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Skin and Bones: Post-Mortem Markets in Human Tissue

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R. Alta Charo*

TABLE OF CONTENTS

I. INTRODUCTION	422
II. PROPERTY AND PERSONAL AUTONOMY	424
III. THE LAW OF THE CORPSE.....	425
IV. THE LAW OF CADAVERIC TISSUE DONATION.....	429
V. PRESUMED CONSENT STATUTES AND CORNEAL TRANSPLANTATION	430
VI. THE LAW OF GAMETE SALES.....	432
VII. THE LAW OF TISSUES AND CELL LINES FOR RESEARCH	436
VIII. THE REGULATION OF TISSUE TRANSPLANTATION	442
IX. SUMMARY.....	449

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Immediately the human corpse rises to a dignity and importance in the commercial world which it may not have possessed in its lifetime. It is a commercium, a thing of value, a subject of political economies, perhaps to be bought, sold, and exchanged, and subject to the rules of supply and demand . . . The whole foundation of law and custom is shaken. It becomes a serious question how it shall be rebuilt. A new civilization calls loudly for new definitions of the rights and duties of society to the dead body. Up to the present writing they have not been satisfactorily given.¹

I. INTRODUCTION

This rather modern sounding cry for examination of the market for human tissue actually dates to the late nineteenth century, when the supply of cadavers for medical education was dwindling. Whether one dates the transformation to the nineteenth or to the twentieth century, it is certain that “[f]or better or worse, we have irretrievably entered an age that requires examination of our understanding of the legal rights and relationships in the human body and the human cell.”² Where once the value of the human body was seen exclusively in its ability to perform labor or to produce offspring or to bring sensual and other personal satisfaction, the potential of the human body as a source of transferable physical material has led some to see its value in medical³ and, if made available for sale,⁴ economic terms as well.⁵

1. William Boulier, *Sperm, Spleens, and Other Valuables: The Need to Recognize Property Rights in Human Body Parts*, 23 HOFSTRA L. REV. 693 (1995) (citing Francis K. Carey, *The Disposition of the Body After Death*, 19 AM. U. L. REV. 251 (1885)).

2. *Moore v. Regents of the Univ. of Cal.*, 249 Cal. Rptr. 494 (Cal. 2d Dist. Ct. App. 1988).

3. See generally, Boulier, *supra* note 1.

4. For the past few decades advertisements and schemes have appeared offering the sale of various parts. See, e.g., Michael Finkel, *This Little Kidney Went to Market*, N.Y. TIMES MAG., May 27, 2001, at 26; RUSSELL SCOTT, *THE BODY AS PROPERTY* (Viking Press 1981); Jesse Dukeminier, Jr., *Supplying Organs for Transplantation*, 68 MICH. U. L. REV. 811, 811 n.1 (1970); Will Bennett, *Advert Offered 10,000 Pounds for a Kidney*, INDEP. LONDON, Jan. 10, 1990, at 2; Andy Riga, *Man on Dole Offers Kidney for a Job*, GAZETTE (Montreal), Mar. 12, 1994, at A3; David Adams, *The Organ Theft Scandal*, TIMES OF LONDON, Nov. 18, 1993, at 18; Tim McGirk, *India's Poor Sell "Bits of Their Bodies" to the World's Rich*, INDEP. LONDON, Aug. 13, 1994, at 8; Charles P. Wallace, *For Sale: The Poor's Body Parts*, L.A. TIMES, Aug. 27, 1992, at A1.

5. See Scott, *supra* note 4, at 179–97. Identifying a market value for the sum total of all human tissue is a popular intellectual exercise. In the early 1970s, for example, one student wrote on the possible tax consequences of organ sales, and relied on the figure of \$653.50 as the market value of the constituent minerals in the body including blood serum.

This essay briefly describes the history of using various human non-organ tissues, whether obtained from living or deceased donors, so that the issues surrounding postmortem markets in bone, skin, and other tissues can be better situated within the context of the American market and regulation for tissue generally.

Human tissue is obtained in a variety of ways. Blood may be donated or sold by living persons for use in transfusion or basic research. Hair may be sold by living persons for wig makers, or placental tissue collected after childbirth for cosmetics manufacturers. Surgical procedures may result in pathological samples taken both for diagnostic purposes and for long storage for both clinical uses related to the patient and research uses going far beyond the patient's lifetime.⁶ These tissues may also be manipulated to create replicating cell lines that have characteristics resulting both from the underlying tissue and from the laboratory manipulation. Gametes (sperm and eggs) and fetal tissue from abortions and miscarriages can be collected from donors and transferred to others, usually with reimbursement although technically not with payment that would transform the transaction into a formal sale.⁷ While each of these forms of tissue transfer are interesting, this chapter will focus on a selection of human tissues—specifically, corneas, gametes, and cell lines—in order to illustrate some of the legal and market phenomena typically associated with tissue transfers.

Interestingly, there is relatively little law at either the state or federal level governing tissue transfers, whether with regard to how tissue is obtained, how it is transferred, or how it is manipulated and transplanted. In part, this may be due to the low economic value of most human tissue. In the absence of financially significant disputes, fewer cases come to courts for resolution and there is less pressure for legislative bodies to anticipate and regulate future disputes. In part, it is also due, to the complexities of property law, the primary area of law applicable to the recovery and transfer of human tissue, and its historical inability to reconcile the concerns of the market with the more emotional and spiritual concerns associated with the

See Paul McCarthy, Note, *Tax Consequences of Transfers of Bodily Parts*, 73 COLUM. L. REV. 842, 860 (1973) (citing CHEMICAL AND ENGINEERING NEWS, Nov. 13, 1972, at 60, col. 2). Today that figure would need radical adjustment to account for the potential economic value of gene sequences, rare tissue types, and reproductive material. See LORI ANDREWS & DOROTHY NELKIN, *BODY BAZAAR* (2001).

6. National Bioethics Advisory Comm'n, *Research Involving Human Biological Materials: Ethical and Policy Guidance*, at 1 (U.S. GPO, Washington, D. C. 1999) [hereinafter *Research Involving Human Biological Materials: Ethical and Policy Guidance*].

7. *Id.*

legal characterization of personal control over one's body, both before and after death.⁸ Thus, while there is a growing interest in health and safety based regulation of tissue manipulation and transplantation, and a body of rules governing the distribution of whole organs from cadavers, there is only spotty legal coverage of other areas of what might be termed "tissue law."

The essay begins with a look at the interplay of property law and personal autonomy, and at the origins of the law's treatment of the corpse. It is here that one finds the beginnings of still lively discussions about the relationship between ourselves and our bodies that, in turn, informs discussions about the law and regulation governing markets in human tissue. It turns next to some specific examples of markets in tissue, some in which people know they are releasing tissue for the use of others and some in which that knowledge may be absent. Finally, it summarizes the growing body of regulatory law that governs tissue manipulation and transplantation, an area of general application to many different kinds of tissue from many different sources.

II. PROPERTY AND PERSONAL AUTONOMY

The value of the body is intimately linked to the question of personal autonomy. Depending on which basis is chosen to explain notions of personal autonomy, the removal of cadaver tissue without consent, a frequent proposal in the area of "presumed consent" laws to foster greater availability of transplantable organs and tissue, will or will not violate notions of personal autonomy that run deep in the American legal system.

Autonomy can be promoted through many legal regimes. The value of the body is intimately linked to the question of personal autonomy. Such autonomy can be achieved through many legal regimes. In one, autonomy is premised on the notion that one's body is one's personal property, and that uninvited removal of tissue is a form of theft or trespass. In another, the body is not property, but personal autonomy is premised on liberty interests of the person within, and uninvited removal of tissue is a form of injury and a deprivation of liberty. The question of personal control over one's body is highlighted throughout civil and criminal law. An unwanted touching—whether by a criminal attacker or by a doctor who exceeds the scope of consent to surgery—is a battery. Bodily integrity is a highly protected legal and cultural value in the United States, and informed, uncoerced consent is

8. Bonnie Steinbock, *Sperm as Property: In the Absence of a Compelling Argument Against Posthumous Reproduction, Individual Autonomy Should Prevail*, 6 STAN. L. & POL'Y REV. 57 (1995).

necessary before any bodily invasion. This conclusion can be reached whether or not one views the body as a form of personal property.

