

## ORGAN DONATION AND TRANSPLANTATION: CAN LAW RESOLVE THE DILEMMA OF SCARCITY?

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### An Ethics of Scarcity

In May 2015, the national Organ Procurement and Transplantation Network (OPTN) reached an important milestone: since its establishment in 1987, it has coordinated 500,000 organ transplants from deceased donors, with an estimated 250,000 recipients still living.<sup>1</sup> Despite this achievement, the ethics of human organ donation and transplantation remains an ethics of scarcity: the number of patients awaiting transplants of vital organs increases by several thousand each year, while the number of donors (deceased and living) has flatlined. In 1988, 12,618 transplants were performed with organs from 5,901 donors; the waiting list was 15,029. Over the following 15 years, the number of donors more than doubled, to 13,284—but the reported wait list more than quintupled to almost 82,000.<sup>2</sup> Over the past 10 years, the reported wait list has grown to more than 123,000, while the number of donors has remained stable, between 14,000 and 15,000.<sup>3</sup> More than 80 percent of those on the waiting list seek a kidney transplant, and thus can receive an organ from a living donor. However, the number of living kidney donors peaked in 2004 at 6,647, and declined to 5,539 in 2014.

A comprehensive study published in 2003 reported significant increases over the previous decade in living and cadaveric donations;<sup>4</sup> that progress clearly has not continued. The deaths of those on the waiting lists serve as daily reminders of these trends: while an average of 79 people receive transplanted organs each day, another 22 waiting for an organ pass away.<sup>5</sup> The average wait for a donated kidney is now five years.<sup>6</sup>

For more than four decades, American law has attempted to address this problem of scarcity, and to ensure the equitable allocation of those organs made available and suitable for transplant. Several core ethical principles and conclusions have guided these legal developments: that affirmative consent of the deceased recorded prior to death, or the consent of the family at time of death, be required; that donation be wholly voluntary and altruistic; and that vital organs not be marketed or otherwise commoditized. Over the same period, the unresolved dilemma of scarcity has inspired proposals to depart

from these principles. It is a debate worth having; as the recent half-million milestone reminds us, organ transplantation is not an exotic corner of medical practice, and its successes and failures—including the failure to find a suitable donor—touch thousands of lives each year. We offer here a brief summary of current law, the chief proposals for reform, and a legal and ethical appraisal of whether the gains from such proposals are worth compromising the principles that have heretofore guided the transplant system. Due to space limitations, proposals for ameliorating scarcity through the compensation of donors must be the subject of a future article.

### Current Legal Structures

Federal and State governments play a distinct but complementary role in regulating the donation, procurement, and allocation of deceased donor organs suitable for transplant. Broadly speaking, federal law, commencing with the 1984 enactment of the National Organ Transplant Act (NOTA),<sup>7</sup> governs the process of procurement and allocation, while state law, reflected in the universal adoption of the Uniform Anatomical Gift Act (UAGA), governs the process of organ donation and donor registry. Pursuant to authority created by NOTA and HHS regulations,<sup>8</sup> the system for procuring and distributing vital organs is under the management of 58 regional Organ Procurement Organizations (OPO), which oversee the activities of 249 transplant centers.<sup>9</sup> An OPO must be a member of the national Organ Procurement and Transplantation Network (OPTN), administration of which has been contracted (since 1987) to the United Network for Organ Sharing (UNOS), based in Richmond, Virginia.<sup>10</sup> When an organ is donated within an OPO service area, the allocation matching system matches the donor with the database of waiting transplant candidates. The OPO evaluates the potential donor, checks the deceased's state donor registry, discusses the potential donation with the deceased's family members, and through the OPTN runs a match list to arrange for the recovery and transport of the donated organ.<sup>11</sup> The decision to accept or decline a matched donation is up to the transplant center, based on professional judgment.<sup>12</sup>

leisure time make the boundaries between work and personal life increasingly porous.

Ignorance about how something works can lead to a distorted relationship with the technology. Turkle points out that unfamiliarity with how computer hardware works, or how software is coded, enables us to relate to the technology as human-like. This may explain why people confide in robots or computer-based therapists (with no actual person involved) even though the robot's or computer's responses are programmed, not human. Perhaps, like Riley's friend Bing Bong in the movie *Inside Out*, technology has become the adult version of an imaginary friend.

