs available to them.<sup>243</sup> Although the exact number of HIV-positive patients awaiting a transplant is unknown, the potential HIV-positive donor pool (if estimates are correct) is much larger than the number of HIV-positive organ recipients.<sup>244</sup> Second, because HIV-positive patients are more likely to die while awaiting a transplant, they are less likely to accumulate a significant amount of time on an organ waitlist. Finally, the higher rejection rates among HIV-positive patients could mean that they are more likely to need repeat transplants. The combination of these factors could favor excluding HIV-positive patients from HIV-negative organ registries because: (1) they have a sufficient pool of HIV-positive organs, (2) they likely have accumulated less waiting time than HIV-negative patients, and (3) they should

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<sup>239</sup> See *supra* notes 228-29 and accompanying text.

<sup>240</sup> See *supra* notes 164-65 and accompanying text.

<sup>241</sup> See *supra* note 164.

<sup>242</sup> See *supra* note 165.

<sup>243</sup> Although an increase in *the number of organs* available to an HIV-positive patient depends on the presumption that the patient would be willing to accept an HIV-positive organ, the availability of organs generally will increase for all patients regardless of which organs they are willing to accept. See *supra* notes 221-222.

<sup>244</sup> Compare *OPTN Proposal*, *supra* note 36, at 1 (stating that 137 HIV-positive patients received transplants in 2013), with Boyarsky et al., *supra* note 35, at 1209 (estimating a pool of 500 to 600 potential HIV-positive donors). The number of HIV-positive organ recipients may not be a completely accurate reflection of the pool of HIV-positive patients in need of a transplant, however, because it may reflect the discrimination against HIV-positive patients in accessing the waitlist and receiving organs.



not waste the limited supply of HIV-negative organs through their potentially increased need for multiple transplants.<sup>245</sup>

Perhaps most importantly though, because all organ allocation policies consider the amount of time a patient has spent on the waitlist, and because the HIV-positive population and its main subpopulations—MSM and black people—experience discrimination in accessing these waitlists, providing HIV-positive patients access to a larger supply of organs begins to remedy the problems with queuing and unfair equality of opportunity. In the first instance, allowing HIV-positive-to-HIV-positive transplantation provides HIV-positive candidates with a greater likelihood of receiving an organ because they do not have to compete with HIV-negative patients for HIV-positive organs—patients who, collectively, have better access to organ registries. In this way, separate HIV-positive organ waitlists are free of the queuing problem that arises on current UNOS waitlists due to HIV-positive patients' unequal access.<sup>246</sup> Expanding the potential donation pool to include HIV-positive as well as HIV-negative organs is further necessary to remedy HIV-positive patients unequal access by providing them with the greatest opportunity to receive organs.

However, the existence of a separate organ registry for HIV-positive patients does not resolve the potential for unequal access *among* HIV-positive patients. It may well be the case that disadvantaged sexual and racial minorities will still have diminished access to and a decreased likelihood of being placed on HIV-positive organ waitlists compared to other HIV-positive patients.<sup>247</sup> Furthermore, one could argue that merely allowing access to both lists does not do enough to address the pervasive discrimination and inequality of opportunity faced by the HIV-positive population. Additional efforts may be needed to address this problem, such as consideration of race and social status as prioritizing factors on all waitlists.<sup>248</sup> While giving HIV-positive patients the option to accept HIV-positive and/or HIV-negative organs therefore does not provide a complete remedy to the discrimination they face in accessing and receiving organs, it certainly provides a needed step in the right direction.

Preventing HIV-positive patients from receiving HIV-negative organs could also exacerbate the stigma surrounding HIV, race, and sexual orientation. Such a restriction would treat HIV-positive patients differently from HIV-negative patients and could create a perception of HIV-positive patients as inferior and only deserving of HIV-positive organs. Treating HIV-positive patients equally

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<sup>245</sup> *But see supra* note 165.

<sup>246</sup> *See supra* note 189.

<sup>247</sup> *See supra* notes 95-98.

<sup>248</sup> An in-depth exploration of additional means of combatting the inequalities present in the organ transplantation system is a topic for future scholarship.

by allowing them to continue to receive HIV-negative organs could thus reduce the stigmatization of HIV-positive individuals.<sup>249</sup>

Finally, transplant hospitals have to report statistics on their transplant outcomes. HIV-positive-to-HIV-positive transplants could have comparatively worse outcomes that skew hospitals' statistics and impact the continued operation of their transplant programs.<sup>250</sup> Consequently, it is unclear how many hospitals will allow HIV-positive-to-HIV-positive transplantation.<sup>251</sup> If HIV-positive patients were unable to receive HIV-negative organs, and if the transplant hospital closest to them did not provide HIV-positive organ transplantations, they could be effectively excluded from receiving any organs at all.<sup>252</sup> Therefore, HIV-positive patients must be allowed to access both HIV-positive and HIV-negative organs in order to prevent their exclusion from organ transplantation altogether.

