ORGAN PROCUREMENT NOW: DOES THE UNITED STATES STILL “OPT IN?”

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Organ-donation systems are often thought to fall into two categories: opt-in and opt-out. In the United States, the goal of maximizing the pool of donors has led to a patchwork system that has moved beyond its opt-in origins to become a “mixed” system with strong opt-out elements. Even where the system still reflects an opt-in approach, it fails to adequately seek and affirm informed individual choice. This Article explores various procurement strategies and their ethical underpinnings. It concludes that although incremental changes to organ donation laws and policies have improved donation and transplantation rates, they have come at a moral cost. Opt-out strategies have been adopted without public awareness or debate and are impacting end-of-life care and treatment of the deceased body in ways that increasingly raise concern. The final Part of this Article recommends that the U.S. should either recommit to the opt-in principle and reforms its laws or openly move toward an opt-out system. In the absence of legislative will for either, the Article suggests changes in the way organ donation is promoted and implemented within the current legal structure to achieve greater public trust, an important element for maintaining and increasing organ donation rates.

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Consider the following scenario:
A tragic automobile accident has left a man unconscious and dying in the hospital. His family, after learning the extent of his severe neurological injury and grim prognosis, is considering withdrawing life support. Several months ago, the patient executed an advance directive that re-
fuses life-sustaining treatment in the event of a terminal condition. He has never signed anything regarding organ donation.

Over the next few days, without the knowledge of the patient’s family, organ-procurement personnel at the hospital review his medical records and perform tests to determine if the patient would be a suitable organ donor. During this time, healthcare providers continue life-sustaining interventions in order to maintain the perfusion of his organs. The patient’s physicians defer discussion with the family about withdrawing ventilatory and other life-sustaining measures. An employee from the regional organ-procurement organization (“OPO”) sits with and supports the grieving family, although the family has not clearly been told the employee’s role. They believe she is a member of the medical team.

The organ-procurement personnel establish the patient’s physical suitability for organ donation, and the patient is now dead by neurological criteria (“brain dead”). The OPO employee turns to the man’s parents and begins talking to them in a way that presumes that they will agree to organ donation. She explains that over 120,000 people in the country are awaiting a transplant and that, by donating their son’s organs, they have the ability to make him a hero by saving eight people’s lives tonight. She finishes the conversation by saying that if the family has no further questions, she will guide them through the process.2

Does this scenario describe an opt-in or an opt-out system of organ donation? Does it describe a series of events more likely to take place in the United States (an opt-in country) or Spain (an opt-out country)? The patient has neither registered a decision to be an organ donor nor refused to be one. He nevertheless is subjected to tests and interventions for the purpose of donation without his healthcare agent’s or family’s consent and in violation of his advance directive. His family is asked to consent to donation, but their answer is presumed to be “yes” until specifically stated as “no.” They are not asked what he would want.

This is the U.S. system today. It is not that different from Spain’s.3 (There, too, family members are asked about donation—though in a more patient-centered approach, they are asked whether they know of any reason their relative would object to organ donation.)4 Yet, the U.S.

1. The numbers of donors and people on the waiting list are available at the website of the Organ Procurement and Transplantation Network. In 2015, 121,503 people were on the transplant list in the U.S. Organ Procurement and Transplantation Network, U.S. DEPT HEALTH & HUMAN SERVS, https://optn.transplant.hrsa.gov/data/ (last visited April 3, 2017). There were 9,080 deceased donors and 5,957 living donors in that year. Id. A total of 30,973 transplants took place. Id.

2. The language used by the OPO employee in this scenario is drawn from the suggested presumptive language for requesting organ donation in Sheldon Zink & Stacey Wertlieb, A Study of the Presumptive Approach to Consent for Organ Donation: A New Solution to an Old Problem, 26 CRITICAL CARE NURSE 129, 129 (2006).


4. Interview with David Paredes, Transplant Coordinator of University of Barcelona Hospital, Spain (October 2015); see also David Rodriguez-Arias et al., Success Factors and Ethical Challenges of the Spanish Model of Organ Donation, 376 LANCET 1109, 1110 (2010) (“The law establishes that ab-
system is always described as an opt-in and Spain’s as an opt-out; scholars and policy-makers debate which system is better in terms of the number of organs procured and transplanted and the ethical values of each. Debate and investigation continue apace about whether an opt-out system would be acceptable to the American public and constitutionally permissible. The urgency of these questions intensifies as the longstanding gap between the supply and demand for transplantable organs remains severe.

Our current system of altruistic donation in the United States consists of a patchwork of state laws—modeled on the Uniform Anatomical Gift Act ("UAGA"); federal regulations governing hospitals through their participation in Medicare and Medicaid; policies of hospital and organ-procurement organizations; and the practices of donor registries and state Departments of Motor Vehicles ("DMVs"). Early on, the National Organ Transplant Act of 1984 rejected a commercial market for organs by prohibiting the transfer of organs for valuable consideration. Since then, financial incentives for organ transfer have been periodically considered but repeatedly rejected. Scholars and policy-makers have

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5. See, e.g., Bramhall supra note 3, at 271 (discussing both the Spanish and U.S. systems, noting that though one has presumed-consent laws and the other does not, both have high rates of organ donation—55 per million population ("PMP") for Spain and 25 PMP for the United States—and both have also experienced a "rapid increase" in organ donation in a "relatively short period of time"); see also Lee Shephard et al., An International Comparison of Deceased and Living Organ Donation/Transplant Rates in Opt-in and Opt-Out Systems: A Panel Study, 12 BMC MED. 131, 132 (2014) [hereinafter Shephard, International Comparison] (categorizing various countries as having opt-in or opt-out systems to compare rates of donation).


7. 42 C.F.R. § 482.45 (2016).


10. 42 U.S.C. § 274e (2012). "Human organ" is broadly defined in the act to include "the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof . . . . " Id. § 274e(c)(1); see also Revised Unif. ANATOMICAL GIFT ACT § 6, 8A U.L.A. 19 (2006) (amended 2009).

11. Reid Kress Weisbord, Anatomical Intent, 124 YALE L. J. 117, 119 (2014), http://www.yalelawjournal.org/forum/anatomicalintent ("[A] growing chorus of scholars and commentators have called for (and debated) the development of a regulated market in which organ donors would be permitted to accept valuable consideration."); see also Michele Goodwin, Altruism’s Limits: Law, Capacity, and Organ Commodification, 56 RUTGERS L. REV. 305, 310 (2004) ("Opponents of incentives locate their concerns in social, moral, and legal terms, revealing fears about alienating human biological tissues."); David Horton, Indescribability, 102 CAL. L. REV. 543, 575 (2014) (describing concerns that support the prohibition of compensation for organs but then arguing that "the concerns that have
shown more interest in exploring the possibility of a presumed-consent, or opt-out, system.12

What is often unappreciated, however, is that state and federal laws already include a number of provisions that reflect an opt-out approach. Legal provisions that borrow from an opt-out policy approach have been around since at least the 1960s, when state laws allowed the removal of corneas by medical examiners without individual or family consent.13 Because those provisions only applied to bodies in the possession of corner’s offices, they did not have widespread impact.14 They have also recently faced constitutional challenges and been phased out; these provisions are no longer included in the most recent version of the UAGA.15

More concerning are the number of less obvious opt-out strategies that have been incorporated into the U.S. system in recent years, such as allowing OPO personnel to conduct premortem examinations and requiring continued life-support measures for individuals who have not yet been determined to be donors.16 Some of these strategies are impacting end-of-life decision making in ways that increasingly raise concerns. Most of the opt-out strategies incorporated into the law have been adopted in incremental fashion, without public awareness or debate. Some of them may seem small, others may seem technical, but they cumulatively raise doubt about the integrity of our procurement system. Although in combination they appear to have been successful in increasing the number of designated donors and the percentage of eligible organs recovered for transplant purposes,17 these gains have come at a moral cost.

prompted the UAGA to make body parts market inalienable arc less forceful when applied to the newly deceased”); Julia D. Mahoney, The Market for Human Tissue, 86 Va. L. Rev. 163, 184, 194 (2000) (“[T]he question of whether compensation should be paid to tissue sources amounts to nothing more than a choice between a regime in which human biological materials are initially donated and afterwards become the subject of market exchanges and one in which market activity begins with the initial transfer.”).

12. About a decade ago, an Institute of Medicine Committee studying a range of proposals to increase the rate of organ donation found much to recommend in a presumed-consent system, but concluded that enacting presumed-consent policies in the United States would be premature given the current lack of social support for such a system. INST. OF MED. OF THE NAT’L ACADS., ORGAN DONATION OPPORTUNITIES FOR ACTION 10 (James F. Childress & Catharyn T. Liverman eds., 2006) [hereinafter OPPORTUNITIES FOR ACTION].


14. Id. at 302-03.

15. Id. at 300.

16. See infra Subsection II.A.1.

17. Laura A. Siminoff et al., Consent to Organ Donation: A Review, 23 PROGRESS TRANSPLANTATION 99, 99 (2013) (discussing the success of efforts to increase first-person authorization and other efforts of the Organ Donation Breakthrough Collaborative initiated by the Health Resources and Services Administration’s Division of Transplantation); see also H.M. Traimo et al., Interim Results of a National Test of the Rapid Assessment of Hospital Procurement Barriers in Donation (Rapid), 12 Am. J. Transplantation 3094, 3094 (2012) ("After the substantial gains made between 2003 and 2007, largely associated with the Collaborative’s work, donation rates have plateaued at ap-
While the success of a society’s organ-procurement system is often evaluated only by quantitative factors, such as the number of organs donated, organs transplanted, or lives saved by transplantation,\textsuperscript{18} success must also be evaluated by whether the organ-procurement system meets the policy objectives and ethical values on which it is based and whether its processes and aims are transparent.\textsuperscript{19}

A cohesive, carefully implemented opt-out policy for organ donation can be ethically justified. Justifying a system that cobbles together aspects from various competing policies presents a more difficult challenge, however, especially given that the necessary social, educational, and legal supports for such policy components are not in place. Strategies to increase organ donation that are antithetical to the opt-in principle have been adopted without open and transparent debate about their wisdom and acceptability and have been implemented with a disturbing lack of public awareness about their existence. There has never been a concerted effort on behalf of either state or federal authorities to educate the public about the fundamental elements of our organ-procurement system and, in fact, there is good reason to wonder whether certain aspects have been intentionally rendered opaque.\textsuperscript{20}

Part I of this Article provides a brief overview of leading procurement policies and strategies, the values upon which they are based, and the social conditions that must be met before they can be successfully adopted and ethically implemented. Part II describes and critiques the elements that have been introduced into the U.S. system as incremental strategies to increase the volume of donated organs but which deviate from a pure opt-in policy. Part III turns to questions of reform. Ideally, the U.S. system should either recommit to the opt-in principle and reform its laws and practices to conform to it, or, following an open and transparent process, move towards an opt-out system. Neither of these solutions may be practical at this time, however. The latest version of the UAGA has only recently been adopted by the states, making further attention at the legislative level unlikely for the near future. There are, nevertheless, practical steps that can be taken by federal and state aen-


\textsuperscript{19} James F. Childress, Practical Reasoning in Bioethics 266 (1997).

\textsuperscript{20} Seeinfra Sections II.A (discussing premortem examinations and maintenance measures), II.C (discussing donor registration at the DMV and through online registries).
cies, hospitals, and OPOs to address the most troubling aspects of our current system. Recognition that we currently have a “mixed” system—with both opt-in and opt-out components—can enable us to take a hard look at the many components of that system and ask with respect to each one whether it merits change or, if it is worth saving, whether the necessary social, educational, and legal mechanisms are in place to support it. Specific suggestions for reform are provided in this final Part. If implemented, greater public trust in the organ-procurement system might be achieved, an important element in its own right for maintaining and increasing organ donation rates.21

I. PROCUREMENT POLICIES AND THEIR ETHICAL FRAMEWORKS

The main procurement policies and strategies debated or adopted in whole or in part in various countries, including the United States, are the following: opt-in (with greater or lesser reliance on first-person, as compared to family, consent), opt-out (either routine removal or presumed consent), and mandated choice.