### Medicine, Science, and Technology

One place to begin in evaluating new technologies is to ask what goal they serve. My colleague Michael Sleasman has observed that medicine and technology should always function in the service of human flourishing. Science can serve human flourishing, but also can be pursued simply in the "wonder of God" and his creation. Before buying the next wearable technology, you might ask if and how it will help you to flourish? Or will it make you more and more dependent upon the technology? And, before criticizing funding for basic research, we might consider that condensed-matter

physics research linked with string theory gives us more insight into black holes.<sup>7</sup> For me, that is an awe-inspiring, wonder-of-God's-creation moment. ●●●

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- 2 Institute of Physics, *Physics.org*, <http://www.physics.org/facts/apollo-really.asp> (accessed July 1, 2015).
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- 4 Katherine Shaver, "Safety experts to pedestrians: Put the smartphones down and pay attention," *Washington Post*, September 20, 2014, [http://www.washingtonpost.com/local/trafficandcommuting/safety-experts-to-pedestrians-put-the-smartphones-down-and-pay-attention/2014/09/19/278352d0-3f3a-11e4-9587-5dafd96295f0\\_story.html](http://www.washingtonpost.com/local/trafficandcommuting/safety-experts-to-pedestrians-put-the-smartphones-down-and-pay-attention/2014/09/19/278352d0-3f3a-11e4-9587-5dafd96295f0_story.html) (accessed July 23, 2015).
- 5 Sherry Turkle, *Alone Together: Why We Expect More from Technology and Less from Each Other* (New York: Basic Books, 2011), xii.
- 6 Sherry Turkle, "Connected, but Alone?" *TED Talk*, April 2012, [http://www.ted.com/talks/sherry\\_turkle\\_alone\\_together/transcript](http://www.ted.com/talks/sherry_turkle_alone_together/transcript).
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### ORGAN DONATION—CONTINUED FROM PAGE 1

The process of becoming and being recognized as a donor is under the purview of state law. The UAGA, first drafted in 1968 and revised in 1987 and 2006, has been enacted in all states, although seven have not updated to the 2006 revision.<sup>13</sup> The UAGA respects the dominant ethos in the United States regarding organ donation: that it be the result of a free and voluntary decision made by the donor (or by a designated health-care proxy or close family member in the case of a permanently incapacitated patient). Its revisions conformed state laws to the system of organ procurement developed under NOTA to simplify the process of donation and expand the potential supply of donated organs. For example, the 2006 revision, now the law in most states, emphasizes the principle of first-person authorization; the donor's family thus has no legal right to override the deceased's prior decision to donate (although they suffer no legal penalty if they do so). Practices in response to this development vary. Some OPOs remain reluctant to oppose a family's effort to override the deceased's decision, but there also is evidence that the incidence of such objections has declined and that families of designated donors accept the principle of first-person authorization.<sup>14</sup> The UAGA also provides for the establishment of state organ donor registries (now adopted in all states), donor designations on driver licenses, and more efficient access by OPOs to such registries and records.

State and federal law reinforce each other on two salient points: the prohibition on financial incentives for organ donation, and the establishment of "routine inquiry" or "required consent" protocols, mandating that the families of donor-eligible patients be given the option to donate. Both sets of provisions merit further discussion, as the latter has been promoted (but largely failed)<sup>15</sup> to increase the supply of cadaveric organs, and the former criticized as an impediment to increasing both deceased and living organ donation—particularly of kidneys, which account for 80 percent of the current shortfall.<sup>16</sup>

### Routine Inquiry to Presumed Consent?

Congress in 1986 required that hospitals participating in Medicare and Medicaid establish written protocols to identify potential organ donors and assure that families of such potential donors are made aware of their option to donate organs or tissue and their option to decline.<sup>17</sup> The following year, the Health Care Financing Administration (HCFA; now the Centers for Medicare & Medicaid Services or CMS) issued regulations, updated in 1998, requiring hospitals to incorporate an agreement with an OPO under which it must timely notify the OPO of individuals whose death is imminent or who have died in the hospital; OPO will then make a determination of medical suitability for organ donation. The hospital must collaborate with the OPO to ensure that a representative of the