But while it is clear that a living, competent person's body parts cannot be removed without his or her consent, the law of bodily integrity is less clear after someone has died. Here, the question of whether the body is property becomes pertinent, as the liberty interests that support an alternative theory of personal autonomy are usually considered to have died with the person. Thus, by characterizing the body as property, personal control over the removal of tissues can continue even after death, by virtue of testamentary wishes in a will or ownership interests in heirs and next of kin. In the context of determining decision-making authority for research and clinical uses of organs and tissue, courts have tended to recognize that the source of the tissue has decision-making authority—even over interventions that will occur after death, or after the tissue has been removed—but at the same time to eschew a clear jurisprudence of the body as a form of property. The result is legal confusion in the market and quasi-market for human tissue. Adding to the confusion is the fact that questions of control are distinct from the issue of commercialization. Thus, in most cases, the donor of a cadaver organ for transplantation cannot be paid for the organ,⁹ but the living donor of certain types of tissue (blood, sperm, eggs, genes) may be compensated. And doctors or researchers who claim intellectual property rights in altered versions of other people's cell lines or genes can earn millions.¹⁰

III. THE LAW OF THE CORPSE

The earliest Anglo-Saxon cases to consider ownership of human tissue, specifically corpses, were decided almost 1000 years ago by special ecclesiastical courts in England who were given complete jurisdiction over all matters concerning burials and disposition of corpses.¹¹ With few

9. The federal National Organ Transplant Act prohibits payment for organs in interstate commerce when those organs are being used for transplantation. 42 U.S.C. § 274e (2000). However, under the California Anatomical Gift Act, the donor can be paid, but a middleman cannot. CAL. HEALTH & SAFETY CODE ANN. § 7155 (2000). Pennsylvania passed a law allowing a modest compensation—up to \$3000 to pay for funeral expenses of organ donors. 20 PA. CONS. STAT. ANN. § 8622(b)(1).

10. *Genetic Engineering News* publishes an annual list of “molecular millionaires.” Prominent among them are researchers who have patented patients' genes. Brian O'Neill, *Biotechnology Bay State has share of “Molecular Millionaires,”* BOSTON GLOBE, Apr. 21, 1999, at D4.

11. PERCIVAL JACKSON, *THE LAW OF CADAVERS AND OF BURIAL PLACES* (Prentice-Hall, N.Y., 1936).

exceptions, control of dead bodies remained within the exclusive jurisdiction of the church courts until the nineteenth century, when the growth of medical schools and their need for cadavers for dissection created a challenge to ecclesiastical dominion over bodies.¹²

In the earliest recorded treatise of the subject of property rights in the human body, Lord Edward Coke wrote: “[t]he buriall [sic] of the *cadaver* (that is *caro data vermibus*) is *nullius in bonis*, [the goods of no one] and belongs to *ecclefiastical cognifance*, [sic]”¹³ a statement that became the foundation for the Anglo-American law that human body parts cannot be property.¹⁴

In colonial America, the absence of ecclesiastical courts resulted in civil jurisdiction over bodies and the application of common law principles. There were no commercial rights in cadavers, no right for a decedent to direct the manner of burial, and no burial rights enforceable by the next of kin; common law courts were more focused on commercial disputes than sentimental concerns.

During the 1800s, however, common law doctrine was increasingly viewed as incapable of managing the real emotional distress associated with mismanagement of bodies, and courts began assigning to the next of kin an enforceable right to possession of a body for burial. To preserve the continuity of common law principles, the right was sometimes characterized as a “property right.”¹⁵ This right became so well established that in 1891, a court suggested that the “fact that a person has exclusive rights over a body for the purposes of burial leads necessarily to the conclusion that it is his property in the broadest and most general sense of that term.”¹⁶

Judicial references to property rights in corpses were misleading, however.¹⁷ While common law property rights generally include the right to

12. Richard J. Sideman & Eric D. Rosenfeld, *Legal Aspects of Tissue Donations from Cadavers*, 21 SYRACUSE L. REV. 825 (1970).

13. 3 EDWARD COKE, *INSTITUTES OF THE LAWS OF ENGLAND* 203 (1644).

14. See *Griffith v. Charlotte, Columbia & Augusta R.R. Co.*, 23 S.C. 25, 32 (1884). The Court noted that “Coke was understood to say that ‘a dead body was the property of no one.’ No matter what he did say; this understanding, or misunderstanding, has come down to us *as law*.” *Id.*

15. See JACKSON, *supra* note 11.

16. *Larson v. Chase*, 50 N.W. 238, 239 (Minn. 1891).

17. Property is generally viewed not as a single indivisible concept but as a bundle of legally protected interests, including the right to possess and use, to transfer by sale or gift, and to exclude others from possession. Although the property concept can be invoked to protect various legal interests, one’s right to use property is commonly limited to uses that do

possess and use, to transfer by sale or gift, and to exclude others from possession,¹⁸ few of these rights were applied to bodies. For instance, the theft of a cadaver was not larceny, the sale of a cadaver was not a common law crime, the heirs had no right to repossess a body wrongfully taken from them, and a cadaver could not be the subject of a lien. Recognizing the limited applicability of property law to corpses, twentieth century American courts retreated from the broad pronouncement of bodies as property and began referring to more limited “quasi property rights” vested in the next of kin and arising out of their legal duty to bury the dead. These rights include the right to possession and custody of the body for burial, the right to have it remain in its final resting place, and the right to recover damages for any outrage, indignity, or injury to the body of the deceased.¹⁹

The family’s interest in the dead body was subject to various interests of the state government, including concern for public sensibility, promotion of public health, identifying cases of murder, and protecting the economic interests of undertakers and insurers. Quasi property analysis became the prevailing rule in both the United States and England during the early twentieth century and continues to be applied to disputes over funeral arrangements.²⁰

In the 1930s, American jurists and legal scholars began questioning the applicability of property law concepts to cases involving wrongful conduct toward corpses. Gradually, the newly developing tort law framework of intentional infliction of emotional distress (also called “outrageous conduct”) was viewed as a more appealing theoretical basis for a legal claim against anyone who wrongfully removes, mutilates, or operates on the body of a dead person, or who prevents its proper interment or cremation.²¹ The cause of action is a personal right of the survivor rather than a right of the decedent or his estate, as the courts are not primarily concerned with the extent of the physical mishandling or injury to the body per se, but rather

not offend public safety or sensibilities. For example, a person may own a car but not have a right to use it without first obtaining a driver’s license.

18. RAY ANDREWS BROWN, *THE LAW OF PERSONAL PROPERTY* § 15 (Walter B. Raushenbush 3d ed. 1975).

19. 22A AM. JUR. 2D *Dead Bodies* §§ 1–30 (2001).

20. William Boulier, *Sperm, Spleens, and Other Valuables: The Need to Recognize Property Rights in Human Body Parts*, 23 HOFSTRA L. REV. 693, 705 (1995); Paul Matthews, *Whose Body? People as Property*, 36 CURRENT LEGAL PROBLEMS 193 (1983).

21. RESTATEMENT (SECOND) OF TORTS § 868 (1977).

with the effect of such improper activities on the emotions of the surviving kin.²²

Even these rights, however, are tempered by the public interest. In American jurisdictions, a person may dictate the disposal of his or her remains through a will, and if she fails to do so, the decedent's family may exercise the power.²³ This power, however, is subject to limitation by rights of coroners and medical examiners. If the state interest is compelling enough, the relatives of the decedent may lose any quasi-property right.²⁴

Overall, courts have backed away from adopting a property theory for the body, for example by discussing and rejecting conversion²⁵ claims with respect to corpses, in part because of the belief that the partial remains of a human body have no inherent value.²⁶ On the other hand, they have conflated quasi-property rights in the corpse with torts claims for infliction of emotional distress due to improper handling of the corpse, leaving the extent to which there is a legally recognized property interest in the body still unclear.²⁷

22. *Id.*

23. Monique C. Gorsline & Rachele L.K. Johnson, *The United States System of Organ Donation, the International Solution, and the Cadaveric Organ Donor Act: "And The Winner Is . . ."* 20 J. CORP. L. 5, 10 (1995).

24. *See* State v. Powell, 497 So. 2d 1188 (Fla. 1986) (holding that the state interest in providing sight to blind citizens is compelling enough to allow removal of corneas from a corpse without notice to the next of kin).

