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The Whole is Not Always Greater Than the Sum of Its Parts: A Call For Stricter Regulation of Post- Mortem Human Tissue

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I. Introduction

It would seem axiomatic that what is of paramount value in life would necessarily depreciate in death. This is not true of the human body. With the emergence of biotechnology and the consequent need for post-mortem human tissue, the human cadaver has become quite valuable. In pieces and parts or in its entirety, organizations will pay top dollar for the human body, long after it houses the human spirit.¹

Throughout history, civilizations have found uses for the bodies, organs, and tissue of their dead.² The potential for the human cadaver is expansive and ever-expanding. Since 1954, human organs have been successfully transplanted into living recipients who would otherwise die.³ Modern researchers use cadaver tissue to study physiological processes and conduct testing.⁴ Clinicians restore transplant recipient functions through procedures that include skin grafts and cornea transplants.⁵ Cadavers are indispensable to medical school anatomy classes, forensics experts measuring body decomposition, and testers of impact safety.⁶ Undoubtedly, the demand for donated cadavers is limitless.

Donor and family altruism comprises the underpinning of the human tissue donation system in the United States.⁷ Under the Uniform Anatomical Gift Act (UAGA), adopted by all 50 states,⁸ a donor may gift all or part of her body “for purposes such as medical education,

¹ R. Alta Charo, *Skin and Bones: Post-Mortem Markets In Human Tissue*, 26 NOVA L. REV. 421, 422 (2002).

² See generally MARY ROACH, *STIFF: THE CURIOUS LIFE OF HUMAN CADAVERS* (Tantor Media Inc. ed., 2003).

³ Kelly Ann Keller, *The Bed of Life: A Discussion of Organ Donation, Its Legal and Scientific History, and a Recommended “Opt-Out” Solution to Organ Scarcity*, 32 STETSON L. REV. 855, 855 (2003).

⁴ See generally John J. Zodrow, *The Commodification of Human Body Parts: Regulating the Tissue Bank Industry*, 32 SW. U. L. REV. 407 (2003).

⁵ *Id.* at 407

⁶ ROACH, *supra* note 2, at 87.

⁷ DEP’T OF HEALTH & HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, *Informed Consent in Tissue Donation*, REP. NO. OEI-01-00-00440, at i (2001) [hereinafter *OIG Report on Informed Consent*].

⁸ Charo, *supra* note 1, at 428.

research, and transplantation.”⁹ Donation is achieved through one of several procedures.¹⁰ A competent individual who is at least 18 years of age¹¹ may effectuate a donation via a will or a donor card.¹² Next of kin consent also makes organ donation possible. Organ and tissue donation is regarded as a true gift of self for which donors are seldom financially compensated.

Individuals primarily donate their bodies for selfless reasons with realistic and understandable expectations that their tissue will be used for vital medical purposes.¹³ Donors and their families take comfort in the belief that their generosity will save or at least improve the lives of others.¹⁴ Further, donor families assume that their loved one’s donation will be procured, processed, and handled respectfully.¹⁵ Those who donate their bodies to science may envision medical students in white lab coats, diligently hovering over their hallowed cadaver. A donor reasonably proceeds in the expectation that the body and organ donation system runs as a benevolent and charitable enterprise for the common good. Regrettably, those who adopt this belief are often misinformed.

At death, the body is customarily relegated to the services of a funeral home which functions in a highly regulated industry.¹⁶ Licensed funeral directors, embalmers, and crematory managers follow strict Federal regulations in the disposition of the bodies entrusted to their

⁹ Charo, *supra* note 1, at 429.

¹⁰ Susan H. Denise, *Regulating the Sale of Human Organs*, 71 VA. L. REV. 1015, 1016-17 (1985).

¹¹ Sean R. Fitzgibbons, *Cadaveric Organ Donation and Consent: A Comparative Analysis of the United States, Japan, Singapore and China*, 6 ILSA J. INT’L. & COMP. L. 73, 84 n.68 (1999) (The minimum age is 18 in most states, however, New Mexico and Washington state have lowered the age to 16. Iowa allows minors age 14-17 to become donors with parental consent.). See N.M. Stat. Ann. §§ 24-6A-2 (2006); Iowa Code Ann §§ 142 C.3 (2006).

¹² Denise, *supra* note 10, at 1016-17 (Very few hospitals in the United States will recover organs from a decedent without the consent of the next of kin, even in the presence of a valid donor card.). See also Monique C. Gorsline & Rachelle L.K. Johnson, *The United States System of Organ Donation, the International Solution: And the Winner Is...*, 20 J. CORP. L. 5, 31 (1995).

¹³ *OIG Report on Informed Consent*, *supra* note 7, at 3.

¹⁴ *Id.*

¹⁵ *Id.* at 4.

¹⁶ Mark Flatten, *Horror Stories Show Body Procurement Trade*, EAST VALLEY TRIBUNE, Jul. 12, 2004, available at <http://www.eastvalleytribune.com/index.php?sty=24652>.

care.¹⁷ Decedents who elect to donate their organs prior to interment or cremation enjoy the protection of a decidedly structured,¹⁸ while not perfect organ procurement system. On the contrary, the tissue banking industry is significantly less regulated¹⁹ throughout the harvesting, processing, handling and disposition of post-mortem human tissue.²⁰

From the rise in both the supply and demand of donated tissues, flows the equally important responsibility of government oversight. Oversight of donated cadaver tissue is important to achieve: “technical and ethical performance” in the industry.²¹ The technical aspect of tissue bank oversight includes both safety and efficiency. The concern for safety stems from the potential transmission of communicable diseases to tissue processors and recipients.²² In terms of efficiency, oversight serves to maximize the probability that “tissues and cells are made available on a priority basis to patients in need of lifesaving procedures and undergoing reconstructive procedures.”²³ Ethically, regulation is needed to ensure that handling of donated human tissue comports with donor and family expectations.²⁴

The current regulation of the post-mortem tissue industry longs for revision. Shortcomings in current regulation result in both the unsafe and unethical handling of donated human cadaver tissue. At present, six different regulatory standards apply to tissue banks.²⁵ Depending on an organization’s specific activities, tissue banks are subject to governance by the Office of Human Resource Protections (OHRP), FDA human resource protections, federal

¹⁷ Incidentally, the funeral industry leads the charge in calls for regulation presumably to maintain its reputation.