A. Opt-In Policies

The defining characteristic generally recognized for purposes of denoting a system as “opt-in” is that individual and family interests in organs and tissues are prioritized over societal or governmental interests.22 In the absence of express consent from either the decedent or an individual with authority to direct the disposition of the body (generally an agent appointed by the decedent prior to death or a family member chosen from a statutory hierarchy), the organs cannot be recovered.23 The default rule, then, is nononation.24

The primary ethical justification for an opt-in policy is the belief in the supremacy of an individual’s right to determine what shall be done with his or her body following death.25 Accordingly, opt-in policies generally promote “first-person consent,” sometimes called “donor designation,” in which an individual decides prior to death to donate some or all of his or her organs, or parts thereof, for specific purposes following

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21. OPPORTUNITIES FOR ACTION, supra note 12, at 81 (“If citizens believe that the system of organ recovery and allocation is ineffective or unfair or that it fails to respect other important ethical standards, they would have little reason to support the system by donating organs.”).


23. OPPORTUNITIES FOR ACTION, supra note 12, at 9; see also James F. Childress, Ethical Criteria for Procuring and Distributing Organs for Transplantation, 14 J. HEALTH POL. POLICY & L. 87, 90–95 (1989) (discussing the ethical foundations for an express-donation policy, as well as the UAGA’s general adoption of express donation).


death. The United States has explicitly chosen such an opt-in policy through adoption by all of the states and the District of Columbia of some form of the Uniform Anatomical Gift Act, first drafted by the National Conference of Commissioners on Uniform State Laws in 1968 and later revised in 1987, 2006, and 2009. Under the UAGA, an individual may “opt in” to organ donation through legally recognized documentation designating the individual as an organ donor, such as a driver’s license denotation or a donor registry.

U.S. law has long allowed family members of a decedent to make an anatomical gift as well. The UAGA specifies a hierarchy of family members who have the legal authority to make an anatomical gift as long as the decedent has not expressed opposition to donation in a manner recognized by the UAGA. Family involvement is justified by the family’s traditional interest in the disposition of the body of next of kin. This family interest has been recognized in some court cases as a quasi-property right and in others as a constitutional privacy right.

27. The UAGA is a model act. Variations occur in the anatomical gift acts of state jurisdictions. Id. at 1, introductory cmt.
29. Revised Uniform Anatomical Gift Act § 5 (amended 2009) (Unif. Law Comm’n 2006). A person may also make a gift orally, under certain conditions. Id.
30. Id. § 9. The 1968 UAGA prohibited family members from making an anatomical gift if they had “actual notice of contrary indications by the decedent . . . .” Anatomical Gift Act § 2(b) (amended 2009) (Unif. Law Comm’n 1968). The 1987 UAGA prohibited family members from making an anatomical gift if they knew of “a refusal or contrary indications by the decedent . . . .” Anatomical Gift Act § 3(b)(2) (amended 2009) (Unif. Law Comm’n 1987). The 2006 UAGA’s restrictions on family-member consent are much narrower—they must heed a decedent’s objection to donation only if it is documented as a formal refusal. Revised Uniform Anatomical Gift Act §§ 7, 9 (amended 2009) (Unif. Law Comm’n 2006); see infra Subsections I.C.2, I.C.3. Of note, the 2006 UAGA also makes clear that family members cannot make an anatomical gift if the decedent has already done so. Revised Uniform Anatomical Gift Act § 8(a) (amended 2009) (Unif. Law Comm’n 2006). This revision attempted to strengthen first-person consent rights by signaling that it would be inappropriate to ask family members to consent to an anatomical gift already made by the decedent prior to death because they would have no authority to speak to the issue. Although the 1968 UAGA also made clear the individual’s right to make a donation whether the family concurred or not, in the decades following the UAGA’s passage, healthcare providers generally sought the consent of family in addition to, or instead of, honoring any gift document that an individual may have signed prior to death. Revised Uniform Anatomical Gift Act § 8 cmt. (amended 2009) (Unif. Law Comm’n 2006). The reasons for this are generally presumed to be several: reluctance on the part of healthcare providers to insist on organ donation at a time of family grief, fear of adverse publicity, and fear of litigation (though actual liability would be unlikely due to a broad good faith immunity provision in the Uniform Anatomical Gift Act). Id. § 18(a); Anatomical Gift Act § 11 (amended 2009) (Unif. Law Comm’n 1987); Anatomical Gift Act § 7 (amended 2009) (Unif. Law Comm’n 1968)).
31. See Newman v. Sathyavaghwaran, 287 F.3d 786, 796-97 (9th Cir. 2002) (holding that “the [plaintiff’s] had property interests in the corneas of their deceased children protected by the Due Process Clause of the Fourteenth Amendment”); Brotherton v. Cleveland, 923 F.2d 477, 482 (6th Cir. 1991) (holding that “the aggregate of rights granted by the state of Ohio to [the plaintiff] rises to the level of a ‘legitimate claim of entitlement’ in [the decedent’s] body, including his corneas, protected by the due process clause of the fourteenth amendment”). But see Florida v. Powell, 497 So. 2d 1188, 1193.
More recently, and in keeping with increasing respect for personal autonomy and the development of laws to recognize advance directives for health care decisions, an individual may, instead of executing a gift document, specify an agent who may make the decision about donation in the event of the individual’s incapacity or death. If such an agent is specified, he or she has higher authority than family members from the statutory hierarchy.

It is these provisions, which give primary preference to first-person consent, secondary preference to family consent, and which default to nondonation in the absence of either, that mark the U.S. system as primarily an opt-in system. A system that recognizes the voluntary choice to donate—and especially one that honors choices from the individuals whose organs are to be procured—is in keeping with U.S. common-law and constitutional-law traditions that recognize the rights to self-determination and bodily integrity.

B. Opt-Out Policies

Opt-out policies permit the removal of organs or tissues in the absence of prior objection by the decedent or, in places such as Spain, absent the current, explicit dissent of the decedent’s surrogate or family. (Spain, incidentally, has the highest rate of deceased donation in the world.) In the absence of an objection, the default rule is donation.

Opt-out policies are often characterized as either presumed consent or routine removal. The difference between the two is in their distinct understandings of the relationship between the State and individuals’ bodies. In presumed consent, procurement is based on a public understanding and presumed voluntariness to donate, whereas in routine removal, procurement is based on social ownership or social obligation. Routine removal is a communitarian approach, while presumed consent remains individualistic in the sense that donations are based on an indi-

(Fla. 1986) (holding that plaintiffs “have no protectable liberty or property interest in the remains of their decedents”); Georgia Lions Eye Bank, Inc. v. Lavant, 335 S.E.2d 127, 128 (Ga. 1985) (“[I]n Georgia, there is no constitutionally protected right in a decedent’s body. Rather, the courts have evolved the concept of quasi property in recognition of the interests of surviving relatives in the possession and control of decedents’ bodies. We do not find this common law concept to be of constitutional dimension.”) (italics omitted).

33. Id. § 9.
34. See, e.g., Cruzan v. Dir. Mo. Dept’ of Health, 497 U.S. 261, 278 (1990) (determining that prior cases support a constitutional-liberty interest in refusing unwanted medical treatment based on notions of bodily integrity and that common law supports the same).
35. OPPORTUNITIES FOR ACTION, supra note 12, at 205; Rodríguez-Arias et al., supra note 4, at 1109.
36. Rodríguez-Arias et al., supra note 4, at 1109.
37. OPPORTUNITIES FOR ACTION, supra note 12, at 205.
38. Id. at 206-09.
39. Id. at 206, 208.
indual’s consent, although presumed in the absence of objection or other notice of contrary intentions.40

I. Presumed-Consent Policy

Presumed-consent policy is based on the presumption that every person has consented to donate his or her organs after death, and thus no need to ask for express consent to donation exists.41 Competent persons have the right to refuse donation and to record their refusal (i.e., to opt out). In some variations, the next of kin has the right to refuse as well.

Based on family members’ involvement in the process, presumed-consent policies can be understood as strong or weak.42 In weak versions, in the absence of a previously expressed objection on the individual’s part, family members would be asked if they are aware of an individual’s preference and/or if they prefer not to donate.43 In strong versions, there is no need to consult with family members, and organs may be procured following death.44 Although the differences among various countries’ laws may appear stark, in actual practice the differences between strong and weak presumed-consent systems may be small, as family members usually play some role in the process.45 The tendency to involve family members in the process emerges from the general reluctance of procurement teams, physicians, nurses, and intensive-care-unit personnel to increase the grief of families or to come into conflict with them.46 Hence, even in countries with strong presumed-consent legal frameworks, in practice, family members are asked in most cases whether they want to give their approval for organ retrieval.47

Presumed-consent policies appear to have had a positive, sizeable effect on deceased donor organ donation rates.48 While some scholars attribute the higher donation rates in presumed-consent countries to fac-

40. Id. at 206.
41. There are at least three different models of presumed consent: tacit, or silent, consent; consent based on “what reasonable, altruistic people should and would do”; and assumptions of what a deceased person would decide if he or she could be asked. Id. at 210.
42. Id. at 210-12.
43. OPPORTUNITIES FOR ACTION, supra note 12, at 211.
44. Id. at 210-11.
46. Jeffrey M. Pottas, Organ Procurement in Europe and the United States, 63 MILBANK MEMORIAL FUND Q. HEALTH & SOC’Y 94, 102 (1985); Rosenblum et al., supra note 45.
tors other than presumed-consent legislation.\textsuperscript{49} Most studies indicate that presumed-consent policies have increased the rate of donation.\textsuperscript{50} In particular, one study suggests that when other determinants of donation rates are accounted for (e.g., the country being a common-law or civil-law system, the number of deaths caused by motor-vehicle accidents and cerebro-vascular diseases, religious beliefs, education, and medical infrastructure), on average, presumed-consent countries have roughly 25–30% higher donation rates than countries requiring express consent.\textsuperscript{51} The authors of this study hypothesized that the default of donation, even if not enforced, “may affect the consent decisions of the families.”\textsuperscript{52} In other words, even if families are asked, their answers are more likely to be positive given the social expectations created by an opt-out system.

Opponents of presumed consent argue that, without the actual consent of the individual, there is no consent and that presuming consent undermines individual autonomy and is “an affront to the moral principle that is the foundation of consent itself.”\textsuperscript{53} Public awareness and education about the presumption, along with the ease of opting out, reduce some of these concerns.\textsuperscript{54} Conversely, without sufficient public awareness, a presumed-consent system might be understood as a routine-removal system in disguise.\textsuperscript{55} In addition, some scholars who are not opposed in principle to presumed consent object to the adoption of such a policy so long as access to transplantable organs remains inequitable.\textsuperscript{56}

Despite the potential of presumed consent to increase the rates of transplantable organs, it is not the foundation for organ-procurement policy in the United States, and the professional consensus is that replacing the current opt-in policy with an explicit and comprehensive presumed-consent system would be premature.\textsuperscript{57} Before such a policy could be successfully adopted, a number of essential elements would need to be

\textsuperscript{49} For instance, one study suggests that “[w]hen the national organ donation rates are corrected for the mortality rates, . . . the donor efficiency rate shows that opting-out systems do not automatically guarantee higher organ donation rates . . . .” Coppen et al., supra note 18, at 1278. Spain’s success is commonly attributed to its organizational structure, which places donor coordinators in every hospital. Bramhall, supra note 3, at 270–71; Rodriguez-Arias et al., supra note 4, at 1198.


\textsuperscript{51} Abadi & Gay, supra note 47, at 607, 610.

\textsuperscript{52} Id. at 613.


\textsuperscript{54} OPPORTUNITIES FOR ACTION, supra note 12, at 210 (“To be ethically acceptable, a policy of presumed consent would require widespread and vigorous public education to ensure understanding, along with clear, easy, nonburdensome, and reliable ways for individuals to register dissent.”).

\textsuperscript{55} See Aaron Spital, Conscription of Cadaveric Organs for Transplantation: Neglected Again, 13 KENNEDY INST. ETHICS J. 169, 171 (2003); see also OPPORTUNITIES FOR ACTION, supra note 12, at 207 (identifying Florida and Georgia cornea-retrieval statutes as routine-removal rather than presumed-consent policies).


