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THE RE-GIFT OF LIFE: CAN CHARITY LAW PREVENT FOR-PROFIT FIRMS FROM EXPLOITING DONATED TISSUE AND NONPROFIT TISSUE BANKS?

Robert A. Katz*

INTRODUCTION

In the United States, a billion dollar industry exists to recover human tissues (e.g., bone, skin, and heart valves) from deceased persons and process them for therapeutic implantation into living persons.¹ This industry is driven by an uneasy combination of selflessness and self-interest. It obtains its basic inputs from altruistic individuals²

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² In a telephone survey of 507 next of kin who donated loved ones' tissues, "46.6% stated their desire to help others, 19.2% said they knew their loved one wanted to donate, and 14.2% felt their loved one would [have] want[ed] to donate." Michael P. Scott et al., Adequacy of Informed Consent Process for Tissue Donation: A Survey of Donor Families 57 (University of Florida Tissue Bank, Aug. 2000) (on file with author). See also John P. Moyer, Andy's Gift: A Donor Family's Perspective, in TRANSPLANTING HUMAN TISSUE: ETHICS, POLICY AND PRACTICE 87, 88 (Stuart J. Youngner et al. eds., 2004) [hereinafter TRANSPLANTING HUMAN TISSUE] (author's son would have wanted his tissues to be used to relieve other peoples' pain; "He was so giving and caring").
who donate cadaveric tissue\(^3\) to charitable nonprofit organizations\(^4\) known as tissue banks.\(^5\) These entities then transfer raw tissue to entities that process it into implantable material called allografts.\(^6\) Many of these processors are for-profit businesses; others are set up as nonprofit organizations. Some of these firms earn significant revenues from their processing activities.\(^7\) The largest for-profit processor, Regeneration Technologies, Inc. (RTI), reported net revenues of $92.7 million in 2004.\(^8\)

For-profit processors are a mixed blessing for the tissue industry. On one hand, they have pioneered some of the industry's most important technological advances and helped fuel its rapid growth. In recent years, for example, scientists have learned how to make skin grafts that will not be rejected by a recipient's body by removing the donated skin's cells while preserving its vascular channels.\(^9\) The leading manufacturer of acellular dermal material is LifeCell Corporation, a for-profit business.\(^10\) On the other hand, some people are troubled by the fact that for-profit businesses enrich their owners by processing tissue. Some commentators believe that "huge earnings are inappropriate in a domain bolstered by altruism and selflessness,"\(^11\) and that "[l]arge scale financial operations may overshadow the underlying al-

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3. See infra notes 102–110 and accompanying text. In 1999, an estimated 20,000 people became tissue donors upon death. Transplanting Human Tissue, supra note 2, at xi.

4. See infra note 117 and accompanying text. The terms "nonprofit" and "charitable" are not synonymous, but for convenience, I will use these terms interchangeably unless otherwise indicated. For discussion of the differences between these terms, see infra notes 272–286 and accompanying text.

5. I define the term "tissue bank" as an entity that recovers donated tissue. I use this term more narrowly than is customary in the tissue industry, which applies it to entities that either recover or process tissues, or both. See, e.g., Martha W. Anderson & Renie Schapiro, From Donor to Recipient: The Pathway and Business of Donated Tissues, in Transplanting Human Tissue, supra note 2, at 3 (defining "tissue bank" as "[a]n organization that recovers, processes, stores, and/or distributes tissues for clinical transplantation") (internal citation omitted).

6. Oxford Reference Online, Concise Medical Dictionary, http://www.oxfordreference.com/views/ENTRY.html?subview=main&entry=T60.e299 (last visited Feb. 7, 2006) (defining "allograft" as "a living tissue or organ graft between two members of the same species; for example, a heart transplant from one person to another").

7. See infra notes 132–134 and accompanying text.


9. See infra notes 155–161 and accompanying text.

10. See infra notes 162–166 and accompanying text.

A report prepared by the United States Department of Health and Human Services (HHS) explains this ambivalence:

Today's tissue banking industry and the beneficial uses of human tissues and related products have become more complex and costly. New ways of using tissue for medical treatment have been developed. Tissue banking has been infused with capital and entrepreneurial practices. Processed tissue often is marketed and sold like any other medical product. *For some, these practices call into question the non-profit basis of the tissue banking community.*

Some industry actors fear that publicizing the involvement of for-profit businesses in the tissue industry will discourage donations. This fear is not ungrounded: one suspects that if more people knew of this involvement, they would bar for-profit firms from processing their donations, or refuse to donate tissue altogether. *The Christian Century,* a leading journal for American Protestants, asserts that

*When a family gives permission for the removal of tissues and organs from a loved one who has died, it does not imagine it is providing raw material for a profit making industry . . . People who are happy to offer their heart to save a life are not necessarily eager to donate their skin to . . . [increase] someone else's bank account.*

Unease over for-profit involvement in the tissue industry has sparked demands to publicize this involvement. In California, state law requires tissue banks to inform potential donors that for-profit businesses process raw tissue, and separately allow donors to withhold

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13. Id. at 12 (emphasis added).
14. See, e.g., Scott D. Boden, M.D., Electronic Comments on proposed Centers for Medicare & Medicaid Services (CMS) Regulations, 42 C.F.R. § 486.342, at 27 (May 2, 2005), http://www.cms.hhs.gov/eRulemaking/Downloads/3064%20P%2035-79.pdf (last visited Jan. 10, 2006) [hereinafter Boden Comments] (opposing proposal to require providing potential tissue donors with "information (such as for-profit or nonprofit status) about organizations that will recover, process and distribute" donated tissue. Boden stated: "Inevitably, if the proposed language is adopted, consenting individuals may be forced to restrict the use of their loved ones' tissues either a for-profit or a non-profit entity. My fear is that the overwhelming majority will choose non-profit entities . . . "). Id.
15. E-mail from Heidi Baumgaertner, Advertising Manager, *The Christian Century,* to Robert Katz, Associate Professor of Law and Philanthropic Studies, Indiana University School of Law—Indianapolis (Jan. 4, 2006, 14:36 CST) (on file with author) ("*The Christian Century* is considered the journal of record for American Protestants.").
The federal government has proposed regulations to require similar disclosures.\textsuperscript{18}

Public relations aside, is there anything wrong with for-profit businesses earning profits by processing donated tissue? This Article argues that there is nothing inherently unlawful, unethical, or otherwise improper about for-profit involvement in the tissue industry. The National Organ Transplant Act of 1984 (NOTA or the Act)\textsuperscript{19}—the statutory charter of the United States's transplantation system—creates a scheme that, if realized, would eliminate tension between selflessness and self-regard in the transplantation system. In practice, however, the tissue industry uses donated resources for private gain. This Article uses economic analysis to explain NOTA's philanthropic goals and how these are thwarted. It then considers whether charity law can help advance these goals.

NOTA bans the sale of body parts for use in transplantation by prohibiting their transfer for "valuable consideration."\textsuperscript{20} This prohibition reflects several concerns—most notably (for our purposes) the belief that transplant body parts "should be given as a gift, either to a specific individual or to society at large."\textsuperscript{21} NOTA can be seen as an instrument for redistributing these gifts from donors to allograft recipients, the donors' intended beneficiaries. Although NOTA prohibits their transfer for valuable consideration, it does not—indeed cannot—erase the economic value of body parts in general, and cadaveric tissue in particular.\textsuperscript{22} This value arises from the willingness and ability of some people to pay for allografts made from such tissue.\textsuperscript{23}

Although NOTA prohibits the sale of body parts, it also recognizes that if transplantations are to occur, intermediaries must be fairly compensated for recovering tissues and processing and developing allografts. To this end, the Act permits "reasonable payments" associated with these activities.\textsuperscript{24} In economic terms, reasonable payments enable an intermediary to recoup its actual expenses and earn "normal" profits—the returns it would have earned had it invested in a

\textsuperscript{17} See infra notes 89–92 and accompanying text.
\textsuperscript{18} See infra note 94 and accompanying text.
\textsuperscript{20} 42 U.S.C. § 274e(a); Pub. L. No. 98-507, § 301(a).
\textsuperscript{22} See infra notes 208–215 and accompanying text.
\textsuperscript{23} See infra notes 208–215 and accompanying text.
\textsuperscript{24} 42 U.S.C. § 274e(c)(2); Pub. L. No. 98-507, § 301(c)(2). See infra notes 64–6 and accompanying text.
comparably risky venture. This compensation cap is essential to NOTA's scheme for redistributing the value of donated tissue. When intermediaries earn no more than normal profits, they are rewarded for adding value to tissue, but are not paid for the tissue itself. If every intermediary earns no more than normal profits, the tissue's economic value is preserved intact for allograft recipients. This value is reflected in what recipients do not pay because raw tissue is gifted rather than sold. Conversely, when intermediaries receive unreasonable payments ("supernormal" profits), they earn more than their expenses and opportunity costs—they are paid for the tissue itself. In this way, supernormal payments enable intermediaries to capture the tissue's value.

If followed, NOTA's scheme would transfer the tissue's value to allograft recipients and fairly compensate intermediaries for adding value to it. The presence of for-profit businesses in the tissue industry would not interfere with the Act's philanthropic goals. Moreover, if the markets for raw and processed tissues were perfectly competitive, market forces would produce the results that NOTA intends as a matter of course, thereby making the Act unnecessary.

In practice, NOTA's philanthropic goals are not fully realized for several reasons. First, the government does not enforce the Act—it takes no steps to prevent intermediaries from selling tissue or earning supernormal profits (which here amounts to the same thing). The burdens of nonenforcement, however, fall more heavily on donors and recipients than intermediaries. Intermediaries know how to look after themselves—they can be counted on to seek payment for their activities. Unless NOTA is enforced, however, only self-restraint can stop them from seeking supernormal profits. Second, the tissue markets are imperfectly competitive in various ways: some processors have greater access to raw tissue than others; some use patented technology to produce unique allografts with few substitutes; and some cultivate more brand loyalty for their allografts. These conditions enable advantaged processors to earn supernormal profits.

Can charity law help illuminate or advance NOTA's philanthropic goals? There are good reasons to think so. Charity law and NOTA share certain ends: each seeks to deliver charitable resources to a class

25. See infra notes 203–207 and accompanying text.
26. See infra notes 218–221 and accompanying text.
27. See infra note 207 and accompanying text.
28. See infra notes 216–222 and accompanying text.
29. See infra notes 58–63 and accompanying text.
30. See infra notes 223–268 and accompanying text.
of beneficiaries and prevent these resources from being diverted or unduly exploited. This Article examines NOTA’s philanthropic goals from a charity law perspective and asks two questions: Do any actors or arrangements in the tissue industry violate charity law and, if so, can charity law be used to stop such violations? This exercise identifies what charity law can and cannot do on NOTA’s behalf, suggests ways that charity law could better serve NOTA, and points to certain problems with NOTA and in charity law that should be scrutinized and perhaps amended.

This Article’s charity law analysis is organized around two doctrines. The first is the nondistribution constraint, which prohibits a nonprofit organization from distributing profits to its controllers. It applies most clearly to nonprofit tissue banks that are controlled by for-profit processors as subsidiary or captive entities. The Article explains how the nondistribution constraint (also known as the ban on private inurement) can protect captive tissue banks and their resources from being exploited by their for-profit controllers.

The second charity law doctrine is the ban on private benefit, which restricts the secondary benefits that charitable activity can confer on noncharitable parties. The ban on private benefit puts a spotlight on tissue banks that supply raw tissue with its economic value intact. Such transfers are troubling because they give the tissue’s for-profit transferees an opportunity to capture the tissue’s value for private gain. This scenario points out the limitations of charity law as a tool for advancing NOTA’s aims: once charitable resources leave a nonprofit’s hands, charity law can do relatively little to prevent transferees from exploiting these resources. The surest way to prevent for-profit processors from selling donated tissue is to stop supplying them with tissue. Yet this drastic measure is unwise because of the many health benefits and other advantages that for-profit processors provide.

Analyzing NOTA from a charity law perspective draws attention to the Act’s understanding of exploitation, commonly defined as “[t]he

31. The ban on private benefit applies to nonprofit organizations that are exempt from paying federal income tax under § 501(c)(3) of the Internal Revenue Code. The ban denies tax exemption to nonprofits whose charitable activities excessively or purposely benefit private interests.

32. See infra notes 347–349 and accompanying text.

33. See infra notes 421–428 and accompanying text.

34. See infra notes 421–428 and accompanying text.
use for unacceptable purposes of an economic resource . . . "$^{35}$ Under NOTA, the relevant charitable resources (cadaveric tissues) are exploited by commodifying them—treating them as materials that can be bought and sold. Under this view, any intermediary that sells (captures the economic value of) tissue is an enemy: the intermediary’s status as a nonprofit or for-profit entity is irrelevant. Under charity law, by contrast, charitable resources are exploited when they are siphoned off or excessively applied for private gain. From this perspective, an entity’s legal form is decisive. When a for-profit business sells an asset, it will likely use the net profits to enrich its owners and investors. When a nonprofit entity sells a charitable resource, it must use the net profits to advance its charitable mission. The former exploits; the latter does the Lord’s work.

Analyzing NOTA from a charity law perspective also underscores flaws in its unwieldy scheme for achieving its philanthropic goals. NOTA proposes to deliver a gift (the tissue’s economic value) by passing the tissue through the hands of every party that stands between donors and allograft recipients. This plan gives each intermediary an opportunity to appropriate gifted resources for itself. For this plan to succeed, every intermediary must transfer the donated tissue’s economic value intact to the next intermediary—it must re-gift this value $^{36}$—until it is distributed to allograft recipients. Because NOTA is unenforced, however, that is unlikely to happen.

What is to be done? In the concluding section, the Article surveys a range of options—enforce NOTA, abolish it, or maintain the status quo. If we take NOTA’s philanthropic goals seriously, however, we


$^{36}$ See Word Spy, http://www.wordspy.com/words/regift.asp (last visited Jan. 8, 2006) (defining “regift” as “v. To give as a gift something that one received as a gift”). According to Word-spy, the word “regift” was popularized by the TV show Seinfeld in the episode titled The Label Maker, which first aired on January 19, 1995. Id. Word Spy quotes the relevant dialogue as follows:

George: The wedding is off. Now you can go to the Super Bowl.
Jerry: I can’t call Tim Whatley and ask for the tickets back.
George: You just gave them to him two days ago, he’s gotta give you a grace period.
Jerry: Are you even vaguely familiar with the concept of giving? There’s no grace period.
George: Well, didn’t he regift the label maker?
Jerry: Possibly.
George: Well, if he can regift, why can’t you degift?
Jerry: You may have a point.
George: I have a point, I have a point.

Id.
should consider another option: authorize nonprofit tissue banks to sell donated tissue to for-profit processors, thereby redistributing the tissue’s economic value from the latter to the former. This change could have significant and beneficial consequences. As nonprofit organizations, tissue banks must use any new income to further their missions. They could use additional resources to educate the public about donation and transplantation, provide bereavement care for donor families, improve the quality of their facilities, and subsidize transplants for people who need but cannot otherwise afford them. They could also direct the production and development of allografts based on medical need and social concerns, rather than profit.

The thought of authorizing anyone to sell human tissue—even nonprofit organizations—may be jarring. Absent effective enforcement of NOTA, however, the most pressing, normative question is not whether human tissue should be sold, but who should capture its value. As between nonprofit entities and for-profit businesses, donors would likely choose the former, as they are more secure and direct vehicles for altruistic transfers. From the donors’ perspective, a partial revocation of NOTA might be an improvement over the status quo.

This Article proceeds as follows. Part II discusses the legal regime that regulates the United States’s system for transplanting human organs and tissue. Part III surveys the tissue industry, its leading actors, and the path that cadaveric tissue travels from donors to allograft recipients. It pays special attention to efforts by certain for-profit processors to obtain raw tissue by starting or affiliating with nonprofit tissue banks. Part IV uses economic analysis to explain NOTA, its scheme for achieving its philanthropic goals, and how this scheme fares under conditions of perfect and imperfect competition. Part V analyzes the tissue industry from a charity law perspective and considers whether and how charity law can help implement NOTA’s scheme. The Conclusion observes that the tissue industry, by its success and rapid growth, has exacerbated the tension between its selfless and self-interested elements.

37. See infra notes 41–95 and accompanying text.
38. See infra notes 96–194 and accompanying text.
39. See infra notes 195–268 and accompanying text.
40. See infra notes 269–438 and accompanying text.
II. THE REGULATION OF HUMAN ORGAN AND TISSUE TRANSPLANTATION

This Part surveys the legal regime that regulates the United States's system for transplanting human organs and tissue. This regime authorizes people to make anatomical gifts and prohibits them—or any party—from selling organs and tissues for use in transplantation. As compared to the organ industry, the tissue industry is relatively unregulated. Most notably, federal law does not require the tissue industry's leading actors (e.g., tissue banks and processors) to be nonprofit or tax-exempt under § 501(c)(3) of the Internal Revenue Code (I.R.C.). In practice all tissue banks are nonprofit organizations, and in most places they are not required to publicize the involvement of for-profit businesses in the industry.

A. The Power to Donate Body Parts for Use in Transplantation

Cadaveric human tissue must be obtained with a person's advance consent (to take effect upon death) or the consent of a decedent's next of kin (the donor family).\(^41\) This principle was established by the Uniform Anatomical Gift Act (UAGA), which has been adopted in some form by every state and the District of Columbia.\(^42\) The UAGA recognizes a competent adult's right to authorize an anatomical gift upon his or her death for use in transplantation, therapy, education, and research.\(^43\) It also empowers next of kin to donate all or part of a decedent's body absent knowledge of the decedent's opposition to donation.\(^44\) In many jurisdictions, a person's next of kin cannot set aside

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41. A decedent whose body or body parts are donated is called a "donor," although the term can be somewhat misleading. See Tom L. Beauchamp & James F. Childress, Principles of Biomedical Ethics 66 (5th ed. 2001) (observing that it is a "risky overextension of consent language [to refer] to a cadaveric source of organs for transplantation as a 'donor' when he or she never 'donated,' that is, never chose to donate"). Within the industry, a donor's next of kin is called a "donor family." See, e.g., National Kidney Foundation, What is the National Donor Family Council?, http://www.kidney.org/transplantation/donorFamilies/about.cfm (last visited Feb. 8, 2006).


the decedent's expressed wish to make an anatomical gift. The drafters of the UAGA hoped that its widespread adoption would "encourage the making of anatomical gifts," and thereby "facilitat[e] therapy involving such procedures."

B. The Ban on the Sale of Organs and Tissues for Transplantation

Federal law prohibits the purchase or sale of transplant body parts. Section 301(a) of NOTA, which Congress enacted in 1984, states that "[i]t shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation . . . ." The Act defines the term "organ" to include both tissues and solid organs (e.g., kidneys and hearts). NOTA's prohibition applies to "any person," a category that includes both natural persons (e.g., donors and allograft recipients) and legal persons (e.g., tissue banks and processing firms).