25. The essence of the tort of conversion is interference with the owner's right of possession or control. The plaintiff in a conversion suit must therefore show a right to possess the property or the suit will fail. Historically, establishing a property interest in a bodily part has been quite difficult. As discussed earlier, the sale or disposition of cadavers, cadaver tissues, or the cadaver organs has generally been restricted. In addition to demonstrating a property interest in the tissue, a successful suit for conversion must show that the plaintiff has suffered some injury through interference with the property. One form of injury is a diminution in the availability (and hence the value) of the property to the plaintiff, but "raw" tissues and cells have little pecuniary value in themselves.

26. *Shults v. United States*, 995 F. Supp. 1270, 1272 (D. Kan. 1998). Whether a change in the market demand for raw tissue would affect this analysis remains to be seen.

27. Michelle Bourianoff Bray, *Personalizing Personalty: Toward a Property Right in Human Bodies*, 69 TEX. L. REV. 209, 231 (1990). In a number of prominent scandals, crematoria and funeral homes have been the subject of class-action suits following disclosure of improper handling of corpses, including a \$31 million suit in 1984 to the relatives of 5,000 people whose ashes were dumped on land instead of over the ocean; and \$25 million suit in 1991 to relatives of people whose bodies were harvested for tissue and then cremated, with mixed ashes returned to the families; and, most recently, a suit for improper disposal of hundreds of bodies at a Georgia crematorium. Duane Stanford, *Lawyers Target Funeral Homes, Not Crematory*, ATLANTA J. & CONST., March 3, 2002, at 1A.

Without a clear notion of whether interference with the body is an interference with property or an invasion of privacy, it is difficult to develop a coherent and consistent set of rules governing control over the body and its tissues. While either theory can support rules that permit dispositional control to rest with the person, while alive, and with the person's kin, after death, only a property theory can easily support a commercial market in tissues, whether taken from live donors (or, perhaps, better defined as sellers) or from cadavers now owned by those who inherit the body from its "owner." In light of the existing markets and quasi-markets in tissue, and in light of the growing range of commercial uses of tissue, this lack of clarity poses a challenge to the orderly development and regulation of tissue transfers for research, transplantation, and other uses.

IV. THE LAW OF CADAVERIC TISSUE DONATION

The first phenomenon to put pressure on this lack of clarity in the status of human tissue arose in the mid-twentieth century, when scientific advances led to an increasing need for transplantable tissue. From 1947 until 1968, forty states enacted statutes permitting anatomical donations from cadavers for transplantation or scientific research.²⁸ Variations among the statutes lead to the formation of a special committee of the Commissioners on Uniform State Laws to draft a uniform donation statute.²⁹ The result of this effort is the Uniform Anatomical Gift Act (UAGA), which has been adopted throughout the fifty states and the District of Columbia.³⁰

The UAGA permits any competent adult to make a gift—to take effect upon death—of all or any part of his body for purposes such as medical education, research, and transplantation.³¹ Donations for research purposes may only be made to hospitals, physicians, medical and dental schools, and tissue banks.³² Post mortem donations of human tissues and cells to noncommercial biomedical researchers are therefore permitted, although transfers from noncommercial researchers to commercial researchers are not

28. Sideman, *supra* note 12, at 841.

29. E. Blythe Stason, *The Uniform Anatomical Gift Act*, 23 BUS. LAW. 919, 920 (1968).

30. *Id.* The UAGA supersedes only those areas of the common law of cadavers that are addressed by the act. *Id.* at 921–22.

31. *Id.* at 925.

32. *Id.*

addressed by the model law.³³ It has been argued that the UAGA recognizes rights in the human body that may be classified as property rights, but the UAGA does not discuss inter vivos (during life) gifts, nor does it say anything about the sale of organs or other body parts.³⁴ The chairman of the committee that drafted the UAGA has written that it was intended neither to encourage nor prohibit sales.³⁵

In 1984, Congress enacted the National Organ Transplant Act (NOTA).³⁶ NOTA prohibits the sale of a human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin. Although the act makes it a felony to purchase specified human organs for transplantation, reasonable payments for a living donor's expenses (e.g., travel, housing, and lost wages) are permitted.³⁷ Despite this prohibition, there is a quasimarket in organs such as corneas.

V. PRESUMED CONSENT STATUTES AND CORNEAL TRANSPLANTATION

Corneal transplants have been done since 1905, and the Eye Bank Association of America (EBAA) estimates that 45,000 people around the world need such transplants each year.³⁸ EBAA has 110 member eye banks operating in over 100 locations in forty-three states, the District of Columbia, Puerto Rico, Canada, Europe, the Middle East, and Australia.³⁹

Corneas are considered "organs" under NOTA and many state statutes, and many corneas are acquired by ordinary, voluntary donation practices, such as prior authorization from the deceased or donation by next of kin.⁴⁰

33. Stason, *supra* note 29, at 924. Gifts may be made either by will or by a gift document such as a donor card. In the absence of contrary instructions by a decedent, the next of kin may authorize a gift. *Id.* at 926.

34. *Id.* at 924.

35. *Id.*

36. National Organ Transplant Act of 1984, Pub. L. 98-507 (codified at 42 U.S.C. §§274-274e (2001)).

37. The statute's organ sale prohibition was based primarily on congressional concern that permitting the sale of human organs might undermine the nation's system of voluntary organ donation. It was also driven by concern that the poor would sell their organs to the rich, to the detriment both of poor people who might feel economically coerced to become organ suppliers and those who need but cannot afford transplantable organs. It may also reflect congressional distaste for sales of human body parts generally.

38. The Eyebank Ass'n of Am., at <http://www.restore sight.org/pubsct.htm> (last visited Nov. 8, 2001).

39. *Id.*

40. Julia D. Mahoney, *The Market for Human Tissue*, 86 VA. L. REV. 163, 184 (2000).

There is, however, an additional, lesser known process for gathering corneas for transplantation. Statutes in approximately twenty states permit a coroner to remove the corneas of a cadaver on which an autopsy is performed if there is no known objection from surviving relatives.⁴¹ Commonly referred to as “presumed consent” laws, these statutes were enacted in the 1960s, 1970s, and 1980s in order to ward off shortages.⁴²

Harvesting cornea tissue under presumed consent laws has resulted in several challenges to the constitutionality of state laws that would remove dispositional control over corneas from the next of kin. In a number of cases, the state courts first found that the laws were valid under the state constitutions and second, that there was no property interest in the deceased person’s body. Several courts held that the next of kin of the deceased has no property right in the dead body.⁴³ One of these courts also rejected the argument presumed consent statutes invade a fundamental privacy right in a person’s body,⁴⁴ holding that a right of privacy concerns the right to make decisions about one’s own body, and that this right dies with the person.⁴⁵

At the same time, however, these courts have acknowledged a quasi-property right in the surviving relatives of the decedent to possession of the body for purposes of burial. Indeed, two more recent cases in the federal courts have suggested that next of kin may have a stronger property interest in the dead body of a relative than these state cases would suggest, and that their dispositional authority might go beyond mere control over burial.⁴⁶ The cases, however, do not develop this point enough to make it possible to generalize to other tissues or other forms of more purely voluntary donation.⁴⁷

According to Professor Julia Mahoney of the University of Virginia:

The ability of coroners to harvest the corneas of corpses entrusted to them creates opportunities for market transactions, as coroners’

41. *Id.*

42. Alexander Powhida, Comment, *Forced Organ Donation: The Presumed Consent to Organ Donation Laws of the Various States and the United States Constitution*, 9 ALB. L.J. SCI. & TECH. 349 (1998).

43. *State v. Powell*, 497 So. 2d 1188 (Fla. 1986); *Georgia Lion Eye Bank, Inc. v. Lavant*, 335 S.E.2d 127 (Ga. 1985); *Tillman v. Detroit Receiving Hosp.*, 360 N.W.2d 275 (Mich. Ct. App. 1984).

44. *Tillman*, 360 N.W.2d at 275.

45. *Id.* at 277.

46. *Whaley v. County of Tuscola*, 58 F.3d 1111 (6th Cir. 1995); *Brotherton v. Cleveland*, 923 F.2d 477 (6th Cir. 1991).