D. *Providing HIV-Positive Organs to HIV-Negative Patients?*

Many of the conclusions above rely on the HOPE Act's expectation that only HIV-positive patients will be eligible to receive HIV-positive organs. This raises the question: Should HIV-negative patients ever be allowed to receive HIV-positive organs? Very recently, some scholars have begun to consider such a system with respect to HCV-positive organs.<sup>253</sup> This discussion

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<sup>249</sup> See Mgbako et al., *supra* note 130, at 1640 (“[T]ransplant using HIV+ organs can serve as an important example of abandoning the paradigm of placing unique restrictions around the conduct and care of individuals with HIV.”).

<sup>250</sup> *Id.* (“If HIV+ organs are transplanted, clinical complications such as infections and rejection are likely to worsen transplant center outcomes. . . . Poor outcomes can lead to audits by OPTN and [the Centers for Medicare & Medicaid Services], loss of patient referrals or closure of the transplant program.” (footnotes omitted)).

<sup>251</sup> *Id.* at 1641 (“Until there is a resolution of these tensions between the valid interests of transplant professionals in maximizing patient access to organs versus their interests in protecting center outcomes, the acceptance of organs from HIV+ donors will likely remain limited.”); see also Marcus, *supra* note 100 (quoting a hospital's transplant program director explaining that because deaths can impact a transplant center's performance, HIV-positive patients in certain states may have to go out-of-state to get transplants).

<sup>252</sup> Because all organ allocation policies consider a potential recipient's location, the recipient's proximity to a transplant center is crucial. Daubert, *supra* note 12, at 470-71 (observing that while a patient can list at multiple transplant centers, this may not be financially feasible for most patients); see also Higgins & Fishman, *supra* note 89, at 2557 (noting that the OPO or DSA where a patient lists is a factor that accounts “for differences in transplantation rates between races after listing”).

<sup>253</sup> See, e.g., Peter P. Reese et al., *Transplanting Hepatitis C-Positive Kidneys*, 373 NEW ENG. J. MED. 303 (2015). While some of the concerns are similar, there are meaningful differences between knowingly infecting an uninfected recipient with HCV compared to HIV. For example, existing antiviral therapies are often able to cure HCV, while existing antiretroviral therapies cannot yet “cure” HIV. *Id.* at 303. Another article raises the possibility of allowing transplantation of HIV-positive organs into HIV-negative patients in

foreshadows future ethical and legal debates that could impact HIV-positive donation and the evolution of the HOPE Act.

The first concern with transplanting HIV-positive organs into HIV-negative recipients is the ability of transplant physicians to obtain proper informed consent from HIV-negative patients. While the exact risks of transplanting an HIV-positive organ into an *HIV-positive recipient* are still unknown, the uncertainty is even greater when it comes to transplanting an HIV-positive organ into an *HIV-negative recipient*. Nevertheless, doctors frequently obtain informed consent in the context of clinical research where the treatment's attendant risks are unknown. In these contexts, physicians should focus on patients' understanding of the information being disclosed, rather than merely adhering to the professional practice or reasonable patient standards for disclosure. Recently, scholars have proposed an "extended disclosure" model—using multiple informed consent discussions—as a means of obtaining better informed consent.<sup>254</sup> The Public Health Service currently recommends this model for the transplantation of organs that pose a higher risk of disease transmission.<sup>255</sup> The use of such a model would be a requisite first step in obtaining the informed consent of HIV-negative patients.

On the other side of informed consent is patients' autonomous right to choose what happens to their bodies. Allowing uninfected patients to accept HIV-positive organs could be seen as a grant of substantial decisional autonomy, much in the same way that individuals can elect to undergo inherently risky surgeries, such as gastric bypass surgery.<sup>256</sup> Therefore, the principle of autonomy, coupled with the expanding legal recognition of

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discussing the potential for HIV-positive-to-HIV-positive transplantation. Mgbako et al., *supra* note 130, at 1638.

<sup>254</sup> E.g., Adam Nishimura et al., *Improving Understanding in the Research Informed Consent Process: A Systematic Review of 54 Interventions Tested in Randomized Control Trials*, 14 *BMC MED. ETHICS* 1, 10 (2013) ("The approach of using extended discussion was associated with significant increase in understanding scores . . .").