OPO (not the hospital) inform the family of a potential donor of the option to donate or decline.<sup>18</sup> The UAGA includes parallel provisions;<sup>19</sup> in practical effect, these merely replicate the more specific federal requirements which, being tied to Medicare/Medicaid reimbursement and designation of OPOs, create a much stronger mandate. Even prior to the revision of the UAGA on this issue, virtually all state legislatures had enacted routine inquiry or required consent laws; these were subject to varying degrees of enforcement and regulatory implementation by State health departments.<sup>20</sup> In addition to these legal requirements, the transplant safety standards of the Joint Commission<sup>21</sup> require hospitals to have a written agreement with an OPO and to work with the OPO to develop a written donation policy for asystolic organ recovery.<sup>22</sup>

Under these schemes of regulation, the American system of organ donation remains an “opt-in” system—meaning that the donor beforehand, or the family at time of death, must affirmatively consent to the donation of organs. Because these measures have not appreciably increased the supply of cadaveric organs, some propose that the United States adopt a system of “presumed consent,” under which the deceased is presumed to have consented to donation unless he or she has affirmatively “opted-out” before death,<sup>23</sup> or a system of “mandated choice” in which all adults would be required to express their preferences regarding organ donation, perhaps when obtaining a driver’s license or filing a tax return.<sup>24</sup> A hybrid of these two systems could also be devised: the “mandated choice” aspect would require all adults to indicate their preference, and the “presumed consent” aspect would provide that those who do not reply are deemed to have consented to donation.<sup>25</sup> The American Medical Association (AMA) has recommended that pilot programs for each system be established to determine whether “ethically appropriate models of presumed consent or mandated choice for deceased donation would positively or negatively affect the number of organs transplanted.”<sup>26</sup>

Proponents of presumed consent point to the fact that in continental Europe (as opposed to England, and with the exception of Germany), presumed consent laws are the norm.<sup>27</sup> Conceptually, presumed consent provides no role for family members in the decision to donate organs.<sup>28</sup> Under Austrian law, for example, relatives have no right even to be informed of organ removal, and the stricter notion of presumed consent has struck “deep roots.”<sup>29</sup> In practice, however, some measure of affirmative consent endures, and is even required. Even in Austria, families are often consulted to confirm the intent of the deceased, and in Spain, which enjoys a high rate of organ donation, next of kin are routinely consulted even if the deceased has not opted-out of donation.<sup>30</sup>

### ***Is Presumed Consent Effective?***

The pivotal questions are whether presumed consent leads to higher rates of organ donation and if so, whether adoption of the system would lead to similar results in the U.S. Cadaveric donation rates in the U.S. are comparable to those of many “presumed consent” countries (Spain being a high-rate outlier, even among European nations); the medical literature often reflects that donation rates in presumed consent countries are not much higher relative to affirmative consent countries.<sup>31</sup> Abadie and Gay’s

living organ donation, and that it could generate an adverse response without first building sufficient social support for the policy.<sup>33</sup> Given the fractiousness of current U.S. debates over health care policy, the latter point is, if anything, understated.

It seems clear that when accounting for cultural factors, the reported success of presumed consent (which, to repeat, never exists in its “pure” form) is contingent on a society’s receptiveness to what Richard Thaler and Cass Sunstein have described as the “nudge” factor.<sup>34</sup> In Europe, the specific history of presumed consent to necropsy and the general acceptance of communitarian obligations, often reinforced by law, create circumstances where presumed consent for organ donation will not only be accepted, but lead (or nudge) families to affirmatively agree when approached after the death of a loved one.<sup>35</sup> If the deceased has not opted out, the family will infer that the deceased had a desire to donate—even if the family has no specific knowledge on that point.<sup>36</sup> The law thus nudges families to consent, which, even though not strictly required by law, is likely to facilitate higher rates of donation.