¹⁸ Paul A. Raslavicus, *Of Tissues, Organs, and Pathologist*, College of American Pathologists President’s February 2002 Desk Column, available at http://www.cap.org/apps/docs/cap_today/feature_stories/pres_column_0202.html.

¹⁹ Zodrow, *supra* note 4, at 409

²⁰ Charo, *supra* note 1, at 423.

²¹ Am. Ass’n of Tissue Banking, <http://www.aatb.org> (last visited April 25, 2005) [hereinafter AATB Website].

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ *Law of Tissue Banks and Stem Cells in Flux* MCDERMOTT NEWSLETTER (McDermott, Will & Emory, Boston), Apr. 28, 2004, http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/00ac9368-11da-4d83-a75e-742a49cc45e0.cfm [hereinafter MCDERMOTT NEWSLETTER].

privacy protections under the Health Insurance and Portability and Accountability Act of 1996 (HIPAA), the FDA tissue system (effective May 25, 2005), the National Organ Transplantation Act (NOTA), in addition to applicable state law.²⁶

Beyond creating confusion, the current regulations do not sufficiently oversee the recovery, handling, processing and utilization of human tissue. Until March of 2004, the government did not require the majority of tissue banks to register with the FDA.²⁷ Even with the new registration requirement, problems persist. For example, the FDA's registration requirement only applies to entities performing research or transplantation.²⁸ Therefore, the regulation does not reach an incalculable number of tissue banks engaged only in tissue storage and transportation.²⁹ Many of the FDA regulations similarly do not apply to hospitals that collect and store tissue for in-house use.³⁰

The current lack of guidance leaves the door open for the sale and even profiteering from harvested post-mortem tissue. While the UAGA remains silent on the sale of organs and tissue,³¹ the National Organ Transplantation Act (NOTA) strictly forbids the sale of most human organs and tissue on the donor level.³² Additionally, the American Medical Association (AMA) Code of Ethics bans the commercial use of a human tissue without express patient consent.³³ The NOTA does however permit "reasonable fees" for the "recovery, processing, and distribution of parts and tissues."³⁴ However, what constitutes reasonable has never been addressed. As a result of this dearth of guidance, tissue brokers, who have developed into an

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ Unif. Anatomical Gift Act (1987).

³² 42 U.S.C. § 274 (1991).

³³ Charo, *supra* note 1, at 441.

³⁴ Nat'l Organ Transplantation Act, 42 U.S.C. §§ 274, *et seq.* (1991).

industry of “middle men,” profit greatly through the resale of human tissue. Due to technological advances, the trade in body parts has developed into a \$500 million dollar business.³⁵

Despite the absence of a true market for human tissue on the donor level, this relatively unknown secondary market thrives.³⁶ In the absence of proper guidelines, donated tissue is increasingly mishandled, mislabeled, and treated as a mere marketable medical product. This poor accountability poses safety risks to tissue handlers and recipients in addition to demonstrating disrespect toward donors and donor families. Most donors assume that their remains will be treated with dignity and respect, not offered to the highest bidder. It is reasonable to provide some level of compensation to those engaged in the business of processing post-mortem human tissue, however, the concept of profiteering as a result of someone’s selfless donation is ethically questionable.³⁷

Recognizing these issues, the FDA recently promulgated three regulations in an attempt to standardize the tissue banking industry.³⁸ The new regulations, coined the “FDA Tissue System,” reach all tissue donations including those from live donors, however, the impact of the new regulation on live donor tissue donation is beyond the scope of this paper. The primary focus of the new regulations is the insurance of safety in all stages of tissue usage from recovery to transplantation or other final disposition.³⁹ The trilogy of regulations reflects long-awaited improvements in the tissue banking industry, however, in many ways they fall short. The new rules fail to reach several critical concerns in the industry to include tissue bank accreditation,

³⁵ Amy Ling, Note, *UCLA Willed Body Program Comes Under Scrutiny as Companies Sued for the Purchase of Body Parts*, 32 J.L. MED. & ETHICS 532, 533 (2004).

³⁶ Julia D. Mahoney, *The Market For Human Tissue*, 86 VA. L. REV. 163, 194 (2000).

³⁷ Mahoney *supra* note 36, at 195.

³⁸ MCDERMOTT NEWSLETTER, *supra* note 25.

³⁹ U.S. Food and Drug Administration, *Questions and Answers for Roll-Out of GTP Final Rule*, <http://www.fda.gov/cber/rules/gtpq&a.htm>, (last visited _____) [hereinafter *FDA Q&A on GTP*].

informed consent, and the disclosure of tissue bank finances. Additionally, critics warn that the FDA does not possess sufficient resources in terms of money or manpower to fully implement the pending legislation.⁴⁰

This paper examines the current law and urges the greater regulation of the post-mortem human tissue industry. Part II illustrates the many post-mortem uses of the human body. Part III describes several post-mortem misuses and abuses of donor cadavers, organs and tissue resulting from a gap in current regulation. Part IV lays out the entities involved in the oversight of the tissue banking industry and explains the current state of regulation, including pending legislation and its potential effectiveness in addressing past shortcomings. Part V examines why the current and pending legislation does not adequately address the industry problems and urges greater regulation of the post-mortem tissue banking system.