<sup>255</sup> Debbie L. Seem et al., *PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation*, 128 *PUB. HEALTH REPS.* 247, 253 (2013) (recommending informed consent discussions regarding the risks related to disease transmission for organs "known to be infected with HBV or HCV, or donors at increased risk for HBV, HCV, or HIV infection" both before the transplant candidate is placed on the waitlist and prior to transplantation). OPTN's Policies themselves, however, only state that transplant programs must obtain "specific informed consent," and do not explicitly incorporate the model proposed by the PHS Guideline. OPTN POLICIES, *supra* note 5, § 15.3.

<sup>256</sup> See Longitudinal Assessment of Bariatric Surgery (LABS) Consortium et al., *Perioperative Safety in the Longitudinal Assessment of Bariatric Surgery*, 361 *NEW ENG. J. MED.* 445, 446 (2009) (detailing common concerns about the risks associated with bariatric surgery); see also Reese et al., *supra* note 253, at 304 ("The ethics of knowingly infecting transplant recipients with HCV depends on the rigor of informed consent and the willingness of medical professionals to give greater weight to patients' autonomy . . .").

patients' right to autonomous choice,<sup>257</sup> might support transplantation of HIV-positive organs into uninfected recipients, but only if the informed consent process were sufficiently rigorous.

One of the main concerns with infecting HIV-negative patients through the use of HIV-positive organs is non-maleficence. Although the Hippocratic Oath and its modern iterations do not actually contain the words "first, do no harm," that prescription is deeply embedded in medical ethics.<sup>258</sup> Knowingly infecting HIV-negative patients with HIV runs directly counter to this ideal, and transplant physicians may be unwilling to transplant an HIV-infected organ into an HIV-negative patient.<sup>259</sup> Infecting an HIV-negative organ recipient also puts the recipient's intimate partner(s) at risk.<sup>260</sup> By knowingly infecting uninfected patients, physicians could be liable for more than mere negligence, perhaps even involuntary manslaughter.<sup>261</sup>

However, the principle of utility requires that these harms be balanced against the benefits of receiving an HIV-positive organ.<sup>262</sup> For some patients, accepting an HIV-positive organ could mean the difference between life and death.<sup>263</sup> Also, the efficacy of current antiretroviral treatments could minimize

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<sup>257</sup> See, e.g., Ian Lovett & Richard Pérez-Peña, *California Governor Signs Assisted Suicide Bill into Law*, N.Y. TIMES (Oct. 5, 2015), [http://www.nytimes.com/2015/10/06/us/california-governor-signs-assisted-suicide-bill-into-law.html?\\_r=0](http://www.nytimes.com/2015/10/06/us/california-governor-signs-assisted-suicide-bill-into-law.html?_r=0) [<http://perma.cc/F3ZG-TEDH>] ("California will become the fifth state to allow doctors to prescribe life-ending drugs to terminally ill patients . . .").

<sup>258</sup> Cedric M. Smith, *Origin and Uses of Primum Non Nocere—Above All, Do No Harm!*, 45 J. CLINICAL PHARMACOLOGY 371, 371 (2005).

<sup>259</sup> See VEATCH & ROSS, *supra* note 32, at 223.

<sup>260</sup> Mgbako et al., *supra* note 130, at 1638; Reese et al. *supra* note 253, at 304.

<sup>261</sup> See, e.g., CAL. PENAL CODE § 192(b) (West 2014); N.Y. PENAL LAW § 125.15 (McKinney 2009) ("A person is guilty of manslaughter in the second degree when: 1. He recklessly causes the death of another person . . ."); MODEL PENAL CODE §§ 2.02, 210.1, 210.3-4 (AM. LAW. INST. 1985) (defining recklessness, negligence, criminal homicide, manslaughter, and negligent homicide); see also DENNIS J. BAKER, *THE RIGHT NOT TO BE CRIMINALIZED: DEMARCATING CRIMINAL LAW'S AUTHORITY* 173-76 (2011) ("I conclude that, regardless of consent, certain grave harms [such as transmitting fatal diseases] violate a person's dignity as a human being to a serious degree and therefore are wrongful and criminalizable."). One issue with such hypothetical liability, however, would be proving causation.

<sup>262</sup> See BEAUCHAMP & CHILDRESS, *supra* note 95, at 233 ("[M]ost risks will be considered acceptable or unacceptable in relation to the probable benefits of the actions that carry those risks. . ."). In terms of the Model Penal Code and the New York Penal Code, how society views the balance of benefits and harms impacts whether the risk is unjustifiable, and, thus, whether the physician could be held liable for reckless manslaughter for knowingly infecting an HIV-negative transplant recipient. N.Y. PENAL LAW § 15.05; MODEL PENAL CODE § 2.02 ("A person acts recklessly . . . when he is aware of and consciously disregards a substantial and *unjustifiable* risk . . ." (emphasis added)).