### ***Barriers to Presumed Consent in the U.S.***

Adoption of presumed consent in the

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2006 study applied regression analysis to factors such as GDP, health expenditures, religious beliefs, and rates of death from motor vehicle accidents and cerebrovascular disease.<sup>32</sup> They concluded that presumed consent countries have roughly 25–30 percent higher donation rates. However, the authors caution that adoption of presumed consent would not be a silver bullet to eliminate the shortage of donated organs in the U.S., that it may result in a reduction in the rate of

U.S. faces formidable legal barriers as well as related ethical objections, with the uncertain prospect that such reform would result in an appreciable net increase in available organs. Any such change would require coordinated efforts to overhaul the NOTA and its implementing regulations, as well as the laws of every state. The UAGA, now close to 50 years old and adopted in some form in every state, has always been based on the principle of affirmative consent, even

as it has been revised to expand opportunities for persons to register their consent to donate, and ensure that such consent is known and given full legal effect. Thus, the principle of affirmative consent is as deeply imbedded in American legal culture as presumed consent is in most

a system of presumed consent, or “default to donation,” is “completely consistent with the existing bioethical framework governing organ and tissue procurement. Respect for persons and voluntary altruistic consent remain the moral foundation for making organs available.”<sup>37</sup>

unlikely to lead to any greater acceptance of presumed consent as a non-coercive means of increasing organ donation.

### **Mandated Choice: A Less Coercive Option?**

Recognition of these barriers to a policy of presumed consent—whether of the “strong” (Austrian) or “weak” (Spanish) variety—has led to advocacy for, and limited adoption of, the policy of “mandated choice.”<sup>39</sup> By requiring all adults to either opt-in, opt-out, or “defer to family wishes,”<sup>40</sup> mandated choice, according to its proponents, preserves the autonomy that is lost under a system of presumed consent. No one is required to make a particular decision for or against donation; all that is required is to register *some* decision.<sup>41</sup> In fact, one could say that a limited (and inconsistently applied) form of mandated choice already exists under the rubric of “routine inquiry.” Mandated choice may be less coercive than presumed consent, and it may pass constitutional muster as violating no rights to privacy or free speech.<sup>42</sup> However, it still involves a measure of coercion that (particularly in practice) places at risk the principles of voluntarism and altruism underlying current legal norms on organ procurement and donation, all with uncertain effect on the rate of organ donation and procurement.

The current “model” for mandated choice is Illinois’ First Person Consent Act (FPCA). The FPCA requires the Secretary of State to offer to each applicant for a new or renewed driver’s license the opportunity to be included in a First Person Consent registry for organ or tissue donation; once placed on the registry, the donor’s decision may not be overridden by family objections at the time of death.<sup>43</sup> Individuals can also join the registry by mail, phone, or online. In practice, those obtaining or renewing a license in person are required to answer the question: Do you want to be an organ donor?<sup>44</sup> Virginia also requires a choice to be made at the time of renewing a license, but offers the options of “yes,” “no,” and “undecided.”<sup>45</sup>

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nations of continental Europe. A fundamental reorientation from affirmative to presumed consent would disrupt settled expectations and practice, and quite possibly result in a patchwork of state laws that could complicate the national organ procurement process.

Under principles of federalism, Congress would have limited authority, if any, to impose a change from affirmative to presumed consent on the states; moreover, reforming NOTA in this manner would have the same disruptive effects. Although the AMA and others have suggested “pilot projects” to test the effectiveness of presumed consent, designing such a project to produce valid comparative data poses numerous difficulties. Laws would need to be changed in one or more jurisdictions, perhaps at the federal level as well, and a generous amount of time, at least a decade and probably more, would be needed to assess whether the change in law and practice increased the number of cadaveric organs suitable for transplant.

Proponents would likely point out that incremental legal change, even if disruptive, often leads to progress, and that on this issue, the lack of progress has become a matter of life and death for thousands of Americans. They also question the validity of the standard ethical objections to presumed consent—that it would infringe on autonomous decision-making, undermine the principle of voluntariness, and result in procurement of organs from persons who, if asked, would not have consented. Noted bioethicist Arthur Caplan contends that

Citing the nudge factor, Caplan contends that society’s familiarity with defaults in other areas might with increase comfort with this manner of procuring organs—thus replicating the experience in much of Europe.

The best that can be said of these arguments is that even if presumed consent were adopted, families would still likely be asked to ratify the process of donation, as they are to varying degrees in Europe, thus preserving in fact some element of affirmative consent. But the contention that the *design* of presumed consent serves equally well the principles of individual consent, voluntarism, and altruism that underlie U.S. law on organ donation is far less persuasive. The paths of affirmative and presumed consent diverge at critical ethical and jurisprudential points, and reflect different accounts of humankind’s relationship to the state—which may explain Germany’s adherence, along with the common-law countries, to the less coercive scheme of affirmative consent.