II. Post-Mortem Uses of the Body

A. Organ Donation

In death, the human body has the unique potential to generate life. Today, one donor can potentially save the lives of eight recipients through the donation of organs.⁴¹ Medicine has achieved this accomplishment in a remarkably short period of time. The first successful, whole-organ transplantation took place in the United States in 1954.⁴² Since that time, the practice of organ procurement and transplantation has evolved into a relatively efficient system. Organ transplantation is regulated by the UAGA and implemented by a series of not-for-profit organ procurement organizations.⁴³ The United Network for Organ Sharing (UNOS) is a non-profit,

⁴⁰ DEP'T OF HEALTH & HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, *Oversight of Tissue Banking*, REP. NO. OEI-01-00-00441, at ii-iii (2001) [hereinafter *OIG Report on Oversight*].

⁴¹ N.Y. Organ Network, http://www.donatelifeny.org/organ/o_statistics.html (last visited Apr. 25, 2005) [hereinafter *N.Y. Organ Network*].

⁴² Keller, *supra* note 3, at 855.

⁴³ Denise, *supra* note 10, at 1017.

educational and scientific organization that operates the only Organ Procurement and Transplantation Network (OPTN) in the United States.⁴⁴ Congress contracted with UNOS in 1986 to manage the OPTN through the facilitation of organ donations, the collection of organ donation statistical data, and by maintaining a dialogue within the community regarding practice and policy.⁴⁵ Organ Procurement Organizations (OPOs) collaborate with hospital staffs to locate donors, collect and maintain recovered organs, and match donor organs to prospective recipients.⁴⁶ OPOs are subject to strict government regulation and peer accreditation standards, fostering a reputation for safety and efficiency within the community.⁴⁷

B. Tissue Banking

Both living recipients and the scientific research community benefit from tissue donation. For regulatory purposes, tissue is defined as “human cell, tissue, and cellular and tissue-based products” (HCT/Ps).⁴⁸ HCT/Ps include:

Any tissue derived from a human body, which; 1) [i]s intended for transplantation to another human for the diagnosis, cure, mitigation, treatment, or prevention of any condition or disease; 2) [i]s recovered, processed, stored or distributed by methods that do not change tissue function or characteristics; 3) [i]s not currently regulated as a human drug, biological product, or medical device; 4) [e]xcludes kidney, liver, heart, lung, pancreas, or any other vascularized human organ, and 5) [e]xcludes semen or other reproductive tissue, human milk, and bone marrow.⁴⁹

The donation of corneal, skin, bone and other tissue from a single cadaver can enhance the lives of up to 50 living recipients.⁵⁰ Doctors utilize donated human tissue in numerous medical procedures.⁵¹ Cadaver skin is used in skin grafting procedures for burn patients. Donated heart valves improve the quality of life in children and adults with heart valve

⁴⁴ United Network for Organ Sharing, www.unos.org/whoweare (last visited Apr. 25, 2005).

⁴⁵ *Id.*

⁴⁶ Denise, *supra* note 10, at 1017.

⁴⁷ Raslavicus, *supra* note 18.

⁴⁸ 21 C.F.R. § 1271.1(a) (2004).

⁴⁹ 21 C.F.R. § 1270.3 (1999).

⁵⁰ *N.Y. Organ Network*, *supra* note 41.

⁵¹ *OIG Report on Informed Consent*, *supra* note 7, at 1.

deficiencies.⁵² Donated bone has many purposes, including joint replacement and bone cancer treatment. Additionally, dentists use donated bone that is ground into a powder to supplement deteriorating jaw bone in dental reconstruction surgery.⁵³

Unlike the organ donation system, which is primarily operated by not-for-profit entities, donated cadaver tissue is subject to processing by agencies that stand to profit.⁵⁴ Donated tissue is frequently harvested by a not-for-profit organization, but frequently processed by a separate, for-profit agency. The for-profit companies process the tissue into a usable “product” which is marketed and sold in the same manner as other medical supplies.⁵⁵ Scientists purchase tissue for use in research. Hospitals procure tissue for use in transplantations and medical treatments.⁵⁶ Tissue banking continues to be a growth industry. In recent years, the number of tissue donors in the U.S. soared from 6,000 in 1994 to 20,000 in 1999.⁵⁷

C. Medical Teaching

Cadaver training is a long-established element of the medical school curriculum. Professors of medicine believe the experience of dissecting a human cadaver is quintessential. Donors may opt to leave their bodies to a medical school’s “Willed Body Program,” where first year medical students learn anatomy through a hands-on dissection of the human body. These programs support their parent medical schools by receiving, storing and preparing donated cadavers to be studied by medical students. Medical students traditionally treat their donated

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Congress Examines Often Unregulated Tissue Banking*, D.C. ASSOCIATED PRESS, May 25, 2001 [hereinafter *Congress Examines Tissue Banking*].

⁵⁵ Mahoney, *supra* note 36, at 194. (stating that the altruism or possibly even ignorance “of donors leads to economic benefits for both nonprofit institutions that closely resemble profit-making institutions in their operations such as transplant operations associated with hospitals, and for profit-seeking enterprises such as biotechnology companies”).

⁵⁶ *OIG Report on Informed Consent*, *supra* note 7, at i.

⁵⁷ *Congress Examines Tissue Banking*, *supra* note 54.

subjects with profound reverence.⁵⁸ Students cover the head and face of the teaching cadaver out of respect until the time comes to work on the head. Many willed-body programs conduct a memorial service in honor of the donors at the conclusion of the school year.⁵⁹ When operating within proper guidelines, willed body programs provide a valuable service to society in the education of our nation's doctors.

D. Scientific Research and Training

The donation of one's body to science is noble indeed. The question that is often unanswered is: What is science? Under the UAGA, "donations for research purposes may only be made to hospitals, physicians, medical and dental schools, and tissue banks."⁶⁰ However, donated human cadavers are used in venues far beyond this enumerated group. This provision of the UAGA, designed to restrict donations to organizations deemed appropriate, in fact does very little to ensure cadavers and cadaver tissue go to one of these five organizations. There is no guarantee that hospitals, physicians, and medical schools will not further dispose of the bodies entrusted to their care. Further, tissue banks, lacking adequate regulation, have the potential to sell or dispose of human tissue in an unanticipated manner.⁶¹

The numerous scientific uses for whole cadavers, cadaver parts, and cadaver tissue continue to drastically increase the demand for dead bodies.⁶² Researchers use donated human cadavers to conduct an array of experiments in the fields of safety testing, forensics, and other experiments. Religious historians have even used cadavers to simulate the crucifixion of Jesus.⁶³ The potential scientific uses for a cadaver are virtually endless. How the scientific community

⁵⁸ ROACH, *supra* note 2, at 37-39.