<sup>263</sup> See Mgbako et al., *supra* note 130, at 1638 ("We acknowledge that HIV+ to HIV-negative transplantation would be appropriate only in rare cases where the risks of

potential harms resulting from HIV infection. Nonetheless, the patients for whom the benefits are likely to outweigh the risks—the sickest and most disadvantaged—are some of the most vulnerable,<sup>264</sup> raising additional issues of consent and voluntariness.

Finally, concerns for justice weigh heavily on the decision to allow HIV-negative patients to obtain HIV-positive organs. As I explained above, one of the main reasons for granting HIV-positive patients access to both HIV-positive and HIV-negative organs is to remedy the inequality of opportunity and discrimination they face in accessing the organ transplant system and receiving transplants. Allowing HIV-negative patients to receive HIV-positive organs could affect the availability of organs for HIV-positive patients and could create the same unfair queuing that exists on current OPTN waitlists. Additionally, after receiving an HIV-positive organ, uninfected patients would need to receive antiretroviral treatment. In 2010, the lifetime costs of treating HIV were \$379,688.<sup>265</sup> These costs may limit the potential pool of uninfected recipients eligible to receive an HIV-positive organ to wealthy patients with the ability to pay for HIV treatment, whether out of pocket or through insurance.<sup>266</sup> This restriction could disproportionately exclude socioeconomically disadvantaged persons, as well as racial and ethnic minorities who generally have less insurance coverage.<sup>267</sup>

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transmitting HIV infection are clearly outweighed by the risks of continuing to wait for a transplant . . . . This scenario may exist when a candidate's medical urgency for transplant is so severe that the risks of waiting include imminent death.”); cf. BEAUCHAMP & CHILDRESS, *supra* note 95, at 234 (explaining that fast-track approval for new drugs “allows patients with ‘seriously debilitating’ or ‘life-threatening’ conditions to accept greater risks . . . in the absence of acceptable alternatives”); Reese et al., *supra* note 253, at 303 (“[T]he resulting expansion of the donor pool [through transplantation of HCV-positive organs into uninfected recipients] could save hundreds of lives each year.”). This reality may be particularly acute for racial and ethnic minorities; black people “wait longer than whites to receive a first kidney transplant,” even though they have higher rates of end-stage renal disease. See BEAUCHAMP & CHILDRESS, *supra* note 95, at 266.

<sup>264</sup> Cf. Reese et al., *supra* note 253, at 304 (“[T]ransplant physicians should offer HCV-positive organs to uninfected patients who have a high risk of health deterioration if they continue dialysis (e.g., elderly patients or those with serious coexisting conditions . . . ), disadvantageous blood types, or other conditions . . .”).

<sup>265</sup> *HIV Cost-effectiveness*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/hiv/prevention/ongoing/costeffectiveness/> [http://perma.cc/936V-4AM9].

<sup>266</sup> Cf. Reese et al., *supra* note 253, at 304-05 (raising the question of whether “payment for post-transplantation HCV treatment in uninfected patients [can] be guaranteed,” and stating that cost concerns could derail an initiative to allow HCV-negative patients to accept HCV-positive organs). Although physicians cannot consider a patient's financial status in organ allocation decisions, see *supra* note 31 and accompanying text, they can consider financial status in determining whether to list a transplant candidate on an organ waitlist, see *supra* note 28.

<sup>267</sup> See *supra* note 91.

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Because the HOPE Act does not envisage the provision of HIV-positive organs to HIV-negative patients, any such system would require amendments to the Act and OPTN standards. Due to the potential adverse impact on racial minorities and vulnerable patients, including potentially undoing or undermining the beneficial remedies the HOPE Act accords for redressing discrimination against the HIV-positive population, HIV-negative patients should not be allowed to access HIV-positive organs, at least not initially. The tremendous ethical and legal concerns accompanying such a proposal necessitate further scholarship and debate before serious consideration of any amendment is warranted.

#### CONCLUSION

Thanks to the HOPE Act, HIV-positive organ donation and transplantation will likely become a reality in the United States within the next decade. Although intended to benefit the HIV-positive population and the transplant community at large, the HOPE Act could do more harm than good if not properly implemented to protect HIV-positive patients. From both a legal and ethical standpoint, HIV-positive patients must be given the choice to accept HIV-positive or HIV-negative organs. Aside from violating legal and ethical mandates, denying HIV-positive patients access to HIV-negative organs would vitiate the goal of the HOPE Act and would perpetuate discrimination against HIV-positive patients. Whether the HOPE Act should be extended further to allow for the transplantation of HIV-positive organs into uninfected recipients is a question that requires additional dissection before such a provision could be appropriately enacted.