\textsuperscript{57} OPPORTUNITIES FOR ACTION, supra note 12, at 225; Siegal & Bonnie, supra note 56, at 419–20.
in place, including public understanding and education about the policy, easy and accessible procedures to opt out, and buy-in by the healthcare professionals needed to carry out such a policy.\textsuperscript{58} The constitutionality of a presumed-consent system is also unclear. Two recent federal court decisions have recognized that Fourteenth Amendment procedural due process protects family members’ limited property rights in the bodies of their deceased family members, though details on what kind of process might be required are uncertain.\textsuperscript{59} These legal rulings have prompted the repeal of many of the early state statutes that permitted medical examiners to remove corneas or other organs and tissues from bodies in their possession without notice or consent.\textsuperscript{60}

2. \textit{Routine Removal}

Under routine removal, the State has the right to access the organs or tissues of all deceased persons. The ethical justification for this right may rest either in the State’s ownership and dispositive authority over bodies of the deceased or in individuals’ or families’ obligations to provide organs to society postmortem.\textsuperscript{61} Proponents of routine-removal policies argue that, although individuals and their families have surviving or persisting interests in the body of the deceased, these interests are not strong enough to trump living peoples’ interests in needed organs.\textsuperscript{62} Therefore, consent, either express or presumed, from an individual or a family member “is inappropriate as a ‘gatekeeper’ for cadaver donations.”\textsuperscript{63} Although proponents of routine removal prioritize organ procurement over respect for autonomy, some nevertheless avoid taking an absolutist approach and favor setting up narrow opportunities for opting out (for instance, based on conscientious objections).\textsuperscript{64} For this reason, routine removal is often considered under the general label of opt-out policies along with presumed consent.

The perceived practical advantages of routine removal are the potential for a dramatic increase in available organs, reduced costs of procurement (since there is no need to run public-education campaigns, establish registries to record decisions to opt in or out, or train consent

\begin{thebibliography}{9}
\bibitem{58} Opportunities for Action, supra note 12, at 223-25.
\bibitem{59} Newman v. Sathyavigswaran, 287 F.3d 786, 796-97 (9th Cir. 2002) (holding that “the [plaintiffs] had property interests in the corneas of their deceased children protected by the Due Process Clause of the Fourteenth Amendment”); Broherton v. Cleveland, 923 F.2d 477, 482 (6th Cir. 1991) (holding that “the aggregate of rights granted by the state of Ohio to [the plaintiff] rises to the level of a ‘legitimate claim of entitlement’ in [the decedent’s] body, including his corneas, protected by the due process clause of the fourteenth amendment”). Prior state-court opinions, however, had ruled against such Fourteenth Amendment claims. See State v. Powell, 497 So. 2d 1191–92 (Fla. 1986); Ga. Lions Eye Bank Inc. v. Lavant, 335 S.E.2d 127, 128 (Ga. 1985).
\bibitem{60} ORIENTLICHER, supra note 13, at 305-488.
\bibitem{61} Opportunities for Action, supra note 12, at 206.
\bibitem{62} Erin & Harris, supra note 53.
\bibitem{63} John Harris, Organ Procurement: Dead Interests, Living Needs, 29 J. MED. ETHICS 130, 130 (2003).
\bibitem{64} Spital, supra note 55, at 170.
\end{thebibliography}
requestors), avoidance of delays experienced when seeking consent, and a strengthening of distributive justice in organ allocation since all people will share the burdens of procurement (assuming that they are also sharing in the potential benefits).65

To identify whether an opt-out procurement policy is based on routine removal or presumed consent, one should consider the practical features of the system.66 The presence of opt-out registries or routines to inform family members about their choice to opt out or public-education campaigns would suggest a presumed-consent, rather than a routine-removal, system.67 The stated underlying ethical and philosophical principles supporting such policies can also be used to distinguish between these two opt-out approaches.68

Wholesale, explicit adoption of routine removal in the United States is even less likely than presumed consent. Such a policy would not comport with the current ethical and legal principles of individual and familial dispositional authority over the deceased’s body.69 Nevertheless, there are some aspects of the U.S. system that resemble routine removal—most notably, the current practice of conducting premortem examinations and interventional measures on all hospitalized patients who meet medical criteria consistent with possible organ recovery prior to determining whether an anatomical gift has, or will, be made.70 Although organs are not removed prior to actual consent, bodies are sustained for a period of time to enable donation, and there is no opportunity to opt out of that practice. In addition, it is probably most accurate to consider the early authority given to medical examiners to remove corneas without consent or notice to the family—a provision now repealed by many states—as “routine removal.”71

C. Mandated Choice

The mandated-choice strategy,72 endorsed in principle by the American Medical Association (“AMA”) twenty years ago, requires individuals to declare their preferences regarding organ donation while performing certain state-regulated tasks.73 Individuals are free to choose to

65. Id. at 171.
66. Opportunities for Action, supra note 12, at 207 (describing cornea-retrieval statutes as routine-removal policies rather than their more common description as presumed-consent policies).
67. Even then, it might be difficult to distinguish between a routine-removal system with a conscientious opt-out option and a strong presumed-consent system with poor public awareness.
68. Opportunities for Action, supra note 12, at 206.
69. Id. at 208.
70. See infra Subsection II.A.1.
71. Opportunities for Action, supra note 12, at 207; see infra Subsection II.A.5.
donate (or not) and to specify or limit the parts donated. In some proposals of mandated choice, individuals may also assign decision making about donation to family members.\textsuperscript{74} A mandated-choice strategy still honors the choices that individuals make but some of the voluntariness associated with “opting in” is lost, as some decision, whether yes or no, must be made.

The perceived advantages of mandated choice include expansion of the number of designated donors by making people decide in advance of a crisis, promotion of autonomy (since individuals’ preferences are recorded and respected), and elimination of any family barrier in the process of obtaining consent (since family refusal rates are higher than individuals’ refusal rates, at least when individuals are asked about their willingness to donate).\textsuperscript{75} The opponents of mandated choice object to the compulsory nature of the decision, arguing that such compulsion does not respect the autonomy of individuals not to choose. Some critics point out that it is not clear that an individual’s choice, while living, should prevail over a family’s choice following death as the interests of the deceased individual can no longer be recognized.\textsuperscript{76} Others argue, more practically, that mandated choice may backfire in that individuals confronted with a forced choice may find saying “no” to be the safer, easier choice.\textsuperscript{77} Experiments with mandated choice in Texas and Virginia did not lead to higher donation rates,\textsuperscript{78} and no state appears to use mandated choice at this time.\textsuperscript{79} Current “required request” laws in the United States, however, bear some similarity to mandated choice.\textsuperscript{80}


74. Chouhan & Draper, supra note 72, at 158.


76. Ann C. Klassen & David K. Klassen, \textit{Who Are the Donors in Organ Donation? The Family’s Perspective in Mandated Choice}, 125 ANNALS INTERNAL MED. 70, 71 (1996) (writing that many aspects of organ recovery—such as the requirement that families sometimes hold off withdrawing life-support to allow the patient to progress to brain death or the inability of parents to hold their children as heartbeat and respiration cease—have important emotional impacts on family that should be respected).


78. See Laura A. Siminoff & Mary Beth Mercer, Public Policy, Public Opinion, and Consent for Organ Donation, 10 CAMBRIDGE Q. HEALTHCARE ETHICS 377, 380 (2001) (“[E]xperiments with Mandated Choice in the state of Texas [were] counterproductive, with at least 80% of individuals refusing to designate themselves as organ donors with a concomitant reduction in organ procurement.”). Siminoff and Mercer also found that only 43.2% of families agreed with the concept of mandated choice. \textit{Id.} They also report that most people want family consent to continue to be a part of organ donation, at least in part, because of fear that designated donors will be treated less aggressively than patients who have not registered their decision to donate. \textit{Id.; see also} Klassen & Klassen, supra note 76, at 72 (reporting that in Virginia, mandated choice at the DMV resulted in only a 31% donor-registration rate).

79. Siegal & Bonnie, supra note 56, at 422 n.9; see also Kristy L. Williams et al., \textit{Just Say No to NOTA: Why the Prohibition of Compensation for Human Transplant Organs in NOTA Should Be Repealed and a Regulated Market for Cadaver Organs Instituted}, 40 AM. J.L. & MED. 275, 298 (2014)
II. THE MIXED SYSTEM OF THE UNITED STATES

Various legal provisions and routine practices cause the current U.S. procurement system to fall short of a robust opt-in system in which the decedent has primary premortem control over the decision to donate. 81

First are the laws and practices that resemble opt-out or mandated-choice systems. Many of these laws and practices have been recently adopted or strengthened. Generally, they reflect new approaches in the medical management of potential donors and the interactions between sophisticated organ-procurement organizations and the families of potential donors.

Second, but equally concerning, are some of the seemingly more mundane, mechanical provisions of the UAGA that provide for how anatomical gifts can be made, limited, revoked, and refused by individuals or families. These provisions may not resemble opt-out policies per se, but they are antithetical to a strong opt-in, first-person policy. In general, in the absence of a clearly documented gift or refusal, the rules do not encourage efforts to discern or honor an individual’s intent but instead leave an opening to allow a later gift by family members.

A. Opt-Out Elements in the Current U.S. System

I. Premortem and Postmortem Examinations and Maintenance Measures Prior to Verification of Organ Donor Status

As illustrated in the scenario that opens this Article, current organ-procurement practices incorporate premortem as well as postmortem examinations and other measures, such as ventilatory support, to ensure the initial and continued suitability of organs for donation. 82 These interventions routinely take place before verification of the patient’s donor status (first-person consent) or family consent. 83 They can also take place when consent for donation will ultimately be denied because surrogates and family members are generally unaware of the tests and other inter-

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80. See infra Section II.B.
81. REVISED UNIF. ANATOMICAL GIFT ACT (NATL. CONFERENCE OF COMMR'S. ON UNIF. STATE LAWS 2006) (Prefatory Note). Of the three “policy determinations” the drafters of the 2006 UAGA specified as grounding the act, the second was “honor and respect [for] the autonomy interest of individuals to make or not to make an anatomical gift of their body or parts.” Id. The first policy determination listed was to encourage the making of anatomical gifts; the third was to preserve the system of altruistic donation as opposed to sale. Id.
82. See Bramhall, supra note 3.
83. Id. at 270.
ventions to permit organ recovery and therefore cannot object.84 Even a patient who has gone through the trouble to document a refusal to donate might still undergo such interventions until the refusal is discovered.85 These practices—all legally authorized and sometimes required—constitute an opt-out component in our current system. In essence, all patients who are near death or who die in the hospital are, at least for some period of time, treated as if their bodies will be donated for organ-transplantation purposes.

This was not always the case. In the early days of organ transplantation, the interventions that might be done to the body to enable donation—either to determine the medical suitability of organs for donation or to maintain the health of organs and tissues—took place after death, and legal authority for their performance depended on consent for donation.86 The 1968 UAGA provided that an anatomical gift “authorizes any examination necessary to assure medical acceptability of the gift for the purposes intended.”87 Because anatomical gifts were not effective until after death,88 the examinations this provision contemplated were postmortem.89 The 1987 UAGA contained a similar provision.90

Today, the federal regulations specifying the conditions for hospital participation in Medicare and Medicaid require hospitals to notify their contracted regional OPO for every patient whose death is imminent or who has died.91 According to the interpretive guidelines for the regulations, the hospital must notify the OPO before the potential donor is removed from a ventilator92 and, whenever possible, before brain death is declared and before the option of organ donation is presented to the family of the potential donor.93 The regulations assign responsibility for determining the medical suitability of organs for donation to the OPO,

84. See Sipes, supra note 18, at 517.
86. UNIF. ANATOMICAL GIFT ACT §§ 2(d), 7 (NAT'L CONFERENCE OF COMMRS. ON UNIF. STATE LAWS 1968).
87. Id. § 2(d).
88. Id. § 4(a).
89. Id. § 2(d) (commentary) (“Subsection (d) is added at the suggestion of members of the medical profession who regard a post mortem examination, to the extent necessary to ascertain freedom from disease that might cause injury to the new host for transplanted parts, as essential to good medical practice.”).
90. UNIF. ANATOMICAL GIFT ACT § 11 (NAT'L CONFERENCE OF COMMRS. ON UNIF. STATE LAWS 1987) (“An anatomical gift authorizes any reasonable examination necessary to assure medical acceptability of the gift for the purposes intended.”). According to the commentary, the purpose and scope of the section remained the same as the UAGA of 1968. Id. (commentary) (“Subsection (a) is Section 2(d) of the original Act. The purpose of this subsection was explained in a Comment to the original Act.”).
91. 42 C.F.R. § 482.45(a)(1) (2016) (regulating conditions of participation in organ, tissue, and eye procurement in Medicare and Medicaid programs).
93. Id. at 446.
including certain physical examinations and laboratory tests required by the Organ Procurement Transplantation Network ("OPTN"), the federal, public-private partnership that implements the donation and transplantation system.\textsuperscript{94}

State laws, through the 2006 UAGA revisions, accommodate these federal requirements by allowing both premortem and postmortem examinations and also by allowing the continuation of premortem and postmortem measures necessary to ensure the suitability of the body for donation purposes, such as mechanical ventilation, all prior to verifying first-person consent or securing family consent.\textsuperscript{95} As a result, dying patients and patients who have succumbed to brain death may be maintained on ventilatory and other support solely for the purpose of potential organ donation. Sometimes providers will initiate, rather than simply continue, invasive procedures, such as the placement of central lines in still-living patients, to allow for organ procurement.\textsuperscript{96} Because the family has not yet been approached for donation, these measures may be undertaken by healthcare providers without any explanation that such treatments are not for the patient’s benefit.\textsuperscript{97} Such interventions are explicitly permitted by the law until an individual has been ruled out as a potential donor.