⁵⁹ *Id.* at 37.

⁶⁰ Charo, *supra* note 1, at 429.

⁶¹ See Mahoney, *supra* note 36, at 164 (suggesting that the under current regulations, the absence of advertising of human tissue should not suggest a market does not already exist).

⁶² Lloyd R. Cohen, *Increasing the Supply of Transplant Organs: The Virtues of a Futures Market*, 58 GEO. WASH. L. REV. 1, 3 (1989).

⁶³ ROACH, *supra* note 2, at 157.

obtains cadavers and what kind of “science” is performed on them will continue to be a concern as technology advances.

Whether the above-stated experiments are acceptable uses for human cadavers is debatable. Many are appalled at the thought of their own or any dead body being destroyed by gunshots or land mines.⁶⁴ Others regard such experiments as a service to society and an efficient way to dispose of their body.⁶⁵ It does not really matter upon which side of the debate one lands. What is of the utmost importance is that through proper regulation, those who would not want to donate their body for use in such experiments are protected from unwitting participation.

III. Post-Mortem Misuses of the Body

The opportunity for profit frequently breeds abuse. Exploitation in the system of body and tissue donation tarnishes its reputation and threatens its future. The media waste little time reporting scandals involving dead bodies. Sensational reports involving the mistreatment of human remains capture the public’s attention and leave a long-lasting impression. Individuals who mishandle remains are subject to civil liability and criminal penalties,⁶⁶ yet gaps in regulation persist. Beyond ethical implications, the improper handling of human remains can lead to the transmission of diseases such as hepatitis and HIV.⁶⁷ Action in the form of increased regulation and oversight is required to preserve the altruistic model of body and tissue donation,⁶⁸ increase public confidence and prevent the spread of life-threatening communicable diseases.⁶⁹

⁶⁴ *Donated Bodies Blown Up in Land Mine Tests*, ASSOCIATED PRESS, March 11, 2004, [hereinafter *Donated Bodies Blown Up*].

⁶⁵ ROACH, *supra* note 2, at 152-153.

⁶⁶ Ling, *supra* note 35, at 532.

⁶⁷ *OIG Report on Informed Consent*, *supra* note 7, at i.

⁶⁸ *Id.* at 4.

⁶⁹ *FDA Q&A on GTP*, *supra* note 39.

A. Body Snatchers: The Unwitting Donation of Organs and Tissue

Human remains increasingly find their way into the wrong hands. In several recent incidents, funeral directors released cadavers to medical examiners for autopsies resulting in the bodies being “stripped for parts” in a manner akin to that of an abandoned car.⁷⁰ The Fall 2004 Newsletter of the Funeral Ethics Organization highlights the story of Sue Sedgwick, an Arizona woman who requested a private autopsy be performed on her deceased mother, Florence. The funeral director offered to facilitate an autopsy followed by cremation for \$2,000, and two days later Sue received an urn complete with ashes. Several weeks passed and Sue had not received a copy of the autopsy report. Her visit to the hospital where the autopsy was performed unveiled a disturbing finding. Despite Florence or Sue’s lack of consent, Florence Sedgwick’s name appeared on the hospital organ and tissue donor log. Morgue personnel had presumably harvested Florence’s usable tissue and organs for use within the hospital or for potential sale to an outside agency. Distressingly, Florence Sedgwick had died of sepsis, making most of her tissue and organs unusable and extremely dangerous.⁷¹ Florence Sedgwick was in good company. The hospital logbook contained the names of other non-consenting donors as well. Increased regulation is needed to eliminate the incentive to harvest and sell tissue for profit in the absence of donor consent.

B. Tissue Banking and Profiteering

The tissue banking system is comprised of numerous not-for profit as well as for-profit agencies. The prevalence of for-profit companies engaging in this trade raises at least two issues. First, there is a concern that the motivation to generate a profit will outweigh the public’s

⁷⁰ Lisa Carlson, *Body Parts: An Unregulated Business*, FALL NEWSLETTER 2004 (Funeral Ethics Organization, Hinesburg, Vt.), Fall 2004, <http://www.funeralethics.org/fall-04.pdf> [hereinafter Carlson, Funeral Ethics Newsletter].

⁷¹ *Id.* ¶ 3.

interest in the safe handling, processing, and use of donated human tissue.⁷² The incentive to produce great amounts of usable tissue in short periods of time jeopardizes the safety of both the researchers who study tissue and human tissue recipients. Second, the idea of companies profiting from tissue for which the donor family was not compensated may be regarded as ethically incompatible with the spirit of donor selflessness that characterizes tissue donation.⁷³

With the great demand and expanding uses for human tissue, tissue processors have in some instances shifted from profiting to profiteering. It is estimated that one donated cadaver can generate \$220,000 in processed tissue products.⁷⁴ Those involved in the trade of body parts often receive compensation in the form of “donations,” “commissions,” and “finder’s fees.”⁷⁵ Limitations on such fees are not prescribed and fees have been exorbitant in many cases.

The potential for profit also encourages the black-market sales of tissue. Cases have been documented of non-transplantable tissue being marked and sold as transplantable. Black-market sales also include those made to agencies not properly credentialed to receive donated tissue. The existence of a black-market in the human tissue industry poses serious harm on both practical and ethical levels.

When improperly screened and processed, donated tissue meant to contribute to a recipient’s quality of life can ultimately cause death. While the FDA considers such cases to be rare, transplanted tissue and tissue-based products have resulted in the “transmission of viral, bacterial, fungal, and other diseases.”⁷⁶ In 2002 alone, the Center for Disease Control (CDC)

⁷² *Congress Examines Tissue Banking*, *supra* note 54.