45. See, e.g., IND. CODE ANN. §29-2-16-2.5(b)(2) (West Supp. 2000) (next of kin "have no legal standing or authority to . . . prevent the donor's anatomical gift from being made"). In practice, however, a person's desire to make an anatomical gift may be vetoed by the would-be donor's next of kin after the death. Elizabeth J. Church, Organ Donation and Transplantation, 73 RADIOLOGIC TECH. 537, 552 (2002). Participants in the transplantation process strongly advise potential donors to discuss their wishes regarding donation with family members. The American Association of Tissue Banks notes:

It is important to let close family members know your feelings regarding donation. Physicians and medical caregivers pay close attention to the wishes of the family. If you wish to donate, inform your family and have at least one family member witness your signature on an organ/tissue donation card . . . .


47. The original UAGA (1968) did not expressly address the legality of the purchase or sale of body parts. The revised UAGA (1987) incorporates NOTA's prohibition on the purchase or sale of a body part for transplantation or therapy. UNIF. ANATOMICAL GIFT ACT § 10(a) (1987), 8A U.L.A. 25 (1987).


49. 42 U.S.C. § 274e(c)(1) (defining the term "human organ" to include tissues such as "bone marrow, cornea, eye, bone, and skin," as well as solid or vascular organs such as the "kidney, liver, heart, lung, [and] pancreas"). NOTA was not intended to prohibit the sale of blood and blood derivatives, "which can be replenished and whose donation does not compromise the health of the donor." S. REP. No. 98-382, at 16-17 (1984), as reprinted in 1984 U.S.C.C.A.N. 3975, 3982. Even so, the term tissue "is not a precise concept" and could also include gametes, embryos, stem cells, and others. Norman Fost, Developing Hospital Policy: The University of Wisconsin Experience, in TRANSPLANTING HUMAN TISSUE, supra note 2, at 160, 161.

50. Unless otherwise indicated, I use the term "donor" to refer to both the decedent whose body parts are donated and the next of kin who agree to donate the decedent's body parts. See supra note 41 and accompanying text.
NOTA's ban on the sale of transplant body parts reflects a range of concerns, including: (a) the belief that such parts should be given as gifts;51 (b) the belief that human body parts should not be viewed as commodities;52 (c) the desire to promote fair access to donated body parts53 and reduce the role of wealth in determining their allocation;54 and (d) concerns that poor people, driven by economic necessity, might endanger themselves by selling a kidney or other body part.55 This Article focuses mainly on the first concern, which informs the Act's efforts to make the transplantation system a secure vehicle for donor philanthropy.

NOTA's prohibition on selling tissue resembles a covenant that runs with land and whose restrictions bind the land's present holder and all subsequent takers indefinitely.56 Under NOTA, every person who receives body parts for use in transplantation is subject to the Act's restrictions. Because NOTA is a statute, all persons who handle

51. See supra note 21 and accompanying text.
53. See, e.g., S. REP. NO. 98-382, at 4, as reprinted in 1984 U.S.C.C.A.N. 3975, 3978. The Act "seeks to support development of a rational and fair national health policy regarding organ transplantation." Id. (emphasis added). See also United Network for Organ Sharing, Newsroom Factsheets, Monitoring Compliance with Organ Transplant Policy in the United States, http://www.unos.org/inTheNews/factsheets.asp?fs=8 (last visited Aug. 17, 2004) ("Organ donation is dependent upon the public's trust that the nation's transplant system is operated fairly. Organ transplant policy is based on the latest medical and scientific findings and continually refined to be as equitable as possible given the severe shortage.").
54. This is a recurring theme in United States discourse on healthcare. See, e.g., Ellis Henican & David Zinman, Dukakis' Healthy America Plan, NEWSDAY, Sept. 21, 1988, at 5 ("[Michael] Dukakis drew a standing ovation in his campaign speech at Western Kentucky University, in Bowling Green, Ky., when he said the first question a sick person should hear is not 'How can you pay?' but 'Where does it hurt?'"). Dukakis, a former governor of Massachusetts, was the Democratic nominee for President in 1988. He lost.
55. See, e.g., ARTHUR M. OKUN, EQUITY AND EFFICIENCY: THE GREAT TRADEOFF 19 (1975) (arguing that people have a "right not to act out of desperation").
56. See BLACK'S LAW DICTIONARY 393 (8th ed. 2004)(defining "covenant" to include "covenant running with the land," which is "[a] covenant that, because it relates to the land, binds successor grantees indefinitely . . . The land cannot be conveyed without the covenant."); see also Gouveia v. Tazbir, 37 F.3d 295, 299 (7th Cir. 1994) (holding that debtor cannot sell land free and clear of restrictive covenants). Professor Roger Bernhardt explained that [t]he important consequence of a covenant running with the land is that its burden or benefit will thereby be imposed or conferred upon a subsequent owner of the property who never actually agreed to it. Running covenants thereby achieve the transfer of duties and rights in a way not permitted by traditional contract law.

BLACK'S LAW DICTIONARY, supra note 56, at 363 (quoting ROGER BERNHARDT, REAL PROPERTY IN A NUTSHELL 212 (3d ed. 1993)).
body parts for transplantation have notice—actual or constructive—of its provisions.

Persons who violate NOTA may be fined up to $50,000 and imprisoned for up to five years. The U.S. Government has rarely enforced the Act, and never has done so successfully. Although NOTA has never resulted in criminal penalties, an Arkansas state court has invoked it to defeat a donor's payment demand for tissue she supplied. In Wilson v. Adkins, a woman agreed to supply bone marrow to her ailing sister in exchange for her nephew's promise to pay her $101,500 as compensation "for the risk, difficulties, and insurance consequences of [her] marrow donation." After supplying the tissue but receiving no payment, the woman sued her nephew for breach of contract. The Arkansas Court of Appeals rebuffed the woman's complaint on grounds that the contract violated NOTA.

Although NOTA prohibits the sale of transplant organs and tissues, it permits some commerce among intermediaries in the transplantation system. Section 301(c)(2) accomplishes this by defining the term "valuable consideration" to exclude "reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ [or tissue] . . . ." Neither NOTA nor courts have defined what constitutes reasonable payments to intermediaries for their activities associated with transplantation. Section 301(c)(2) of the Act also defines "valuable con-

57. OXFORD REFERENCE ONLINE, A DICTIONARY OF LAW, http://www.oxfordreference.com/views/ENTRY.html?subview=main&entry=T49.e769 (last visited Jan. 10, 2006) (defining "constructive notice" as "knowledge that the law presumes a person to have even if he is actually ignorant of the facts. A purchaser of unregistered land has constructive notice of all matters that a prudent purchaser would discover on inspection of the property or proper investigation of the title.").


61. Id. at 441.

62. Id. at 440. Her complaint also alleged fraud and detrimental reliance. Id.

63. Id. at 443 (affirming the trial court's dismissal of the plaintiff's complaint).

64. 42 U.S.C. § 274e(c)(2) (2000).

65. On September 30, 2005, I performed a terms-and-connectors search for "('national organ transplant act' or NOTA) and 'reasonable payments'" in the LEXIS database "Federal & State Cases, Combined." The only case that this search retrieved was Wilson v. Adkins, discussed supra notes 60--63, where the Arkansas Court of Appeals stated: "While [NOTA] does allow
consideration" to exclude "the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ." This apparently refers to living donors of kidneys, bone marrow, and other expendable or replenishable body parts.

C. Regulating the Organ Transplantation System

NOTA created the legal framework for the national organ transplantation system. The Act provides for the establishment of a national network to facilitate the recovery, transportation, and allocation of organs. It requires this network—called the Organ Procurement and Transplantation Network (OPTN)—to be organized as a nonprofit entity and to be governed by representatives of various actors in the organ industry and the general public.

The OPTN's most prominent members are Organ Procurement Organizations (OPOs). OPOs are responsible for identifying potential organ donors and soliciting and recovering donated organs. Federal law requires OPOs to be nonprofit, tax-exempt organizations. There are currently fifty-eight OPOs in the United States, each with a designated service area that may cover all or part of a state. Each OPO is the only entity authorized to recover transplant organs within its designated area.

The federal government uses the Medicare program to induce hospitals to promote organ and tissue donation. In order to participate in the program, a hospital must inform the families of potential donors of 'reasonable payments' for the cost of the procedure and incidental expenses, it is clear that $101,500.00 [which the nephew promised to pay his aunt in return for donating bone marrow to his sick mother] is not payment for reasonable incidental expenses" but rather compensation for the bone marrow itself. Wilson, 941 S.W.2d at 442.

67. Id.
68. Id. § 274(b)(1)(A)–(B). Since 1986, the OPTN has been operated by the United Network for Organ Sharing (UNOS), a nonprofit organization based in Richmond, Virginia. See The United Network for Organ Sharing, Who We Are, http://www.unos.org/whoWeAre/ (last visited Nov. 11, 2003) [hereinafter UNOS, Who We Are].
69. 42 U.S.C. § 273(b)(1)(A); 42 C.F.R. § 486.306(a) (2005) ("To be designated as the OPO for a service area, an organization must . . . [b]e a nonprofit entity that is exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1986."). For a discussion of the distinction between nonprofit, charitable, and tax-exempt organizations, see infra notes 272–290 and accompanying text.
70. UNOS, Who We Are, supra note 68. This number is current as of January 8, 2006. Id. For a list of these OPOs, see UNOS, Membership, Organ Procurement Organizations, http://www.unos.org/members/directory.asp (last visited Jan. 10, 2006).
71. UNOS, Who We Are, supra note 68.
72. 42 U.S.C. § 1320b-8(b)(2) ("The Secretary may not designate more than one organ procurement organization for each service area . . . ."); 42 C.F.R. § 486.302.
about donation for transplantation and notify the designated OPO about the death or imminent demise of potential donors.\textsuperscript{73} Additionally, hospitals and OPOs must cooperate with one or more tissue banks to facilitate tissue donations.\textsuperscript{74}

\section*{D. Regulating the Tissue Transplantation Industry}

\subsection*{1. General Oversight}

Whereas the organ industry is strictly regulated, federal law says relatively little about how the tissue industry should be structured. The law does not require tissue banks, processors, and other intermediaries to be nonprofit organizations or tax-exempt under I.R.C. § 501(c)(3). The law does not grant tissue banks a monopoly over tissue recovery within a designated area. In many places, multiple tissue banks compete for referrals of potential donors.\textsuperscript{75} There are over 150 tissue banks in the United States.\textsuperscript{76} Government regulation of the tissue industry focuses mainly on health and safety concerns. The United States Food and Drug Administration (FDA) requires tissue banks and processors to follow procedures for preventing the spread of communicable diseases through transplanted tissue.\textsuperscript{77} Only a handful of states require tissue banks to be licensed, and even fewer states inspect banks.\textsuperscript{78}

The tissue industry regulates itself to some extent. The most important source of self-regulation is the American Association of Tissue

\footnotesize{\textsuperscript{73} 42 U.S.C. § 1320b-8(a)(1); 42 C.F.R. §§ 482.45, 485.643.  
\textsuperscript{74} 42 C.F.R. § 482.45(a)(2); see also 42 U.S.C. § 273(b)(3)(I).  
\textsuperscript{76} DeP't Health & Human Servs., Oversight of Tissue Banking, at ii (2001), http://www.fda.gov/cber/tissue/ovrst0101.pdf (internal citations omitted) [hereinafter HHS OVERSIGHT]. In researching the oversight system for tissue banking, the HHS Office of Inspector General identified 154 tissue establishments.  
\textsuperscript{77} See 21 C.F.R. § 1271.1 (2005).  
\textsuperscript{78} HHS OVERSIGHT, supra note 76, at 5–6 (internal citations omitted).}
Banks (AATB). The AATB is a “scientific, not-for-profit, peer group organization” that promotes safe and high-quality tissues and tissue-based products for transplantation. Membership in the AATB is voluntary, as is accreditation for compliance with its standards. Most of the leading tissue banks and processors are AATB members. Eighty-nine tissue establishments have obtained AATB accreditation.

2. Disclosure of For-Profit Involvement in the Tissue Industry

As a general rule, each tissue bank decides for itself whether to inform donor families about the involvement of for-profit businesses in the tissue industry. Some tissue banks routinely disclose this information, while others do not unless specifically asked. The AATB believes that disclosure should be left to each tissue bank’s discretion, to be exercised in a sensitive and responsible manner. In some cases, says the AATB, it may be appropriate to disclose this information even without an inquiry, “depending upon the circumstances surrounding the donation and the potential gift(s) . . . .”

Among regulators, there is growing interest in requiring tissue banks to disclose for-profit involvement. This interest reflects a perceived gap between how the tissue industry operates and how donors
believe it operates. A 2003 California Senate report asserted that if donors are not informed about for-profit involvement, "it may be difficult to assert that genuine informed consent was obtained." The California state legislature subsequently enacted a statute mandating consent procedures that: (a) advise donors that "tissue banks work with both nonprofit and for-profit tissue processors . . ."; and (b) "allow the donor or donor's representative to withhold consent for . . . [d]onated tissue to be used by for-profit tissue processors . . ." This statute has reportedly increased the number of donors who withhold consent for for-profit involvement. In September 2005, twenty-four legislators in the Wisconsin state legislature introduced a bill very similar to the California statute. In February 2005, HHS proposed a rule that would require OPOs to ensure that donor families receive information about the "profit or non-profit status . . . [of] organizations that will recover, process, and distribute tissue . . ." This proposed regulation has not been finalized.

III. THE TISSUE TRANSPLANTATION INDUSTRY

The tissue industry is large—it is estimated that over $1 billion was spent in 2004 to purchase human tissues to implant in 900,000 patients—and growing at an estimated rate of ten to fifteen percent each year. The tissue industry has outpaced the organ industry in many respects. More people are eligible to donate tissues than or-

88. HHS INFORMED CONSENT, supra note 12, at ii ("[T]he reality of tissue banking raises some underlying tension with [donor] families' assumptions.").


91. Id. § 7158.3(b)(2)(C). Tissue banks and their agents violating the statute face civil liability and loss of their licenses. Id. § 7158.3(b)(4), (c).

92. E-mail from Karen Richards, Program Manager, University of California San Francisco (UCSF) Tissue Bank, to Robert Katz, Associate Professor of Law and Philanthropic Studies, Indiana University School of Law—Indianapolis (Aug. 15, 2005, 16:16 EST) (on file with author) ("In 2004, approximately 13% of our families opted out for Profit and 15% in 2005.").


96. Young, supra note 1.

gans, more tissues are donated than organs, and each donor can yield more tissues than organs for transplantation. This Part provides an overview of the tissue industry and how it operates. It also discusses the experiences of two for-profit processors that have forged close ties with or actually formed nonprofit tissue banks in order to ensure access to raw tissue.

A. The Path From Tissue Donors to Allograft Recipients

This section surveys the path that tissue travels from donors to allograft recipients, focusing on tissue banks and processors. Allografts are marketed and distributed to healthcare providers through a variety of channels, including processors, tissue banks, and third-party distributors.

1. The Donation Process

In the hospital context, the recovery of cadaveric tissue typically begins when a hospital notifies the OPO of a patient’s actual or imminent death. Outside the hospital context, tissue banks may learn about potential donors from medical examiners, coroners, and funeral home directors. The OPO or tissue bank, if a separate entity, then assesses whether the patient or decedent might be a suitable tissue donor. If the answer is yes, the OPO or tissue bank asks the potential donor’s family to consent to donation. Once this consent is obtained, the tissue must be recovered within twenty-four hours of the
The tissue bank bears the costs associated with the recovery process.\textsuperscript{107} Many families derive comfort from donating a loved one’s body parts for transplantation and from contemplating how the donation will improve or save the recipients’ lives.\textsuperscript{108} OPOs and tissue banks provide donor families with various “aftercare” resources designed to help them through the donation process, funeral arrangements, grief, and other end-of-life concerns.\textsuperscript{109} These may include resources on dealing with loss and grief, informal counseling, support groups, donor recognition events, letters of appreciation from recipients or general information about them, medals, keepsake boxes, and teddy bears.\textsuperscript{110}

\section{Tissue Banks}

Some tissue banks recover many types of tissues for transplantation, including bones,\textsuperscript{111} tendons, ligaments, cartilage, heart valves,\textsuperscript{112} skin,\textsuperscript{113} eyes, and corneas.\textsuperscript{114} Other tissue banks recover a specific type of tissue only, such as skin or eyes. OPOs or tissue banks initiate the extensive process for ensuring that donated tissue will not transmit disease.\textsuperscript{115} This entails, \textit{inter alia}, reviewing a donor’s medical records,

\begin{footnotesize}\begin{enumerate}
\item \textsuperscript{106} Id. at 6.
\item \textsuperscript{107} See LifeLink Foundation, Myths and Facts About Organ and Tissue Donation, http://www.lifelinkfound.org/myth.asp (last visited Feb. 8, 2006) (stating that “[d]onor families are not charged for the medical costs associated with organ and tissue donation”).
\item \textsuperscript{108} Id. ("Studies show that donation most often provides immediate and long-term consolation. Donation can be especially comforting when the death is unexpected and the donor is young.").
\item \textsuperscript{109} See, e.g., LifeCenter Northwest, Family Support Services, http://www.lcnw.org/services/family/index.html (last visited Feb. 8, 2006) (explaining that this OPO provides services to donor families for a year following the donation).
\item \textsuperscript{111} LifeLink Foundation, About Tissue Donation, http://www.lifelinkfound.org/tdonation.asp (last visited Feb. 8, 2006) (“An estimated 700,000 bone grafts are done yearly. Banked bone is used to replace bone that has been destroyed by tumors, trauma, and infection, allowing limbs to be spared that would otherwise have to be amputated.").
\item \textsuperscript{112} Id. ("The heart valves may be used from hearts which can not be used for transplantation. Ideally, the heart valves should be obtained from a heart-beating cadaver, however, the heart valves of a non heart-beating cadaver of up to 12 hours can also be considered for donation if there is a documented time of death.").
\item \textsuperscript{113} Id. (“Transplanted skin is used as replacement tissue over 1,000,000 times per year. Three quarters of this usage occurs in life-saving circumstances such as severe burns.").
\item \textsuperscript{114} Id. (“Corneas are used in over 44,000 transplant procedures yearly to restore sight.").
\item \textsuperscript{115} See supra note 104 and accompanying text.
\end{enumerate}\end{footnotesize}
inquiring into a donor’s social history for high-risk behaviors for transmissible diseases, and testing a donor’s blood for HIV, hepatitis, and syphilis.\footnote{116}

All tissue banks are organized as nonprofit and charitable entities under state law, and most are tax-exempt under I.R.C. § 501(c)(3).\footnote{117} Tissue banks may be structured in a variety of ways. Some are independent entities that operate one or more offices.\footnote{118} They may also belong to a network or alliance of tissue banks.\footnote{119} Others are controlled by a separate nonprofit entity, such as an OPO\footnote{120} or a nonprofit processor,\footnote{121} or by a for-profit processor.\footnote{122}

A tissue bank can arrange for processing in one of three ways. First, the tissue bank can transfer tissue to a processor, outright and with no strings attached, in exchange for a fee to cover tissue recovery services.\footnote{123} The processor then determines how to process the tissue, which products to manufacture, how to distribute the tissue, and so on. The tissue bank’s service fee is known as a Standard Acquisition

\footnote{116. See, e.g., Anderson & Schapiro, supra note 5, at 6. One tissue bank explained: Every donor is thoroughly screened and tested before donation can take place. This screening includes comprehensive medical and social histories, including high-risk behaviors for transmissible diseases that automatically eliminate any possibility of donation. Potential donors with histories of any condition that can affect the quality and long-term performance of the bone and/or tissue are also excluded. MTF, Donation FAQs: Who Donates Bone and Tissue Allografts?, http://www.mtf.net/donor/index.html (last visited Mar. 29, 2006).