Both designated donors (those who have given first-person consent) and individuals who have not made an anatomical gift are affected. One might argue that a designated donor has implicitly consented to these

\textsuperscript{94} 42 C.F.R. §§ 482.45(a)(1), 121.6. ("The suitability of organs donated for transplantation shall be determined as follows: (a) Tests. An OPTN [Organ Procurement Transplantation Network] member procuring an organ shall assure that laboratory tests and clinical examinations of potential organ donors are performed to determine any contraindications for donor acceptance, in accordance with policies established by the OPTN. (b) HIV, ... The OPTN shall adopt and use standards for preventing the acquisition of organs from individuals known to be infected with [human immunodeficiency virus]. (c) Acceptance criteria. Transplant programs shall establish criteria for organ acceptance, and shall provide such criteria to the OPTN and the OPOs with which they are affiliated.").

\textsuperscript{95} Section 14(c) provides that:

When a hospital refers an individual at or near death to a procurement organization, the organization may conduct any reasonable examination necessary to ensure the medical suitability of a part that is or could be the subject of an anatomical gift for transplantation, therapy, research, or education from a donor or a prospective donor. During the examination period, measures necessary to ensure the medical suitability of the part may not be withdrawn unless the hospital or procurement organization knows that the individual expressed a contrary intent.

\textsuperscript{96} Arvind Venkat et al., \textit{Ethical Controversies Surrounding the Management of Potential Organ Donors in the Emergency Department}, 47 J. EMERGENCY MED. 232, 234 (2014). According to Venkat et al., because "maintenance" is undefined it can mean: 1) continuing existing treatments in a patient who is a potential organ donor; 2) escalating existing treatments but not adding further treatments; 3) implementing full organ preservation protocols designed to maximize perfusion until a decision on donation has been made, or 4) performing surgical procedures to control damage to allow the performance of brain death examinations. ... Some commonly supported maintenance protocols ... may even involve invasive procedures, such as central lines, which normally require informed consent[.]

\textit{Id.}

\textsuperscript{97} \textit{Id.}
procedures by registering as an organ donor, but this argument is weak; while donors certainly expect postmortem measures, little to no-information about how premortem care may be altered is made available at the time people register their intention to donate, nor have efforts been made to more broadly educate the public about these measures. In fact, in an attempt to dispel fears about donation, the U.S. Department of Health and Human Services’s website (“organdonor.gov”) has the following question and answer about medical care prior to donation: “If I’m a registered donor, will it affect the quality of medical care I receive at the hospital? No! The medical team trying to save your life is separate from the transplant team. Every effort is made to save your life before donation is considered.”

This answer is somewhat misleading. In attempting to address concerns that efforts will not be made to save or extend the lives of designated donors, the answer assures people that their individual care will not be altered for purposes of donation. But medical care can, and even likely will, be altered by the premortem examinations and initiation or continuation of maintenance measures.

A similar lack of transparency can be found on the webpage for patient education of the United Network for Organ Sharing (“UNOS”), the private nonprofit organization that serves as the designated federal OPTN. There, one finds the explanation that “[o]rgan donation can only be considered after brain death has been declared by a physician.” This statement implies that nothing in the care of patients is altered by virtue of being an organ donor. While it is true that organ recovery can only take place after brain death has been declared, organ donation is foremost in the minds of the OPO personnel who have been contacted about the hospitalized patient, and may be present in the hospital, and are requesting or placing orders for examinations and maintenance measures for the purposes of facilitating donation.

Family members and surrogate decision-makers generally will not know, at least for some time, that these interventions are taking place.

98. See infra Subsection III.A.1.
100. This statement further fails to acknowledge that organ recovery may also take place after cardiac death, although surrogate consent is still required for the more invasive medical interventions necessary to successfully recover organs following cardiac death.
101. Moreover, these changes in care may be more likely for registered donors than other patients because surrogates and families have less authority to challenge such alterations in medical care when an anatomical gift has already been made.
and cannot prevent them. In fact, opacity is built into the system by the expectation that medical suitability will be determined prior to approaching the family for consent.  

This puts physicians and nurses who have been caring for the patient in a special bind, as they find themselves unable to ask families for permission for these extra medical measures even though the patients are still under their care.  Unless the physicians and nurses are “designated requesters” under the Centers for Medicare and Medicaid Services’ (“CMS”) regulations—which is uncommon—they are not permitted to seek consent for donation from the family and, by implication, are not to interfere with the OPO’s examination and consent-for-donation process by seeking consent for OPO examinations or otherwise disclosing the true purpose of these examinations. Similarly, physicians may delay discussing with the family a decision to withdraw ventilator support from a dying patient since that discussion could prompt a premature mention of the possibility of donation.  

None of this means that the medical care of patients is necessarily compromised in any substantial way. But physicians and nurses who are trained and obligated to put the best interests of patients first—and, indeed, have a fiduciary duty to do so—must allow others to determine a course of treatment that, while not necessarily harmful to patients, is not beneficial to them. Their duties of loyalty and truth-telling to family and surrogate decision-makers are also strained and potentially compromised.

Together, these laws and related practices represent an opt-out approach—at least for some period of time—for hospitalized patients near death. They resemble routine removal more than presumed consent because they apply to every hospitalized patient at or near death with little to-no-opportunity to opt out. Even people who might have recorded a refusal may become subject to the examinations and interventions since OPOs do not have ready access to documentation of refusals. Registries and state motor-vehicle departments generally only record gifts, not refusals, a natural consequence of a system that ostensibly relies on opting

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103. Family members cannot be asked to consent to the examinations or maintenance measures without involving them in a conversation about consent for donation, which is delayed until physical suitability for organ donation is determined; therefore, the UAGA authorizes OPOs to proceed without consent.

104. Venkat et al., supra note 96, at 234.

105. Id. at 233 (“[T]here is little incentive for an OPO to train designated requesters among hospital staff. Medicare holds the OPO ultimately accountable for meeting standards on deceased organ procurement. As a result, few designated-requestor training programs are publicized or offered by OPOs.”).

106. See infra Subsection II.A.5.

107. In the language used by OPOs, such premature conversations would be noted as a “pre-mention,” which, according to the implicit or explicit agreements between hospitals and OPOs, are to be strictly avoided.
in rather than opting out. In any event, the number of people who have
gone through the trouble to document a refusal—given that there is no
established process or distributed form to do so—is unknown but likely
very small.

2. **Overriding Advance Directives—Presumptions About the
Importance of Donation When Patient Intent Is Unclear**

Can an advance directive that limits life-sustaining treatment preven
t the implementation of life-sustaining measures for purposes of po
tential donation? The answer is no, not immediately, and not without the
agreement of the donor’s surrogate decision-maker(s).

The UAGA does not grant hospitals and OPOs the authority to con
inue maintenance measures when they know that the individual ex
pressed a “contrary intent.” Such a contrary intent might be inferred
from an advance directive that expresses a patient’s wishes for life
sustaining measures to be withheld or withdrawn if those measures only
prolong the dying process (typical language found in advance directives).
But the language of the UAGA does not support that inference. Instead,
when the terms of a written advance directive would preclude donation
by discontinuing maintenance measures like ventilation, the donor’s sur
rogate decision-maker and the attending physician are instructed under
Section 21 to confer to resolve the conflict. Until the matter is resolved,
measures necessary to ensure the suitability of organs may not be with
held or withdrawn unless “contraindicated by appropriate end-of-life

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search to determine if patient has made an anatomical gift, but not whether he or she has refused to
make one); see also infra Subsection II.C.4.

interpreted to mean an intent contrary to donation or an intent contrary to the continuation of
maintenance measures. The language is ambiguous. As explained above, an intent contrary to do
nation is unlikely to be known prior to approaching the family for consent, which means maintenance
measures will be continued for at least some time for the benefit of organ donation for most patients
who fit the physical criteria for donation.

110. **Id. § 21.** This section provides:

(b) If a prospective donor has a declaration or advance health-care directive and the terms of the
declaration or directive and the express or implied terms of a potential anatomical gift are in con
flict with regard to the administration of measures necessary to ensure the medical suitability of a
part for transplantation or therapy, the prospective donor’s attending physician and prospective
donor shall confer to resolve the conflict. If the prospective donor is incapable of resolving the
conflict, an agent acting under the prospective donor’s declaration or directive, or, if none or the
agent is not reasonably available, another person authorized by law other than this [Act] to make
healthcare decisions on behalf of the prospective donor, shall act for the donor to resolve the
conflict. The conflict must be resolved as expeditiously as possible. Information relevant to the
resolution of the conflict may be obtained from the appropriate procurement organization and
any other person authorized to make an anatomical gift for the prospective donor under Section
9. Before resolution of the conflict, measures necessary to ensure the medical suitability of the
part may not be withheld or withdrawn from the prospective donor if withholding or withdrawing
the measures is not contraindicated by appropriate end-of-life care.

Section 21(a) defines a “declaration” to mean “a record signed by a prospective donor specifying the
circumstances under which a life support system may be withheld or withdrawn from the prospective
donor.” **Id. § 21(a)(2).**
care.” 111 This means that even when an advance directive directly states that maintenance measures should be withdrawn or never initiated, the advance directive should not be interpreted, at least not initially, as a refusal of the pre-mortem maintenance measures necessary to facilitate donation. This section applies to both patients who are designated donors as well as to patients who are not. 112

As model advance-directive forms evolve, they might be drafted in a way to avoid conflict with anatomical gift decisions. For example, future advance-directive forms could include an opportunity for individuals to make an anatomical gift through the advance directive itself (as some currently do) and, if carefully drafted, could provide guidance to physicians, OPOs, and surrogates on which instructions in the advance directive should be given greater weight. For such forms to facilitate informed decisions, however, they will need to explain how medical care of the individual may be altered in a way to permit donation (for example, by extending the time period for which a patient will be kept on life-support).

Current advance-directive forms do not generally contain information about how end-of-life instructions might conflict with an anatomical gift nor do they specify which instructions should take precedence when a conflict exists. 113 The UAGA’s commentary specifies that the patient’s probable intention should resolve the conflict, but in contrast to typical rules for determining intent in similar contexts—like property, wills, or contracts—it does not give greater weight to the more recently executed document. 114 It also does not give greater weight to the document (the advance directive) that speaks to the patient’s wishes concerning his or her own care and, importantly, that specifically addresses life-sustaining treatment. 115 The consequences of initiating or continuing unwanted mechanical ventilation and related therapies cannot be dismissed as a mere brief prolongation of the process of death. Kompagje et al. point out that such therapies in “patients who are not brain dead, but who are beyond hope of meaningful survival, with the sole intent of

111.  Id. § 21(b). In the first version of the UAGA 2006, this section reads as follows: “If a prospective donor has a declaration or advance health-care directive, unless it expressly provides to the contrary, measures necessary to insure the medical suitability of an organ for transplantation or therapy may not be withheld or withdrawn from the prospective donor.” The section thus presumed that a donor’s decision to donate trumped his or her instruction not to have life prolonged. Id. In response to the criticisms of this subsection, it was revised the following year. See Ana S. Ilitse et al., Organ Donation, Patients’ Rights, and Medical Responsibilities at the End of Life, 37 CRITICAL CARE MED. 310 (2009) (describing the history of the section and critiquing both its past and present form).

112. See REvised UNiF. ANATOMICAL GIFT ACT § 22 (2006) (defining “prospective donor”—to whom § 21 applies—as “an individual who is dead or near death and has been determined by a procurement organization to have a part that could be medically suitable for transplantation, therapy, research, or education. The term does not include an individual who has made a refusal”).


114. See Ilitse et al., supra note 111, at 310(describing the history of the section and critiquing both its past and present form).