47. *Id.*

offices sell the retrieved corneas to tissue “banks” . . . which serve an intermediary function, in turn reselling usable eyes to corneal transplant programs. Late in 1997, press reports documenting a series of such exchanges appeared in the *Los Angeles Times*. From 1992 to 1997, reported the *Times*, the Los Angeles County coroner’s office delivered corneas to the Doheny Eye and Tissue Transplant Bank in exchange for total payments of over \$1,000,000. Doheny paid the coroner’s office \$215 to \$335 per cornea, then resold the corneas for significantly more Eye banks generally pay money to obtain corneas, whether obtained from morgues, hospitals, or otherwise, and in turn receive money from corneal programs. Corneal transplant programs in turn sell transplant services—which, of course, include a cornea as part of the deal—to patients.⁴⁸

Viewed as a question of privacy rights, the use of presumed consent statutes to govern removal of corneas can be regarded as unproblematic for the deceased person, whose privacy interests have also died, leaving only the question of whether the public interest in ensuring adequate supplies outweighs the public interest in protecting the sensibilities of the family. The body itself becomes a kind of public resource, available for harvesting and use to serve public purposes. But if corneas are the private property of the deceased, property that should be controlled by will or the law of intestacy, then this removal constitutes a form of taxation on the estate, or worse, a taking, for which some argument about compelling public purpose must be made, and some form of compensation provided. Without a theory of the body as a public resource, this harvesting of corneas, especially when coupled with financial transactions among intermediaries, is easily perceived by the public as a rather ghoulish form of state-sanctioned theft, rather than as a benign form of human tissue recycling in order to aid the living.

VI. THE LAW OF GAMETE SALES

An example of another large-scale market for human tissue lies in the area of reproductive medicine, where sperm and ova are routinely obtained from donors whose reimbursements for the service of providing gametes strongly resemble a payment for the sale of their gametes. Gametes are retrieved from thousands of Americans every year for use in assisted reproduction. In many cases, the gametes are transferred to someone other than the gamete provider’s partner, a phenomenon commonly referred to as

48. Mahoney, *supra* note 40, at 184–85 (citations omitted).

egg or sperm donation, even where the donors are reimbursed for the gametes. The Centers for Disease Control, for example, estimates that donor eggs were used in approximately ten percent of all Assisted Reproductive Technology (ART) cycles carried out in 1998, or 7756 cycles.⁴⁹ A 1987 study by the congressional Office of Technology Assessment estimated the frequency of sperm donation as considerably higher.⁵⁰

Sperm and egg donors are sought by advertisement, sometimes as low-key as a flyer stuck on a billboard in a medical school and other times as noticeable as an advertisement in a major national newspaper. Ron's Angels bills itself as "the most visited egg and sperm site in the world."⁵¹ Whether or not that is true, the internet site offering to auction sperm and ova from physically attractive people has generated much greater public awareness of the market for human gametes.

Unlike most other developed countries, Americans can buy and sell gametes, although the transactions are sometimes labeled as something other than a sale, for example, where provision of a semen sample is rewarded with a cash payment for "services" as opposed to a product. Similarly, recipients will pay for a fertility service that includes the provision of the necessary gametes, thus avoiding the need to consider the transaction strictly as a purchase of gametes. Indeed, the American Society of Reproductive Medicine condemned the Ron's Angels' site in these terms:

The ASRM Ethics Committee states that reasonable compensation is justified for the time and trouble of both sperm and egg donors. Compensation should not vary based on attributes that a child may have. The "Ron's Angel's" website is essentially a donor egg 'auction' to sell human eggs to the highest bidder in the hopes of providing potential parents with more attractive—and therefore desirable—children. We believe that the "Ron's Angels" website violates the ethical principles outlined by the Committee, promotes unrealistic expectations to potential parents, commercializes what is otherwise a voluntary donation process, offers undue enticement

49. 1998 Assisted Reproductive Technology Success Rates: National Summary and Fertility Clinic Reports, at <http://www.cdc.gov/nccdphp/drh/art98/section3.htm> (last visited Jan. 27, 2002).

50. OTA, *Artificial Insemination Practice in the United States: Summary of a 1987 Survey*, US GPO, Washington D.C. 1988.

51. Ron's Angels, at <http://www.ronsangels.com> (last visited Jan. 27, 2002).

to potential donors, and has great potential to exploit highly vulnerable people.⁵²

The amount offered to reimburse gamete donors has varied over the years. At the time of the 1987 congressional survey, men who met selection criteria (for health, absence of transmissible disease, freedom from family history of significant heritable disorders, and minimum height and physical fitness) appeared to receive between thirty dollars and fifty dollars for each semen sample provided, while egg donors (who must undergo a more arduous, unpleasant, and risk prone retrieval) would receive up to several thousand dollars. In 1998, however, an announcement by a New Jersey fertility clinic of plans to double the compensation offered to egg donors from \$2500 to \$5000 demonstrated that prices for egg donation were rising, and generated extensive press coverage and commentary.⁵³ The *New York Times* reported that accounts of the price increase “put a spotlight on what is perhaps the touchiest issue in the egg donation process: are the eggs a gift or a free-market commodity?”⁵⁴ In March 1999, the price offered for usable ova increased by an order of magnitude when an advertisement placed in the campus newspapers of several Ivy League schools offered a \$50,000 “financial incentive” to an “Intelligent, Athletic Egg Donor.”⁵⁵

Both the pricing regimes and some cases suggest that, regardless of rhetorical presentation, gametes are indeed treated as property. For example, because gametes can also be retrieved from the dead, occasionally widows, fiancées, girlfriends, and parents of men who recently died have requested sperm retrieval, raising the question of dispositional authority over gametes. In *Hecht v. Superior Court*,⁵⁶ which concerned the validity of a provision in a man’s will that his companion of five years be permitted to

52. ASRM Statement on “Ron’s Angels” Website, Statement of R. Jeffrey Chang, M.D. President, American Society for Reproductive Medicine, at http://www.obgyn.net/infertility/articles/asrm_pr.htm (last visited Jan. 27, 2002).

53. Gina Kolata, *Price of Donor Eggs Soars, Setting Off a Debate on Ethics*, N.Y. TIMES, Feb. 25, 1998, at A1; Sharon Lerner, *The Price of Eggs: Undercover in the Infertility Industry*, MS., Mar./Apr. 1996, at 28.

54. Kolata, *supra* note 53, at A1.

55. Sydney Leavens, *Yale U. Students and Professors React to Egg Donation Ad*, YALE DAILY NEWS (New Haven), Mar. 4, 1999, at LEXIS, News Library (describing reactions among members of the Yale community).

56. 20 Cal. Rptr. 2d 275 (Cal. Ct. App. 1993). See also John A. Robertson, *Posthumous Reproduction*, 69 IND. L.J. 1027, 1036–37 (1994); David Margolick, *15 Vials of Sperm: The Unusual Bequest of an Even More Unusual Man*, N.Y. TIMES, Apr. 29, 1994, at B18.

use his semen,⁵⁷ the appellate courts upheld the provision, treating the semen as if it were the property of the deceased and therefore eligible for disposition by testamentary provision.⁵⁸ The status of sperm—and, by extension, other tissue—as the subject of property rights or personal rights also arises in cases where there is no testamentary wish. In the mid-nineties, for example, a newly married young man was killed in a quarrel with police.⁵⁹ His widow requested his semen even though there was no prior indication of his wishes, in a will or by other means.⁶⁰ Physicians acceded to her wishes, as they have on several other occasions to requests from girlfriends and parents.⁶¹

Of course, the fact that courts have at times treated male gametes as if they are property does not necessarily tell us whether this is a form of property that ought to be bought and sold. In her analysis of the *Hecht* case, philosopher Bonnie Steinbock writes:

ownership does not settle the question of the scope of control—that is, what the owner may legally do with the stored sperm. Under certain circumstances one can own something one is not permitted to sell. For example, the Queen of England owns a great deal of land and many art treasures that she may not sell. However, since ordinarily one may sell one's property, the identification of sperm as property creates a presumption that it may be donated, stored, sold, and bequeathed.⁶²

Of course, ownership of something, whether of a pet or a piece of land or one's own tissue, should also convey the right to sell the property is not answerable merely by calling the item one's "property." "Too many incidents are lacking to say that persons own their bodies. Restrictions on transfer and the absence of a liberty to consume or destroy, for example, indicate that persons do not own their bodies in the way that they own automobiles or desks."⁶³

57. *Hecht*, 20 Cal. Rptr. 2d at 276.

58. *Id.* at 290–291.