117. Anderson & Schapiro, supra note 5, at 3-4. RTI Donor Services, a charitable nonprofit tissue bank, is taxable—it is not tax-exempt under I.R.C. § 501(c)(3). See infra notes 174–194 and accompanying text. For discussion of the distinction between nonprofit, charitable, and tax-exempt status, see infra notes 272–290 and accompanying text.

118. See, e.g., IOPO, About IOPO, http://www.iopo.org/aboutiopo.asp (last visited Feb. 8, 2006) (explaining that the IOPO “is a nonprofit health service dedicated to advancing organ, tissue, and eye donation throughout Indiana. IOPO has regional offices in Fort Wayne, South Bend, Evansville and Indianapolis to serve the people of Indiana and more than 130 Indiana hospitals.”).


120. See, e.g., LifeNet, http://www.lifenet.org/ (last visited Feb. 8, 2006) (describing LifeNet, the designated OPO for most of Virginia, as “the nation’s largest nonprofit, full-service organ donation agency and tissue banking system”).

121. See, e.g., infra notes 129–130 and accompanying text.

122. RTI, a for-profit processor, controls RTI Donor Services. See infra notes 174–194 and accompanying text.

123. The processor is bound by NOTA’s restrictions even if it does not promise the tissue bank that it will comply with them. See supra notes 56–57 and accompanying text.}
Charge (SAC).\textsuperscript{124} This fee permits the tissue bank to recoup its actual outlays on tissue recovery, aftercare, education, and "other costs associated with operating a tissue recovery program."\textsuperscript{125} Typically, these fees also include a small percentage or margin that provides the tissue bank with excess revenue for future expansions, savings, and other needs.\textsuperscript{126}

In the second model, a tissue bank contracts with another entity to process the recovered tissue according to the tissue bank's specifications.\textsuperscript{127} The processor later returns the processed tissues to the tissue bank. In this way, the tissue bank retains "title" to the underlying tissues, even when these are in the processor's custody.\textsuperscript{128}

In the third model, a single entity (or group of related entities) both recovers raw tissue \textit{and} processes it.\textsuperscript{129} This entity retains both custody and control over the tissues until distributed to healthcare providers. The components of this entity may be exclusively nonprofit (i.e., a nonprofit entity operates both tissue banking and processing operations),\textsuperscript{130} or both nonprofit and for-profit (i.e., a for-profit processor and a subsidiary nonprofit tissue bank).\textsuperscript{131} In theory, this entity could be exclusively for-profit, as the law does not require tissue banks to be nonprofit.\textsuperscript{132}

3. \textit{Tissue Processors}

Processors transform raw tissue into allografts for implantation. Historically, the tissue industry was relatively small and dominated by

\textsuperscript{124} Anderson & Schapiro, \textit{supra} note 5, at 10.
\textsuperscript{125} \textit{Id. See also supra} notes 109–110, 115–116 and accompanying text.
\textsuperscript{126} Anderson & Shapiro, \textit{supra} note 5, at 10, 12–13. This margin, I argue below, corresponds to the economic concept of normal profits. \textit{See infra} notes 203–207 and accompanying text.
\textsuperscript{127} \textit{See, e.g.,} Press Release, Osteotech, Inc., Osteotech and Musculoskeletal Transplant Foundation Sign New Five Year Agreement (Mar. 27, 1997), http://www.osteotech.com/finnews.htm. Osteotech, a for-profit processor, and MTF, a nonprofit processor and tissue-banking entity, signed an agreement "for Osteotech to continue to be the exclusive processor of musculoskeletal tissue procured and distributed by" MTF. \textit{Id.}
\textsuperscript{128} The tissue bank can then distribute the allografts through third-party distributors or directly to healthcare providers. Anderson & Schapiro, \textit{supra} note 5, at 7–8.
\textsuperscript{129} \textit{See, e.g.,} Community Tissue Services, About Community Tissue Services, http://www.communitytissue.org/about/index.html (last visited Feb. 10, 2006) (Community Tissue Services, a nonprofit tissue bank and processor, "serves the public through recovery, processing and distribution of human tissue grafts used for transplantation"); Community Tissue Services, Processing Tissue Grafts, http://www.communitytissue.org/processing/index.html ("All musculoskeletal and skin tissue grafts procured by each branch [of Community Tissue Services] are processed at the Dayton, OH location and then returned to the branches for distribution.").
\textsuperscript{130} This is true of the nonprofit Community Tissue Services. \textit{Id.}
\textsuperscript{131} \textit{See infra} notes 174–194 and accompanying text.
\textsuperscript{132} \textit{Cf. supra} notes 68–69 (explaining that federal law requires the OPTN and OPOs to be organized as nonprofit organizations).
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nonprofit entities. Over the past two decades, it has become a competitive, multi-million-dollar industry increasingly dominated by for-profit businesses. These businesses have played a leading role in the industry's technological advancements and dramatic growth. This section discusses three kinds of allografts and processors that produce them: cryopreserved heart valves, demineralized bone matrices, and acellular dermal tissue. As this discussion demonstrates, a processor's access to proprietary technology can significantly affect its fortunes.

a. Heart Valves

Surgeons use cadaveric human heart valves to treat patients with defective heart function. CryoLife, Inc., a for-profit firm founded in 1984, was the first company to commercially develop a process for cryopreserving (preserving through freezing) heart valves for transplant. The company boasts "thirteen exclusive cryopreservation patents..." At one time, CryoLife was the undisputed leader in the market for transplant heart valves, with an estimated eighty-three percent market share. After a series of missteps and setbacks, including the distribution of infected tissue, the firm's market share fell to thirty to forty percent. CryoLife's troubles have increased demand for heart valves supplied by competing processors, including...

134. Id. The website of one for-profit distributor of processed tissue tells prospective customers that "[w]e recognize that you have the opportunity to choose a tissue bank that you feel best meets your needs or the needs of the surgeons at your contracted hospitals." Bone Bank Allografts, http://www.bonebank.com/index.html (last visited Sept. 2, 2004).
135. See Frost, supra note 49, at 164.
141. Young, supra note 139.
for-profit Regeneration Technologies, Inc. (RTI) and nonprofit LifeNet.¹⁴²

b. Demineralized Bone Matrix for Spinal Fusion Surgery

Cadaveric tissue can be used for spinal fusion,¹⁴³ a procedure that welds vertebrae together as treatment for spinal injuries, slipped disks, scoliosis, and other conditions.¹⁴⁴ This procedure can be performed using a material known as demineralized bone matrix (DBM).¹⁴⁵ DBM is prepared by combining demineralized bones (bones with most of their minerals removed) with other substances.¹⁴⁶ DBM enhances spinal fusion by providing a medium for bone-forming cells to travel to the bone defect site¹⁴⁷ and by serving as a scaffold to support the regeneration of new bone.¹⁴⁸ Some types of DBM also stimulate cells in the bone defect site to convert into bone-forming cells.¹⁴⁹

The largest supplier of DBM in the United States is the for-profit Osteotech, Inc.¹⁵⁰ When Osteotech began selling DBM in 1991 under


¹⁴⁶. Id. at 2244. Demineralized bone can be combined with glycerol, hyaluronic acid, or calcium sulfate to produce DBM. Each combination may yield DBM with different healing properties. Id.

¹⁴⁷. Id. (“[T]he osteoconductivity of the demineralized bone matrix-carrier complex may be an important factor [in determining the efficacy of a demineralized bone matrix as a bone-graft substitute or extender] since this property promotes migration of osteoprogenitor [bone-forming] cells to the bone defect site.”).

¹⁴⁸. J.F. Keating & M.M. McQueen, Substitutes for Autologous Bone Graft in Orthopaedic Trauma, available at http://www.findarticles.com/p/articles/mi_qa3767/is_200101/ai_n8930230 (last visited Mar. 29, 2006) (“Osteoconductive materials have no capability to form bone or induce its formation. . . . [But they] provide an inert biocompatible scaffold, which local osseous tissue can utilise to regenerate living bone.”).

¹⁴⁹. See generally Peterson et al., supra note 145.

the Grafton label,\textsuperscript{151} it was “the first tissue made available as a commercially promoted ‘product.’”\textsuperscript{152} Osteotech’s dominance of the DBM market can be partly attributed to its patented innovations, whose infringement the company blocked at least twice.\textsuperscript{153} In recent years, Osteotech has faced growing competition from other processors’ DBM products, which have trademarked labels and allegedly distinctive qualities.\textsuperscript{154}

c. Acellular Dermal Tissue

The for-profit LifeCell produces an acellular dermal tissue called AlloDerm.\textsuperscript{155} It is produced from cadaveric human skin by removing the cells responsible for rejection, while preserving the tissue’s vascular channels and other properties.\textsuperscript{156} Once AlloDerm is implanted in the body, it revascularizes and is remodeled into the patient’s own tissues.\textsuperscript{157} AlloDerm can be used to replace lost dermis in burn victims, repair the abdominal walls of hernia patients, and reconstruct breasts following mastectomy.\textsuperscript{158} It can also be used for certain cosmetic procedures, such as reducing the appearance of wrinkles and


\textsuperscript{152} Anderson & Bottenfield, supra note 133, at 19.


increases, augmenting lips to give them "a fuller, more sensual appearance," and increasing the circumference or girth of penises.

LifeCell is the only commercial processor of acellular skin for transplantation, and the demand for AlloDerm has grown considerably. LifeCell has "built an excellent reputation with surgeons as the leading supplier of soft tissue allograft that is safe, flexible and useful in a wide variety of indications." AlloDerm has been "gain[ing] surgeon champions at what appears to be accelerating rates." LifeCell has cultivated surgeon loyalty by educating surgeons on the benefits and use of AlloDerm for various procedures.


160. See Daniel I. Shapiro, AlloDerm . . . It's a Natural, http://www.aestheticsurg.com/alloderm.html (last visited Feb. 10, 2006). But see 2004 ANNUAL REPORT, supra note 158, at 17 ("Although we do not promote the use of our human tissue products for cosmetic applications, clinicians may use our products in applications or procedures that may be considered 'cosmetic.'").

161. See, e.g., New York Phallo, Allograft Dermal Matrix Grafts (AlloDerm), http://www.newyorkphallopasty1.com/phallo_allo.html (last visited Feb. 10, 2006) ("Dr. Whitehead has used Allograft Dermal Matrix Grafts (AlloDerm) exclusively in all of his patients [for penis widening surgery] for six years because of the superior results ...”).


165. Young, supra note 163.

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B. Vertical Integration in the Tissue Industry

Tissue processors are sometimes unable to meet the demand for their products due to a limited supply of raw tissue.167 According to nonprofit processor AlloSource, “the number of [tissue transplantation] procedures is limited by the availability of donor tissue,” and “[t]here is simply not enough to go around.”168 To secure and expand their access to raw tissues, some processors have made special arrangements with particular tissue banks. As part of these arrangements, a tissue bank may commit to supplying a processor with raw tissue for a period of time.169

At least two for-profit processors, Osteotech and RTI, have started nonprofit tissue banks in order to secure a steady and robust supply of tissue for processing. In 1987, Osteotech spent $10 million to create Musculoskeletal Transplant Foundation (MTF), a nonprofit organization that manages a large number of tissue banks.170 Since its founding, MTF has entered into a series of agreements to supply Osteotech with tissue,171 and currently provides two-thirds of Osteotech’s tissue needs.172 Although Osteotech helped create MTF, it does not control MTF. Rather, MTF is an independent entity that negotiates agree-

167. See, e.g., Press Release, Osteotech, Inc., Osteotech Enters Into New Long-Term Processing Agreement With MTF and Settles Patent Lawsuit with MTF and Synthes (June 7, 2002), http://www.osteotech.com/finnews.htm (“[N]otwithstanding the historical growth of our Graftech(TM) Bio-implants [tissue forms], there remains a large unmet demand that we have not been able to meet due to limitations of tissue supply.”).


ments with Osteotech at arm’s length. This was vividly demonstrated in 2005 when MTF unsuccessfully attempted to acquire Osteotech by offering to purchase all of Osteotech’s outstanding stock.173

In 2003, RTI formed Regeneration Technologies Donor Services, Inc. (RTI Donor Services),174 a nonprofit tissue-banking organization.175 According to its website, RTI Donor Services is an “(AATB) accredited tissue recovery organization that works to enhance the lives of others by providing families the option of tissue donation.”176 It “supports [its donor families]’ wishes, while serving as responsible stewards of donated human tissue gifts.”177 It also provides aftercare services to donor families and promotes donation awareness in the community.178

RTI controls RTI Donor Services179 and provides it with an annual operating budget.180 Insiders refer to RTI Donor Services as an “affil-


175. RTI, Regeneration Technologies Announces RTI Donor Services, http://www.rtx.com/news_fullstory.cfm?item=699&lasturl=/news_listing.cfm%3Farchive=yes (last visited Mar. 29, 2006) [hereinafter Announces RTI Donor Services] (“RTI Donor Services will work with the approximately 30 recovery agencies that provide tissues such as bone, tendons, ligaments, heart valves and vascular tissue to Regeneration Technologies for preparation into biological, allograft implants.”).


178. Announces RTI Donor Services, supra note 175.


180. E-mail from Wendy Crites Wacker, Manager of Corporate Communications, RTI, to Robert Katz, Associate Professor of Law and Philanthropic Studies, Indiana University School of Law—Indianapolis (Feb. 9, 2006, 14:51 EDT) (on file with author) (“RTI provides RTI Donor Services with an annual operating budget . . . .”).
"subsidiary" of RTI, but "subsidiary" is the more precise term. RTI's managers believe that this arrangement with RTI Donor Services gives their firm a competitive edge over other processors. As Richard R. Allen, RTI's then Chief Financial Officer, explained in a 2001 interview:

[One] thing that separates [RTI] from . . . other allograft companies is that we work very closely . . . with some recovery agencies around the country. . . . [As a result, we] have more effective control over our supply of the tissue because we are able to help drive and increase the rate of donation in those territories. So we have got probably a very, very solid source as far as supply goes, and the ability to grow supply in the future.

RTI organized RTI Donor Services as a nonprofit entity. This was done, explained Wendy Crites Wacker, RTI's Manager of Corporate Communications, "because it is appropriate for a nonprofit entity to approach families about donation [of a loved one's tissues], especially since families are being asked to donate for humanitarian reasons." RTI Donor Services is also a charitable organization. It promotes health, a legally charitable purpose. Its stated goal is "[t]o provide human donated tissues for the benefit of others through compassionate support, outreach and education to families and communities." Its primary beneficiaries—persons whose lives can be saved or enhanced with allograft implants—constitute a charitable

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181. E-mail from Paula Symons, Manager of Agency Communications, RTI Donor Services, to Robert Katz, Associate Professor of Law and Philanthropic Studies, Indiana University School of Law—Indianapolis (July 15, 2005, 14:20 EDT) (on file with author); E-mail from Wendy Crites Wacker, supra note 180 (referring to RTI Donor Services's "affiliation" with RTI).

182. BLACK'S LAW DICTIONARY, supra note 56, at 368 (defining "subsidiary corporation" as "[a] corporation in which a parent corporation has a controlling share.—Often shortened to subsidiary"). Cf. id. at 63 (defining "affiliate" as "[a] corporation that is related to another corporation by shareholdings or other means of control; a subsidiary, parent, or sibling corporation").


184. E-mail from Wendy Crites Wacker, supra note 180 ("RTI Donor Services is a non-profit organization . . . . The organization's earnings do not benefit private shareholders or individuals.").

185. Mark Flatten, Legislators May Tighten Rules on Tissue Banking, E. VALLEY TRIB., July 14, 2004 (quoting Wacker), http://www.eastvalleymagazine.com/index.php?sty=24740. See also E-mail from Wendy Crites Wacker, supra note 180 ("[T]hese types of services [that RTI Donor Services provides] have been provided by not-for-profit organizations. For the community services RTI Donor Services provides, we feel it is appropriate to be a non-profit company.").

186. E-mail from Wendy Crites Wacker, supra note 180 (RTI Donor Services is "dedicated to charitable, scientific and educational purposes"). As explained below, not all nonprofit organizations are charitable. See infra notes 272–286 and accompanying text.

187. See infra note 277 and accompanying text.

188. RTI 2004 ANNUAL REPORT, supra note 179 (quoting mission statement).
class.\textsuperscript{189} RTI and RTI Donor Services claim that their arrangement advances the latter’s charitable mission. By transferring donated tissue to RTI, "we [RTI Donor Services] can benefit from [RTI’s] science, safety and innovation to ensure the gifts that are entrusted to us are maximized and sterilized through [RTI’s] patented . . . tissue sterilization process, so that more people can receive safe, high quality allograft implants for healthier lives."\textsuperscript{190}

Although RTI Donor Services is a charitable nonprofit organization, it is a taxable and tax-paying enterprise.\textsuperscript{191} Even so, said Ms. Wacker, the organization’s “mission and level of service is [sic] the same as that of a 501(c)(3) organization.”\textsuperscript{192} RTI Donor Services did not pursue tax-exemption under I.R.C. § 501(c)(3), said Ms. Wacker, “because of its affiliation with Regeneration Technologies Inc. (RTI), a for-profit public company.”\textsuperscript{193} Both organizations’ websites prominently state that RTI Donor Services is a nonprofit organization, but fail to mention that it is not tax-exempt.\textsuperscript{194}

IV. WHAT IS THE ECONOMIC VALUE OF DONATED TISSUE, AND WHO CAPTURES IT?\textsuperscript{195}

The National Organ Transplant Act contains provisions whose meanings are uncertain and potentially puzzling. This Part uses economic analysis to explain these provisions and explore the Act’s blueprint for the tissue industry. Section 301(a) may prohibit the transfer of tissue for “valuable consideration,”\textsuperscript{196} but it does not—indeed cannot—abolish the tissue’s economic value.\textsuperscript{197} By prohibiting

\textsuperscript{189} See infra notes 280–282 and accompanying text.

\textsuperscript{190} Announces RTI Donor Services, supra note 175. See also E-mail from Wendy Crites Wacker, supra note 180 ("RTI Donor Services benefits from its affiliation with a for-profit company. The science and innovation provided by companies such as RTI benefit donor families and recipients alike, and serve to maximize the gift to help as many people as possible.") (emphasis added).

\textsuperscript{191} E-mail from Wendy Crites Wacker, supra note 180. Not all charities qualify for tax-exempt status under I.R.C. § 501(c)(3) (1994), and charities that do qualify for tax-exemption can choose to forego it. See infra notes 287–290 and accompanying text. In Part IV, I consider whether RTI Donor Services’s arrangement with RTI precludes tax-exemption, regardless of whether the tissue bank desires that status. See infra notes 382–413 and accompanying text.

