



FDA Oversight of the Tissue Bank Industry

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FDA Oversight of the Tissue bank industry

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ABSTRACT:

Organ donation is regulated zealously, but when it comes to tissue donation, there is little oversight. Lack of proper oversight and mandated guidelines in the human tissue industry is problematic as human tissue can transmit disease. In the early 1990s, several disasters motivated the FDA to provide for an overall regulatory regime in an industry it once declined to regulate at all. However, it is estimated that industry revenue will rise to \$1 billion annually by 2003; up from \$20 million a decade ago. This industry explosion, fueled by biomedical innovation and the entry of for-profit companies, has put added pressure on the FDA to advance more thorough regulatory standards to protect human health and safety. In response, the FDA has advanced a proposed regulatory approach that would address a broader scope of products, include more comprehensive requirements to prevent the transmission of communicable disease, and apply tiered requirements based on the characteristics of such products. However, until the proposed rules are finalized, tissue banks have no external requirements for quality and handling of tissue if they are not accredited by private organizations or licensed by New York or Florida. Furthermore, the human tissue industry is an unfunded mandate and the FDA lacks adequate resources to enforce published standards and regulations. To date, the FDA has chosen not to impose user fees on the industry, though the possibility remains. In the meantime, organ procurement organizations look on with more than benign interest at the developments within the tissue banking industry. Their worry is that negative public image directed at the human tissue industry will be shared unfairly by their industry as the general public does not differentiate between tissue donation and organ donation.

TEXT:

I. INTRODUCTION

On November 9, 2001, 23-year old Brian Lykins died after receiving donor knee tissue contaminated with *clostridia sordelli*, a close relative of the bacteria that cause gas gangrene.¹ In July 2000, Florida-based tissue bank, Regeneration Technologies, announced plans to combine bone and tissue products from multiple donors, despite fears that the process spreads disease.² In 2001, federal investigators reported some human tissue banks repeatedly retest tissue until it complies with safety regulations, a process that is scientifically unsound and unsafe.³

To the uninitiated, the above examples represent what must be stark violations of safety standards imposed by the Food and Drug Administration (FDA), the powerful federal agency whose mission is to: “[P]romote and protect the public health by helping safe and effective products reach the market in a timely way, and monitoring products for continued safety after they are in use.”⁴ However, quite to the contrary, the tissue banks involved in the above examples have committed no violation of pertinent FDA regulatory standards in effect at the time.

Donations of organs like hearts and livers are regulated zealously, but when it comes to human tissues – ligaments, tendons, bones, skin and other body parts – there is little oversight.⁵ As if to emphasize the yawning regulatory hole, an increasing number of for-profit companies have begun to compete with non-profit organizations in the collection and processing of donor tissue. This combination of insufficient regulatory oversight and a booming private industry, worries a growing number of experts, who note that improperly

¹See Sandra Blakeslee, *Lack of Oversight In Tissue Donation Raising Concerns*, N.Y. TIMES, Jan. 20, 2002, at Section 1 Page 1.

²See generally Mark Katches, *Mixing bones from several bodies defies tissue banks’ regulations*, THE ORANGE COUNTRY REGISTER, Jul. 9, 2000.

³See John A. MacDonald, *Human Tissue Banks’ Safety Questioned, Federal Monitoring Called ‘A Shot in the Dark’*, THE HARTFORD COURANT, May 25, 2001, at A2.

⁴See FDA (visited March 6, 2002)<<http://www.fda.gov/opacom/hpview.html>>.

⁵See Blakeslee, *supra* note 1.

handled tissue can transmit dangerous, even lethal infections.

The purpose of this paper is to examine the present state of the human tissue industry and the FDA's efforts to regulate the burgeoning industry. The paper begins with a background discussion about the human tissue industry and the tremendous growth being experienced by the industry. The paper then highlights the major historical developments of FDA's regulatory regime, then briefly examines alternative regulatory bodies, such as professional societies and the States. Finally, the paper will look at the challenges faced by the FDA as it seeks to provide effective oversight in an area that is currently an unfunded mandate.

II. BACKGROUND

A. What Is Tissue Donation?

Tissue donation includes anything from the human body that is not a vital organ.⁶ This includes blood vessels, bone, bone marrow, connective tissues, corneas, heart valves, middle ears, and skin.⁷ Body parts that fall under the broad area of tissue donations can be harvested, sterilized, processed and cut into more than a hundred different pieces, then offered fresh, frozen or freeze-dried for use in more than 400 different surgical procedures.⁸ Accident victims in need of reconstructive surgery would be one example of the kind of surgical procedure that rely on donated tissue.