59. Beth J. Harpaz, *Florida Woman Has Dead Husband's Sperm Saved*, CHICAGO SUN TIMES, Jan. 20, 1995, at A8.

60. *Id.*

61. *Id.*

62. Bonnie Steinbock, *Sperm As Property: In the Absence of a Compelling Argument Against Reproduction, Individual Autonomy Should Prevail*, 6 STAN. L. & POL'Y REV. 57, 60 (1995).

63. *Id.* at 62 (quoting STEPHEN MUNZER, A THEORY OF PROPERTY 56 (1980)).

Looking at the question of personal control over one's body, it is helpful to distinguish between property rights in one's body and personal rights over its treatment:

Property rights are body rights that protect the choice to transfer. Personal rights are body rights that protect interests other than the choice to transfer. To note that someone has dispositional authority over a body or body part is thus not necessarily to acknowledge a property right; dispositional authority may indicate a personal right instead.⁶⁴

At the same time, the law's tolerance of our decisions to donate or sell some of our body parts does suggest that some property rights clearly exist. Whether these property rights include the right of sale hinges on a more complex analysis of the social ramifications of such sales. Steinbock elaborates:

[One should distinguish also] between *weak* property rights, which involve only a choice to transfer gratuitously, and *strong* property rights, which involve a choice to transfer for value. Most countries permit the donation of organs, but forbid their sale. In these countries, people have weak property rights in their organs. In countries where the sale of blood and semen is legal, individuals have strong property rights in these bodily fluids.⁶⁵

The question of whether sperm and ova should be available for sale in the United States, that is, whether they should be the subject of strong property rights, is periodically revisited whenever controversies arise over the scale of such sales or the connection of such sales to purportedly eugenic goals, such as the sale of gametes from intellectually or physically "superior" adults.⁶⁶ But if we should ever conclude that such sales ought to be permitted, then we should be prepared to apply the entire body of the law of sales, as well as the body of tort law governing the sale of products.

VII. THE LAW OF TISSUES AND CELL LINES FOR RESEARCH

As mentioned in the introduction, many human tissues are obtained for use in research, commerce, and clinical care. While most of these tissues are

64. *Id.*

65. *Id.* at 61.

66. Steinbock, *supra* note 62, at 65.

obtained with the knowledge of the tissue source (if he or she is alive) or at least the consent of the kin (when the tissue source is dead), the use of tissues for research is characterized by a mix of both witting and unwitting “donation” for use.

While individuals in the United States may possibly be seen to have a strong property right in their gametes, no such strong property right has been identified in the other tissues of their bodies, even when these tissues are taken while the individual is alive.⁶⁷ Human tissue is routinely excised in medical procedures and stored for both clinical and research purposes. Once stored, the tissues are then transferred among laboratories and researchers for work on such things as genetic epidemiology, but there is virtually no tradition of compensating the individuals from whom the tissues came. Indeed, in many cases these individuals have no knowledge that they have unwittingly made a gift of their human biological materials to the research world.

The medical and scientific practice of storing human biological materials is more than 100 years old. Human biological collections—which include DNA banks, tissue banks, and repositories—vary considerably, ranging from large collections formally designated as repositories to blood or tissue informally stored in a researcher’s laboratory freezer. Large collections include archived pathology materials and stored cards containing blood spots from newborn screening tests (Gunthrie cards). Tissue specimens are stored at military facilities, forensic DNA banks, government laboratories, diagnostic pathology and cytology laboratories, university- and hospital-based research laboratories, commercial enterprises, and nonprofit organizations. Archives of human biological materials range in size from fewer than 200 specimens to more than 92 million. Conservatively estimated, at least 282 million specimens (from more than 176 million individual cases) are stored in the United States, and the collections are growing at a rate of over 20 million cases per year.⁶⁸

The most common sources of human biological materials are diagnostic or therapeutic interventions in which diseased tissue is removed or tissue and other material is obtained to determine the

67. *Id.*

68. *Research Involving Human Biological Materials: Ethical and Policy Guidance*, *supra* note 6, at 1.

nature and extent of a disease. Even after the diagnosis or treatment is complete, a portion of the specimen routinely is retained for future clinical, research, or legal purposes. Specimens also are obtained during autopsies. In addition, volunteers donate organs, blood, or other tissue for transplantation or research, and some donate their bodies after death for transplantation of organs or anatomical studies. Each specimen may be stored in multiple forms, including slides, paraffin blocks, formalin-fixed, tissue culture, or extracted DNA. Repositories provide qualified commercial and noncommercial laboratories with access to specimens for both clinical and research purposes.⁶⁹

In addition to its future clinical use, a specimen of human biological material can be used to study basic biology or disease. It can be examined to determine its normal and abnormal attributes, or it can be manipulated to develop a research tool or a potentially marketable product. Just as a clinician chooses biological materials appropriate to the clinical situation at hand, a researcher's choice of such materials depends on the goals of the research project. The selected tissue can be used only once, or it can be used to generate a renewable source of material, such as by developing a cell line, a cloned gene, or a gene marker. In addition, proteins can be extracted, or DNA isolated, from particular specimens.⁷⁰

There is substantial research value both in unidentified material (i.e., material that is not linked to an individual) and in material linked to an identifiable person and his or her continuing medical record.⁷¹ In the former, the value to the researcher of the human biological material is in the tissue itself and often in the associated

69. *Id.* at 2.

70. *Id.*

71. *Id.*

Human biological materials also may be used for quality control in health care delivery, particularly in diagnostic and pathology laboratories. In addition, these materials are used to identify an individual, such as in paternity testing and in cases of abduction or soldiers missing in action, as well as in other forensic matters for which biological evidence is available for comparison. The advent of technologies that can extract a wide array of information from these materials generally has increased the potential uses—in research and otherwise—of human biological materials that are unrelated to individual patient care.

Id. at 2–3.

clinical information about that individual, without the need to know the identity of the person from whom it came.⁷² . . . In such cases, beyond knowing the diagnosis of the individual from whom the specimen was obtained, researchers may not require more detailed medical records, either past or ongoing.

Sometimes, however, it is necessary to identify the source of the research sample, because the research value of the material depends upon linking findings regarding the biology of the sample with updated information from medical or other records pertaining to its source.⁷³

By using the power of new DNA technologies and other molecular techniques, scientists potentially can turn to millions of stored human biological materials as sources of valuable scientific, medical, anthropological, and sociological information.⁷⁴ Indeed, these

72. *Research Involving Human Biological Materials: Ethical and Policy Guidance*, *supra* note 6, at 2. “For example, investigators may be interested in identifying a biological marker in a specific type of tissue, such as cells from individuals with Alzheimer’s disease or specific tumors from a cancer patient.” *Id.*

73. *Id.* The recently published regulations designed to protect the privacy of medical records and other health information do not appear to affect tissue banks. The regulations, published by the United States Department of Health and Human Services (DHHS) on December 28, 2000, address not only medical records but also other individually identifiable health information maintained by health plans, health care clearinghouses, and certain health care providers. They give consumers access to their health information and control the inappropriate use of that information. They limit non consensual use and release of private health information and give patients new rights to access their records and to know who else has accessed them. The regulations specifically exempt tissue banks, organ procurement organizations, eye banks, and blood banks because they are not considered “health care providers” within the meaning of the regulation.

74. *Id.* at 3.

The demonstrated use of these technical capabilities suggests that human tissue and DNA specimens that have been sitting in storage banks for years—or even a century—could be plumbed for new information to reveal something not only about the individual from whom the tissue was obtained, but possibly about entire groups of people who share genes, environmental exposures, and ethnic or even geographic characteristics. Clearly, the same is true for materials that may be collected in the future. DNA, whether already stored or yet to be collected, can be used to study genetic variation among people, to establish relationships between genes and characteristics (such as single gene disorders), or, more generally, to conduct basic studies of the cause and progression of disease, all with the long-term goal of improving human health.

Id.

technologies are so powerful—even revolutionary—that they also hold the ability to uncover knowledge about individuals no longer alive.