\textsuperscript{192} E-mail from Wendy Crites Wacker, supra note 180.

\textsuperscript{193} Id.


\textsuperscript{195} I am very grateful for the assistance of several economists in developing the analysis in this Part: Marc Bilodeau, Woods Bowman, Dan Cole, Peter Grossman, Janet Netz, Patrick Rooney, Warren Schwartz, Richard Steinberg, and Mark Wilhelm.

\textsuperscript{196} 42 U.S.C. § 274e(a) (2000).

\textsuperscript{197} See infra notes 208–215 and accompanying text.
the sale of donated tissue, NOTA effectively requires donors and intermediaries in the tissue industry to transfer or re-gift this value intact to the next party in line, until it reaches allograft recipients. Section 301(c)(2) of NOTA permits intermediaries to earn "reasonable payments" for activities associated with transplantation, but does not define this term.\textsuperscript{198} Reasonable payments, this Part argues, enable intermediaries to recoup their outlays and opportunity costs (earn normal profits),\textsuperscript{199} and so preserve the tissue's value for allograft recipients.\textsuperscript{200}

If the markets for donated tissue and allografts were perfectly competitive, this Part argues, market forces would effectuate NOTA's scheme as a matter of course.\textsuperscript{201} In practice, however, these markets deviate from the ideal of perfect competition because, among other reasons, some processors obtain more tissue than other processors, use patented technology to produce unique allografts, and cultivate more brand loyalty for their processed tissues.\textsuperscript{202} These imperfections enable some intermediaries to effectively sell donated tissue by earning supernormal profits.

\textbf{A. An Economic Analysis of NOTA's Key Provisions}

Economic analysis provides criteria for defining what constitutes reasonable payments under NOTA and demonstrates the economic value of donated tissue.

\textit{1. What Payments Are "Reasonable"?}

Although NOTA prohibits the sale of donated organs and tissue for transplantation, it recognizes that transplantations will not occur unless intermediaries—OPOs, tissue banks, processors—are fairly compensated for their expenses and efforts. To this end, the Act permits intermediaries to earn reasonable payments for activities associated with transplantation.\textsuperscript{203} In economic terms, reasonable payments enable an intermediary to: (a) recoup what it actually spends on inputs (e.g., labor, fuel, and rent); and (b) cover its opportunity costs, which are the value the firm loses by not using its resources to produce other

\begin{itemize}
\item \textsuperscript{198} 42 U.S.C. § 274e(c)(2).
\item \textsuperscript{199} See infra notes 203–207 and accompanying text.
\item \textsuperscript{200} Limiting tissue banks and processors to "reasonable payments" does not guarantee that the recipients of donated tissue will receive its economic value. For convenience, I ignore the possibility that other intermediaries such as tissue distributors and healthcare providers will capture this value.
\item \textsuperscript{201} See infra notes 216–222 and accompanying text.
\item \textsuperscript{202} See infra notes 223–268 and accompanying text.
\item \textsuperscript{203} 42 U.S.C. § 274e(c)(2).
\end{itemize}
To cover its opportunity costs, a firm must earn at least normal profits, which are the returns it would have earned had it invested in a comparably risky venture. They are the minimum profits necessary to induce a firm to continue its current venture.

When intermediaries earn normal profits, they are rewarded for adding value to the donated tissue, but are not paid for the value of the tissue itself. In economic terms, payments are "unreasonable," or excessive, under NOTA if they enable a firm to earn supernormal profits—more than what the firm needs to recoup its expenses and earn normal profits. Business owners are happiest with their line of work when earning supernormal returns, as these are "a return [on investments] which exceeds the minimum necessary to induce the [entity] to remain within the industry . . . ."

2. The Economic Value of Transplant Tissue

Although NOTA prohibits the transfer of tissue for valuable consideration, it cannot erase the donated tissue's intrinsic economic value. This value arises from what recipients are willing and able to pay for the raw tissue from which allografts are processed. This value equals the difference between: (a) what recipients would be willing and able to pay for allografts if donors had to be paid for raw tissue; and (b) the expenses and opportunity costs that intermediaries incur recovering, testing, storing, transporting, processing, distributing, and implanting the allografts made from donated tissue. The transfer of tissue from altruistic donors to allograft recipients who are willing and able to pay donors creates social wealth—"the total dollar value of benefit society receives from a transaction . . . ."

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205. Id. at 29. The Oxford Dictionary defines the term "required rate of return" as [t]he minimum rate of return on an investment needed to make it acceptable to a business. This may be higher than the rate at which the business can borrow: this is partly to take account of the risks involved in investment, and partly because of the fear in an imperfect capital market that extra borrowing now may increase the cost or difficulty of borrowing in the future. See also Oxford Reference Online, A Dictionary of Economics, http://www.oxfordreference.com/views/ENTRY.html?subview=main&entry=T19.e2668 (last visited Jan. 10, 2006).

206. Macmillan Dictionary of Modern Economics 310 (4th ed. 1992) (defining "normal profits" as the "minimum amount of profit which a firm must acquire in order to induce the firm to remain in operation" within the industry it currently occupies).

207. Id. at 415 (defining "super-normal profits") (emphasis added).

208. 42 U.S.C. § 274e(a).

209. See Seidenfeld, supra note 204, at 40.

210. Id.
To deliver the tissue's value to allograft recipients, it is essential to limit payments to intermediaries to reasonable payments. When intermediaries earn no more than normal profits, they are rewarded for adding value to donated tissue, but are not paid for the tissue itself. If every intermediary earns no more than normal profits, the tissue's economic value is preserved intact for allograft recipients. This value is reflected in what recipients do not have to pay (the sums they save) because raw tissue is gifted rather than sold. Conversely, when intermediaries earn supernormal profits, they are paid for more than their expenses and opportunity costs: they are paid something for the tissue itself. In this way, supernormal payments enable intermediaries to capture the economic value of donated tissue.

To better grasp the economic value of donated tissue, consider a hypothetical market for human heart valves for transplantation, as represented by Figure 1. NOTA prohibits paying donors more than zero dollars per valve (P'). At this “price,” only 8,000 (Q') valves are supplied each year. If donors were permitted to sell valves in a free market, however, they would supply 12,000 valves (Q’’) a year at $20,000 apiece (P’’). On these assumptions, current donors of valves collectively forego $160 million each year—the 8,000 valves currently supplied for nothing multiplied by the $20,000 per valve that the market is prepared to pay. This foregone wealth is represented by shaded rectangle P'P’’XQ’.

B. How the Economic Value of Donated Tissue Would Be Distributed in a Perfectly Competitive Market

The concept of social wealth measures “the total dollar value of benefit society receives from a transaction, regardless of how that ben-

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211. See infra notes 218–221 and accompanying text.
213. Emanuel D. Thorne, When Private Parts Are Made Public Goods: The Economics of Market-Inalienability, 15 YALE J. ON REG. 149, 155 (1998). This assumes that altruistic persons who donate 8,000 valves each year would continue to supply valves if offered $20,000 per valve. Emanuel D. Thorne suggests that if cadaveric human tissue could be purchased and sold like other commodities, some persons who would otherwise donate tissue might “refus[ ] to treat their loved ones' organs in this fashion,” and thus “choose neither to donate nor to sell the organs.” Id. at 152.
214. In truth, the tissue industry expends resources to compensate suppliers through in-kind transfers and steps designed to increase the psychic satisfaction that suppliers derive from the donating tissues. See supra notes 108–110 and infra notes 236–237 and accompanying text.
215. For additional discussion of this graph and the derivation of its demand and supply curves, see PINDYCK & RUBINFELD, supra note 212, at 296–97.
This section explains how under certain, ideal conditions, this benefit would be distributed to allograft recipients.

Allograft recipients are the source of donated tissue’s economic value by virtue of their willingness and ability to pay for allografts. This does not mean, however, that allograft recipients capture the donated tissue’s value. Here then is the $160 million question: How should the economic value of donated tissue be distributed? Under NOTA’s scheme, recipients should capture this wealth. The altruistic donors of the tissue presumably want this result: just as they “sell” tissue for nothing, they likely want recipients to “buy” tissue at the same price. Yet how likely is this to happen? Many parties stand between donors and allograft recipients—tissue banks, processors, and other intermediaries—and each may try to capture some of the tissue’s value. If the markets for donated tissue and allografts were perfectly competitive, however, allograft recipients would capture this entire value.

As Professors Dan Cole and Peter Grossman explained, a perfectly competitive market has the following characteristics:

1. Many buyers and sellers, all of whom have complete information about product qualities, quantities, and prices;
2. No buyer or seller has sufficient market power to control the price;
3. Market participants respond rationally to changing market conditions;

216. SEIDENFELD, supra note 204, at 40 (emphasis added).
(4) firms may enter and exit the market costlessly; and
(5) all resources or amenities within the economy are owned and
priced within the market . . . [as] determined by supply and
demand.217

Perfectly competitive markets benefit society, and these benefits are
reflected in the size of the consumer’s surplus. This term refers to
“the effective increase in wealth a consumer realizes” from acquiring
a good.218 In any given transaction, this surplus equals “the excess
value a consumer places on a good over the price of the good . . . .”219
For example, “[i]f a consumer would pay up to $10 for a good when
the market price is $7, then the consumer is said to have a ‘utility’
surplus of $3 in purchasing the good.”220 In a perfectly competitive
market for a certain good, consumers capture all the social wealth cre-
ated by the good’s transfer from producers to them.221 The good’s
producers, by contrast, can earn no more than their economic costs—
the expenses and opportunity costs (normal profits). In such a mar-
ket, every producer incurs the same economic costs to make a certain
good, and no producer can sell that good for more than its economic
costs without losing all its customers. Conversely, a producer cannot
charge less than its economic costs (which corresponds to the good’s
equilibrium price) without earning subnormal profits and ultimately
leaving the market altogether.222

The foregoing analysis yields a surprising conclusion: if the markets
for donated tissue and allografts were sufficiently competitive, market
forces would effectuate NOTA’s scheme as a matter of course, thus
obviating the need for NOTA and its enforcement. Under these ideal
conditions, tissue banks, processors, and other intermediaries could
earn no more than their actual outlays plus normal profits—what the
Act calls reasonable payments. As a result, allograft recipients would
capture all the social wealth (economic value) created by the gratui-
tous transfer of tissue from altruistic donors to themselves. In the
heart valve hypothetical above, allograft recipients would capture the
entire $160 million in wealth that the donors of 8,000 valves collec-

217. DANIEL H. COLE & PETER Z. GROSSMAN, PRINCIPLES OF LAW AND ECONOMICS 13
(2005). Perfectly competitive markets also create no externalities on third parties and have zero
transaction costs. Id.
218. SEIDENFELD, supra note 204, at 16 (defining “consumer surplus”).
219. Id.
(definition “consumer surplus”).
221. SEIDENFELD, supra note 204, at 41.
222. Id. at 38.
tively forego, with each recipient receiving an average of $20,000 in value.

C. Intermediaries Can Capture the Economic Value of Donated Tissue by Exploiting Market Imperfections

The markets for donated tissue and allografts are imperfectly competitive in several ways: the demand for certain types of tissues outstrips supply;\(^{223}\) some processors have greater access to donated tissue than others;\(^{224}\) some use patented technology to produce unique allografts;\(^{225}\) and some have greater name recognition and brand loyalty for their allografts.\(^{226}\) These conditions create opportunities for intermediaries to earn supernormal profits, and thereby capture some of tissue's economic value intended for allograft recipients.

I. Exploiting NOTA-Created Shortages to Earn Supernormal Profit

Demand outstrips supply for certain types of tissue.\(^{227}\) There is, for example, a national shortage of patellar tendon allografts, which are used to reconstruct a knee joint ligament called the anterior cruciate ligament (ACL).\(^{228}\) This shortage is attributed to a variety of factors including: (a) the growing demand for this tissue, which is many physicians' "first choice for ACL reconstruction grafts";\(^{229}\) (b) "a low supply of suitably qualified cadavers," as "there just aren't a lot of young, healthy cadaver donors with low-risk life styles";\(^{230}\) and (c) the fact that patellar tendon allografts are "difficult to dissect and there is a high error rate for recovery."\(^{231}\)

The shortages of certain tissues are ultimately created by NOTA itself, and would likely diminish if donors could lawfully sell tissue. In

\(^{223}\) See infra notes 227–248 and accompanying text.
\(^{224}\) See infra notes 404–409 and accompanying text.
\(^{225}\) See infra notes 249–260 and accompanying text.
\(^{226}\) See infra notes 261–268 and accompanying text.
\(^{227}\) Telephone Interview with Kevin Cmunt, Executive Vice President, AlloSource (Aug. 29, 2005) (explaining that there are shortages of patellar tendon, cancellous chips, traditional rings, and bone wedges).
\(^{228}\) "The patellar tendon is a structure that attaches the quadriceps muscle group to the tibia (shin bone)." The Athletic Advisor, Patellar Tendinitis, http://www.athleticadvisor.com/Injuries/LE/Knee/patellar_tendinitis.htm (last visited Feb. 20, 2006).
\(^{230}\) Id. See also E-mail from Sam Davis, Director of Professional Services & Public Affairs, IOPO, to Robert Katz, Associate Professor of Law and Philanthropic Studies, Indiana University School of Law—Indianapolis (Sept. 22, 2005, 17:36 EST) (on file with author) ("[E]ven when [a patellar tendon is] recovered with precision, a closer investigation of the tissue itself may reveal natural tearing or other things that weaken its integrity.").
\(^{231}\) E-mail from Sam Davis, supra note 230.
a perfectly competitive market for a certain good (cadaveric tissue), the relevant resources "are owned and priced within the market."232 Transplant tissues are not owned in this sense, and prices are set by the Act—at zero—instead of the market. Competition for raw tissue is thus inherently imperfect. The ban on tissue sales makes it harder to summon more supply to meet increased demand. The resulting shortages enable intermediaries that handle scarce tissue to extract a premium from recipients. This premium is also known as an "economic rent"—a payment to a resource or a factor of production "in excess of what is necessary [as an incentive] to keep it to its present employment."233 These premiums consume at least some of the consumer's surplus that allograft recipients would otherwise enjoy.

Consider how the tissue industry would operate if NOTA were abolished, as depicted in Figure 2. The upward-sloping supply curve (S) signifies that as the price of tissue increases, intermediaries will pay next of kin more for their decedents' tissues. Its downward-sloping demand curve (D) signifies that as the price of tissue increases, consumers will demand fewer allografts. When this market is in equilibrium (E), the quantity of tissue supplied equals the quantity demanded (Q) at the prevailing price (P).234

A change in demand alters the market's equilibrium, as illustrated by Figure 3. If the demand for tissue increases (D to D'), the quantity of tissue demanded at price P initially exceeds what will be supplied at that price. Unless the supply can be increased, there will be shortages. In the short run, one of two things will happen: (a) tissue will be allocated among consumers by some nonprice method, such as rationing or queuing;235 or (b) the price of tissue will rise (P to P'), thereby reducing the number of consumers willing to purchase tissue at the higher price (P'). A price increase yields a new equilibrium (E'). When tissue is sold for P', intermediaries can earn supernormal prof-

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233. MACMILLIAN DICTIONARY OF MODERN ECONOMICS, supra note 206, at 121 (defining "economic rent").
234. P is known as the equilibrium price. See OXFORD REFERENCE ONLINE, A DICTIONARY OF ECONOMICS, http://www.oxfordreference.com/views/ENTRY.html?subview=main&entry=T19.e1021, (last visited Mar. 2, 2006) (defining "equilibrium price" as the "price at which the quantity of a good supplied is equal to the quantity demanded").
235. The Dictionary of Economics defines "shortage" as follows:
If there is a sudden rise in the demand or fall in the supply of a good, law or social convention may prevent the price from rising far enough to clear the market, thus creating a shortage. When this occurs, available supplies of the good must be allocated by some non-price method, such as formal or informal rationing, or queuing.
its—a form of economic rent. These profits are represented by shaded rectangle PP"E'E.

If tissue was a saleable commodity, the tissue market could readily adjust to an increase in demand (D to D'). As depicted in Figure 4, when the price of tissue goes up (P to P''), intermediaries will expand supply by paying next of kin more for their decedents' tissues (S to S') in order to capture the supernormal profits (economic rents) repre-
sent by the shaded rectangle PP"E'E. As next of kin supply more tissue (Q to Q'), the market price will fall (P" back to P). As this happens, the rent available for intermediaries and next of kin to capture will shrink until a new equilibrium is achieved (E"'). At this point, intermediaries can once again earn no more than normal profits.

**Figure 4**

Because NOTA bars the tissue industry from paying next of kin for tissue, it must use moral exhortation and other nonpecuniary means to induce the public to supply more.236 Yet these nonpecuniary means are not costless: social resources must be spent on activities such as public service announcements and education programs for schools and workplaces. Moreover, these means may be marginally less persuasive than cash in inducing the public to supply more tissue. Any reward that donor families receive for donating tissues must take the form of in-kind services (e.g., counseling, memorial services), token gifts (e.g., teddy bears), and altruistic satisfaction.237 Yet the marginal utility that donor families derive from each additional unit of intangible and in-kind rewards may diminish at a faster rate than each additional dollar. After a while, there is only so much consolation to be derived from one more recognition ceremony, medal, or teddy bear.

237. See *supra* notes 108–110 and accompanying text.
There are thus inefficiency costs associated with using nonpecuniary means to make adjustments that a free (and NOTA-free) market in raw tissue could readily handle.\textsuperscript{238} As the demand for tissue expands, NOTA will likely result in endemic shortages of some tissue types.

It may be easier for processors, tissue banks, and other intermediaries to circumvent NOTA by transacting with each other than with donors and donor families. There are unmistakable qualitative differences between exchanging tissue for cash, rather than for in-kind or intangible benefits. If next of kin were paid in cash, such transactions would be relatively easy to detect. Because donor families do not bear the costs of tissue recovery,\textsuperscript{239} any payments they receive could not be cast as reasonable payments for their activities.\textsuperscript{240} By contrast, intermediaries regularly transfer money amongst themselves, as with the Standard Acquisition Charges that processors pay tissue banks in exchange for raw tissue.\textsuperscript{241} In this context, only dollar amounts distinguish reasonable payments (normal profits) from unreasonable payments (supernormal profits). For this reason, it can be difficult to distinguish between payments that compensate an intermediary for the value it adds to tissue, as opposed to the tissue itself.

Do intermediaries in the tissue industry exploit tissue scarcity to earn supernormal profits? Generally speaking, tissue banks do not charge a premium for scarcity. Their fees typically reflect what it costs them to procure, handle, inspect, and ship tissues, plus a five to ten percent mark-up for overhead, capital improvements, and other costs.\textsuperscript{242} This is true of the Indiana Organ Procurement Organization (IOPO), which recovers both organs and tissues for transplantation. According to Sam Davis, IOPO's Director of Professional Services and Public Affairs, "We work with tissue processors that offer a standard recovery reimbursement to us based on our costs. My organiza-

\textsuperscript{238} I thank Patrick Rooney for his assistance in articulating this point.

\textsuperscript{239} The IOPO provides an answer to a frequently asked question:

Q: "Will my family be charged for donation?"

A: "No. All costs related to the donation will be covered by the organ, tissue, and eye recovery agencies."