115. Id.
awaiting brain death and the possibility of organ donation bears some risk that the patient will not die but remain alive in a persistent vegetative state.\textsuperscript{116} Patients in a persistent vegetative state can often later breathe on their own, leaving surrogate decision makers with what many find to be a more difficult decision to make—whether or not to refuse artificial nutrition and hydration.\textsuperscript{117}

More troubling is the fact that nondonors are also included within the reach of § 21 as “prospective donors.”\textsuperscript{118} Even if some delay in the effectuation of the end-of-life wishes of a designated donor can be justified when there is a conflict between an advance-directive instruction to forego life-sustaining treatment and measures necessary for an anatomical gift, in the case of nondonors there is no original intent to make an anatomical gift. Here, there is little basis for presuming that donation was valued by the patient over their end-of-life care wishes.

The approach of § 21 of the UAGA, which permits ignoring end-of-life care instructions when necessary to facilitate donation, is another instance of an “opt-out” measure. Patients can opt out, but they must make their desire to do so perfectly clear. A typical advance directive will not suffice. The required conference between physicians and families—for which there are neither specified processes nor time limits\textsuperscript{119}—resembles mandated choice. Ana Ilitis et al. wrote, “[i]t is reasonable to ask whether families should be required to endure a process of conferring on a matter they see as clear and that does not aim to benefit the patient.”\textsuperscript{120} Concern about forcing families to engage in these conversations is heightened when the “expected donation” approach, in which families are approached with the expectation that they will agree to donate their relative’s organs, is used by OPO personnel.\textsuperscript{121}

3. \textit{Additional Interventions to Allow Organ Donation Following a Circulatory Determination of Death}

Donation following cardiac death—(sometimes referred to as “donation after circulatory determination of death” or “DCDD”\textsuperscript{122})—raises


\textsuperscript{117} \textit{See generally} Lois Shepherd, \textit{In Respect of People Living in a Permanent Vegetative State—And Allowing Them to Die}, 16 \textit{Health Matrix} 631 (2006) (exploring the complications of patients in a permanent vegetative state).

\textsuperscript{118} \textit{See Revised Unif. Anatomical Gift Act} § 2 (22) (2006) (amended in 2009) (defining “prospective donor”); \textit{id.} § 21 (requiring a search to determine if a patient has made an anatomical gift, but not whether he or she has refused to make one).

\textsuperscript{119} Ilitis et al., \textit{supra} note 111.

\textsuperscript{120} \textit{Id.} at 311.

\textsuperscript{121} \textit{See infra} Subsection IL A.4.

\textsuperscript{122} This term is preferred by some over “donation after cardiac death.” \textit{Opportunities for Action, supra} note 12, at tbl S-1. Similarly, “donation after neurologic determination of death” (“DNDD”) is preferred over “donation after brain death.” \textit{Id.; see also Inst. Med., Non-Heart-}
additional concerns. Patients who are considered potential DCDD donors may be required to undergo additional interventions while alive to facilitate donation. Because the explicit legal authorization for such additional interventions without consent is absent, they are generally performed only with patient, family, or surrogate consent. There is currently substantial debate over the direction future policy should take—specifically, whether consent for the interventions might be presumed and, if so, under what conditions.

In the very earliest days of transplantation, organs were mostly recovered after the irreversible cessation of circulatory and respiratory functions. Following improvements in the late 1960s to medical support to sustain cardiovulmonary function, protocols establishing neurological criteria of death were developed and incorporated into law. Because organs of patients who died by neurological criteria could continue to be perfused through ventilator support, transplant outcomes improved, and the focus of organ recovery shifted to these types of donors and away from those who died by circulatory criteria. The continuing shortage of transplantable organs, however, has refocused attention back to DCDD. Since the rates of cardiopulmonary deaths are higher than neurological deaths, one of the strategies to increase transplantable organs is the recovery of organs by using cardiac death protocols. CMS and the Joint Commission, the largest hospital-accrediting organization, now requires hospitals to establish and implement protocols for recovering DCDD organs.

Organs and tissues can potentially be recovered when an individual has died from either a controlled or uncontrolled cardiac death. In controlled DCDD, a hospitalized patient is on life support; after a separate decision to discontinue life support, life support is removed, death is declared, and organs are recovered. In uncontrolled DCDD, the patient has already suffered from a sudden cardiopulmonary arrest causing

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123. **IOM Report on Non-Heart-Beating Organ Transplantation, supra note 122.**

124. See UNIF. DETERMINATION OF DEATH ACT, 12 U.L.A. 340 (Supp. 1991). The act reads, in part: “An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead.” Id. Some version of the Uniform Determination of Death Act has been adopted in almost every state. See generally Jerry Mennick, The Importance of Being Dead: Non-Heart-Beating Organ Donation, 18 ISSUES L. & MED. 3 (2002) (analyzing DCDD in the controlled setting and determinations of death).

125. **IOM Report on Non-Heart-Beating Organ Transplantation, supra note 122, at 8.**


128. **IOM Report on Non-Heart-Beating Organ Transplantation, supra note 122, at 8–9.**
death, and organs must be recovered rapidly before they become unusable. 129

Organ recovery from these two types of patients raise separate concerns, which are briefly addressed below.

a. Controlled DCDD

In order for organ recovery following controlled DCDD to be successful, certain premortem interventions must be undertaken. Measures can include “administration of medications such as heparin to prevent the formation of emboli, vasodilators to improve organ perfusion, bronchoscopy to rule out infection, placement of a nasogastric tube to decompress the stomach, and/or the placement of arterial and/or venous cannulae for rapid access at the time of death.”130 Obtaining consent for these measures is emphasized in procurement standards established by the OPTN.131 According to these standards, no medications or procedures should be administered or performed without consent.132 The AMA has also determined that consent for controlled DCDD should include a discussion about premortem measures.133 Because the medical condition of the patient is sufficiently stable to allow a controlled death through withdrawal of life support, there is enough opportunity to obtain either the patient’s consent (assuming he or she still has decision-making capacity) or the surrogate’s consent for the administration of premortem measures. To date, an individual’s making of an anatomical gift, such as through his or her driver’s license, is not by itself considered to be sufficient consent to these additional procedures.

The practical effect of the necessity of separate consent for premortem measures in DCDD is that surrogate decision makers can, in effect, override a patient’s decision to donate.134 This seems appropriate, however, given people’s lack of knowledge at the time of donor registra-

129. Id. at 8.
130. American Thoracic Society, supra note 127, at 106. Premortem interventions in controlled DCDD may also include “administration of preservative solution or use of extracorporeal oxygenation (ECMO).” Id. The ethical controversy around these measures is the potential reinitiation of some physiological functions. For instance, “the use of ECMO [extracorporeal membrane oxygenation] after the declaration of death causes reinitiation of circulation and may stimulate brain or other organ functions. Use of ECMO in ways that clearly restore cerebral circulation is ethically and legally problematic.” Id.
131. Congress established the OPTN through passage of the National Organ Transplant Act in 1984. The OPTN is charged with maintaining a national registry for organ matching and is operated under federal contract. See Organ Procurement and Transplantation Network History & NOTA, HEALTH RES. & SERVS. ADMIN., http://optn.transplant.hrsa.gov/governance/about-the-optn/history-nota/ (last visited April 4, 2017). The United Network for Organ Sharing (“UNOS”) has contracted with the federal government to administer the OPTN since 1986. Id.
134. This is true despite the 2006 UAGA’s efforts to prevent family members from overriding a first-person donor designation. REVISED UNIF. ANATOMICAL GIFT ACT § 8 (2006).
tion about the necessity for such interventions or even about the possibility of donation following cardiac death.

b. Uncontrolled DCDD

In cases of uncontrolled DCDD, a patient arrives at the hospital after a fatal cardiac event. Some invasive procedures, such as the insertion of cannulae and cooling of the body, must be performed promptly, which leaves no time to obtain the consent of family members or the patient’s surrogate decision maker. The ethical acceptability of these interventions prior to obtaining consent is the subject of an ongoing debate. The AMA declares that in uncontrolled DCDD, prior consent of the decedent or decedent’s surrogate is required and, as such, perfusion without consent to organ donation violates requirements of informed consent and is not permissible. A registered donor may reasonably be considered to have consented to these procedures since they are postmortem. It will often be difficult in the time available, however, to determine whether the decedent is a registered donor. In the absence of evidence of donor designation, hospitals that proceed with such interventions do so on the basis of presumed consent.

There may be good reasons to permit these interventions to take place—for example, to allow a search for documentation of donor designation or to preserve the family’s opportunity to choose donation. Some proponents argue that if the legal authority to undertake preservation procedures (i.e., “maintenance measures” like ventilator support) is implicit in the context of death by neurological criteria, it is logical that the same standard is applicable in the context of cardiac death. All of these arguments, however, are based on the acceptability of some form of presumed consent. To our knowledge, protocols for uncontrolled DCDD are not commonly in use in the United States; they are, however, common in some European countries.

136. OPPORTUNITIES FOR ACTION, supra note 12, at 133.
137. AM. MED. ASSN, supra note 133.
139. Id. at 742.
140. But see James F. Childress, Organ Donation After Circulatory Determination of Death: Lessons and Unsolved Controversies, 36 J.L. MED. & ETHICS 766, 766-67 (2008) (arguing that temporary measures to preserve organs in this situation can be ethically justified as enhancing, rather than limiting, autonomy and that the fiction of presumed consent can thereby be avoided).
141. OPPORTUNITIES FOR ACTION, supra note 12, at 133.
4. OPO Solicitation of Families in Hospitals: Expected Donation or Presumptive Approach

OPO representatives traditionally approached families for donation using a value-neutral approach. They offered donation as an option for the family to consider and assured family members that whatever choice they made would be supported.142 This value-neutral approach was believed necessary to respond to public distrust in the early days of transplantation. Even today, people express concern that a designated donor’s medical treatment may be compromised to hasten death for organ recovery.143 To avoid conflicts of interest, or the appearance of conflicts of interest, all versions of the UAGA have prohibited the physician who attends a donor at death or certifies death from participating in the procedures of organ recovery or transplantation.144 Similarly, there is a strong consensus that, for donors who will die of cardiac death, a decision to withdraw life support should be made prior to any mention of organ or tissue donation.145 Placing the responsibility for approaching families upon OPO requesters146 who used a value-neutral approach served a similar purpose—the request would be made by someone assuming the role of an objective third party, rather than healthcare providers who might be perceived as having an interest in the decedent’s organs that could be in conflict with their duties to care for a patient.147

Under the newer “expected donation” or “presumptive approach,” requesters assume that families will consent to donation because donation is the right thing to do.148 Rather than a difficult decision, requestors present donation as an obvious choice.149 Requesters are encouraged to present donation as an opportunity for family members to save lives and to make their loved one a hero.150 Requesters may be introduced as members of a medical team or as donation experts for the intended pur-

142. Zink & Wertlieb, supra note 2, at 130.
143. See Srinivas & Mercer, supra note 78.
144. REVISED UNIF. ANATOMICAL GIFT ACT § 14(i) (2006); UNIF. ANATOMICAL GIFT ACT § 8(b) (1987); UNIF. ANATOMICAL GIFT ACT § 7(b) (1968).
145. AM. MED. ASSN, supra note 133; see generally Gribbs, supra note 127.
146. A number of terms are currently used to describe individuals who request donation from families: organ-procurement coordinator (“OPC”), family-advocate, requestor, or family-support services. Ashley E. Anker & Thomas Hugh Fiecky, Asking the Difficult Questions: Message Strategies Used by Organ Procurement Coordinators in Requesting Familial Consent to Organ Donation, 16 J. Health Comm. 633, 644 n.1 (2011).
147. Zink & Wertlieb, supra note 2, at 130. Spain takes a different approach:
Spanish professionals are mostly ICU doctors or anaesthesiologists who work part-time as in-hospital transplant coordinators. Their access, familiarity, and authority in the ICU prevent loss of donors due to non-detection or lack of staff motivation. When transplant coordinators are also ICU doctors who have participated in treatment of the patient, their contact with the family provides an opportunity to promote family satisfaction with treatment received and trust in the doctor, factors that facilitate the request for donation.
Rodriguez-Arias, supra note 4, at 1109.
148. Zink & Wertlieb, supra note 2, at 129.
149. Id. at 131.
150. Id. at 132-34.
pose of building a relationship of trust between them and the families.\footnote{151} At the same time the requesters are building these trust relationships, however, they are supposed to identify “with the organ recipients as much as, or perhaps more than, with the grieving families of potential organ donors.”\footnote{152}