- In 1997, [for example,] scientists at the University of Oxford announced that they had compared DNA extracted from the molar cavity of a 9,000-year-old skeleton (known as Cheddar Man) to DNA collected from 20 individuals currently residing in the village of Cheddar; this resulted in the establishment of a genetic tie between the skeleton and a schoolteacher who lived just half a mile from the cave where the bones were found.⁷⁵
- Scientists have used enzyme linked assays to analyze tissues more than 5,000 years old and to track the historic spread of diseases such as malaria and schistosomiasis, obtaining knowledge that can enlighten current efforts to control infectious disease.⁷⁶
- In early 1999, a United States pathologist and a group of European molecular biologists announced that they had found DNA sequences in the Y chromosome of the descendants of Thomas Jefferson that matched DNA from the descendants of Sally Hemings, a slave at Monticello.⁷⁷ The data establish only that Thomas Jefferson was the most likely of several candidates who might be the father of Eston Hemings, Hemings' fifth child, but also have raised a storm of controversy.⁷⁸

In light of these new uses for stored human tissue, academic and government bodies have begun to ask whether the tissues may only be used with permission of the individuals from whom they came—a position consistent with the notion that these tissues are the property of those

75. *Id.* See also Marriette DiChristina, *Stone Age Kin*, POPULAR SCIENCE, June 1997, at 90.

76. *Research Involving Human Biological Materials: Ethical and Policy Guidance*, *supra* note 6. See also Mummy Tissue Bank, at <http://www.museum.man.ac.uk/new/mummy.html> (last visited Jan. 27, 2002).

77. *Research Involving Human Biological Materials: Ethical and Policy Guidance*, *supra* note 6. See also Eugene A. Foster, et al., *Jefferson Fathered Slave's Last Child*, NATURE, Nov. 5, 1998, at 27.

78. *Research Involving Human Biological Materials: Ethical and Policy Guidance*, *supra* note 6, at 3.

individuals—or whether the tissues are a kind of public resource that can be used with impunity, provided that no undue harm would befall these individuals by virtue of a release of tissue information to employers, insurers, or family members who might misuse or misunderstand its import. To date, it is this latter position that has guided federal policy, even while, in other respects, professional societies have called for recognizing that individuals do have an interest in the uses to which their body tissue is put.⁷⁹ In addition, the AMA Code of Ethics requires that patients' consent must be obtained before their tissue is used for commercial purposes.⁸⁰

While federal human subjects research regulations and the 1999 report of the National Bioethics Advisory Commission both call for a practice of seeking consent from individuals in most cases, this practice is premised not on a theory of property, but on a theory of personal privacy; and since information revealed by studying the tissue may render these individual research subjects vulnerable, they ought to have the privilege of declining participation if they wish.⁸¹ Indeed, where risks are minimal and obtaining consent is unwieldy, both current regulations and NBAC's proposals for revised practices permit use of stored tissue without any authorization from the person whose body provided the materials.⁸² This is a sure sign that the tissues are not the subject of strong property rights. It is also consistent with the leading common law case on the question of property rights in excised tissue, *Moore v. Regents of the University of California*,⁸³ in which the influential supreme court of California held that a patient whose cells had been removed and used by others to construct a valuable cell line did not have a cause of action for conversion, citing the lack of any precedent holding that an individual has a property interest in excised cells.⁸⁴

79. Ellen Wright Clayton, et al., *Informed Consent for Genetic Research on Stored Tissue Samples*, 274 JAMA 1786 (1995). Ethical opinions, professional guidelines, and court decisions are increasingly recognizing the importance of an individual's control over his or her tissue outside of the body. A workshop of the National Institutes of Health and Centers for Disease Control developed a protocol for the collection of tissue samples that recognizes the personal and religious implications of tissue donation and allows people to control what use is made of the tissue removed from their bodies. *Id.* More recently, the NIH adopted most of the NBAC recommendations concerning the management of research on stored human tissue. See http://ohsr.od.nih.gov/info/ninfo_14.php3.

80. AMA CODE OF ETHICS, E-2.08 (2001).

81. *Id.*

82. *Id.*

83. 793 P.2d 479 (Cal. 1990).

84. *Id.*

One strong public policy reason advanced for withholding property status to these excised tissues is the effect that would have on important research and on the protection of human subjects of research. If considered personal property, then much tissue could be used only with explicit permission, something logistically difficult to obtain for the many thousands of stored samples collected years ago from people who have since moved, changed names, or otherwise become difficult to locate. Given the important genetic and viral epidemiology that can be done on these stored samples, prohibiting all uses without explicit donor consent would be a major blow to public health and medical research. Of course, consent would be unnecessary in situations in which the tissue is considered abandoned, but under such an abandonment theory, the tissue could be used with impunity, and without regard for the potential invasions of privacy and social interests that might arise on occasion, when analysis reveals stigmatizing information about the person from whom the tissue was taken. By viewing the tissue not as property, but as an invasion of privacy interests, a more nuanced public policy can develop, in which tissue is used with permission where possible, and without permission when the public interest in use is significant and the possible dignitary or pecuniary harm to the individual is *de minimis*.

VIII. THE REGULATION OF TISSUE TRANSPLANTATION

Regardless of whether tissue is viewed as personal property, or whether as personal property it can be sold, it is nonetheless possible to comprehensively regulate tissue transactions for the purpose of ensuring minimum safety in transplantation settings.

Tissue banking, the term that describes the process of removing and then storing human tissue for future use, originated in the United States in the 1940s.⁸⁵ The first tissue banks established were eye banks, which stored corneas, and bone banks, which stored bone removed during surgery for use in future patients.⁸⁶ In 1950, the United States Navy established the United States Navy Tissue Bank, which pioneered techniques for recovering, processing, and preserving cadaver tissue.⁸⁷ It was not until the late 1960s that the federal government became involved, when a group of American ophthalmologists approached the Division of Biologic Standards at the National Institutes of Health and suggested the implementation of federal

85. Michael D. Strong, *Tissue Banks: Drafting New Rules for Grafting*, 79 BUS. & SOC'Y REV. 42, (1991).

86. *Id.*

87. *Id.*

guidelines for corneal storage media.⁸⁸ At the time, however, “[t]ransplantation was regarded as part of the practice of medicine or surgery, and no effort was made to regulate the procedure or the human organs and tissues being transplanted.”⁸⁹ The “FDA [merely] encouraged the development of voluntary guidelines by those who retrieved, processed, and stored human tissue intended for transplantation,” which did indeed occur.⁹⁰

In 1976, the American Association of Tissue Banks (AATB) was established to develop standards and procedures and to assist new programs in complying with standards.⁹¹ The AATB’s accreditation system “evaluates tissue banks for compliance with a comprehensive set of standards through document review and site visits.”⁹² “The AATB standards cover acquisition, processing, preservation, storage, labeling, and distribution of tissue.”⁹³ As of 2002, the AATB’s website lists seventy-four tissue banks in the United States operating under AATB accreditation.⁹⁴ The Eye Bank Association of America (EBAA) serves a similar function for human eye banks.⁹⁵

Throughout the 1980s, the FDA continued its 1970s policy of encouraging the development of voluntary industry standards.⁹⁶ In 1985,

88. Stuart L. Nightingale, *FDA Regulatory Philosophy*, 46 *FOOD DRUG COSM. L.J.* 4 (1991).

89. *Id.* at 4–5.

90. *Id.* at 6. In 1976, the FDA considered the possibility of regulating tissue banks, but came to the conclusion “that FDA jurisdiction over tissues would be asserted only in response to an immediate need.” *Id.* at 5. FDA’s human tissue policy remained noninterventionist throughout the 1970s. The goal was to “monitor what was taking place in the field of transplantation and be particularly alert to instances of disease transmission by allografts, but to refrain from formal regulation unless it was clearly necessary.” *Id.* at 6.

91. Human Tissue Intended for Transplantation, 58 *Fed. Reg.* 65,514 (Dec. 14, 1993) (to be codified at 21 C.F.R. pts. 1270).

92. *Id.* at 65,515.

93. *Id.*

94. *Accredited Bank List*, at <http://www.aatb.org/aatbac.htm> (last visited Jan. 27, 2002).