⁷³ Mahoney, *supra* note 36, at 195.

⁷⁴ *Tissue Banks Lack Checkups*, SANTA ANA Associated Press, Jan. 6, 2001.

⁷⁵ Carlson, Funeral Ethics Newsletter, *supra* note 70.

⁷⁶ Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement; Final Rule, 69 Fed. Reg. 68,612, 68,651 (proposed November 24, 2004) (to be codified at 21 C.F.R pts. 16, 1270, and 1271) [hereinafter GTP Proposed Rule].

documented 26 instances of recipient infections, one of which also resulted in death.⁷⁷ In March of 2003, a 23-year old Minnesota man died from an infection contracted from donated human tissue used in a knee transplant surgery.⁷⁸ CryoLife, Inc., the supplier of the infected tissue, was subsequently linked to more than twenty-four additional infections in patient recipients.⁷⁹ In response to this rash of infections, the Food and Drug Administration directed CryoLife to cease distribution of cadaver tissue until it could guarantee an infection-free product.⁸⁰ CryoLife, a publicly traded company, suffered both lawsuits and a sharp decrease in the price of its stock as a result of the scandal.⁸¹ However, the recipients of the infected skin grafts experienced the greatest hardship as a result of CryoLife's negligence.

The FDA's intervention in the CryoLife matter came too late. The government's reactive approach in monitoring the tissue banking industry lacks the appropriate measure of vigilance. Stricter regulations for tissue banks would allow the FDA to proactively enforce the proper screening, testing, and processing of cadaver tissue before it ever moves into the stream of commerce.

C. Willed-Body Program Scandals

Many U.S. medical schools operate "willed-body programs." Each year, the medical school at the University of California-Los Angeles (UCLA) receives approximately 175 donated bodies and at least 11,000 people have committed to donating their bodies to UCLA upon their death.⁸² Some willed-body programs, specifically those located in populated areas, actually

⁷⁷ GTP Proposed Rule, *supra* note 76, at 68,651.

⁷⁸ *CryoLife Settles Fatal Human Tissue Suit*, KENNESAW, GA ASSOCIATED PRESS, March 2003 [hereinafter *Cryolife Settles Fatal Suit*].

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² Ling, *supra* note 35, at 532.

benefit from a surplus of donated cadavers.⁸³ The existence of excess cadavers provides the opportunity for exploitation and profit as tissue brokers serving as “middle men” are eager to purchase whole bodies, body parts, and human tissue for the going rate and then “flip” them for an even greater profit. A regrettable result of this market uncovered in 2001 by the Orange County Register is that “burn victims are often forced to compete with cosmetic surgeons for skin.”⁸⁴

Three prominent willed body programs have recently come under scrutiny for the gross maltreatment and black-market sales of human cadavers and body parts. Willed body programs at the UCLA, Tulane Medical School, (Tulane), and the University of Texas Medical Branch at Galveston (UTMB) have been at the center of recent scandals. In March 2004, authorities arrested and charged UCLA Willed Body Program Director, Henry Reid with grand theft.⁸⁵ Between 1998 and 2003, Reid allegedly sold hundreds of surplus donated cadavers on the black-market for a total of \$704,600.⁸⁶ A former mortuary worker purchased the cadavers from Reid and in-turn sold them to various medical research companies including Johnson & Johnson.⁸⁷ Johnson and Johnson has since issued a statement, stating that it takes “using human tissue samples for medical research and education very seriously.”⁸⁸ Johnson and Johnson further contends that Mitek, its wholly owned buyer, did not “knowingly receive samples that may have been obtained in an inappropriate way.”⁸⁹ Affected donor families subsequently filed civil suit against both Johnson and Johnson and Mitek for each company’s role in the scandal.⁹⁰ Once

⁸³ Stan Wilson, *UCLA Suspends its Willed Body Program*, CNN, Mar. 9, 2004, <http://www.cnn.com/2004/LAW/03/09/ucla.cadaver.suit/>.

⁸⁴ *Cryolife Settles Fatal Suit*, *supra* note 78.

⁸⁵ Ling, *supra* note 35, at 532.

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ Wilson, *supra* note 83.

⁸⁹ *Id.*

⁹⁰ Ling, *supra* note 35, at 532.

assured that UCLA would provide them with cremated remains, the families are left to ponder the uncertainty of their loved one's final resting place.

Tulane Medical School contracted with the National Anatomical Service (National) to redistribute its surplus corpses, believing the bodies would be sent to other medical schools for use in academic programs.⁹¹ Unlike UCLA, which sold its excess cadavers, Tulane actually paid National a \$1,000 fee to process and redistribute the bodies.⁹² In January of 2003, Tulane learned that seven of the cadavers were sold to the U.S. Army for \$25,000-\$30,000 each.⁹³ National therefore collected not only the \$1,000 fee per cadaver from Tulane, but over \$175,000 from the Army.⁹⁴ While the price inflation itself is alarming, the Army's chosen use of the cadavers donated for medical science shocks the conscience. In the clear absence of donor consent, the seven cadavers were ultimately exploded in Army land mine experiments.⁹⁵ There is little doubt that this use was beyond the contemplation of the individuals who willed their bodies to the Tulane Medical School program. Assuming that land mine testing, while disturbing, is necessary and justified, the use of these particular donated cadavers was a breach of donor and donor family trust.

Similarly, the University of Texas Medical Branch at Galveston recently faced numerous lawsuits for improper accountability and handling of donated cadavers.⁹⁶ Willed Body Program supervisor Allen Tyler sold cadaver parts, mostly torsos, but including \$18,000 worth of fingernails, to a lab in Utah. Further, the remains of over 70 decedents who were to be cremated

⁹¹ Rachel Pearson, *Lost Bodies, Broken Promises: Lawsuits Pending After UTMB Botched Willed-Body Program*, THE DAILY TEXAN, October 27, 2004, available at <http://www.dailytexanonline.com/news/2004/10/27/TopStories/Lost-Bodies.Broken.Promises-782458.shtml> [hereinafter Pearson, *Lost Bodies, Broken Promises*].