Some proponents of the presumptive approach argue that it is consistent with contemporary American values of individual choice because, when surveyed, most people indicate a willingness to donate their organs, despite the fact that many fail to actually register as donors prior to death.\footnote{153} Under this argument, families are merely prompted to make the decision that the decedent likely would make.\footnote{154}

But Robert Truog points out that it is misleading and disingenuous for OPO requesters to present themselves as part of the medical team and then to act as advocates for potential recipients.\footnote{155} OPOs also have their own interests in securing donations to meet outcome measures for certification by CMS.\footnote{156}

In addition to concerns about conflicts of interest, the presumptive approach raises concerns about the voluntariness of the consent secured.\footnote{157} Simon Rippon has argued that presumed consent is actually

\begin{itemize}
\item \footnote{151} Id. at 132.
\item \footnote{152} Id.
\item \footnote{153} See id. at 129.
\item \footnote{154} According to Gil Siegal and Richard Bonnie, the presumptive approach might also be justified under a set of ethical values that emphasizes reciprocity as much as altruism (“reciprocal altruism”), which understands that “everyone is a potential recipient as well as a potential donor.” Siegal & Bonnie, supra note 56, at 416. Siegal and Bonnie believe that, long-term, a shift to a legal rule of presumed consent is ultimately preferable to the presumptive approach, but argue that such a change would be premature until there is greater public understanding of reciprocal altruism as the moral basis of organ donation and until access to transplantation services are more universal, so that everyone actually could be a potential recipient. Id. at 140.
\item \footnote{155} Robert D. Truog, Consent for Organ Donation—Balancing Conflicting Ethical Obligations, 388 N. ENGL. J. MED. 1209, 1210 (2008).
\item \footnote{156} 42 C.F.R. § 486.301–348 (2017) (Centers for Medicare and Medicaid Services, Subpart G—Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations); see id. § 486.318(a)(1) (stating outcome measure requirements; specifying a required OPO “donation rate of eligible donors as a percentage of eligible deaths is no more than 1.5 standard deviations below the mean national donation rate of eligible donors as a percentage of eligible deaths”); Transmittal 115, Dep’t of Health & Human Servs. Ctrs. for Medicare & Medicaid Servs., CMS Manual System, Pub. 10007 State Operations Provider Certification (May 23, 2014), http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R115SOMA.pdf (Appendix Y providing interpretive guidance on conditions for coverage for organ procurement organizations); see also Mohamed Y. Rady et al., Mass Media Campaigns and Organ Donation: Managing Conflicting Messages and Interests, 15 MED. HEALTH CARE & PHIL. 229, 235 (2012) (“Procurement coordinators are . . . required to reach certain benchmarks in rates of consent and donor conversion at designated donor hospitals and are faced with penalties for poor performance.”) (citations omitted).
\item \footnote{157} Simon Rippon, How to Reverse the Organ Shortage, 29 J. APPLIED PHIL. 344, 345 (2012). Rippon writes that: “Is there a danger that the presumptive approach could threaten a person’s ability to make a properly informed autonomous choice about the matter at hand? It is rather clear that it could, since the counsellors used under the presumptive approach are charged with encouraging ascent to donate, and their subjects, exposed to a unidirectional persuasive influence (without having chosen to be so exposed), are consequently vulnerable to making decisions that are less likely to reflect their own fully-informed reflective preferences.”
\end{itemize}
morally preferable to the presumptive approach, which, with its persuasive influence in a time of vulnerability, can “threaten a person’s ability to make a properly informed autonomous choice.” For these reasons, the presumptive approach has been described as “imposed consent.”

5. Cornea Removal Provisions Remaining in Some States—Presumed Consent or Routine Removal

For several decades, beginning in the 1960s, a number of states expressly permitted medical examiners to recover organs and tissues from bodies in their possession in the absence of any known objection by the decedent or next of kin. Some of these provisions only covered corneas and other eye tissues, but others included any human body part for transplantation or therapy. Some required the medical examiner to make a reasonable effort to inform the next of kin about the option to make or to object to making an anatomical gift, but others, such as Florida’s (which covered only corneas), did not. The 1987 UAGA included a similar provision allowing medical examiners to recover parts from bodies in their possession. It required a search for next of kin so that family members might be informed of the option to donate or refuse to donate the decedent’s organs, although the reasonableness of the search was judged by the useful life of the part, which at the time of drafting was about six hours following death for the recovery of corneal tissue.

Most, but not all, of these statutes have since been repealed as states have adopted the 2006 version of the UAGA, which eliminated the special organ and tissue recovery provisions for bodies in the possession of medical examiners. These provisions have been characterized as either “presumed-consent” or “routine-removal” according to the ethical justification offered to support them (i.e., a presumption about the decedent’s intent or the strength of society’s interest in organ recovery for the

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*Id.* at 355. Truog has raised the additional concern that in cases of DCDD, family members may face pressure to consent to premature measures on the assumption that a patient’s willingness to become an organ donor indicates a willingness to undergo these measures. *Id.* at 344.

156. Rady et al., *supra* note 156, at 345.
158. *See UNIF. ANATOMICAL GIFT ACT § 4 (1987).*
159. FLA. STAT. § 765.5185 (West 2016). The commentary to the 1987 UAGA reported that some states had already experienced a great increase in the number of corneal transplants following the passage of such statutes; in Alabama, the number of corneas available for transplant exceeded demand. *UNIF. ANATOMICAL GIFT ACT § 4 (1987) (commentary); see also* Michelle Goodwin, *Rethinking Legislative Consent Law?*, 5 DEPAUL J. HEALTH CARE L. 257, 277 (2002).
160. *UNIF. ANATOMICAL GIFT ACT § 4 (1987).*
161. *Id.* (including commentary).
162. *See generally Orentlicher, supra* note 13, at nn. 20-21 (detailing state-law changes following UAGA 2006).
163. *See* e.g., FLA. STAT. § 765.5185; IND. CODE § 36-2-14-19 (2016); WIS. STAT. § 157.062m (2016).
164. *See REVISION OF UNIF. ANATOMICAL GIFT ACT § 22(c) (2006).*
public’s health) or according to the degree to which opportunities to register objection are facilitated. 168

According to David Orentlicher, use of this type of opt-out policy—which he calls a “little-known experiment” in presumed consent 169—peaked in 1991 and has generally been abandoned as a result of federal lawsuits calling into question the statute’s constitutionality. 170

B. A Form of Mandated Choice—Required Request of Families 171

Although the focus of this Article has been on the opt-out elements of our current system, or the ways in which it is far from purely opt-in, it is worth mentioning that families of deceased or dying hospitalized patients are put to something like a “mandated choice.” CMS regulations require hospitals to “ensure . . . that the family of each potential donor is informed of its option to donate . . . or to decline to donate” (although families need not be asked when the patient himself has registered as a donor). 172 A request for organs must be made only by an OPO representative or a requester designated by a hospital and trained and approved by the OPO. 173 In practice, the person making the request is almost always an OPO employee. 174 Hospitals cannot make a judgment that certain families should not be approached, for example, because of grief or suspected religious objection to donation. 175

This approach resembles mandated choice in that families are required to choose to donate or not—they cannot avoid making an express choice. Family members, when approached for consent, are not merely

168. See Maryellen Liddy, The “New Body Snatchers”: Analyzing the Effect of Presumed Consent Organ Donation Laws on Privacy, Autonomy, and Liberty, 28 FORDHAM URB. L.J. 815, 833 (2001) (describing cornea removal as a presumed-consent policy); OPPORTUNITIES FOR ACTION supra note 12, at 207 (describing some of the cornea-removal regulations as routine-removal policy); Orentlicher, supra note 13, at 295 (describing cornea removal as a presumed-consent policy). In Florida v. Powell, 497 So.2d 1188, 1193-94 (Fla. 1986), the court invoked the preservation of public health and restoring eyesight to the blind as the basis for the constitutionality of this statute and did not base its conclusion on the presumed consent of the decedent or the family members. See also Ga, Lions Eye Bank, Inc. v. Lavant, 255 S.E.2d. 127 (Ga. 1985); see generally Siminoff et al., supra note 17 (explaining adoption of “routine notification” and “required request” laws and policies and their effects).
169. Orentlicher, supra note 13, at 295.
170. Id. at 307-08.
171. While this Subsection points out the mandated-choice aspects of the legally required request of family members, it could also be argued that the rules governing how individuals can make, or refuse to make, an anatomical gift amount to a quasi mandated-choice system. The only way for individuals to ensure that their wishes are honored is to either make a gift themselves, document a formal refusal to make a gift, or designate an agent to make the donation decision for them. In other words, they must make some form of documented choice. Otherwise, family members may make decisions about donation that do not reflect their preferences. See discussion infra Subsections II.C.2, II.C.3.
172. 42 C.F.R. § 482.45(a)(5) (2016). The interpretive guidelines make clear that once an OPO determines the medical suitability of a patient for donation purposes, “that person’s family must be informed of the family’s donation options.” CMS INTERPRETATIVE GUIDELINES, supra note 92, at § 482.45(a)(3).
173. 42 C.F.R. § 482.45(a)(3).
174. Truong, supra note 155, at 1210.
175. CMS INTERPRETATIVE GUIDELINES, supra note 92, at § 482.45(a)(4).
making a voluntary choice to “opt in” to a system; they are required to make a decision to be “in” or “out” and cannot avoid a conversation with OPO personnel about donation.

One of the purported advantages of mandated choice—requiring decision making in advance of a crisis—is lost when applied to families who are approached at a time of crisis or grief. Moreover, by focusing on the family, rather than the individual, the current “required request” practice cannot elicit the individual’s preferences regarding organ donation to the extent a mandated-choice strategy focused on the decedent’s choice can. While one might argue that families, rather than individuals, have a greater stake in the donation decision and thus a mandated-choice strategy is more appropriately utilized with families post-death rather than individuals pre-death, it is individual rather than family choice that is the current, primary focus of U.S. organ policy and the public service messages surrounding it.

C. Other System Elements Counter to First-Person Opt-In

1. Information Deficiencies in First-Person Donor Designation

The UAGA provides two primary ways for an individual to register the intention to donate—signing up through online donor registries and through application for a driver’s license, learner’s permit, or identification card from state DMVs. Individuals can also make an anatomical

176. Klassen & Klassen, supra note 76, at 71 (“To families experiencing the devastating loss of a spouse or child, especially under the shocking and often violent situations typical of brain injury and death, the ability to even hear about a total stranger’s need for organ transplantation is, in our opinion, a truly amazing act of altruism.”).

177. Even if, in a first-person mandated-choice strategy, an individual only designates another person to make the donation decision for her following death, the designated agent may be more likely to make the choice the individual would have wanted—either because of prior conversations with the decedent or better knowledge of the decedent’s general values. At the least, we can honor the decedent’s wish to entrust the decision to a particular, selected individual. Moreover, that agent would know that the deceased had not been categorically opposed to organ donation from the fact that, when asked “yes” or “no” to donation, she did not register a “no” decision. Susan E. Herz, Two Steps to Three Choices: A New Approach to Mandated Choice, 8 CAMBRIDGE Q. HEALTHCARE ETHICS 342 (1999); see also Veatch, supra note 22, at 1248.

178. Klassen & Klassen, supra note 76, at 71 (“Many technical aspects of solid organ procurement have a strong effect on the family and structure of the end of life. The emotional effect of these events differs for each family, and these differences should be fully respected.”).

179. REVISED UNIF. ANATOMICAL GIFT ACT § 5 (2006). According to Donate Life America, 48% of the adult population had registered as donors as of December 31, 2013, DONATE LIFE AMERICA, 2014 NAT’L DONOR DESIGNATION REP. CARD 1 (2014), http://donatelife.net/wp-content/uploads/2016/06/Report-Card-2014-4422-Final.pdf. Many of these donor designations occur through the DMV and Donate Life America’s Donor Designation Collaborative, which was launched in 2006 and has established a goal of each state achieving a minimum 50% “donor designation rate,” that is, “the rate at which individuals join or remain in the state donor registry as a percentage of all driver’s licenses and ID cards issued within a specific period of time.” Id. at 2; see also Chana Joffe-Walt, For More Organ Donors, Just Head to the Local DMV, NPR: PLANET MONEY (Feb. 21, 2014), http://www.npr.org/sections/money/2014/02/21/280759139/for-more-organ-donors-just-head-to-the-local-dmv (explaining that in Michigan in 2012, the first year that DMV clerks asked about organ do-
gift by will or other forms of writing, and even orally, in the case of a terminal illness or injury.\textsuperscript{180} Donor registries are accessible online, and registration is free and easy.\textsuperscript{181} Donor designation through the DMV is also simple.