95. Human Tissue Intended for Transplantation, 58 *Fed. Reg.* 65,515 (Dec. 14, 1993).

96. In 1983, the FDA submitted a statement to a United States House of Representatives subcommittee that was holding hearings on the National Organ Transplant Act explaining why the agency had not sought to regulate human organs. Nightingale, *supra* note 88, at 6. In spite of the fact that the statement by its literal terms encompassed only FDA’s position on human organs, and did not reference human tissue, the statement was an important one for the human tissue industry. For each of the arguments the FDA put forth regarding the regulation of human organs, an analogous one could be made regarding the regulation of human tissue. In its statement, the FDA maintained that, although an organ arguably could be classified as a drug within the meaning of the Federal Food, Drug, and Cosmetic Act (FDCA),

amid growing concern regarding the Human Immunodeficiency Virus (HIV), FDA worked with the Human Milk Banking Association of North America to develop practices that would minimize the possibility of the transmission of HIV through donor breast milk.⁹⁷ Then, in 1988, the FDA and the Centers for Disease Control and Prevention (CDC) published a joint statement outlining their views on what constituted safe sperm banking practices.⁹⁸ The statement was endorsed by the American College of Obstetricians and Gynecologists, the American Fertility Society, and the AATB.⁹⁹

Despite its progress in encouraging self-imposed voluntary standards, the FDA's position by 1990 on the regulation of human tissue was somewhat different from what it had been in 1976. Although it was still the FDA's policy "to promote the development of voluntary standards; to remain constantly alert to any hazards to public health," the agency also vowed "to promulgate regulations when needed and to publicize any regulatory intentions on the part of the FDA."¹⁰⁰ No longer would the FDA confine itself to acting only in the face of immediate need.¹⁰¹ The FDA, in accordance with the growing concerns over the safety of the human tissue supply, would take a more proactive attitude toward human tissue regulation.

The next six years witnessed several of the FDA's regulatory attempts in the human tissue area, as well as a number of abandoned or unsuccessful

such a classification would not be in accord with either the traditional medical concept of the term drug or the FDA's own current administrative definition of "drug." Likewise, although a transplanted organ might be susceptible to regulation under the Medical Device Amendments of 1976 as an implant, the FDA concluded that because organs are in no respect man-made products, deeming organs to be "devices" would violate legislative intent. Finally, the FDA noted that it arguably could regulate organs under the Public Health Service (PHS) Act by labeling organs as "biological products." The Act allows regulation of material that is "analogous" to, *inter alia*, blood, and because blood is essentially a liquid organ, solid organs such as hearts and livers could be considered "analogous products." Nonetheless, the FDA rejected this rationale, citing its belief that such an interpretation would be contrary to the legislative history of the PHS Act. Thus, the FDA concluded, "under an expansive legal interpretation, human organ transplants could possibly be regulated as drugs, devices, or biological products. It would by no means, however, be clear that such an interpretation would be consistent with the legislative intent underlying the definitions . . . or that it would withstand judicial challenge." *Id.* at 7.

97. *Id.*

98. *Perspectives in Disease Prevention and Health Promotion Semen Banking, Organ and Tissue Transplantation, and HIV Antibody Testing*, MORTALITY & MORBIDITY WKLY. REP., Feb. 5, 1988.

99. Nightingale, *supra* note 88, at 7-8.

100. *Id.* at 9.

101. *Id.*

congressional attempts to regulate the field. The FDA's initial attempts at regulation were not efforts designed to impose safeguards on the entire human tissue banking industry; rather, the FDA sought to regulate the industry with regulations targeted for specific tissues.¹⁰² As the scope of its efforts increased, though, so did resistance from the industry, which identified legal and practical problems with the FDA's actions.¹⁰³ This

102. One approach the FDA took when promulgating these regulations was to define the tissue in question as a "medical device," in spite of its 1983 statement to Congress. Gordon Johnson, Director of the Office of Health Affairs at the FDA's Center for Devices Radiological Health, defined human tissue devices as "tissues of human origin—usually cadaveric—that have been processed, that have been changed or altered in some way, shape, structure, or character. They may be cut and sculptured, disinfected, sterilized, or freeze-dried. Any number of things may occur. These are tissues that have some structure or structural character." Gordon C. Johnson, *Regulating Tissues (and Organs?) as Devices*, 46 FOOD DRUG COSM. L.J. 28 (1991) [hereinafter Johnson]. For example, the FDA classified human lenticules, a product derived from human cornea and applied to the cornea to correct vision problems, as post-amendment Class III devices, for which manufacturers of were required to obtain premarket approval for those "products." *Id.* at 30. In addition, the FDA determined that dura matter (the outer meningeal covering) allografts constituted pre-amendment devices. *Id.* at 31. Those distributors who could not document having distributed dura matter allografts prior to May 1976 would have to file premarket notifications, and all distributing facilities were required to register as device manufacturers. Cardiovascular Devices; Effective Date of Requirement for Premarket Approval; Replacement Heart Valve Allograft, 56 Fed. Reg. 29,177 (June 26, 1991) (codified at 21 C.F.R. pt. 812).

103. The piecemeal regulation that caused the most controversy was the decision to regulate human heart valves as medical devices. Johnson, *supra* note 102, at 31. The origins of the controversy lay in a 1987 rule that required the filing of a premarket approval application, or a notice of completion of a product development protocol for the replacement heart valve, a medical device. *Id.* This regulation attracted little controversy and the notice of proposed rulemaking prompted only one comment, which was not related to the FDA's classification of replacement heart valves. Cardiovascular Devices; Effective Date of Requirement for Premarket Approval; Replacement Heart Valve Allograft, 56 Fed. Reg. 29,177 (June 26, 1991) (codified at 21 C.F.R. pt. 812). The FDA embroiled itself in controversy, however, when it published a June 1991 notice of applicability of a final rule (NAFR) stating that the 1987 regulation would apply not only to mechanical replacement heart valves, but to replacement human heart valves as well. Therefore, the premarket approval requirement would apply to replacement human heart valve allografts. Cardiovascular Devices; Effective Date of Requirement for Premarket Approval; Replacement Heart Valve Allograft, 56 Fed. Reg. 29,177 (June 26, 1991) (codified at 21 C.F.R. pt. 812). Pointing out that it was illogical to test a human heart valve to see if it works safely and effectively in humans, as it clearly does, the tissue banking industry argued that forcing companies to go through the lengthy and expensive process of obtaining premarket approval was wasteful and unnecessary because heart valves are already known to be the most effective replacement heart valves available.

resulted in the FDA backing away from its initial approach,¹⁰⁴ despite successfully resisting judicial challenges from the industry,¹⁰⁵ and accepting instead an approach that regulated all tissues under a common regime focused on maintaining public health and safety.¹⁰⁶

Finally, at an October 16, 1991 FDA-sponsored public hearing on federal regulation of human tissue, the National Tissue Bank Council (NTBC), an organization comprised of nonprofit tissue banks, presented an alternative regulatory plan to the FDA. Under the NTBC's plan, public standards for dealing with different types or classes of tissues would be promulgated by the FDA, following consultation with the public and experts. Such a system, the NTBC maintained, would obviate the need for premarket approval.

On December 14, 1993, the FDA issued an interim rule "to require certain infectious disease testing, donor screening, and recordkeeping to help prevent the transmission of AIDS and hepatitis through human tissue used in transplantation."¹⁰⁷ Unlike the FDA's previous regulatory efforts in the area of human tissue, this rule applied not just to one type of tissue, such as heart valves or dura matter, but rather applied to all types of human tissue.¹⁰⁸ The

104. The industry mounted an effort, ultimately successful, to push back the date by which FDA had mandated that investigational device exemptions (IDEs) or premarket approval applications (PMAs) must be in effect to continue marketing. Heart Valve Allograft Processors Ask Court to Prohibit FDA Call for PMAs; Non-Profit Tissue Bank Coalition Calls for "Monographs" for Tissue Products, M-D-D-I REP. ("The Gray Sheet"), Oct. 21, 1991, available in LEXIS, EXEC Library, GRAY File.

105. Six tissue banks filed suit against FDA, alleging that human heart valves were neither devices nor replacement heart valves within the meaning of FDA's prior regulations. *Alabama Tissue Ctr. of Univ. of Ala. Health Serv. Found. v. Sullivan*, 975 F.2d 373 (7th Cir. 1992). The Seventh Circuit rejected both of these claims, ruling that human heart valves are "implants" within the meaning of the applicable law. *Id.* at 378. The final rule notice was a reasonable interpretation of prior regulations and "[a]ccordingly, the [rule was] an interpretive rule not subject to appellate review." *Id.* at 379.

106. The FDA announced in October 1994 that it would no longer enforce the extension of the regulation to human as well as mechanical heart valves. In explaining its action, the FDA cited its belief that special controls effectiveness of heart valve allografts. The decision to abandon this interpretation of NAFR marked not only the end of the human heart valve controversy, but also indicated the end of the FDA's attempts to regulate human tissue using a piecemeal approach. Concluding that the piecemeal approach left too many questions unanswered, the FDA decided to take a broader approach to the regulation of human tissue, a decision that played a part in the agency's rescission of its rule on human heart valves as well. *Id.* at 373.