\textsuperscript{240} This was the Arkansas court's finding in Wilson v. Adkins, 941 S.W.2d 440 ( Ark. Ct. App. 1997). See supra notes 60–63, 65 and accompanying text.

\textsuperscript{241} See supra notes 124–126 and accompanying text.

\textsuperscript{242} See supra notes 124–126 and accompanying text.
tion does not charge more for a patellar tendon [than] it does for an Achilles tendon.”

Among tissue processors, for-profit businesses may be more likely to exploit shortages than nonprofit entities. Kevin Cmunt, Executive Vice-President of the nonprofit processor AlloSource, reported that his firm charges $1,700 for a patellar tendon allograft, and that other nonprofits charge as little as $1,000. He contrasted these prices with those of the for-profit CryoLife, which he says charges approximately $3,000 per tendon. Cmunt believed that CryoLife charges more “because they can get [it].” (CryoLife would undoubtedly attribute these price differentials to higher quality and better service.) AlloSource refrains from charging more, said Cmunt, in order to provide more value to its consumers—the healthcare providers who buy its allografts and the patients who ultimately receive them.

2. Raising Prices in Response to Patent-Based Monopolies

If the allograft market were perfectly competitive, every processor would use identical processes to produce identical products. In practice, some processors use patented technology to produce unique allografts, thereby reducing competition in the allograft market and enabling lucky patent holders to earn supernormal profits. This state of affairs reveals a deep tension between the goals of NOTA and intellectual property law.

Some tissue processors have special access to patented processes and products that have unique qualities and few substitutes. Intellec-

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243. E-mail from Sam Davis, Director of Professional Services & Public Affairs, IOPO, to Robert Katz, Associate Professor of Law and Philanthropic Studies, Indiana University School of Law—Indianapolis (Sept. 9, 2005, 14:46 EST) (on file with author).
244. Telephone Interview with Kevin Cmunt, supra note 227.
245. Id.
246. Id.
247. CryoLife’s website states that:
   CryoLife’s strict donor screening and testing procedures and quality specifications yield superior [bone tendon] allografts for transplant. We permit physicians to select tissue on a number of size dimensions thereby ensuring a proper patient-graft match and decreasing graft preparation time in the operating room. A CryoLife Technical Representative can be present to assist with tissue thawing and dilution. Upon request, CryoLife representatives will conduct a thawing and dilution “in-service” workshop for physician and hospital staff—an offering unique to CryoLife.
248. Telephone Interview with Kevin Cmunt, supra note 227.
249. I am very grateful to Kenneth Crews for his help in developing the analysis in this section.
250. See SEIDENFELD, supra note 204, at 35.
tual property law gives patent holders the exclusive right to exploit an invention for a period of years.251 In some instances, a processor’s patented technology has enabled it to dominate certain segments of the allograft market for many years. This is true of LifeCell, which is the only commercial processor of acellular skin for transplantation, the demand for which has grown considerably.252 It was also true of CryoLife, which was “the first company to commercially develop the ultra-low temperature preservation of viable human heart valves for transplant[.]”253 and which continues to be a dominant source of cryopreserved heart valves.254 CryoLife’s website proudly announces that “the company holds thirteen exclusive cryopreservation patents . . . .”255

Our legal system grants temporary, patent-based monopolies in order to encourage investment in socially useful innovations.256 To some extent, an inventor's monopolistic earnings reimburse the economic costs (expenses and opportunity costs) that he or she incurred to develop the patented process or product,257 and also to finance research and development that bore no fruit. Yet part of a patent holder’s revenues are purely monopolistic profits,258 and this is by design. A patent-based monopoly, like all monopolies, results in an inefficient use of resources and so fails to maximize social welfare. Yet we tolerate such localized inefficiencies in the short run because we be-

251. 35 U.S.C. § 271 (2000) (giving a patent holder rights against anyone who makes the patented invention without the holder’s authority); 35 U.S.C. § 154(a)(2) (providing that a patent lasts for a term of twenty years from the date of filing the patent application).

252. See supra notes 162-166 and accompanying text.


256. OXFORD REFERENCE ONLINE, A DICTIONARY OF ECONOMICS, http://www.oxfordreference.com/views/ENTRY.html?subview=main&entry=T19.e2282 (last visited Jan. 15, 2006) (defining “patent” as “[a] legal device to encourage and reward invention by giving exclusive rights to inventors. . . . This right can be used either through their own business, or by charging a licence fee to other users.”).

257. COLE & GROSSMAN, supra note 217, at 103.

258. OXFORD REFERENCE ONLINE, A DICTIONARY OF ECONOMICS, http://www.oxfordreference.com/views/ENTRY.html?subview=main&entry=T19.e2029 (last visited Jan. 15, 2006) (defining “monopoly profit” as “[a]n excess of profits over the normal rate which a firm is able to make by exploiting a monopoly position. If the market were open to competitive entry, such profits would be competed away . . . .”),
lieve (hope?) that this will yield greater efficiency across all markets in the long run.²⁵⁹

On some level, NOTA and the patent system are fundamentally inconsistent. After a certain point, it becomes exceedingly difficult to distinguish between: (a) the unlimited profits that patent law permits patent holders to earn from their innovations; and (b) the supernormal profits that NOTA prohibits intermediaries to earn from their transplantation-related activities. Unwieldy distinctions such as this arise in other contexts. For example, “People with special abilities may receive some element of economic rent, but it is hard to distinguish this from a return on the time and effort that leading baritones or barristers put into their specialized training.”²⁶⁰ Which rules should prevail—NOTA or intellectual property law? One might argue that it is “reasonable” to let tissue processing innovators earn supernormal profits for a period of time, but this redefinition makes NOTA’s reasonable payments restriction meaningless.

3. Brand Loyalty

A processor can earn supernormal profits if its customers are especially loyal. “Brand loyalty” refers to the tendency for consumers to “buy brands they have used before, or seen widely advertised, in preference to unbranded products or unfamiliar names.”²⁶¹ In the tissue industry, for-profit tissue processors were the first to brand their products and cultivate brand loyalty through advertising, marketing, and professionally trained sales representatives.²⁶² Osteotech pioneered this strategy by marketing its demineralized bone matrix (DBM) under the Grafton trademark.²⁶³ Over time, doctors develop preferences for certain brands of processed tissues. According to Sam Davis of IOPO, they “go with what they are familiar with and data they believe to be most accurate.”²⁶⁴ For many years in Indiana, for exam-


²⁶². Anderson & Bottenfield, supra note 133, at 19.

²⁶³. See supra notes 150–152 and accompanying text.

²⁶⁴. E-mail from Sam Davis, Director of Professional Services & Public Affairs, IOPO, to Robert Katz, Associate Professor of Law and Philanthropic Studies, Indiana University School of Law—Indianapolis (Sept. 23, 2005, 13:09 EST) (on file with author).
pie, most cardiovascular surgeons preferred CryoLife's heart valves over other processors' valves. 265

Consumers loyal to a particular brand may be willing to pay more for it, even if other companies' products are less expensive and of comparable or superior quality. 266 In such cases, a producer can exploit brand loyalty to earn supernormal profits by charging more for products that are identical to its competitors, or by charging the same price for products that are of lesser quality and less expensive to produce than its competitors. These dynamics may occur in the tissue industry. CryoLife has sold heart valves for approximately $12,000, as compared to LifeNet, which charges approximately $8,000. 267 The higher price for CryoLife's valves, said IOPO's Davis, "could be considered subjective and arbitrary." 268

V. CAN CHARITY LAW PREVENT FOR-PROFIT PROCESSORS FROM EXPLOITING DONATED TISSUE AND NONPROFIT TISSUE BANKS? 269

NOTA posits a scheme for distributing a charitable resource—the economic value of donated tissue—to its donors' intended beneficiaries. It prohibits any party from selling tissue; rather, each party must re-gift the tissue's value intact to the next party in line until delivered to allograft recipients. NOTA also promotes health by authorizing compensation for intermediaries—their expenses plus normal profits—for adding therapeutic value to donated tissue. If this scheme were followed, the presence of for-profit businesses in the tissue industry would not interfere with the Act's philanthropic goals. In practice, however, this scheme is not fully realized.

This Part uses the analytical tools of charity law to examine NOTA's philanthropic goals for the tissue industry. This exercise promises both intellectual and practical payoffs. Charity law provides an alternative account of philanthropic aims, how to achieve them, and how they can be thwarted. Insofar as NOTA and charity law share goals, the latter seems like a promising enforcement ally.

After surveying the charity law most relevant to our analysis, this Part applies that law to the tissue industry. It addresses two questions: do industry actors and arrangements violate charity law, and can char-

265. E-mail from Sam Davis, supra note 230.
266. See supra note 261 and accompanying text.
267. See e-mail from Sam Davis, supra note 264.
268. Id.
269. I am very grateful to John Colombo and Woods Bowman for their assistance in developing the analysis in this Part.
ity law help advance NOTA's philanthropic goals? The discussion is organized around two charity law doctrines. The first is the ban on private inurement, also known as the nondistribution constraint, which protects nonprofit organizations from exploitation by insiders.\textsuperscript{270} It invites us to scrutinize a for-profit processor like RTI that controls a nonprofit tissue bank like RTI Donor Services. The second doctrine, called the ban on private benefit, deals with the indirect private benefits of charitable activity—including benefits conferred on unrelated and noncharitable third parties. For example, when a nonprofit organization improves facilities at a public lake, it also advances the private interests of people who own lake front property.\textsuperscript{271} The private benefit doctrine draws attention to tissue banks that transfer tissue to for-profit processors, as such transfers may enable the transferee to capture the tissue's economic value for private gain.

\textbf{A. A Primer on Charity Law}

This section explains the differences between nonprofit, charitable, and tax-exempt organizations, and surveys the rules that govern them. It pays special attention to the rules that restrict the use of nonprofit organizations and their assets for private gain.

\textbf{1. Nonprofit, Charitable, and Tax-Exempt Organizations}

There is substantial overlap among nonprofit, charitable, and tax-exempt organizations and the rules that govern them, but these organizations are not coextensive. The broadest category consists of nonprofit organizations. Charities are a type of nonprofit entity, and many charities are tax-exempt under I.R.C. § 501(c)(3).

A nonprofit entity is organized and operated for some purpose other than earning profits for those who control it. It is prohibited from distributing its profits to insiders—for example, founders, directors, managers, and contributors—except as reasonable compensation for goods, services, or other resources rendered.\textsuperscript{272} This is known as the nondistribution constraint,\textsuperscript{273} and Professor Henry B. Hansmann posited it as the defining characteristic of nonprofit entities.\textsuperscript{274} A nonprofit's earnings, if any, must be used to advance its mission—typically

\begin{thebibliography}{99}
\bibitem{270} See infra notes 272–275, 315–327 and accompanying text.
\bibitem{271} See infra notes 347–349 and accompanying text.
\bibitem{272} Henry Hansmann, The Ownership of Enterprise 228 (1996).
\bibitem{273} Marion R. Fremont-Smith, Governing Nonprofit Organizations: Federal and State Law and Regulation 248–49 (2004); Hansmann, supra note 272, at 228.
\bibitem{274} Henry B. Hansmann, The Role of Nonprofit Enterprise, 89 Yale L.J. 835, 838 (1980).
\end{thebibliography}
by increasing the output of the services and goods it was formed to provide.275

A charity or charitable organization is a nonprofit entity that is formed for a purpose deemed "charitable" under the state law of charitable trusts.276 Legally charitable purposes include the promotion of health,277 the relief of poverty,278 and "other purposes that are beneficial to the community."279 Additionally, the organization's beneficiaries must constitute a "charitable class."280 This means that the beneficiaries must comprise a sufficiently large number of people, or a sufficiently indefinite class of persons, such that their consumption of the organization's output advances a public interest.281 Poor, sick, or elderly persons can be a charitable class,282 as are disadvantaged arti-

275. HANSMANN, supra note 272, at 228.
276. See RESTATEMENT (THIRD) OF TRUSTS § 28 (2003); Evelyn Brody, Charity Governance: What's Trust Law Got to Do With It?, 80 CHI.-KENT L. REV. 641, 642 (2005) ("The definition of charity set forth in the Restatement of the Law of Trusts controls across the board, from inheritance disputes to federal tax law.") (internal citation omitted). Unless otherwise indicated, I will use the terms "nonprofit" and "nonprofit organization" to refer exclusively to "charitable" and "charity," respectively. A nonprofit's purpose need not be charitable. Non-charitable nonprofits include mutual benefit organizations such as social clubs and trade associations, which "hold themselves out as benefiting, representing and serving a group of individuals or entities." AM. B. ASSOC., REVISED MODEL NONPROFIT CORPORATION ACT, at xxviii (1987) [hereinafter RMNCA]. This is true of "mutual benefit" organizations such as social clubs, trade associations, and fraternal organizations. Id.
278. Id. § 28(a).
279. Id. § 28(f).
281. Id.; GEORGE GLEASON BOGERT & GEORGE TAYLOR BOGERT, TRUSTS AND TRUSTEES § 365 (2d ed., rev. 1991). As Professor John Columbo explained, under the common law, a trust is considered "charitable" only if the trust provides a benefit to the general public, as opposed to specific private individuals. In other words, a charitable trust has to have a broadly-defined set of beneficiaries. Hence, a trust to maintain a public graveyard was considered charitable at common law, while a trust to maintain a particular individual's tomb was not because it served private, rather than public, interests.


282. Ruth Rivera Huetter & Marvin Friedlander, Disaster Relief and Emergency Hardship Programs, in EXEMPT ORGANIZATION CONTINUING PROFESSIONAL EDUCATION TECHNICAL INSTRUCTION PROGRAM FOR FY 1999, at 219-21 (1998), available at http://www.irs.gov/pub/irs-tege/eotopick99.pdf. This article was written by IRS officials for inclusion in the IRS's series of Continuing Professional Education (CPE) texts. The IRS states that "[t]hese materials were designed specifically for training purposes only. Under no circumstances should the contents be used or cited as authority for setting or sustaining a technical position." IRS, Charities & Non-Profits, EO Tax Law Training Articles, http://www.irs.gov/charities/article/0,,id=96441,00.html (last visited Feb. 20, 2006).
sans in developing societies. A charity may be organized as a charitable trust or a nonprofit corporation, but most are set up as corporations.

Most nonprofits seek tax exempt status. Charities typically qualify for tax exemption under I.R.C. § 501(c)(3), which applies to entities "organized and operated exclusively" for "exempt" purposes. Exempt purposes under I.R.C. § 501(c)(3) substantially overlap with the purposes that trust law deems charitable. Like charitable trusts, tax-exempt organizations must also benefit a charitable class.

2. The Fiduciary Duties of Charitable Fiduciaries Under State Law

The trustees of a charitable trust and the directors of a nonprofit corporation have certain duties under state law. Trustees and directors must place the organization's interests before their own or those of a noncharitable third party (the duty of loyalty). They must also manage their organization and its assets in an informed and responsible manner.

284. The archetypal charitable trust is created when a donor (settlor) executes a written instrument that obligates another party (the trustee) to use donated property for a charitable purpose. PAUL G. HASKELL, PREFACE TO WILLS, TRUSTS AND ADMINISTRATION 77 (2d ed. 1994); RESTATEMENT (THIRD) OF TRUSTS § 2 (2003). A donor can also create a charitable trust or its equivalent within a nonprofit corporation by making a restricted gift to the entity. RESTATEMENT (SECOND) OF TRUSTS § 348 cmt. f (1959) ("Where property is given to a charitable corporation and it is directed by the terms of the gift to devote the property to a particular one of its purposes, it is under a duty, enforceable at the suit of the Attorney General, to devote the property to that purpose.").
285. A nonprofit corporation formed for a charitable purpose is known as a charitable or "public benefit" nonprofit corporation. See RNMCA, supra note 276, §§ 1.40(28), 2.02(a)(2)(i) (discussing public benefit nonprofit corporations); see also MARILYN E. PHELAN, NONPROFIT ENTERPRISES: CORPORATIONS, TRUSTS, AND ASSOCIATIONS § 1:01 (2002), available at http://www.westlaw.com (under the RNMCA, "all Section 501(c)(3) organizations (charitable nonprofits) must be public benefit corporations").
289. Exempt purposes under I.R.C. § 501(c)(3) include "religious, charitable, scientific, ... or educational purposes ...." Id.
291. See infra notes 294–299 and accompanying text.
ble manner (the duty of care). Although a director's duties are generally less demanding than a trustee's, trust law sets normative standards to which directors can aspire.

At its core, the duty of loyalty demands that fiduciaries comply with the nondistribution constraint by not distributing the organization's profits to themselves. The duty obliges trustees to "administer the trust . . . solely in furtherance of its charitable purpose." A trustee can derive incidental benefits from a charity's activities, so long as his or her decisions aim to advance the charity's best interests. Additionally, a trustee must not subordinate the trust's interests to those of a noncharitable third party. A director's duty of loyalty demands that he or she act "in a manner the director reasonably believes to be in the best interests of the corporation." A director violates the duty of loyalty by unjustly siphoning off corporate assets for the director's private gain.

The duty of care requires trustees to exercise reasonable effort and diligence in administering a charitable trust. When selling trust property, a trustee must "fully employ [his or her] care, skill and judgment toward obtaining a fair market value for such property." Similarly, a director is obliged to manage a corporation's assets with a degree of diligence, care, and skill. As a procedural matter, directors who wish to transfer corporate property must first "obtain all ma-

292. See infra notes 300-305 and accompanying text.
294. See supra notes 272-275 and accompanying text.
296. Id. § 78 cmt. d(1).
297. Id. § 78 cmt. f.
298. RMMCA, supra note 276, § 8.30(a)(3). See also Brody, supra note 276, at 653 (nonprofit director's duty of loyalty arises from RMMCA § 8.30(a)(3)). Unlike a trustee, a nonprofit director can generally transact with the corporation that he or she directs on terms that are fair to the corporation. See RMMCA, supra note 276, § 8.31.
302. See United Cancer Council, Inc. v. Comm'r, 165 F.3d 1173, 1180 (7th Cir. 1999). A director's duty of care requires the director to act "with the care an ordinarily prudent person in a like position would exercise under similar circumstances . . . ." RMMCA, supra note 276, § 8.30(a)(2).
terial information reasonably available to [them] regarding” the transfer. As a substantive matter, directors cannot give corporate assets away or waste them, for example, by exchanging assets “for consideration so disproportionately small as to lie beyond the range at which any reasonable person might be willing to trade.”

Trustees are obliged to advance the settlor’s charitable purpose. Some commentators claim that nonprofit managers have an analogous duty to affirmatively advance their corporation’s mission. This so-called “duty of obedience” underscores the nonpecuniary mandate of nonprofit corporations and their directors, as compared to their for-profit counterparts. As Professor Harvey Goldschmid observed: “For-profit directors and officers are principally concerned about long-term profit maximization. While nonprofit directors and officers keep economic matters in mind, they are principally concerned about the effective performance of the nonprofits’s [sic] mission.”