Typically, online registries and DMVs provide minimal, if any, information about the procurement process. The information that is provided focuses on reinforcing positive attitudes about donation and dispelling any fears surrounding donation (such as the fear of poorer medical care) by labeling them as myths.\textsuperscript{182} At the DMV, scripted messages are communicated to individuals through mass audiovisual entertainment media, print materials, and interpersonal interaction.\textsuperscript{183}

Despite the various interventions that are necessary to enable recovery of transplantable organs, minimal, if any, information about them is made available to people at the time they register their intention to donate, nor have efforts been made to implement broader public education regarding the use of these measures.\textsuperscript{184} When all medical tests and interventions were only performed postmortem, it may have been reasonable to solicit donations without much information about the procurement process. The strict requirements of “informed consent” found in the healthcare context do not generally apply to decisions about post-mortem matters, such as cremation versus burial.\textsuperscript{185} But, as explained earlier, the organ-procurement practices of today differ markedly from those used in the early days of transplantation. While people have long feared that providers might compromise their medical care in order to hasten their death and procure their organs,\textsuperscript{186} today, a more realistic fear may be that their lives will be prolonged beyond the point desired to enable donation.\textsuperscript{187}

Other inadequacies in the information made available to people when making an anatomical gift—either at the time of registration of donation or through general public education efforts—include a failure to

\textsuperscript{183} Rady et al., \textit{supra} note 156, at 229.
\textsuperscript{184} See generally Woien et al., \textit{supra} note 182 (reviewing the content of websites and consent forms for public enrollment for organ donation).
\textsuperscript{185} Whether the term “consent” in the context of anatomical gifts is even the appropriate term to use is open to debate, and some have argued that the term “informed choice” may better distinguish the level of information that should be required. \textit{Opportunities for Action}, \textit{supra} note 12, at 176-77.
\textsuperscript{186} Childress, \textit{supra} note 19, at 269 (citing a Gallup poll from 1985); \textit{Opportunities for Action}, \textit{supra} note 12, at 81-83; James M. DuBois & Tracy Schmidt, \textit{Does the Public Support Organ Donation Using Higher Brain-Death Criteria?}, 14 J. CLIN. ETHICS 26, 30 (2003).
\textsuperscript{187} See \textit{supra} Subsection II.A.1.
inform people how their body parts might be used (for example, in cosmetic surgery rather than life-saving procedures\textsuperscript{188}), how to limit their gifts or revoke them, and the steps they would need to take to document a refusal.\textsuperscript{189} Information of this nature might affect whether or not a person would choose to make an anatomical gift or the type of gift that he or she might choose. For example, with the focus of campaigns on the value of organ donation, many people are unaware of the uses to which their tissues—such as skin and bones—may be put, and may even be unaware when signing up to be an “organ donor” at the DMV that they have signed up to be a tissue donor as well.\textsuperscript{190}

2. Rejection of Substituted Judgment for Family Decision Making

If a person has not made a donor designation or agency appointment prior to death, the decision about organ donation falls to his or her family.\textsuperscript{191} The UAGA of 1968 set out a family hierarchy for determining who could make this decision.\textsuperscript{192} It did not state any criteria by which the authorized family member should make that decision, although donation was prohibited if the family member had “actual notice of contrary indications by the decedent.”\textsuperscript{193} This rule recognized the interests of family members in the disposition of the bodies of their next of kin, as well as the interests of individuals in choosing the disposition of their own bodies, assuming they had previously communicated their preferences.

Since the 1970s and the adoption of the original Act, common-law and constitutional rights of individuals to make their own healthcare decisions—rather than have family members or doctors make them—has been firmly established in legal cases involving informed consent and the right to refuse life-sustaining treatment, among other forms of medical treatment.\textsuperscript{194} There is also broad statutory recognition of these rights, as well as state rules for determining who will make decisions for those who lack decision-making capacity and on what basis.\textsuperscript{195} In general, surrogates

\textsuperscript{188} Joseph Shapiro, Am I a Tissue Donor, Too?, NPR (July 18, 2012), http://www.npr.org/2012/07/18/156688033/am-i-a-tissue-donor-too.

\textsuperscript{189} See infra Subsection II.C.3.

\textsuperscript{190} Shapiro, supra note 188 (explaining variation among state forms as to how much specificity can be provided by the donor about his or her gift, including links to donor forms by state).


\textsuperscript{193} Unif. Anatomical Gift Act § 2(b) (1968).


(either appointed agents or family members) must make the decision the patient would likely make (commonly referred to as “substituted judgment”98 or, in the absence of sufficient knowledge to make that determination, must make a decision in the patient’s best interest.99

In keeping with the development over the last fifty years of legal recognition of individual rights, particularly regarding treatment of the body, revisions to the UAGA, as well as public service messages and commentary surrounding organ donation, have placed increasing emphasis on “first-person consent.” For example, the 2006 UAGA makes clear that family members cannot make an anatomical gift if the decedent has already done so.100 This revision attempted to strengthen first-person consent rights by signaling that it would be inappropriate to ask family members to assent to an anatomical gift already made by the decedent prior to death because those family members would have no authority to speak to the issue. Although the very first UAGA also made clear the individual’s right to make a donation whether the family concurred or not, in the decades following the Act’s passage, healthcare providers generally sought the consent of the family in addition to, or instead of, honoring any gift document an individual may have signed prior to death.101 The 2006 revision sought to put an end to this practice.

But despite this emphasis on first-person consent and the now well-established rule in healthcare decision-making that surrogates will make decisions as they believe the patient would, the 2006 UAGA does not adopt the substituted-judgment standard when families are asked to consent in the absence of a donor designation. Families are not required to consider the decedent’s probable intent or wishes. Instead, family members are allowed to make a donation decision on any basis they choose so long as the decedent has neither made a gift already nor executed a document refusing to make a gift.102 Despite the increasing emphasis on first-person consent in the most recent UAGA, the Act expands a family

196. See Alan Meisel, Supreme Schindlers Had Won the Schiano Case, 61 U. MIAMI L. REV. 733, 744-45 (2007) (describing the substituted-judgment standard, which was adopted in Quinlan and has become the predominant standard). According to Meisel, “[p]ut most simply, the substituted judgment standard seeks to determine the now-incompetent patient’s probable wishes concerning treatment.” Id; see also PRESIDENT’S COMM’N FOR THE STUDY OF ETHICAL PROBLEMS IN MED. & BIOMED. & BEHAVIORAL RESEARCH, DECIDING TO FORGO LIFE-SUSTAINING TREATMENT 132 (1983) (“The substituted judgment standard requires that a surrogate attempt to reach the decision that the incapacitated person would make if he or she were able to choose.”). For a comprehensive explanation of the law of end-of-life decision-making, see generally Alan Meisel & Kathy L. Cermakara, The Right to Die: The Law of End-of-Life Decisionmaking (3d ed. 2004) (providing a broad overview of statutory and case law surrounding end-of-life decision-making).

197. See Meisel & Cermakara, supra note 196, at § 8.08 (noting inconsistent statutory support for the best-interests standard).

198. REvised UNIF. ANATOMICAL GIFT ACT § 8(a) (2006).

199. Id. (commentary to § 8). The reasons for this are generally presumed to be several: reluctance on the part of healthcare providers to insist on organ donation at a time of family grief, fear of adverse publicity, and fear of litigation (though actual liability would be unlikely due to a broad good-faith immunity provision in the UAGA. REvised UNIF. ANATOMICAL GIFT ACT § 18(a) (2006); UNIF. ANATOMICAL GIFT ACT § 11 (1987); UNIF. ANATOMICAL GIFT ACT § 7 (1968)).

200. REvised UNIF. ANATOMICAL GIFT ACT § 7 (comment).
member’s ability to make a gift: family members must heed a decedent’s objection to donation only if it is documented as a formal refusal, rather than (as stated in prior versions of the UAGA) if they have “actual notice of contrary indications by the decedent.” The Commentary to the 2006 UAGA reads, “[t]o the extent that an individual is concerned that the person [with authority to make an anatomical gift] may not take adequate account of the individual’s personal preferences regarding anatomical gifts, the onus is on the individual to either make or bar the making of an anatomical gift.” Another way of stating this is to say that if an individual wants to ensure that he is not an organ donor, he must opt out.

While there is some evidence that family members do take into account the wishes of the decedent with respect to organ donation, this is not legally required, and one can easily see how family members might be persuaded to donate contrary to a decedent’s probable wishes when approached by personnel of OPOs using the presumptive approach. The discretion given to family members who favor making a gift to ignore a decedent’s probable wishes is at odds with a robust “first-person” consent system and runs counter to the development of the legal rights of individuals to make healthcare decisions for themselves.

3. **The Mechanics of Making, Limiting, Revoking, and Refusing a First-Person Gift**

   a. Limiting an Anatomical Gift

   The UAGA’s approach to limitations on gifts similarly favors donation over respect for decedent intent. If a donor has made a gift of certain parts (and thus declined to make a gift of other parts) or limited the gift to certain purposes, these more restrictive gifts are not interpreted as an unwillingness to make a broader gift and therefore do not bar family members from making gifts of other organs or tissues after death or from expanding the purpose of the gift indicated by the donor. For instance, if an individual made a gift of her kidneys for the purposes of transplantation and therapy, after death family members can expand the gift to include the entire body for purposes of transplantation, therapy, education, and research. This rule runs counter to the traditional rule of contract in-

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201. *Id.* §§ 7, 9.
interpretation that “mention of one matter implies exclusion of all others.”

Forms provided for donation generally do not point out this
counterintuitive interpretation of a donor’s gift and may in fact contribute to
misunderstanding about the legal effect of a limited gift. Consider the
following suggested form language offered by drafters of the UAGA in
its official commentary:

I wish to donate my organs, eyes, and tissue. I give:

__ Any needed organs, eyes, and tissue
__ ONLY the following organs, eyes, and tissue: ______________.

A donor who checked the second box could certainly be excused for
thinking that only the organs, eyes, and tissue that were specified would
be recovered following his or her death. And yet he or she could well be
wrong. The UAGA gives clear authority to family members or an
appointed agent to donate all other organs, eyes, and tissue.

The UAGA’s rule on limited gifts, combined with the ability of
family members to ignore a decedent’s probable intent and wishes, is
troubling. Even more so is that the State itself creates forms such as these
that reinforce potential donors’ likely beliefs that, by limiting a gift, they
have not simply left donation decisions to their families but that they
have precluded donation of unmentioned parts or donation for purposes
they have not indicated.

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206. Steven v. Fidelity & Cas. Co. of N.Y., 377 P.2d. 284, 289-90 (Cal. 1962) (explaining the
meaning of the traditional rule expressio unius est exclusio alterius in a case involving an airline life
insurance policy); see also 17A C.J.S. CONTRACTS § 415 (2015) (“Under the maxim ‘expressio unius est
exclusio alterius,’ when certain things are specified in detail in a contract, other terms of the same
general character relating to the same matter generally are excluded by implication.”).

207. REVISED UNIF. ANATOMICAL GIFT ACT § 5 (2006) (comment). Similar wording is offered by
the registry service for the District of Columbia, but the language is ambiguous. The website offers
potential donors the ability to limit their anatomical gift and suggests that doing so would mean that
the organs specified as not donated would not be recovered when, in fact, the law may allow the decedent’s
family to consent to donate those parts:

Would you like to specify donation limitations? A donation limitation is a particular donation
you wish to exclude from the Registry and explicitly states you do NOT give your legal consent
for those organs and/or tissues to be recovered. Limitations may include: heart, lungs, liver, kidneys,
pancreas, bowel, eyes/cornea, skin grafts, heart for valves, bones and connective soft tissue
(i.e.; tendons) and the use of each organ or tissue can be limited. If you check a box it means do
not use for that purpose; if you leave it unchecked it may be recovered.

Sign Me Up Today, DONATE LIFE D.C., https://www.donatelifedc.org/register/ (last visited April 4,
2017). Whether this amounts to a refusal is unclear. See D.C. CODE §§ 7-1531.07 (2016) (including
the language from section eight of the UAGA that a limitation of a gift does not preclude authorized
others from making a later gift of parts unless there is an express indication that such a gift cannot be
made). Links to the forms of other states can be found in Shapiro, supra note 188 (noting that eleven
states’ registry forms do not include the option to limit gifts).