Whether or not it is coercive in practice, presumed consent is coercive in principle, even if the coercion is of the “soft” or “weak” variety that allows for an opt-out and ratification by family. It has been argued that no one has the right to say what should be done to their body after death, because the body “can only legitimately be regarded as on extended loan from the biomass.”<sup>38</sup> On this view, no immoral coercion would exist because there is no moral claim to ownership of the body or expectation of its disposition. But the radical nature of the premise is

For reasons not easily explained, the Illinois law has resulted in 60 percent of adults reportedly registered as organ donors, well above the national average, while Virginia's rate (31 percent) is actually below the national average (40 percent).<sup>46</sup> (Virginia's "undecided" option does not appear to be the cause, as 45 percent of respondents affirmatively choose not to donate). California more recently adopted legislation modeled on the FPCA, with a specific requirement that a motor vehicle employee verbally ask every registrant whether he or she wishes to join the registry.<sup>47</sup> An estimated 10 million Californians are currently on its donor registry.

Despite the inconsistent evidence from the few states that have adopted mandated choice, we can presume that the more people are asked—and required to answer—whether they wish to donate organs, the more organ donors will be recognized and registered. Public opinion polls show widespread support for donation, and for willingness to donate, even if current rates of affirmative consent donation do not reflect that level of support. Much will depend on how mandated choice is implemented—it is not difficult to imagine that if the same poll respondents were asked whether their state's motor vehicle department was the best venue in which to be compelled to make a decision, the approval numbers would decline significantly. But even if well-handled at the bureaucratic level, and successful in raising the number of registered donors, it is legitimate to question whether mandated choice compromises autonomy and to what effect.

### **Issues Regarding the "Non-Donor" and Autonomy**

A chief feature of the Illinois and California laws, in contrast to the Virginia law, is that the names of those who decline to register as donors are not placed on a "non-donor" registry—meaning that the families of those who have affirmatively chosen not to donate may, at the time of death, nonetheless be asked to give approval to donate, thereby overriding the wishes of the deceased. Proponents

of mandated choice assert that the state has a legitimate public health interest in compelling persons to make a decision one way or the other—even by the compulsive effect of withholding a driver's license renewal or a tax refund.<sup>48</sup>

But is the state acting even-handedly when it chooses to record the wishes only of those who select the state-preferred option of donation? Of course, it may be presumed that all who are not listed on the donor registry must have declined at some point in receiving or renewing their driver's license, but they are not given the option of affirmatively stating and having recorded their decision. The situation is different from that under a pure affirmative consent model—there, the state (and perhaps no one else) has never asked the deceased or near-decedent whether he or she wishes to donate, and it is fair to ask the family to fill the gap in the interests of altruism and beneficence to others. But if the state, under compulsion of law, has required one to make a decision, is it not incumbent on the state (under the principle of "first-person consent") to honor that choice, however it comes out?

Furthermore, simply increasing the number of registered donors is weak justification for this inversion of the principle of autonomy. Creating more registered donors does nothing to ameliorate the shortage of organs unless an appreciable number of those donors will be in a position, at some point, to actually donate. Odds are, happily, heavily against that eventuality. Of the two million who die in the U.S. each year, only a small fraction, around 12,000, do so under the unfortunate circumstances in which vital organs are amenable to donation.<sup>49</sup> Under the prevailing system—one of affirmative choice, first-person authorization, and required inquiry—family consent is available where no first-person decision has been made. Evidence is lacking that family refusal in such cases is a systemic impediment to increasing the number of transplantable organs (as opposed to merely increasing the numbers of people who are registered to donate, and in all likelihood will never be in a position to do so). The consent rate for

donation from eligible deceased donors is 75 percent; up from 50 percent in the early years of this century.<sup>50</sup> First-person consent is already the law in most states; in practice, families are still consulted and it is likely they will continue to be consulted even if the first-person authorization has been obtained through a system of mandated choice. Even if Illinois and California lead a broader trend toward mandated choice, it is doubtful that a significant increase in transplantable organs will result.