As a general rule, a state attorney general has standing to bring suit when directors breach their fiduciary duties. A state court can remove disloyal or reckless directors and order them to repay corporate assets that were looted or wasted. In extreme cases, a state court

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304. 3A WILLIAM MEADE FLETCHER, FLETCHER CYCLOPEDIA OF THE LAW OF PRIVATE CORPORATIONS § 1102 (rev. vol. 2002); see also supra note 22 and accompanying text.

305. See FLETCHER, supra note 304, § 1102, at 131 & n.9. See also Grobow v. Perot, 539 A.2d 180, 189 (Del. 1988) (finding that a director who wastes corporate assets violates a duty of care where “what the corporation has received [for the asset] is so inadequate in value that no person of ordinary, sound business judgment would deem it worth that which the corporation has paid”). When a nonprofit corporation merges with a for-profit business, directors generally must obtain the corporation’s fair market value as if it were “operated as a business concern . . . .” RMNCA, supra note 276, § 11.02(a)(4).

306. RESTATEMENT (THIRD) OF TRUSTS: PRUDENT INVESTOR RULE §379 cmt. a (1990) (explaining the trustee is obliged “to administer [the trust] solely in the interest of effectuating the charitable purposes”).


308. Id.


310. FISHMAN & SCHWARZ, supra note 286, at 254-57.

311. See, e.g., RMNCA, supra note 276, § 8.33(a). This section provides:

Unless a director complies with the applicable standards of conduct . . . , a director who votes for or assents to a distribution made in violation of this Act is personally liable to the corporation for the amount of the distribution that exceeds what could have been distributed without violating this Act.

Id.
can dissolve the corporation. The unrestricted assets of a dissolved corporation are distributed as set forth in its organic documents, or are transferred to other entities engaged in the same or similar activities.

3. The Bans on Private Inurement and Private Benefit Under Tax-Exempt Law

Charitable organizations and assets are sometimes used in ways that benefit the private interests of persons other than the assets’ intended beneficiaries. For example, when a charity hires a for-profit fundraising firm to solicit donations on its behalf, this arrangement benefits the for-profit firm’s owners. The federal law of tax-exempt organizations (tax-exempt law) contains two doctrines designed to restrict the use of an exempt organization (EO) and its assets for private gain.

a. The Ban on Private Inurement

Tax-exempt law prohibits an EO from distributing its earnings and other economic assets to organizational insiders—founders, directors, officers, and key employees—for their private gain. This prohibition, known as the ban on private inurement, enacts the nondistribution constraint into tax-exempt law and complements an EO director’s duty of loyalty. According to the IRS, private inurement is likely to arise when an EO transfers “financial resources to an individual solely by virtue of the individual’s relationship with the organization, and without regard to accomplishing exempt purposes.”

312. See, e.g., id. § 14.30(a)(1)(iii) (the appropriate state court “may dissolve a corporation . . . in a proceeding by the attorney general if it is established that . . . the corporation is a public benefit corporation and the corporate assets are being misapplied or wasted”).

313. See PHELAN, supra note 285, § 4:10. A charitable corporation’s articles of incorporation must state that on dissolution its assets will be distributed to another charitable undertaking. RMNCA, supra note 276, §§ 2.02(a)(6), 14.06(a)(6).

314. See infra note 370 and accompanying text.

315. BRUCE R. HOPKINS, THE LAW OF TAX-EXEMPT ORGANIZATIONS 488 (8th ed. 2003) (noting an EO’s insiders include its founders, directors, officers, key employees, relatives, and certain entities controlled by these persons).

316. See United Cancer Council, Inc. v. Comm’r, 165 F.3d 1173, 1176 (7th Cir. 1999) (finding that a ban on private inurement was designed “to prevent the siphoning of charitable receipts to insiders of the charity”).


318. See supra notes 294–299 and accompanying text.

Classic private inurement occurs when an EO pays more, or receives less, than fair market value (FMV) for an economic resource as a result of an insider transaction not negotiated at arm's length. Examples include selling corporate assets to insiders for inadequate consideration, charging insiders below-market rent to lease corporate property, and paying excessive salaries to directors and officers.

The ban on private inurement originates in the text of I.R.C. § 501(c)(3), which provides that “no part of [an EO’s] net earnings [may] . . . inure[ ] to the benefit of any private shareholder or individual . . . .” As used in this context, “net earnings” refers to an EO’s accounting profits and other economically valuable resources, and “private shareholder or individual” refers to an EO’s insiders. The IRS can revoke the tax exemption of an entity whose resources have been siphoned off by insiders. The IRS can also impose “intermediate sanctions” on insiders who derive excess benefits from their transactions with the EO and on managers who knowingly permit such transactions to occur.

b. The Ban on Private Benefit

A charitable activity can generate both public and private benefits. The ban on private benefit restricts an EO's ability to engage in activities that benefit persons other than its intended charitable benefi-
ciaries.\textsuperscript{328} This "other than" class includes both EO insiders\textsuperscript{329} and people who are not insiders—also known as organizational outsiders or disinterested parties.\textsuperscript{330} The ban on private benefit focuses on the secondary private benefits of an EO's otherwise charitable activities; the ban demands that EOs refrain from such activities that excessively or unduly benefit private interests.\textsuperscript{331} As Professor John Colombo explained, the private benefit ban is very different from the trust law principle that a charitable trust must benefit a charitable class, such as poor or infirm persons.\textsuperscript{332} The state law principle "focus[es] on the breadth of the charitable class directly served by the organization rather than the benefits flowing to private interests \textit{as a result of serving the charitable class}."\textsuperscript{333}

The ban on private benefit is an administrative and judicial gloss on I.R.C. § 501(c)(3), which does not refer to the ban. Some authorities claim that it inheres in I.R.C. § 501(c)(3)'s requirement that an EO be operated exclusively for exempt purposes.\textsuperscript{334} Treasury regulations elaborate this requirement by prohibiting EOs from applying more than a small portion of their energies to benefiting private interests—the ultimate nonexempt purpose.\textsuperscript{335} The IRS can deny or revoke tax-exemption to an entity that confers private benefit.\textsuperscript{336}

Compared to private inurement, private benefit is a relatively recent development in tax-exempt law. According to John Colombo,

\begin{itemize}
  \item \textsuperscript{328} Andrew Megosh et al., \textit{Private Benefit Under I.R.C. 501(c)(3), in Internal Revenue Service Continuing Professional Education Text for Fiscal 2001}, at 135, 139 (2000), http://www.irs.gov/pub/irs-tege/eotopich01.pdf ("Private benefit ... can involve benefits to anyone other than the intended recipients of the benefits conferred by the organization's exempt activities.").
  \item \textsuperscript{329} Private inurement is a subset of private benefit. \textit{Id.} at 135.
  \item \textsuperscript{330} Am. Campaign Acad. v. Comm'r, 92 T.C. 1053, 1069 (1989) (noting that private benefit can refer to an EO's "conferral of benefits on disinterested persons," where the term "disinterested" is used to distinguish persons who are not EO insiders).
  \item \textsuperscript{331} See infra notes 341–378 and accompanying text.
  \item \textsuperscript{332} See Colombo, supra note 281, at 511.
  \item \textsuperscript{333} \textit{Id.}
  \item \textsuperscript{334} See, e.g., Redlands Surgical Servs. v. Comm'r, 113 T.C. 47, 74 (1999).
  \item \textsuperscript{335} The American Campaign Academy court, for example, noted: [S]hould the petitioner [an organization seeking tax-exempt status] be shown to benefit private interests, it will be deemed to further a nonexempt purpose under section 1.501(c)(3)-1(d)(1)(ii), Income Tax Regs. This nonexempt purpose will prevent petitioner from operating primarily for exempt purposes absent a showing that no more than an insubstantial part of its activities further the private interests or any other nonexempt purposes.\textit{American Campaign Academy}, 92 T.C. at 1066.
\end{itemize}
the unofficial historian of the present-day private benefit doctrine, the IRS conceived the doctrine in the late 1970s, and the United States Tax Court adopted it in 1989 in American Campaign Academy v. Commissioner. The concept gained further legitimacy when Judge Richard Posner discussed it favorably in United Cancer Council, Inc. v. Commissioner, a Seventh Circuit decision issued in 1999. This section surveys how the IRS, the tax court, and Judge Posner have each formulated the doctrine.

i. IRS: Private benefits impermissible if avoidable or substantial, relative to an activity’s public benefits

Under the IRS’s standard an EO can engage in a charitable activity that benefits outsiders, so long as these private benefits are relatively insubstantial and unavoidable. An activity’s private benefits are permissible if they are both: (a) insubstantial compared to their public benefits (or “quantitatively incidental” to the public benefits); and (b) “a necessary concomitant” or “mere byproduct” of the activity, such that its public benefits “can be accomplished only by benefiting certain private individuals” (i.e., the private benefits are “qualitatively incidental” to the activity). A charitable activity is

337. Today’s private benefit doctrine differs from earlier formulations advanced by the IRS but which never took hold. See Colombo, supra note 281, at 508–09.
338. Id. at 508 (internal citations omitted).
339. Id. at 510 (citing 92 T.C. 1053).
340. 165 F.3d 1173 (7th Cir. 1999).
341. I.R.S. Gen. Couns. Mem. 39,598 (Jan. 23, 1987), available at 1987 IRS GCM LEXIS 2, at *15–16. There is controversy over the IRS’s methodology for assessing whether a charitable activity’s private benefits are substantial relative to its public benefits. According to the IRS, the key inquiry is whether a particular activity’s private benefits are substantial compared to its public benefits—even if these private benefits are insubstantial compared to the public benefit generated by all the organization’s activities. Id.; I.R.S. Gen. Couns. Mem. 39,862 (Nov. 21, 1991), available at 1991 IRS GCM LEXIS 39, at *34. Professor Colombo has criticized this methodology as “indefensible as a legal and policy matter.” Colombo, supra note 281, at 524 (internal citations omitted). In American Campaign Academy, the tax court seemed to look at the totality of an EO’s activities. See infra notes 361, 366–367 and accompanying text.
343. Megosh et al., supra note 328, at 137.
345. Id. at *16. Cf. I.R.S. Gen. Couns. Mem. 39,732 (May 19, 1988), available at 1988 IRS GCM LEXIS 44, at *12–13 (rejecting the argument that joint venture with for-profit entities confers nonincidental private benefit unless the exempt entity can show that this arrangement was the only way to pursue its charitable purpose).
impermissible if its private benefits are *either* quantitatively *or* qualitatively nonincidental to its public benefits.  

Qualitatively incidental benefits are illustrated by Revenue Ruling 70-186. This ruling involved an organization that maintained and improved recreational facilities at a public lake. Its activity obviously advances the private interests of people who own lake front property. At the same time, “it would be impossible for the organization to accomplish its purposes without providing [private] benefits” to these owners.

The IRS’s approach focuses on the actual benefits generated by an activity—the benefits themselves, and their relative magnitude and avoidability. It matters less whether the EO engaging in the activity *intended* to generate these private benefits. This view finds support in Revenue Ruling 76-206, which involved a nonprofit organization that promoted classical music programs broadcast by a for-profit radio station. According to IRS officials, “[T]he motivation of the organization’s creators was purely a desire to continue the broadcasting of classical music in their community”—an educational and hence tax-exempt purpose. The IRS nevertheless denied tax-exempt status on grounds that the organization’s activity disproportionately benefited the for-profit station relative to the public benefits. These activities included efforts to enlarge the station’s audience, sell the

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346. This is implicit in the IRS’s assertion that “[a]ny private benefit arising from a particular activity must be ‘incidental’ in both a qualitative and quantitative sense to the overall public benefit achieved by the activity . . . .” IRS GCM 39,862, supra note 341, at *34.


349. Id.

350. *But see* I.R.S. Gen. Couns. Mem. 39,862, supra note 341, at *34 (observing that private benefits that are “a necessary concomitant of the activity that benefits the public at large”—and thus qualitatively nonincidental—“might also be characterized as indirect or unintentional”).


352. Megosh et al., supra note 328, at 138.

353. *See, e.g.*, Rev. Rul. 64-175, 1964-1 C.B. 185 (finding that a nonprofit corporation formed “to stimulate, promote and develop interest in the dramatic arts, to educate the American public in the dramatic arts, to advance the national culture in the field of dramatic arts, and to bring the dramatic arts to areas and population centers that are not adequately served in this respect” qualified for exemption as an educational organization under I.R.C. § 501(c)(3)). *See Rev. Rul. 76-206, 1976-1 C.B. 154 (“Rev. Rul. 64-175 supports the view that a nonprofit organization that preserves and maintains classical music programming in a particular locale is serving an educational purpose.”).

station's program guide, recruit businesses to sponsor the station, and encourage the public to patronize these sponsors.\footnote{355}

Under the IRS's approach, even an FMV transaction between an EO and a private party can confer prohibited private benefit. The IRS established this in General Counsel Memorandum (GCM) 39862,\footnote{356} which denied tax-exemption to a joint venture between a nonprofit hospital and staff physicians in its surgery clinic. The hospital contracted to sell the clinic's net revenue stream to this joint venture. The IRS accepted the representation that the joint venture paid FMV for this revenue stream,\footnote{357} but this fact did not preclude excessive private benefit. As IRS officials explained, "[U]nlike [private] inurement, finding private benefit does not require that payments [by the would-be exempt organization] for goods or services be unreasonable or exceed fair market value."\footnote{358} In GCM 39862, the joint venture was defective because the private benefits it generated for the physicians were "substantial" compared the public benefits it generated.\footnote{359}

\textit{ii. Tax court: Private benefits impermissible if intentional and a substantial portion of an organization's activities}

In \textit{American Campaign Academy}, the tax court endorsed the concept of prohibited private benefit, but not the IRS's conception of it. The tax court's private benefit analysis focuses more on "the purpose towards which an organization's activities are directed," rather than "the nature of the activities themselves."\footnote{360} To determine whether private benefits are qualitatively nonincidental, the tax court asked whether an EO \textit{intends} to benefit a particular set of private interests, rather than whether these private benefits are avoidable. To determine whether private benefits are quantitatively nonincidental, the tax

\footnote{355. \textit{Id.} These private benefits may have been unavoidable (qualitatively incidental) if the for-profit radio station was the only outlet for classical music in the community—for example, if there was no public radio station.}


\footnote{357. \textit{Id.} at *2 (accepting as fact the hospital's claim "that the purchase price for the revenue stream was established at fair market value after arm's length negotiations, and was properly discounted to present value"); \textit{id.} at *7.}

\footnote{358. Megosh et al., \textit{supra} note 328, at 138.}

\footnote{359. The IRS found that public benefits produced by the joint venture—greater utilization of the clinic and more net income for the hospital—did not substantially advance the hospital's charitable mission. I.R.S. Gen. Couns. Mem. 39,862, \textit{supra} note 341, at *35–36. The IRS also held that the arrangement constituted private inurement. \textit{Id.} at *27 ("Giving (or selling) medical staff physicians a proprietary interest in the net profits of a hospital under these circumstances creates a result that is indistinguishable from paying dividends on stock.").}

\footnote{360. \textit{Am. Campaign Acad. v. Comm'r}, 92 T.C. 1053, 1078–79 (1989).}
court asked whether these benefits were substantial relative to all the public good an organization accomplishes.361

In American Campaign Academy, the tax court reviewed the IRS’s refusal to grant tax exemption to the American Campaign Academy (the Academy), a nonprofit entity that trained political campaign workers. The Academy was a bona fide charity under state law: it advanced a charitable purpose (education), and its primary beneficiaries (students) constituted a charitable class.362 The problem, according to the IRS, was that the Academy’s activities excessively benefited the Republican candidates and entities that employed most of the Academy’s students.363

The tax court upheld the IRS’s refusal on two grounds. First, it found that the Academy specifically intended to advance particular private interests: the Academy “conducted its educational activities with the partisan objective of benefiting Republican candidates and entities” that hired its students.364 The purposefulness of these private benefits makes them qualitatively nonincidental to the Academy’s otherwise charitable activity.365 Second, the purposeful advancement of Republican interests was a substantial part of the Academy’s activity,366 and thus quantitatively nonincidental to that activity. The Academy’s primary purpose may have been to educate its students, said the tax court, but it was also “formed with a substantial purpose” to advance the private interests of these particular, noncharitable parties.367 Advancing Republican interests was part of the Academy’s raison d’être.

361. Id. at 1066. See supra note 335. See also Darryll K. Jones, Private Benefit and the Unanswered Questions From Redlands Surgical Services, 29 EXEMPT ORGS. TAX REV. 433, 444 (2000), available at http://www.lexisnexis.com (“[American Campaign Academy] supports the . . . conclusion that private benefit is only fatal if the private benefit is substantial when compared to the public good an entity accomplishes.”) (internal citation omitted).


363. 92 T.C. at 1077 (“Petitioner has not established that the specific Republican entities and candidates which benefited by its educational programs were members of a charitable class.”). Private inurement was absent because Republican candidates and entities did not control the Academy. Id. at 1065 (“[The IRS] does not contend that [the Academy’s] earnings inure to the benefit of private shareholders or individuals . . . .”).

364. Id. at 1070.

365. Id. at 1069.

366. Id. at 1075 (affirming the IRS’s determination that “more than an insubstantial part of [American Campaign Academy’s] activities were performed to further a nonexempt purpose”—namely, to benefit Republican entities and candidates).

367. Id. at 1078 (“[W]e find the administrative record supports [the IRS’s] contention that [American Campaign Academy] was formed with a substantial purpose to train campaign professionals for service in Republican entities and campaigns . . . .”).
Under the tax court’s approach, charitable activity that generates secondary private benefits is not prohibited unless the charity targets these benefits towards a particular private party—unless they are qualitatively nonincidental. This differs from the IRS’s approach, which prohibits charitable activity whose secondary private benefits are either qualitatively or quantitatively nonincidental.

iii. Judge Posner: Non-FMV transactions can confer private benefit

Judge Posner opines that an EO’s directors, if careless, can unilaterally confer private benefit on outsiders through non-FMV transactions negotiated at arm’s length. This conception of private benefit enacts the nonprofit director’s duty of care into tax-exempt law.

Judge Posner presented his views on private benefit in United Cancer Council. 368 This case considered the IRS’s decision to revoke tax-exemption status for United Cancer Council, Inc., (UCC), a nonprofit corporation formed to promote cancer prevention and to help cancer victims. 369 In 1984, UCC contracted with Watson & Hughey Company (W&H), a for-profit fundraising firm, to solicit donations on UCC’s behalf. From 1984 to 1989, W&H’s fundraising campaign grossed $28.8 million, but netted only $2.3 million for UCC. 370 The IRS later revoked UCC’s tax exemption (retroactive to 1984) on grounds that its contract with W&H resulted in the private inurement by W&H. 371 The IRS argued (as paraphrased by Judge Posner) that “the contract was so advantageous to W&H and so disadvantageous to UCC that the charity must be deemed to have surrendered the control of its operations and earnings to the noncharitable enterprise that it had hired to raise money for it.” 372 The tax court affirmed the IRS’s decision on the basis of private inurement by W&H as a UCC insider. 373 The IRS also claimed that UCC conferred private benefit on W&H as an UCC outsider, but the tax court did not reach this claim. 374 Judge Posner rejected and reversed the tax court’s judgment. There could be no private inurement by W&H, Judge Posner held, because W&H’s managers were not UCC insiders, as evidenced by the fact that the contract between the organization and the fundraising firm had been negotiated at arm’s length. 375 The case was re-

368. 165 F.3d 1173 (7th Cir. 1999).
370. 165 F.3d at 1175.
371. Id. at 1174–75.
372. Id. at 1175.
373. Id. at 1174–75.
374. Id.
375. Id. at 1176, 1178.
manded back to the tax court for a determination as to whether UCC conferred prohibited private benefit on W&H.