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *Donated Bodies Blown Up*, *supra* note 64.

⁹⁶ *Id.*

by UTMB for donor families were commingled during the cremation and unable to be returned. Many families filed lawsuits against UTMB, but the courts have consistently sustained the medical school's sovereign immunity as a state entity as a defense precluding the families' claims.⁹⁷

The thread of continuity in each of these incidents is a tissue broker or "middle man" able to profit due to a lack of regulation in the human tissue industry.⁹⁸ All three willed body programs provided donated cadavers to an intermediary who sold the cadavers to a third party, often at a marked-up price. Such "middle men" are clearly not subject to the appropriate level of oversight or regulation.

IV. The Current State of Tissue Banking Regulation: What is Being Done

The current state of regulation of the tissue banking field is "in flux."⁹⁹ Several agencies collaborate to oversee the industry. The relationship among the agencies is not formal or mandated, yet a professional dialogue and informal monitoring is maintained.¹⁰⁰

A. The Food and Drug Administration

The Federal Agency charged with the regulating HCT/Ps is the Food and Drug Administration (FDA), an agency of the Department of Health and Human Services (DHHS).¹⁰¹ Under the Public Health Service Act (PHSA) of 1999, Congress authorizes the Secretary of the DHHS to establish and implement certain regulations pertaining to tissue banking.¹⁰² Specifically, Section 361 of the PHSA allows for the creation of "such regulations as deemed

⁹⁷ *Id.*

⁹⁸ Mahoney, *supra* note 36, at 196.

⁹⁹ See MCDERMOTT NEWSLETTER, *supra* note 25.

¹⁰⁰ Michael J. Joyce, *American Association of Tissue Banks: A Historical Reflection Upon Entering the 21st Century*, CELL AND TISSUE BANKING 1:5-8, 1 (2000).

¹⁰¹ Barbara Indech, *The International Harmonization of Human Tissue Regulation: Regulatory Control Over Human Tissue Use and Tissue Banking in Select Countries and the Current State of International Harmonization Efforts*, 55 FOOD & DRUG L.J. 343, 346 (2000).

¹⁰² *Id.* at 347.

necessary to prevent the introduction, transmission or spread of communicable diseases from state to state or from foreign countries into the United States.¹⁰³ Section 361 further provides for the destruction of contaminated materials.

While vested with ample authority, the FDA has been slow to subject the tissue banking industry to much needed regulation.¹⁰⁴ Until the 1990s, the FDA limited its oversight to a minority of human tissue-based products classified as “medical devices.”¹⁰⁵ Regulation of these products, such as dura mater, heart valve allografts and corneae fell under the Federal Food, Drug, and Cosmetic Act (FDCA).¹⁰⁶ Early in the 1990s, two major incidents alarmed the FDA to systemic problems in the tissue industry. First, several organ and tissue recipients contracted HIV from an untested, infected donor.¹⁰⁷ Second, the FDA became aware that some tissue companies were purchasing untested tissue from outside of the U.S.¹⁰⁸ One imported tissue sample tested positive for Hepatitis B.¹⁰⁹

Faced with heightened criticism by the government, the medical profession, and the general public about a sensitive and risky industry that appeared to be spiraling out of control, the FDA issued an interim final rule on December 14, 1993 that addressed three areas.¹¹⁰ The rule, effective immediately, first required all tissue banks “to perform serological tests to screen for viruses such as hepatitis and HIV.”¹¹¹ Second, the regulation provide that the FDA may inspect any facility that “recovers, processes or distributes tissue for transplant” with or without

¹⁰³ 21 C.F.R. pts. 16, 1270

¹⁰⁴ Indech, *supra* note 101, at 346.

¹⁰⁵ *Id.* at 347.

¹⁰⁶ *Id.*

¹⁰⁷ *OIG Report on Informed Consent, supra* note 7.

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ 21 C.F.R. § 1270 (1997).

¹¹¹ Northwest Tissue Center, http://www.nwtc.org/regulations_standards/default.htm (last visited Apr. 25, 2005).

notice.¹¹² Third, the rule established new standards for imported tissue, requiring tissue to meet certain FDA standards before entering the U.S.¹¹³ The rule became final on July 29, 1997 when it was published in the Federal Register.¹¹⁴ While well received by the industry, the new regulations made little practical progress in ensuring good practice for tissue banks as problems with contamination and improper accountability persisting.¹¹⁵

In the wake of continued reports of contaminated samples, the FDA began work on the “FDA Tissue System” in 1998. This three-part regulatory scheme aims to overhaul the tissue banking system.¹¹⁶ The goal of the new system is “the improved protection of the public health without the imposition of unnecessary restrictions on research, development, or the availability of new products.”¹¹⁷ The FDA focused on three persistent areas of concern: the registration of tissue banks, good tissue practices (GTPs), and donor suitability.¹¹⁸

In 2000, The Secretary of Health and Human Services formally directed the Office of the Inspector General to examine certain aspects of the tissue banking industry. Of specific concern was Federal oversight of the tissue banking system and informed consent practices. While safety and oversight were continually scrutinized, concerns over informed consent appeared to fall by the wayside. In 2001, a panel comprised of members of the Government Affairs Investigations Subcommittee convened before Congress to present findings of an extensive investigation into the operation of U.S. tissue banks.¹¹⁹ Beyond presenting gross incidents of unsafe and improper processing of human cadaver tissue, the chairperson of the Investigations Subcommittee expressed her greatest concern as not knowing the true scope of the problem, in that the number

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ MCDERMOTT Newsletter, *supra* note 25.

¹¹⁶ *Id.*

¹¹⁷ Indech, *supra* note 101, at 351.

¹¹⁸ MCDERMOTT Newsletter, *supra* note 25.