### **Conclusion**

*"I am profoundly skeptical whether any change of legislation in and of itself could modify a social reality which is supported by the majority. The sequence of events goes the other way around. Laws are good laws when they conform with that which has been accepted by society and when they do not try to modify society by coercion."<sup>51</sup>*

Decades of legal initiatives have supported the progress of a world-class organ transplantation system in the United States, saving and prolonging hundreds of thousands of lives, and allowing new technologies to develop and flourish. Under critical federal oversight and coordination, the system incorporates a strong "local" component, with a variety of OPOs and an even greater number of transplant centers implementing protocols for procurement and allocation with substantial flexibility. Furthermore, the states have the dominant role in governing the process of consent for donation.

Yet this system of laws and procedures has not bridged the increasing gap between donated organ needs and organ availability from deceased donors. As the preceding discussion suggests, there may be inevitable limits to the law's capacity to do so, even if it departed from some of the bedrock principles under the current system. More radical departures from those principles, including the compensation of living donors (chiefly of kidneys and livers) and expanding the concept of who may be considered a "dead donor,"

are subjects for a future essay. ●●●

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- 2 It is widely recognized that the "reported" wait list is inflated by as much as one-third through inclusion of inactive and medically-ineligible patients. The United Network for Organ Sharing admits, and defends, its practice of including inactive and ineligible potential recipients on the reported wait list. However, prominent bioethicists such as Arthur Caplan and other experts have sharply criticized the practice. Rob Stein, "A Third of Patients On Transplant List Are Not Eligible," *Washington Post*, March 22, 2008, <http://www.washingtonpost.com/wp-dyn/content/article/2008/03/21/AR2008032102981.html?sid=ST2011022308018> (accessed August 20, 2015). The wait list is further inflated by "multiple listing" of patients who register at more than one transplant center. Arthur Caplan, "Organ Transplantation," in *From Birth to Death and Bench to Clinic: The Hastings Center Bioethics Briefing Book for Journalists, Policymakers, and Campaigns*, ed. Mary Crowley, 129-132 (Garrison, NY: The Hastings Center, 2008), [http://www.thehastingscenter.org/uploadedFiles/Publications/Briefing\\_Book/organ%20transplantation%20chapter.pdf](http://www.thehastingscenter.org/uploadedFiles/Publications/Briefing_Book/organ%20transplantation%20chapter.pdf) (accessed August 20, 2015).

- The phenomenon is not limited to the United States. Cf. Nereo Zamperetti et al., "Reflection on Transplant Waiting Lists," *The Lancet* 378, no. 9791 (August 13, 2011): 632-635.
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  - 7 Public Law 98-507, 98 Statute 2339 (Oct. 19, 1984), codified, as amended, at U.S. Code 42 §§ 273-274 (hereafter referred to as "NOTA").
  - 8 The Centers for Medicare and Medicaid Services (CMS), formerly known as the Health Care Financing Administration (HCFA) is responsible for HHS regulations in this area, including the certification of transplant centers and organ procurement organizations. A different branch of HHS, the Health Resources and Services Administration, provides oversight of the OPTN. See *Code of Federal Regulations*, title 42 Part 121.
  - 9 Nathan et al., "Organ Donation in the United States," 29-30.
  - 10 *Ibid.*, 29-30. See also documentation published at OPTN's web site: <http://optn.transplant.hrsa.gov/converge/members> (accessed May 28, 2015).
  - 11 Nathan et al., "Organ Donation in the United States," 29-30. The list can be accessed at <http://organdonor.gov/materialsresources/materialsolist.html> (accessed May 28, 2015).
  - 12 Nathan et al., "Organ Donation in the United States," 33-34. Rates for non-recovery of donated organs vary greatly depending on the organ involved—as low as 7 percent for kidneys and livers, up to about 50 percent for hearts and over 80 percent for lungs.
  - 13 For detailed information see the table at [http://www.organdonor.gov/legislation\\_micro](http://www.organdonor.gov/legislation_micro) (accessed May 28, 2015). The Anatomical Gift Act (2006) is available at [http://www.uniformlaws.org/ActSummary.aspx?title=Anatomical%20Gift%20Act%20\(2006\)](http://www.uniformlaws.org/ActSummary.aspx?title=Anatomical%20Gift%20Act%20(2006)) (accessed May 28, 2015).
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