In discussing the private benefit doctrine, Judge Posner connected it to the nonprofit director's duty of care under state law. He opined that careless directors could unilaterally confer private benefit on an outsider:

[T]he board of a charity has a duty of care . . . and a violation of that duty which involved the dissipation of the charity's assets might . . . support a finding that the charity was conferring a private benefit, even if the contracting party did not control, or exercise undue influence over, the charity.\textsuperscript{376}

More specifically, careless directors can enrich outsiders through non-FMV transactions negotiated at arm's length. Judge Posner continued:

Maybe the [UCC] board did not negotiate as favorable a contract with W&H as the board of a profitmaking firm would have done. . . . Then it could be argued that UCC was in fact being operated to a significant degree for the private benefit of W&H, though not because it was the latter's creature.\textsuperscript{377}

In Judge Posner's discussion, private benefit superficially resembles private inurement in that both can result from non-FMV transactions. Yet the two phenomena differ in cause. Private inurement can occur when disloyal directors enrich themselves through lopsided exchanges with their organization. Private benefit can occur when careless directors enrich outsiders through lopsided exchanges with the latter. Judge Posner suggested that the IRS could use the ban on private benefit "to deal with the problem of improvident or extravagant expenditures by a charitable organization" that benefit outsiders rather than insiders.\textsuperscript{378}

\textbf{B. Can Charity Law Prevent For-Profit Processors From Exploiting Donated Tissue and Nonprofit Tissue Banks?}

This section applies charity law to the tissue industry. It asks two basic questions. Do any actors or arrangements in the tissue industry violate charity law? If so, can charity law be used to advance NOTA's philanthropic goals?

The exposition is organized around the bans on private inurement and private benefit, respectively. The ban on private inurement, which protects nonprofit organizations from exploitation by insiders,

\textsuperscript{376} 165 F.3d at 1180.
\textsuperscript{377} Id. at 1179.
\textsuperscript{378} Id.
applies most forcefully to the for-profit processor (e.g., RTI) that controls a nonprofit tissue bank (e.g., RTI Donor Services). This section explains how a for-profit parent could exploit a captive tissue bank for private gain, and how charity law can deter such exploitation.\textsuperscript{379} The ban on private benefit draws attention to nonprofit tissue banks that supply raw tissue with its economic value intact. Although these transfers advance a tissue bank’s mission, they arguably confer a non-trivial, secondary benefit on the for-profit transferee—they give a transferee an opportunity to capture the tissue’s value for private gain.\textsuperscript{380} The IRS’s formulation of the ban, which focuses on whether private benefits are unavoidable, might impel tissue banks to take steps to prevent for-profit processors from exploiting the donated tissue.\textsuperscript{381}

1. Charity Law Deters For-Profit Processors From Using Captive Tissue Banks for Private Gain

A for-profit processor can exploit a captive tissue bank to increase its profits and become more competitive. The processor can pay less than FMV (or subnormal profits) for its subsidiary’s services, and thereby appropriate that entity’s foregone profits. Even if the processor pays FMV for these services, there are more subtle ways it can use this arrangement to become more competitive. Several charity law doctrines—the bans on private inurement and private benefit and the duties of loyalty and care—can help deter such behavior.

a. For-Profit Processor Violates Ban on Private Inurement by Appropriating a Captive Tissue Bank’s Foregone Profits

The for-profit RTI controls the nonprofit RTI Donor Services,\textsuperscript{382} which supplies the former with raw tissue in exchange for service fees.\textsuperscript{383} Like all nonprofit organizations, RTI Donor Services is not immune from bankruptcy. To avoid insolvency, it must at least break even in an accounting sense. For this reason, RTI Donor Services’s service fees must enable it to recoup expenses like tissue recovery and donor family aftercare.

If RTI Donor Services was an independent entity, it would presumably set its service fees high enough to recoup its expenses and earn \textit{at least} normal profits. This might entail, say, a six percent margin over

\begin{itemize}
  \item \textsuperscript{379} See infra notes 382–399 and accompanying text.
  \item \textsuperscript{380} See infra notes 421–428 and accompanying text.
  \item \textsuperscript{381} See infra notes 429–432 and accompanying text.
  \item \textsuperscript{382} See supra notes 184–194 and accompanying text.
  \item \textsuperscript{383} See supra notes 124, 175 and accompanying text.
\end{itemize}
actual expenses.\textsuperscript{384} There are many reasons why a nonprofit would want to earn normal profits. (Recall that a nonprofit can earn profits, so long as it applies them towards its mission.)\textsuperscript{385} According to IOPO's Sam Davis, a well-run nonprofit can "invest in technology, infrastructure and people to advance the science and fulfill a mission. . . . Those that do [this] can have a lot of impact on their industry."\textsuperscript{386}

A rational, nonprofit tissue bank might even seek supernormal profits. Some tissue banks are operated by OPOs.\textsuperscript{387} An OPO gets paid for its organ transplant services only when organs are actually transplanted.\textsuperscript{388} As a result, its organ-related revenues shrink when organ donations are low.\textsuperscript{389} Tissue banking, by contrast, provides a more stable revenue stream.\textsuperscript{390} An OPO can use profits from tissue banking to subsidize its organ transplant operations. The IOPO, for example, "use[s] the revenue from tissue banking to help control the medical inflation associated with obtaining solid organs for transplantation."\textsuperscript{391}

Because RTI controls RTI Donor Services, there are no arm's length negotiations between the two entities. RTI presumably dictates its subsidiary's service fees. According to Kevin Cmunt of the nonprofit AlloSource, RTI obtains raw tissue from RTI Donor Services for less than what it pays independent tissue banks.\textsuperscript{392} Why is that? A for-profit processor might set its captive tissue bank's service fees too low for it to earn normal profits (recoup its opportunity costs). In this way, a for-profit parent siphons off a financial resource—the normal profits its subsidiary forgoes by underpricing its services—in order to benefit the for-profit's owners and insiders. The parent captures these foregone profits by charging consumers the market price for allografts it produces from underpriced tissue. This siphoning off violates the nondistribution constraint.

\textsuperscript{384} See supra notes 124–126 and accompanying text.
\textsuperscript{385} See supra note 275 and accompanying text.
\textsuperscript{386} E-mail from Sam Davis, Director of Professional Services & Public Affairs, IOPO, to Robert Katz, Associate Professor of Law and Philanthropic Studies, Indiana University School of Law—Indianapolis (Sept. 9, 2005, 13:53 EST) (on file with author).
\textsuperscript{387} The IOPO recovers both organs and tissues. See supra note 118 and accompanying text.
\textsuperscript{388} E-mail from Sam Davis, Director of Professional Services & Public Affairs, IOPO, to Robert Katz, Associate Professor of Law and Philanthropic Studies, Indiana University School of Law—Indianapolis (Sept. 9, 2005, 21:04 EST) (on file with author).
\textsuperscript{389} Id.
\textsuperscript{390} Id.
\textsuperscript{391} Id.
\textsuperscript{392} Telephone Interview with Kevin Cmunt, supra note 227.
If RTI Donor Services—a taxable nonprofit—violates the nondistribution constraint in this way, we must look to state law for recourse. Upon a motion by the attorney general, a state court could remove any RTI insiders who sit on RTI Donor Services’s board for breaching their duty of loyalty, which demands that they put the nonprofit’s interests ahead of the for-profit’s interests.\textsuperscript{393} If any tissue bank directors are not RTI insiders, they could be removed for breaching the duty of care, which enjoins giving away or wasting corporate assets.\textsuperscript{394} In specifying a nonprofit director’s duty of loyalty, a state court might be influenced by the more rigorous standards for charitable trustees. In that case, a director who is not an RTI insider might also be found to violate the duty of loyalty, which prohibits charitable fiduciaries from subordinating a charity’s interests to those of a noncharitable third party.\textsuperscript{395} A court could also compel RTI Donor Services’s directors who breached their fiduciary duties to reimburse the tissue bank for the profits effectively diverted to RTI.\textsuperscript{396} If a substantial part of RTI Donor Services’s mission is to shift profits to RTI, a court might dissolve the corporation and transfer its resources to a truly charitable tissue bank.\textsuperscript{397}

This analysis points to a prescription: federal law should require nonprofit tissue banks to have tax-exempt status under I.R.C. § 501(c)(3). Because RTI Donor Services is not tax-exempt, the state attorney general is the primary enforcer of the nondistribution constraint. This is troublesome because attorney general supervision of nonprofit organizations is generally spotty.\textsuperscript{398} If a nonprofit organization is also tax-exempt under I.R.C. § 501(c)(3), however, the IRS can supplement state authorities by enforcing the ban on private inurement, federal tax law’s counterpart to the nondistribution constraint.\textsuperscript{399}

b. A For-Profit Processor May Derive More Subtle Private Benefits From a Captive Tissue Bank

This section asks whether RTI Donor Services confers prohibited private benefits on RTI and is thus ineligible for tax-exemption. Although the ban on private benefit is typically applied to an exempt

\begin{enumerate}
\item \textsuperscript{393} See supra notes 298–299 and accompanying text.
\item \textsuperscript{394} See supra notes 302–305 and accompanying text.
\item \textsuperscript{395} See supra note 297 and accompanying text.
\item \textsuperscript{396} See supra notes 298–311 and accompanying text.
\item \textsuperscript{397} See supra note 312 and accompanying text.
\item \textsuperscript{398} Geoffrey A. Manne, Agency Costs and the Oversight of Charitable Organizations, 1999 Wis. L. Rev. 227, 250–51.
\item \textsuperscript{399} See supra note 317 and accompanying text.
\end{enumerate}
organization's dealings with outsiders, it also applies to dealings with insiders.\textsuperscript{400} The ban on private inurement prohibits the most blatant ways that a nonprofit's insiders can exploit the organization.\textsuperscript{401} Tax-exempt law's ban on private benefit, by contrast, targets the more subtle ways that nonprofits can further private interests.

The above question is hypothetical because as a taxable, charitable entity, RTI Donor Services is not bound by the ban on private benefit. The question is worth asking, however, because the ban on private benefit posits a norm for how charities ought to behave. If RTI Donor Services violates that norm, this raises questions as to its charitable bona fides.\textsuperscript{402} Indeed, RTI Donor Services may have intentionally declined tax-exemption in order to benefit RTI without risking censure from the IRS.\textsuperscript{403}

RTI clearly finds it more advantageous to obtain tissue from a captive tissue bank rather than from tissue banks it does not control. If this were not so, RTI would simply obtain tissue from autonomous tissue banks, as other for-profit processors do. Critically, RTI can benefit from its influence over its subsidiary even if it pays FMV for its tissue banking services. RTI Donor Services provides its for-profit parent with a robust and stable supply of raw tissue, and this gives RTI a competitive edge over other processors.\textsuperscript{404} By operating an in-house tissue bank, RTI can reduce some of the transaction costs it would incur obtaining tissue from separate entities it does not control.\textsuperscript{405} With more tissue to process, RTI can achieve economies of scale.\textsuperscript{406} By obtaining and processing a whole gamut of tissues, it can

\textsuperscript{400} See supra note 329 and accompanying text.

\textsuperscript{401} See Colombo, supra note 321, at 850 (most instances of private inurement "are not subtle and involve a clear abuse of the economic benefits of exemption").

\textsuperscript{402} See supra notes 186-189 and accompanying text.

\textsuperscript{403} According to RTI spokesperson Wendy Crites Wacker, RTI Donor Services did not pursue tax-exemption under I.R.C. § 501(c)(3) "because of its affiliation with Regeneration Technologies Inc. (RTI), a for-profit public company." See supra text accompanying note 193.

\textsuperscript{404} See supra note 183 and accompanying text.

\textsuperscript{405} See \textit{Oxford Reference Online, A Dictionary of Economics}, http://www.oxfordreference.com/views/ENTRY.html?subview=main&entry=T19.e3177 (last visited Jan. 8, 2006) (defining "transaction cost economics" as "an approach to the economic explanation of institutions. This considers the relative merits of conducting transactions within firms and between different firms using markets. It takes account of bounded rationality, information problems, the costs of negotiating contracts, and opportunism.").

\textsuperscript{406} \textit{Oxford Reference Online, A Dictionary of Economics}, http://www.oxfordreference.com/views/ENTRY.html?subview=main&entry=T19.e942 (last visited Mar. 2, 2006) (defining "economies of scale" as "[t]he factors which make it possible for larger organizations or countries to produce goods or services more cheaply than smaller ones. . . . Specialized equipment usually comes in units of some minimum size, so that a larger total output makes it economic to use more specialized equipment.").
achieve economies of scope.\textsuperscript{407} If it can cut its costs without cutting its prices, RTI can increase its net earnings on each unit of processed tissue it distributes.\textsuperscript{408} Some consumers (e.g., hospitals and doctors) might prefer to deal with a processor with a solid supply of tissue, as it is less likely to run out of particular products. These consumers may be willing to pay a premium for this "in-stock" guarantee as insurance against the risk of inadequate supply.\textsuperscript{409} Lastly, some consumers may prefer to deal with a processor that offers a wide range of products. These consumers may be willing to pay a premium for the convenience and cost savings of "one-stop shopping"—obtaining all their processed tissues from a single source.

RTI Donor Services's activities benefit both the public and RTI's owners and investors. There is nothing inherently objectionable about this. To the contrary, a nonprofit tissue bank may be able to advance its charitable goals more effectively by partnering with a for-profit processor. According to Martha Anderson, an officer of the nonprofit MTF, "[a] tissue bank's goal of maximizing the use of donated tissues can be better realized through these relationships" with for-profit businesses for processing, marketing, distribution, and R&D.\textsuperscript{410} Without such partnerships, wrote Anderson and a colleague, "many nonprofit tissue banks would have found the high costs associated with [these activities] to be prohibitive."\textsuperscript{411} RTI echoes Anderson to justify its arrangement with RTI Donor Services. According to RTI's Wacker: "RTI Donor Services benefits from its affiliation with a for-profit company. The science and innovation provided by companies such as RTI benefit donor families and recipients alike, and serve to maximize the gift to help as many people as possible."\textsuperscript{412}

This statement is true, but it does not resolve the private benefit concerns. Why is RTI Donor Services affiliated with this particular processor rather than with another, or with multiple processors, be they for-profit or nonprofit? The answer is not difficult to fathom: RTI created and controls RTI Donor Services in order to capture the private benefits generated by the tissue bank's activities. For this rea-

\textsuperscript{407} OXFORD REFERENCE ONLINE, A DICTIONARY OF ECONOMICS, http://www.oxfordreference.com/views/ENTRY.html?subview=main&entry=T19.e943 (last visited Mar. 2, 2006) (defining "economies of scope" as "[t]he benefits arising from carrying on related activities. . . . Specialized labour, equipment, and ideas used in one activity are often also useful in related activities.").

\textsuperscript{408} This assumes that RTI would not pass on its savings to its consumers.

\textsuperscript{409} I thank Woods Bowman for this observation.

\textsuperscript{410} Anderson & Schapiro, supra note 5, at 11–12.

\textsuperscript{411} Id. at 12.

\textsuperscript{412} E-mail from Wendy Crites Wacker, supra note 180 (emphasis added).
son, this arrangement appears to meet the *American Campaign Academy* criteria for prohibited private benefit, namely that: (a) RTI Donor Services conducts its otherwise charitable activities in a manner calculated to confer nontrivial benefits on RTI; and (b) advancing RTI’s private interests is part of RTI Donor Services’s *raison d’être.*

The arrangement between RTI and its nonprofit subsidiary is not only doctrinally suspect, it is genuinely troubling. RTI Donor Services may indeed best serve its charitable purposes by supplying its tissue to RTI. The problem is that RTI Donor Services’s board of directors probably did not decide—indeed, independently, on the merits, with full information, after considering the alternatives—that this was in fact the best way to serve its charitable mission. More likely, RTI’s directors decided that it would be in RTI’s best interests for RTI Donor Services to supply it with tissue. As for RTI Donor Services’s board, it may be, as Gertrude Stein said of Oakland: “There is no there there.”

This analysis also supports requiring nonprofit tissue banks to be tax-exempt under I.R.C. § 501(c)(3). If nonprofit tissue banks must comply with the ban on private benefit, they are more likely to decide on the merits how best to advance their organization’s mission, and are less likely to be manipulated by noncharitable insiders.

2. Tissue Banks May Confer Undue Private Benefit on Unrelated Processors

RTI Donor Services is an outlier; most tissue banks are not controlled by for-profit businesses. The ban on private inurement is thus a limited tool for regulating the tissue industry, as it applies only to relationships between nonprofits organizations and their controllers. This section explores two charity law doctrines that govern arm’s length relationships between nonprofit tissue banks and unrelated for-profit processors—the duty of care and the ban on private benefit. Of these, only the duty of care can be used to advance NOTA’s philanthropic goals and effect compliance with its commands.

413. See *supra* notes 366–367 and accompanying text.

a. A Tissue Bank's Directors May Violate Duty of Care by Selling Their Organization's Services to Unrelated Processors for Less Than FMV

A tissue bank's directors are obliged to manage its assets in an informed and responsible manner.\[^415\] This duty of care deters a tissue bank's directors from carelessly dissipating these assets—which include the value of its tissue banking services—by selling them for less than their FMV.\[^416\] (Judge Posner's approach to the ban on private benefit performs the same function by incorporating the duty of care into tax-exempt law.\[^417\])

In practice, the duty of care simply reminds directors to do what they already do—try to serve their organization's best interests. To better serve its charitable mission, a rational tissue bank will seek normal and even supernormal profits.\[^418\] In Professor Colombo's view, patently non-FMV transactions between nonprofit organizations and unrelated outsiders are rare. He believes that when a nonprofit grossly overpays or undercharges a seemingly unrelated outsider, "there has got to be a 'connection' somewhere"—some insiders must be manipulating the charity to serve their private interests.\[^419\] Otherwise, he said, "it's just stupidity," for why else "would someone give away assets to an unrelated party?"\[^420\]

b. What Steps Must Tissue Banks Take to Prevent Processors From Selling Tissue?

Tax-exempt law restricts the private benefits that an EO's charitable activity may confer. This section asks what steps, if any, a tissue bank must take to prevent for-profit transferees from capturing the economic value of transferred tissues.\[^421\]

i. The opportunity to capture the economic value of donated tissue is valuable

The private benefit doctrine restricts EOs from engaging in charitable activity that excessively benefits noncharitable parties. This doc-
trine may seem irrelevant to the nonprofit tissue bank that transfers tissue to for-profit processors in exchange for the FMV of its services. On paper, this is an even trade. In practice, however, the for-profit processor gets the better end of the bargain: it gains an opportunity to sell the transferred tissue (capture its economic value). This opportunity is valuable—even though the processor must violate NOTA to seize it.422

For-profit processors may value the opportunity to sell donated tissue more highly than nonprofit tissue banks. As compared to tissue banks, processors (both for-profit and nonprofit) can more easily exploit imperfectly competitive markets to earn supernormal profits. For example, many processors promote their products by using distinctive trademarks such as Grafton and Osteofil.423 Such branding enables these processors to charge loyal customers a premium.424 Tissue banks, by contrast, generally do not affix brand names to the raw tissues.