107. Human Tissue Intended for Transplantation, 58 Fed. Reg. at 65,516 (codified at 21 C.F.R. pts. 16 & 1270).

108. *Id.*

rule was a sweeping regulatory effort that encompassed the entire human tissue industry.

In explaining its reasons for adopting this approach, the FDA noted that its prior piecemeal efforts had resulted in incomplete coverage of the human tissue field in that they did not cover “bone, ligaments, tendons, fascia, cartilage, corneas, and skin that are used in the treatment of bone disease, orthopedic injuries, ligamentous and joint complaints, degenerative skeletal disease, blindness due to corneal opacification, and burn wounds.”¹⁰⁹ In addition, the FDA referenced the fact that AATB, EBAA, and American Red Cross all had expressed support for the notion of federal human tissue regulation.¹¹⁰ Finally, the agency expressed its concern over the importation of human tissue into the United States from unknown sources and of unknown quality, and discussed its investigation into that issue, stating, “[i]n a relatively brief period of time, the agency was able to ascertain, in a few isolated instances, the availability for importation and distribution of tissue materials that do not meet minimal screening standards for transmission of infectious diseases.”¹¹¹ The FDA concluded,

donation has occurred, and continues to occur, when generally-accepted donor screening through medical history review is largely absent. The agency currently believes that these instances do not represent the predominant practice within the industry. Nonetheless, the traffic in tissue for transplantation without adequate testing or donor screening, whether domestic or imported, cannot be permitted to occur.¹¹²

After explaining its legal basis for issuing the interim rule, the FDA explained further that the “FDA is issuing this interim rule because of an

109. *Id.* at 65,515.

110. *Id.*

111. Human Tissue Intended for Transplantation, 58 Fed. Reg. at 65,516 (codified at 21 C.F.R. pts. 1270).

112. *Id.* The FDA promulgated the interim rule not under the FDCA, but instead under the PHS Act, which authorizes the Secretary of the Department of Health and Human Services (DHHS) “to make and enforce such regulations as judged necessary to prevent the introduction, transmission, or spread of communicable disease . . .” *Id.* If the FDA were to classify human tissue as a drug or device under the FDCA, then a sponsor would have to demonstrate that the product was both safe and effective to obtain FDA approval. As it had been suggested by some that an effectiveness test is inappropriate for human products, and that the FDA should only be concerned with such products’ safety, under the PHS Act, such a problem would be avoided.

immediate need to protect the public health from the transmission of HIV infection and hepatitis infection through transplantation of tissue from donors infected with or at risk of these diseases.”¹¹³ In other words, the FDA did not intend that the interim rule serve as a long-term regulatory program; rather, the agency intended that more extensive and specific regulations would be proposed in the near future. When the FDA promulgated the final rule in 1997, more than three years subsequent to the issuance of the interim rule, it adopted some new definitions and imposed some procedural changes, but otherwise left the substance of the regulatory regime established by the interim rule essentially unchanged.¹¹⁴

The FDA soon began to use the enforcement powers it had granted itself under the interim rule. For example, in February 1993, it ordered AlloTech, a tissue-processing firm that was engaged in the business of importing tissue from Eastern Europe, “to retain or destroy stored tissue and recall previously distributed tissue from about 180 donors.”¹¹⁵ This action was taken despite the fact that there was no evidence that any of the tissue was infected; the action was based on the FDA’s determination that the firm “lacked adequate documentation of medical history screening and disease testing for the tissue.”¹¹⁶

In 1998, the FDA’s new approach described a comprehensive plan for regulating human cells, tissues, and cellular and tissue-based products.¹¹⁷

113. *Id.* Responding to the concern over the transmission of communicable diseases through human tissue transplants, the rule mandated that all tissue donors be tested for HIV-1, HIV-2, hepatitis B, and hepatitis C. Furthermore, the rule specified that the process for determining whether banked human tissue was suitable for transplantation must include ascertainment of the donor’s identity, as well as a determination that the donor’s relevant, accurate medical history “assures freedom from risk factors for or clinical evidence of hepatitis B, hepatitis C, or HIV infection.” Human Tissue Intended for Transplantation, 58 Fed. Reg. at 65,520 (codified at 21 C.F.R. §1270). The rule declared that records must be maintained as to the results and interpretations of tests, the destruction of unsuitable banked human tissue, and information on the identity and medical history of the donor. 21 C.F.R. §1270.33 (2001). The FDA chose not to require premarket approval of banked human tissue. As for enforcement provisions, the interim rule granted the FDA the power to inspect all establishments covered by the rule, and it also provided that, should the agency find tissue to be in violation of the rule, the FDA had the power either to order its destruction or seize and/or destroy it.

114. Proposed Approach to Regulation of Cellular and Tissue-Based Products; Availability and Public Meeting, 21 C.F.R. §1.1 (2001).

115. John Henkel, *Safeguarding Human Tissue Transplants*, FDA CONSUMER 9, 11 (1994).

116. *Id.*

117. 21 C.F.R. §§ 207, 807, 1271 (2001).

Under its new tiered, risk-based approach, the FDA proposed to exert only the type of government regulation necessary to protect the public health,¹¹⁸ such as requiring cell and tissue banks to register with the FDA and submit a list of their human cellular and tissue-based products tissue banks,¹¹⁹ setting standards for suitability determination for donors,¹²⁰ and outlining a general set of rules governing good facility management practices.¹²¹ Together, these rules, when finalized, would establish a comprehensive regulatory program for human cellular and tissue-based products, to be contained in part 1271 of the Code of Federal Regulations.¹²² In January 2001, the FDA published its final rule, the first of these topics, registering tissue banks and their products,¹²³ even before finalization of the donor suitability and GTP proposed rules.

IX. SUMMARY

Human tissue is obtained from those who are dead and those who are alive. At times, the tissue is obtained with the full consent of the tissue source or next of kin, especially in the context of organs and other tissue for transplantation. At other times, it is taken without their knowledge, let alone their consent, as is often the case for corneas or tissue taken for research samples. In general, tissue sales are discouraged, as evidenced by some of the national laws in this area, but tissue such as gametes, hair and blood can be sold, albeit not always because of a coherent view of these tissues as the property of the people from whom they came.

This lack of consistency in the treatment of human tissues has made it difficult to propose models for comprehensive regulation of the human tissue

118. 21 C.F.R. § 207.20. To accomplish this goal, it planned to issue new regulations under the communicable disease provisions of the Public Health Service Act (the PHS Act). *Id.* Some human cellular and tissue-based products would be regulated only under these new regulations, while other human cellular and tissue-based products would also be regulated as drugs, devices, and/or biological drugs. *Id.*

119. *Id.* It also proposed modifications to current registration and listing requirements for drugs and devices under which cell and tissue establishments already regulated under the Federal Food, Drug, and Cosmetic Act (the Act) and/or section 361 of the PHS Act would register and list following the new procedures. *Id.*

120. Suitability Determination for Donors of Human Cellular and Tissue-Based Products, 64 Fed. Reg. 52, 696 (Sept. 30, 1999). Human Cells, Tissues, and Cellular and Tissue-Based Product, 21 C.F.R. §1271 (2001).

121. 21 C.F.R. § 1271 (2001).

122. *Id.*

123. 21 C.F.R. §§ 207, 807, 1271 (2001).

market. In part, this is due to underlying jurisprudential concerns about treating the body and its parts as property, whether of individuals or of the state. It is also partially due to concerns that important scientific endeavors, such as research on banked tissue samples, would be slowed or halted should the samples be considered the property of the people from whom they came, and their use subject to voluntary and informed consent in all cases. It may also be due to the low economic value of most human tissue, at least in its raw form, resulting in relatively few conflicts arising to judicial or legislative attention.

Outside the area of whole organ donation, the only area in which comprehensive market regulation is appearing concerns the safety of the tissue transfers, especially with regard to transplantation. Here, an evolving federal policy has resulted in a new, comprehensive regulatory system that would set federal standards to ensure that transplanted tissue is adequately screened for infectious disease and competently handled and manipulated by the tissue banks that act as intermediaries between those who collect the tissue and those who use it.

A more robust form of national control over the market in human tissue, then, will probably depend upon resolution of political and legal views of the body, so that its treatment, whether as property or as some other thing, will be consistent with underlying political and legal views concerning personal autonomy and the appropriate respect to be paid to our bodies, whether living or dead.