208. REVISED UNIF. ANATOMICAL GIFT ACT § 8(c) (2006) (providing that “(c) In the absence of
an express, contrary indication by the donor or other person authorized to make an anatomical gift
under Section 4, an anatomical gift of a part is neither a refusal to give another part nor a limitation
on the making of an anatomical gift of another part at a later time by the donor or another person”); see
also D.C. CODE §§ 7-1531.07.
If U.S. organ donation policy did not subordinate the goal of honoring individual choices to the goal of increasing procurement rates, the form gift document would be more complete, allowing a person to clearly specify the gifts he or she would like to make and to refuse.

b. Revoking or Refusing an Anatomical Gift

Respecting an individual’s autonomy and free choice to donate also entails respecting an individual’s intention to revoke a decision to donate or to refuse donation. Although the UAGA specifies quite clearly how one might make an anatomical gift, and DMVs and state registries facilitate documentation of a gift, this clarity and facilitation is lacking for revocations and refusals.

Revocation of anatomical gifts made through DMVs is complicated and counterintuitive. The decision of an individual to renew a driver’s license without a donor designation on the new license is not construed as a revocation; instead, the donor designation made on the previous license is still effective. This means that a silently renewed driver’s license is understood as a continued gift rather than a revocation. To revoke a previous DMV donor designation, a person would have to sign a document indicating revocation. It is not common practice, however, for DMVs to supply a form document to accomplish this. The UAGA commentary also does not supply a form document for revocation.

Revocation of gifts made through online donor registries can be done by removing one’s name from the registry. In most of the states’

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209. The commentary to the 2006 UAGA indicates that respecting the choices of individuals to donate or not to donate is of high priority. "By permitting refusals, this Act recognizes the autonomy interest of an individual either to be or not to be a donor.” REVISED UNIF. ANATOMICAL GIFT ACT (2006) (summary of changes in the revised act). The 2006 UAGA’s prefatory note explains the goals of the act more broadly:

"First, the [Act] is designed to encourage the making of anatomical gifts. Second, the [Act] is designed to honor and respect the autonomy interest of individuals to make or not to make an anatomical gift of their body or parts. Third, the [Act] preserves the current anatomical gift system founded upon altruism by requiring a positive affirmation of an intent to make a gift and prohibiting the sale and purchase of organs.”

REVISED UNIF. ANATOMICAL GIFT ACT 2 (2006) (prefatory note). The prefatory note does not acknowledge that the act’s efforts to secure the first goal may be achieved at a cost to the second and even the third (in terms of the requirement of a “positive affirmation of an intent”). Id. Later in the prefatory note, the commissioners are more open about their utilitarian aims, writing that “any change [in the UAGA] that could increase the supply of organs and thus save lives is an improvement.” Id. at 4. (prefatory note).

210. Advance directives for healthcare decisions have undergone an evolution to allow more individual choice of this nature. Whereas early-generation “living will” forms only included a wish to have life-sustaining treatment withheld or withdrawn, forms now often allow for a declaration in favor of some treatments and against others, and/or in different medical conditions, and/or to allow for designation of a healthcare agent to make these decisions at a later time. Shepheard, End-of-Life Law, supra note 113, at 1708, see e.g., FLA. STAT. § 765.365 (2016).

211. REVISED UNIF. ANATOMICAL GIFT ACT § 6 (2006) (comment). (“A later-issued driver’s license that is silent regarding the licensee’s intent to make an anatomical gift would not be inconsistent with a prior driver’s license on which the donor had made an anatomical gift. Thus, the gift on the prior license would still be effective.”).

212. REVISED UNIF. ANATOMICAL GIFT ACT § 6 (2006).
registries, this can be accomplished by updating one’s online profile. The donor wishing to revoke his or her gift may, however, encounter language suggesting the opposite. For example, the webpage for updating the donor profile for the Virginia registry begins, “Thank you for making the decision to save lives by signing up to be a donor.”

Even when a person is successful in revoking a prior donor designation, he or she may not have accomplished what was intended. A person’s decision to revoke his or her donor status has no preclusive effect—it does not bar others from making anatomical gifts from a decedent’s body. A revocation is not taken to be a refusal or even evidence of an intention contrary to donation that family members must honor. To justify the limited effect of a revocation, the UAGA commentary states:

> a donor might want to bind others, but it is as likely that a donor was ambivalent and was more than willing to leave the decision to donate to others. . . . A donor who wishes both to revoke and bind others not to make a gift must sign a refusal.

This argument would be more convincing if the mechanics of effecting a refusal and the limited implications of the revocation were made clear to people who at one time had chosen to become donors. Understanding a revocation as merely ambivalence about donating on the part of an individual may also have been more reasonable in the past when the main ways to donate were donor cards or wills, and one might merely tear them up. But today, people have to take extra steps to revoke their gifts in registries or at the DMV. Because the public has not been educated about the difference between a revocation and a refusal, it would not be surprising if a person who had made a gift, and then took the appropriate steps to revoke it, believed that he or she was indicating a wish not to be a donor.

Refusals are possible under the UAGA. A refusal can be made by a signed document, a will, or, under limited circumstances involving ter-

213. See, e.g., Profile Login, Donate Life VA, https://www.donatelifevirginia.org/profile/ (last visited April 4, 2017) (explaining that to revoke a previously registered gift on the Virginia registry, a person must update his or her “organ donor profile”).

214. See id. Revocation becomes even more complicated when a donor has made her donation via both the DMV and a donor registry. DMVs are supposed to cooperate with donor registries to transfer all relevant information regarding a donor’s making, amending, or revoking an anatomical gift. Revised Uniform Anatomical Gift Act § 20(h) (2006). In practice, however, relationships between donor registries and DMVs are not clear and coherent. For instance, North Carolina provides that if a donor changes her mind about donation, she can remove her name from the registry but because we have readily access to DMV data, it will not change the donor designation on your driver’s license. The next time you renew your driver’s license, please tell the examiner that you would like the donor designation removed from your license, so your online donor record and your DMV donor record will match. In the meantime, your online donor record is the one that will be followed since it is the most detailed record.


216. Id. § 8 (comment).

217. Id. § 7. Although refusals preclude others from making anatomical gifts after death, there is an exception for a refusal by an unemancipated minor. Minors can make a refusal, but if a minor who
minal illness or injury, orally. But like revocations, the means for documenting refusals are not facilitated by the organizations involved in organ donation. Registries are not required to provide services to register refusals and at the time the UAGA was amended in 2006, no known registries provided for the registration of a refusal.

III. REFORMING THE CURRENT SYSTEM

Ideally, the U.S. system should either recommit to the opt-in principle and revise laws and practices accordingly, or, following an open and transparent process, move towards an explicit opt-out system. Because revisions to the UAGA were made as recently as 2009 however, it is unlikely that the legislative changes necessary to move in either direction will be forthcoming. Instead, we must consider changes in the way organ procurement is promoted and implemented within the current legal structure. The following suggested changes may, if adopted, also provide a foundation for future legislation that more firmly follows an opt-in or opt-out strategy, or even one that continues to have aspects of both strategies, but in a fairer and more transparent manner.

A. Better Procedures for Allowing People to Register Their Intentions About Donation—Information and Forms

At the point of first-person donor designation, information about the mechanics of donation, revocation, and refusal should be provided to individuals in a clear, neutral format, as well as information about the procurement process (including premortem examinations and maintenance measures), the potential for conflict between advance directives and donation, and the mechanisms for resolving any such conflict. Methods to register donation, such as forms, whether provided by registries or at the DMV, should include options for limiting, revoking, and refusing to make a donation of all or a part of a person’s body or for specifying certain purposes for which donations may be used, such as transplantation and medical education. Registries and DMVs should also provide

has made a refusal dies under the age of eighteen, the refusal can be overridden by parents. Id. § 8(h). Parents cannot, however, revoke a minor’s gift or refusal while the minor is alive. While it is true that parents can override other healthcare decisions of unemancipated minors, donation is a deeply personal matter and ignoring a minor’s wishes on this matter is antithetical to the ethical underpinning of the opt-in system, especially given the extra steps the minor had to take to register his or her refusal to donate. Indeed, the fact that a minor took the needed steps to denote a refusal suggests that he or she may qualify as a “mature minor,” a legal doctrine under which the healthcare decisions of some minors are legally recognized. See generally Robert L. Stenger, Exclusive or Concurrent Competence to Make Medical Decisions for Adolescents in the United States and United Kingdom, 14 J.L. & HEALTH 209 (2000) (discussing rights of minors to make medical decisions).

218. REVISED UNIF. ANATOMICAL GIFT ACT § 7 (2006).
219. Id. § 2 (comment).
220. Id. Also, OPOs are not required to search registries for refusals. Id. § 14 (comment).
221. Although it is referred to as the 2006 UAGA, revisions were made to the Act in 2009 relating to the effect of advance directives. See supra Subsection II.A.2.
opportunities to record refusals, and OPOs should search registries for
refusals. Advance-directive forms should include opportunities to make,
limit, revoke, or refuse to make an anatomical gift and resolve, to the ex-
tent reasonable, any apparent conflicts between those decisions and oth-
er instructions in the advance directive. Information about the possibility
of donation following a circulatory determination of death should also be
provided, and individuals should be allowed to express their preferences
about donation in these circumstances, including the premortem
measures that would be necessary.

B. Disclosure to Family Members About the Nature and Purpose of
OPO-Directed Premortem Examinations and Maintenance Measures

To the extent an OPO’s premortem examinations involve more
than records review, the purpose of such examinations should be dis-
closed to family members by healthcare providers who are entrusted with
such patients’ care. If maintenance measures are continued or initiated
for the purpose of facilitating organ donation, healthcare providers
should also disclose that purpose. Although, under existing law,
healthcare providers can only request donation if trained to do so by the
OPO, they are not legally barred from disclosing the truth about the in-
terventions that are taking place. One could even argue that they are le-
gally required to present this information to family members and surro-
gates. Ideally, disclosures of this sort would be coordinated with the
OPO so that providers and OPO work together to present an open and
transparent process to families and surrogates.

C. Abandonment of the Presumptive Approach

Although “required request” is part of existing law, OPO requesters
should abandon the more recent presumptive or expected donation ap-
proach and revert to a value-neutral approach to organ donation. This
would not mean that OPOs, governments, and UNOS could not actively
promote donation. Such promotional efforts, however, should be target-
ed toward the general population rather than toward a particular family
for a particular donation.

D. Adoption of Substituted Judgment as the Ethical Norm

Although the UAGA does not require families to make decisions
on the basis of the probable wishes of the decedent (“substituted judg-
ment”), OPOs should encourage decision making on this basis.
E. Consent for Donation from Bodies Under the Medical Examiner’s Authority

In the few states that still permit medical examiners to recover organs and tissues without consent, medical examiners should, unless barred by law, seek the consent of the potential donor’s next of kin even if they are not required to do so.

F. Educating the Public About Donation

Broad public-education efforts about many aspects of donation are in need of an overhaul. Rather than simply “dispelling myths” about donation and presenting selective facts about the procurement process, educational efforts should inform the public about some of the less well-known aspects of donation and procurement. Public input should be sought on unsettled matters, such as the acceptability of temporary preservation of organs in the case of uncontrolled cardiac death. Advocacy for donation by governments and procurement organizations can still take place, but in the context of a fair and accurate portrayal of facts. The importance of public trust in the donation and procurement process has long been emphasized, and might be improved by, thoughtful engagement and education efforts.

IV. Conclusion

The current procurement system in the United States comprises a patchwork of laws, regulations, policies, and practices and has been implemented by a variety of federal, state, and private actors. The goal of maximizing the pool of donors has led to an evolution of our system from its opt-in origins to a mixed system that has opt-out elements. Even where our system still reflects an opt-in approach, it fails to adequately seek and affirm informed individual choice.

Though not much different from the Spanish system, the U.S. system is curiously still almost universally described and understood as an opt-in system. This needs to change, or there will be no recognition of the need to secure fair processes and educational prerequisites for implementing opt-out strategies in an ethical and transparent way.

It may even be time to abandon the description of systems as either “opt-in” or “opt-out” and recognize that, as they have evolved, systems around the world contain many complicated, interrelated, and moving parts. Inadequate attention has been given to those components, how they work individually and in concert, and whether they satisfy the policy objectives and ethical justifications provided for them.

222 Opportunities for Action, supra note 12, at 771 (advocating for a public and transparent process for DDOD programs).