¹¹⁹ *Congress Examines Tissue Banking*, *supra* note 54.

of tissue banks was virtually unascertainable.¹²⁰ Members of the subcommittee appealed to the FDA to significantly augment tissue bank inspections in addition to expanding existing regulations.¹²¹ For the first time, the FDA introduced regulations that permit the agency to close non-compliant tissue banks.¹²²

In 2003, several constituencies were once again called before Congress to share information and address concerns over current shortcomings in the industry.¹²³ Resulting from this convocation was the first rule of the FDA's "tissue system" which became effective on January 21, 2004. Entitled "Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products," this rule requires designated tissue banks to both register with the FDA and provide a list of its HCT/P-based products.¹²⁴ Under this rule, entities that use HCT/Ps in the manufacturing¹²⁵ of drugs, medical devices except for human dura matter and human heart valves, hematopoietic stem cells from peripheral and cord blood, or reproductive cells and tissue were required to register and list with the FDA by March 29, 2004.¹²⁶

In addition, effective May 25, 2005 is the second rule, "Suitability Determination for Donors of Human Cellular and Tissue-Based Products."¹²⁷ This rule aims to significantly reduce the use of contaminated tissues through the use of donor pre-screening and tissue sample testing. It is further designed to increase public confidence in the use of tissue-based products in medical

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² *Id.*

¹²³ *Id.*

¹²⁴ 21 C.F.R. §1271 (2004).

¹²⁵ *FDA Q&A on GTP, supra* note 39, (The term "manufacture" is much broader than one might imagine. In this context manufacturing is defined as "all establishments that recover, process, store, label, package or distribute HCT/Ps, or that screen or test the donor of the HCT/P." However, despite its broad definition, certain tissue entities are able to escape its reach).

¹²⁶ *FDA Q&A on GTP, supra* note 39, (Human dura matter and heart valves are classified as special types of "medical devices" and are regulated under 21 C.F.R. § 820).

¹²⁷ 21 C.F.R. 1271, Subpt. C (2005).

procedures.¹²⁸ Under this new rule, donor tissue may not be transplanted or dispensed until the donor is deemed eligible.¹²⁹ Potential donors must be screened and tested for what the FDA terms, “relevant communicable disease agents and diseases”¹³⁰ Screening includes both a review of the potential donor’s medical and social history. Testing involves a review of autopsy reports if applicable, in addition to the actual testing of recovered tissue.¹³¹

Also effective May 25, 2005 is the FDA’s long-awaited Good Tissue Practices.¹³² GTPs set forth specific programs and guidelines that aim to ensure the quality control of tissue facilities and the personnel who operate them.¹³³ Through GTPs, the FDA desires to increase public health and safety.¹³⁴ By issuing GTPs, the FDA has extended its regulatory reach to certain tissue institutions that have not been subject to FDA regulation in the past, including certain entities specializing in reproductive tissue.¹³⁵ The GTPs additionally give the FDA a heavier hand as the enforcement agency of the industry in that under this rule it may take actions against non-compliant tissue banks in the form of “orders of retention, recall, destruction, or cessation of manufacturing.”¹³⁶

B. The American Association of Tissue Banks

Founded in 1976, the American Association of Tissue Banks (AATB) is a “scientific, not-for-profit, peer group organization.”¹³⁷ The AATB maintains that its most important mission is “the establishment and promulgation of Standards to provide tissue banks with performance

¹²⁸ *FDA Q&A on GTP*, *supra* note 39, at ¶ 4.

¹²⁹ *Questions and Answers for Donor Eligibility Final Rule and Draft Guidance*, U.S. Food and Drug Administration, available at <http://www.fda.gov/cber/rules/suitdonorq&a.htm>, [hereinafter *FDA Q&A Donor Eligibility*], (Human dura matter and heart valves are classified as special types of “medical devices” and are regulated under 21 C.F.R. § 820.).

¹³⁰ To be codified at 21 C.F.R. pt. 1271.3.

¹³¹ *FDA Q&A on GTP*, *supra* note 39, at ¶ 9.

¹³² To be codified at 21 C.F.R. § 1271 Subparts D, E, and F

¹³³ *FDA Q&A on GTP*, *supra* note 39, at ¶ 1.

¹³⁴ *Id.*

¹³⁵ *Id.* at ¶17.

¹³⁶ *Id.* at ¶ 20.

¹³⁷ AATB Website, *supra* 21.

requirements intended to prevent disease transmission and help ensure optimum clinical performance of transplanted cells and tissues.”¹³⁸ Additionally, the AATB promotes education and research to ensure quality and safety in both tissue banking and transplantation.¹³⁹ The AATB sustains a continual dialogue with the FDA regarding tissue banking procedures and the FDA provides informal oversight of certain AATB programs.¹⁴⁰

The AATB operates both an accreditation program for tissue banks and a certification program for tissue bank personnel.¹⁴¹ Both programs implement the promulgated Standards of the Association of Tissue Banking. The accreditation program, established in 1986, examines tissue bank operations to include “retrieval, processing, storage, and/or distribution of tissue.”¹⁴² Tissue banks applying for AATB accreditation must pass to a series of inspections. The personnel certification program is designed to ensure the qualification and proficiency of tissue bank technicians. Tissue bank personnel seeking certification are subject to a written examination that tests knowledge of donor and tissue suitability, tissue processing, decontamination techniques, and labeling.¹⁴³

At first glance, the thoroughness of the AATB’s accreditation and certification programs suggests that the tissue banking industry is well regulated. Alarming however, even under the FDA’s new “Tissue System,” tissue banks in the United States are currently not required to seek accreditation.¹⁴⁴ Similarly, bank personnel are not required to become certified. The AATB website lists 86 accredited banks. It is speculated that there are significantly more tissue banks

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ Joyce, *supra* note 100.

¹⁴¹ AATB Website, *supra* note 21.