Additionally, for-profit processors may have greater incentives and fewer inhibitions about extracting wealth from donated tissue, as compared to nonprofit processors and tissue banks. For-profit businesses generally seek to maximize their profits.425 Nonprofit entities, by contrast, tend to be driven by nonpecuniary missions, which may temper the imperative to maximize profits.426 A nonprofit’s controllers may also have less incentive to maximize profits because of the nondistribution constraint, which bars them from appropriating the entity’s

422. An economic analysis of criminal behavior predicts that a rational utility maximizer will prefer to engage in a criminal act if the expected payoff from committing the offense exceeds the expected punishment. See, e.g., Erling Eide, *Economics of Criminal Behavior*, in *ENCYCLOPEDIA OF LAW & ECONOMICS* 345, 345–46 (1999), http://encyclo.findlaw.com/8100book.pdf. The low probability of incurring sanctions for violating NOTA increases the rational actor’s expected value of violating the Act, as does the relatively mild penalties for violating the Act—$50,000 fine and five years’ imprisonment. 42 U.S.C. § 274e(b) (2000).

423. *See supra* notes 150–154 and accompanying text.

424. *See supra* notes 261–268 and accompanying text.

425. *See, e.g.*, *OXFORD REFERENCE ONLINE, DICTIONARY OF THE SOCIAL SCIENCES*, http://www.oxfordreference.com/views/ENTRY.html?subview=main&entry=T104.e1351 (last visited Jan. 12, 2006) (“As long as the revenue gained from an additional unit of output exceeds its cost, the firm has an interest in continuing production.”); *see also* OXFORD REFERENCE ONLINE, A *DICTIONARY OF ECONOMICS*, http://www.oxfordreference.com/views/ENTRY.html?subview=main&entry=T19.e2471 (last visited Jan. 10, 2006) (defining “profit maximization” and asserting that “[o]ther things being equal . . . businesses prefer higher profits to lower”). *But see id.* (defining “profit maximization” and asserting that “the directors or owners [of a business] may have their own objectives: these range from desire for an easy life, a large empire, or jobs for their relatives, to a reputation as patrons of the arts, sport, or the environment. All these have to be traded off against profits.”).

profits (except as reasonable compensation). There is some evidence to support this prediction: Kevin Cmunt, an AlloSource official, stated that nonprofit processors such as AlloSource are less likely than for-profit processors to raise prices in response to tissue shortages.

ii. NOTA-compliant tissue banks transfer this opportunity to for-profit processors

When for-profit processors obtain donated tissue from NOTA-compliant tissue banks, they thereby acquire an opportunity to capture the tissue's value—albeit by violating the Act. This result implicates the private benefit doctrine. Although the illicit opportunity to earn profits is valuable, do tissue banks violate the doctrine by conveying this opportunity to for-profit processors? Each formulation of the private benefit doctrine would analyze the question differently.

In United Cancer Council, Judge Posner associated private benefit with careless directors who enrich third parties by wasting corporate assets. But that is not what happens here. In our scenario, dutiful directors pass up and pass along an opportunity to capture charitable resources, as NOTA demands they do. The tax court in American Campaign Academy associated private benefit with directors that target the secondary benefits of their organization's charitable activity towards a particular private party. That is not what happens here either. An independent tissue bank does not target an economic benefit—the opportunity to earn profits by selling donated tissue—to anyone in particular. Rather, the tissue bank transfers this benefit indiscriminately to whoever obtains its tissues.

On its face, the IRS's approach might permit a finding of prohibited private benefit in such transactions. In its strictest formulation, this approach prohibits charitable activity that generates secondary private interests if these private benefits are avoidable (qualitatively nonincidental). In one sense, a NOTA-compliant tissue bank cannot avoid giving transferees the opportunity to sell the transferred tissues. At the same time, a tissue bank can arrange for processing without conferring this benefit on for-profit processors. There are at

427. See supra notes 272-275 and accompanying text.
428. See supra notes 244-248 and accompanying text.
429. I will assume that an EO, by transferring this opportunity to a for-profit firm, thereby advances private interests within the meaning of tax-exempt law's private benefit doctrine.
430. See supra notes 368-378 and accompanying text.
431. See supra notes 360-367 and accompanying text.
432. See supra notes 342-349 and accompanying text.
least two ways to do this. A tissue bank can deal exclusively with nonprofit processors such as MTF and AlloSource. Alternatively, a tissue bank can contract with for-profit processors instead of transferring the tissue outright and with no strings attached. This enables the tissue bank to rein in the processor’s profit margin.433

The surest way to avoid private benefit is to stop supplying for-profit processors with raw tissue. This is precisely what the State of California invites individual tissue donors to do— withhold consent for for-profit processors to touch the tissue they donate.434 Yet if nonprofit tissue banks did this en masse, they would harm would-be allograft recipients by creating “a vacuum in the market for the kinds of products for-profit companies make using donated tissue.”435 It would make the tissue industry less efficient and innovative by driving away for-profit capital and entrepreneurialism. It would also prevent some tissue banks from furthering their charitable goals by partnering with for-profit firms.436

A nonprofit tissue bank exists, inter alia, to promote health through allograft implantations. In pursuing that goal, a tissue bank may enable an unrelated for-profit processor to gain an edge over its competitors—for example, by entering a long-term contract to supply that processor with tissue. Yet conferring these secondary benefits is not part of the tissue bank’s raison d’être unless it is controlled by the for-profit beneficiary. This fact rules out private benefit under the tax court’s approach in American Campaign Academy.437 This result is eminently sensible. Although the IRS’s approach technically might permit a private benefit argument, that argument is refuted by the substantial public benefits that flow from for-profit involvement in the tissue industry.438

433. See supra notes 127–128 and accompanying text.
434. See supra notes 89–92 and accompanying text.
435. See Boden Comments, supra note 14, at 27. Boden further explained:
   Each year, donated tissue is utilized in thousands of musculoskeletal surgeries to alleviate pain and restore a patient’s range of motion. This would not be possible without the generous gift of tissue donation, and the enhancement of that gift through the complex technologies developed by for-profit entities in the tissue banking community.
   Id. (emphasis added).
436. See, e.g., supra notes 410–412 and accompanying text.
437. See supra notes 360–367, 431 and accompanying text.
438. I thank John Colombo for his assistance in articulating this point.
V. Conclusion

Many processors are for-profit businesses, and they obtain their basic inputs through altruistic donations to nonprofit tissue banks. Some people are troubled by the fact that for-profit firms earn profits by processing donated tissue (or would be troubled if they knew), and some industry actors prefer not to publicize this fact. If NOTA’s scheme were followed, however, the apparent tension between selflessness and self-interest in the tissue industry would disappear. Allograft recipients would capture the economic value of donated tissue, thereby realizing the donors’ philanthropic goals. At the same time, intermediaries would be fairly compensated for adding value to donated tissue, and thus adequately incentivized to produce allografts for implantation. In such circumstances, it is perfectly appropriate for for-profit actors in the tissue industry to earn (normal) profits.

In reality, NOTA is flawed in both design and execution. Its scheme for redistributing value from donors to recipients is unwieldy if not implausible. Many intermediaries stand between donors and recipients—tissue banks, processors, health care providers, and firms that distribute allografts to these providers. For the Act to succeed, each intermediary must transfer or re-gift the tissue’s economic value intact to the next intermediary until it is distributed to the recipients. That is unlikely to happen.

Public authorities do not enforce the Act, and the markets for donated tissue and allografts are imperfectly competitive. These conditions thwart the donors’ altruistic aims by permitting intermediaries, not allograft recipients, to capture the tissue’s value. Moreover, NOTA’s economic premises are undercut insofar as intellectual property law lets processors earn monopolistic rents from patented technology.

Karl Llewellyn, the great University of Chicago law professor, “is said to have said, ‘Technique without morals is a menace; but morals

439. See supra notes 133–135 and accompanying text.
440. See supra notes 3–4, 102–110, 117 and accompanying text.
441. See supra notes 11–18 and accompanying text.
442. See supra note 14 and accompanying text.
443. See supra notes 24, 64–66, 203–207 and accompanying text.
444. See supra notes 24, 64–66, 203–207 and accompanying text.
446. See supra notes 249–260 and accompanying text.
without technique is a mess.'”447  Although NOTA and charity law share certain moral goals, charity law pursues these in a more methodical way. NOTA looks rather messy by comparison and yields results that some find alarming. The remainder of this Article identifies lessons to be learned from using charity law to advance NOTA’s goals. It then considers our moral goals for tissue transplantation and techniques for achieving them.

A. Charity Law’s Lessons for NOTA and Vice Versa

Charity law can be used to advance NOTA’s and tissue donors’ philanthropic goals. At least one nonprofit tissue bank, RTI Donor Services, is controlled by a for-profit processor, RTI. By enforcing the nondistribution constraint, state authorities can deter a for-profit parent from siphoning off a nonprofit subsidiary’s profits for private gain. If RTI Donor Services, a taxable entity, were also required to be tax-exempt under I.R.C. § 501(c)(3), the IRS could supplement state supervision by enforcing the ban on private inurement. The IRS could also enforce the ban on private benefit, and thereby deter more subtle means of exploiting captive tissue banks.

A charity law analysis of the tissue industry illustrates the limits of charity law’s ability to safeguard charitable resources. Charity law can do relatively little to prevent for-profit processors from capturing the economic value of tissue they obtain through arm’s length transactions with unrelated tissue banks.448 Once a noncharitable party acquires raw tissue with no strings attached, charity law loses jurisdiction over the tissue and the noncharitable parties that handle it. At that point, only NOTA and self-control prevent the transferees from exploiting tissue for private gain. This is troubling because for-profit processors are (all things being equal) more likely than nonprofit entities to act in this manner.449

Applying charity law to the tissue industry also identifies potential problems within charity law. The private benefit doctrine restricts the ability of tax-exempt organizations to benefit private interests.450 This restriction draws attention to how NOTA-compliant tissue banks confer a benefit on for-profit transferees—the opportunity to capture the

448. See supra notes 421–428 and accompanying text.
450. See supra notes 328–378 and accompanying text.
tissue's economic value.\textsuperscript{451} The surest way for tissue banks to prevent this is to deal exclusively with nonprofit processors, but this approach would harm the health of potential allograft recipients.\textsuperscript{452}

A charity law analysis of NOTA draws attention to the Act's distinct moral concerns. It prohibits tissue sales by any party, be it nonprofit or for-profit. The Act's indifference to legal form reflects its peculiar understanding of exploitation. For NOTA, the relevant resource—cadaveric tissue—is exploited by commodifying it. On this view, any intermediary that sells tissue is an enemy: its status as a nonprofit or for-profit entity is irrelevant. For charity law, by contrast, the relevant resources—charitable assets—are exploited when they are siphoned off or excessively applied for private gain. The nonprofit form is designed to reduce the risk of such exploitation. Lastly, this analysis underscores weaknesses in NOTA's scheme for realizing its philanthropic goals. The Act prohibits everybody—and nobody in particular—from selling tissue. It imposes no duty on tissue transferors to block transferees from violating its restrictions.\textsuperscript{453} Charity law, by contrast, imposes special duties on a distinct class of entities—nonprofit organizations—to advance charitable ends and steward charitable resources.

B. What Is to Be Done?

The most pressing normative question for the tissue industry is not whether cadaveric tissue should be sold, but who should capture its value. Under the current regime, intermediaries—especially for-profit processors—are likely to capture the value of donated tissue, not allograft recipients. If this result is morally objectionable, a better alternative must be identified. If not processors, who then should capture the tissue's value, and how can redistribution be achieved? In evaluating the alternatives, the full range of NOTA's goals and concerns must be considered, and any prescription must be partial and qualified. By furthering one of these goals more fully, others might be hindered or foiled. Here are four possible ways to proceed.

1. Enforce NOTA

If NOTA were enforced effectively, recipients would pay less for allografts made from donated tissue and thereby capture the tissue's value. To this end, regulators could be appointed to set reasonable

\textsuperscript{451} See supra note 429 and accompanying text.
\textsuperscript{452} See supra notes 429–436 and accompanying text.
\textsuperscript{453} See supra notes 56–57 and accompanying text.
rates of return for for-profit processors, and to cap allograft prices to keep firms from exceeding these rates.

2. Revoke NOTA

Instead of attempting to enforce NOTA, we might consider revoking it—at least as it applies to cadaveric tissue used in transplantation. Under the current regime, a decedent’s next of kin have two choices: to agree or refuse to donate the decedent’s tissue. Under a free market approach, the next of kin would have another choice: they could sell the tissue and capture its economic value for themselves. This approach commodifies tissue, which NOTA opposes. That said, a free market in cadaveric tissue could promote health by increasing the supply of such tissue, and thus the number of people who can benefit from allografts.454 Because this market would be limited to cadaveric tissue, living persons in desperate straits would still be barred from selling their bones, skin, heart valves, and other tissues.

A market approach to procuring raw tissue would dilute the altruistic sensibility that currently infuses much of the tissue industry. Even so, this approach need not purge altruism from the industry. Individuals could still choose to donate tissue. Moreover, revoking NOTA would help some donors advance their altruistic goals more effectively. When someone donates tissue, he or she runs the risk that a for-profit processor will capture its economic value. A shrewd altruist could reduce this risk by selling cadaveric tissue and donating the proceeds to a nonprofit tissue bank. In this way, an altruist could be more certain that the proceeds will be used to benefit allograft recipients.

3. Permit Nonprofit Tissue Banks to Sell Donated Tissue to For-Profit Processors455

Enforcing or revoking NOTA are not the only choices. There is another option: modify the Act to permit nonprofit tissue banks to sell

454. See supra notes 232–238 and accompanying text.
455. Agnos suggested that

[a]s an extension of charitable trust doctrine and in recognition of the altruistic nature of gifts of human tissue, require payments by for-profit tissue companies for tissue received from nonprofit tissue banks to be based on the fair market value of the tissue. Require proceeds from the sale of tissue by nonprofit tissue banks to private tissue companies that are beyond the bank’s costs of acquiring, storing, processing and transferring the tissue to be placed in a charitable trust, and used for charitable purposes. These could include education on the tissue donation process and / or making tissue products and procedures available for uninsured and underinsured populations.

AGNOS, supra note 89, at 24.
donated tissue to for-profit processors. In other words, nonprofit tissue banks could be exempted from the Act's "reasonable payments" cap on compensation for intermediaries. This would authorize tissue banks to earn supernormal profits when transacting with for-profit processors. This measure could redistribute the economic value of donated tissue from for-profit processors to nonprofit tissue banks.

This option builds upon the observation that a shrewd altruist might prefer to sell tissue and donate the proceeds. Granted, cadaveric tissue would be commodified if nonprofit tissue banks were to sell it to for-profit processors. Yet commodification in this context need not dishonor or exploit donor altruism. To the contrary, it may advance a donor's altruistic aims more effectively than the status quo. Under current conditions, the tissue industry is not a secure vehicle for delivering the economic value of donated tissue to allograft recipients. Instead, it facilitates—if not invites—for-profit businesses to appropriate this value for private gain. As between nonprofit tissue banks and for-profit businesses, altruistic donors would likely want the former to capture the tissue's value.

This change could have significant and beneficial consequences. As nonprofit organizations, tissue banks must use any new income to advance their charitable missions and finance their services. They could use the additional resources to exhort the public to make anatomical gifts, educate them about transplantation, provide aftercare for donor families, and improve the quality of their facilities. If the tissue bank is also an OPO, it could use tissue banking revenues to cross-subsidize its organ procurement activities.

Exempting nonprofits from NOTA's prohibition need not hamper the goal of promoting health. Nonprofit tissue banks could also use additional resources to develop and distribute allografts that serve medical rather than cosmetic needs. Granted, for-profit business will find processing to be less lucrative, as they could earn only normal profits instead of supernormal profits. Even so, this reduction need not drive for-profit processors out of the tissue industry. By definition, supernormal profits are profits that exceed what is necessary to induce a business to remain within an industry, whereas normal

456. More generally, NOTA could be revised to permit nonprofit intermediaries in the tissue industry (e.g., nonprofit tissue banks and processors) to sell tissue to for-profit intermediaries (e.g., for-profit processors and distributors).
457. See supra note 386 and accompanying text.
458. See supra notes 387-391 and accompanying text.
459. See, e.g., supra notes 159-161 and accompanying text.
460. See supra note 207 and accompanying text.
profits are profits that suffice to induce businesses to continue their current activities. 461

Exempting nonprofits from NOTA could also advance the Act’s goal of promoting fairer access to body parts for transplantation. Tissue banks could use additional resources to subsidize allografts for people who need but cannot afford them. This change need not increase the prices for allografts. Because processors do not require supernormal profits to stay in the tissue industry, they might settle for smaller profits (but not less than normal profits), rather than pass on their increased costs to recipients. The Act would still bar individuals from selling tissue. It would thus continue to protect poor people from endangering themselves by selling body parts.

4. Preserve the Status Quo

Before making any changes, we should consider the advantages of the status quo. By letting for-profit processors earn supernormal profits, the status quo gives businesses more incentive and resources to develop more innovative and safer allografts. Although commodification occurs under the current regime, it is partly concealed from public view. This is achieved by interposing nonprofit tissue banks between altruistic donors and profit-maximizing processors. This added degree of separation puts a better face on the transaction, and explains why for-profit RTI went through the trouble to create nonprofit RTI Donor Services—“because it is appropriate for a nonprofit entity to approach families about donation [of a loved one’s tissues], especially since families are being asked to donate for humanitarian reasons.” 462 If NOTA authorized tissue banks to sell tissue to for-profit processors, the commodification inherent in today’s tissue industry would be harder to conceal. This might deter people from becoming donors. Even so, a conscious policy of concealing from donors tissue sales by for-profit firms may itself raise ethical problems.

C. Is the Status Quo Tenable?

The tissue industry relies on altruistic individuals to donate material whose subjective value is intensely personal and even sacral. The fact that for-profit businesses use this material for private gain raises special concerns, and these may become more urgent in the future. As scientists develop new ways to use cadaveric tissue to enhance and save lives, the demand for tissue will inevitably rise. At present, the

461. See supra note 206 and accompanying text.
462. Flatten, supra note 185 (quoting RTI’s Wendy Crites Wacker).
industry thrives because of public ignorance and indifference regarding for-profit involvement: most donors are either unaware of such involvement or it does not trouble them enough to stop donating. If potential donors become more informed and indignant, however, they could stifle the industry’s growth by refusing to supply enough tissue to meet its expanding needs. If that occurs, the government or industry actors will be pressed to address donor concerns in order to ensure the health of both the industry and potential allograft recipients. It is ironic that by its very success, the tissue industry has exacerbated the tension between the selflessness that motivates its donors and the self-interest that drives its for-profit actors.