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ Currently only New York and Florida both license and inspect tissue banks. These states subject tissue banks to inspection and a mandatory reporting system for “adverse incidents.” California, Georgia, and Maryland require tissue banks to be licensed. WILBERT A. GORDON, 3 ORTHOPEDIC TECH. REV. NO. 5, *Tissue Banks: Establishing a Uniform Code*, (2001) available at www.orthopedictechreview.com/issues/sep0ct01/pg32.htm.

in the United States, the number of non-accredited banks is less than certain. This prospect is frightening. The FDA should press beyond its mere dialogue with the AATB and coordinate a system of mandatory accreditation, however, legislation would be required here. At a minimum, the FDA should offer tissue banking entities incentives that encourage such organizations to seek AATB accreditation in the form of training opportunities and resources.¹⁴⁵

V. The Current State of Tissue Banking Regulation: Why it is Not Enough

Until recently, post-mortem tissue regulation on both the Federal and state levels has been largely sporadic.¹⁴⁶ Even with the advent of newly promulgated regulations, the industry still lacks the appropriate controls. The new regulations and GTPs fail to reach a number of issues. Most notably, the GTPs fail to require the accreditation of tissue banks.¹⁴⁷ While registration is now required and most tissue banks are subject to both unannounced and scheduled FDA inspections, the agency does not mandate AATB or any type of accreditation for tissue banks.¹⁴⁸ In its final rule in the Federal Register, the FDA concedes that “there are currently no comprehensive monitoring or enforcement mechanisms governing establishments that choose not to follow voluntary industry standards or seek accreditation, and that may produce and distribute for use HCT/Ps that may present a serious threat to public health and safety.”¹⁴⁹ This has not changed under the system that takes full effect May 25, 2005.

Next, despite the availability of this state-of-the-art technology, the new regulations do not require the three-component sterilization process. Through ultrasound, heat and pressure,

¹⁴⁵ *OIG Report on Informed Consent*, *supra* note 7, at iii.

¹⁴⁶ Charo, *supra* note 1, at 424.

¹⁴⁷ Email from Scott A. Brubaker, CTBS, Chief Policy Officer, Association of Tissue Banks, to _____ (April 18, 2005).

¹⁴⁸ *FDA Q&A for GTP*, *supra* note 39, (Rollout Inspections may include “an assessment of the establishment’s facilities, equipment, finished and unfinished materials, containers, processes, HCT/Ps, procedures, labeling, records, files, papers and controls required to be maintained under the regulations. FDA representatives may review and copy any records required to be kept under 21 C.F.R. pt. 1271. Financial and personnel records are not required records under pt. 1271).

¹⁴⁹ *GTP Proposed Rule*, *supra* note 76, at 68651.

technicians are now able to completely rid tissue samples of viral and bacterial contamination.¹⁵⁰ Many members of the tissue banking community called for the FDA to mandate the use of this process in the new regulations. Some even feel that because it is available, the industry is obligated to implement it.¹⁵¹ However, the FDA declined to address the availability of this new technology in its new “Tissue System.”

Additionally, the new regulations fail to address two ethical concerns. First, industry leaders had hoped the new regulations would strengthen donor consent procedures, a problem spanning the industry.¹⁵² Second, there were also requests that the new regulations would require tissue banks to disclose financial and personnel records.¹⁵³ The lack of availability of such documents fuels the public distrust of an already questionable industry.¹⁵⁴ It is of note that while the new regulations do not specifically prescribe methods for the ethical handling of tissue, certain procedures will necessarily improve the ethical handling of deceased donor tissue. For example, advocates for the respectful treatment of donor remains urge that all donor tissue be marked “donated human tissue.”¹⁵⁵ Regulations requiring such identification in an effort to alert handlers and processors to potential diseases, simultaneously address this ethical concern. However, concerns for the ethical handling of donated tissue should be more than a by-product of safety requirements.

Most alarmingly, the new regulations appear to leave a crack large enough for many of the dreaded “middle men” to slip through. As noted before, the new regulations do not adequately reach organizations that limit their activities to the storage and transportation of

¹⁵⁰ Gordon, *supra* note 144.

¹⁵¹ *Id.*

¹⁵² *OIG Report on Informed Consent, supra* note 7, at 2.

¹⁵³ *Id.* at 15.

¹⁵⁴ *Id.*

¹⁵⁵ *OIG Report on Informed Consent, supra* note 7, at iv.

human tissue.¹⁵⁶ Nothing in the new regulations prevents tissue brokers from procuring post-mortem human tissue and selling at an inflated price. It is quite possible that under the FDA's new "Tissue System," willed-body scandals, Florence Sedgwick-like scenarios and transplantation of diseased tissues will persist.

Finally, critics believe the FDA does not have the budget or manpower to implement the new regulations.¹⁵⁷ At times the FDA has borrowed money from other programs such as plasma and blood for use in regulating the tissue industry.¹⁵⁸ The FDA has itself referred to its duty to regulate tissue banking "an unfunded mandate."¹⁵⁹ While the FDA has the authority to inspect all tissue facilities, it does not have adequate funding to do so.¹⁶⁰ The Federal Government must provide the FDA with the necessary resources to thoroughly regulate the tissue banking system

VI. Conclusion

The dawn of our third millennium has witnessed the emergence of technology, which must be accompanied by commensurate responsibility. What was once taken for granted now yearns for a measure of oversight. The matter of the regulation of cadavers, organs, and tissue finds itself in the midst of this balancing act.

The ultimate goal must be to safely maximize organ and tissue donation while ensuring that donor expectations are realized.¹⁶¹ The safe processing of tissue may not be possible without some measure of profit, however regulations should prevent profiteering and exploitation. The FDA's new "Tissue System" is a positive step toward that end. However, the Federal Government must provide the FDA with the appropriate resources so that it may serve in

¹⁵⁶ MCDERMOTT Newsletter, *supra* note 25.

¹⁵⁷ *OIG Report on Oversight*, *supra* note 40, at ii-iii.

¹⁵⁸ *Id.* at ii.

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ *OIG Report on Informed Consent*, *supra* note 7, at iii.

its essential role. Federal Regulations require further amendment in the aforementioned ways to ensure the effectiveness of this important industry.