In 1999, the number of tissue donors reached 20,000, up from 6,000 in 1994.⁹ One organ and/or tissue donor can help more than 50 people.¹⁰

⁶ *Tissue Banks: Industry Needs Greater FDA Regulation*, AMERICAN HEALTH LINE, Jan. 8, 2001.

⁷ See U.S. Department of Health and Human Services, *Organ & Tissue Donation* (visited March 12, 2002) <<http://www.organdonor.gov/TissueDonorBrochureNewCard.pdf>>.

⁸ Pam Adams, *Organ Donations Raise Ethical Issues*, COPLEY NEWS SERVICE, Dec. 18, 2000.

⁹ See AMERICAN HEALTH LINE, *supra* note 6.

¹⁰ See Adams, *supra* note 8.

B. Compare with Organ Donation

Given the industry's involvement in the harvesting of human body parts, the public often incorrectly analogizes tissue donation to organ donation. However, organ and tissue donation are different, both in the way they are regulated and in their clinical application.

Organ donation is strictly regulated and organ procurement organizations (OPOs) closely align their operations in support of the public interest. The process itself is life-saving. Unfortunately, donor organs are not readily available. Over 80,000 Americans are waiting for life-saving organ transplants.¹¹ Tissue donation on the other hand is life-enhancing. The tissue banks that are largely responsible for the industry are not as closely aligned to the public interest, and the for-profit tissue banks operate with an eye to maximizing returns. In addition, there is no comparable shortage of tissue for donation, or urgency for tissue transplants.¹²

Despite the differences between the two industries, to protect the future of both the industries, it is imperative that the tissue banking industry is held to the same high standards as the organ procurement industry. This is because negative public perception of the tissue banking industry can jeopardize organ donation. For example, at a hospital in Florida, the reported activities of a local tissue bank caused a family to decline their option of organ donation.¹³

C. Tissue Donation and Disease

Lack of proper oversight and mandated guidelines for tissue donation procedures has proven problematic as

¹¹ See American Medical Association (March 15, 2002) <<http://www.ama-assn.org/ama/pub/category/1945.html>>.

¹² *Prepared Testimony of William Minogue, M.D. Chairman, Board of Directors, Washington Regional Transplant Consortium*, FEDERAL NEWS SERVICE, May 24, 2001.

¹³ *Id.*

human tissue can transmit disease. Over the years, the FDA has published a series of rules and guidelines to better protect public health and safety in this burgeoning field. In essence, FDA oversight has attempted to ensure that human tissue pieces conform to strict federal safety standards to prevent the spread of communicable diseases such as HIV and hepatitis.

II. INDUSTRY GROWTH

A. The Growth

The National Organ Transplant Act makes it illegal to buy and sell organs and tissue.¹⁴ It does, however, allow tissue agencies to charge reasonable fees for collecting, shipping, processing, marketing and implanting them.¹⁵ This loophole has helped to fuel a fast-growing industry in which body parts are more likely referred to in terms of *products* and *profits* than as charitable "gifts."¹⁶

Gifts of cadaveric tissue from generous families to private and not-for-profit tissue banks have evolved into a multimillion dollar industry where one tissue donor can easily yield about \$80,000 worth of tissue "products," not including organs, for a commercial business.¹⁷ One body can yield more than 130 pieces of tissue once it is extracted, sterilized, cut up, packaged and sold.¹⁸ The processing fee for a cornea is \$1,600 in Illinois. A heart valve can go for as high as \$4,000. A piece of cartilage for knee surgery can range from \$1,000 to \$4,000 and an Achilles tendon can run from about \$900 to \$2,000, depending on the supplier.¹⁹

A decade ago tissue industry revenue totaled \$20 million, but by 2003 it is estimated that revenue will rise

¹⁴Mike Dorning, *Body Parts Trade Faces U.S. Probe*, CHICAGO TRIBUNE, Jun. 9, 2000, at N1.

¹⁵See Blakeslee, *supra* note 1.

¹⁶See Adams, *supra* note 8.

¹⁷*Id.*

¹⁸See Stephen J. Hedges and William Gaines, *Donor Bodies Milled Into Growing Profits*, May 21, 2000, at C1.

¹⁹See Adams, *supra* note 8.

to \$1 billion annually.²⁰ Revenues of the nation's 10 largest non-profit tissue banks and organ banks dealing in tissue totaled \$230 million in 1998, the last year for which figures are publicly available. Two years prior to that, those same organizations reported revenues of \$183 million.²¹

The engine driving this market growth is biomedical innovation.²² Tissue is being put to new uses, and processing has grown more sophisticated. Entrepreneurial firms have stepped in to develop and market new products and treatments from human tissue.²³ A handful of companies have patented techniques for turning tissues into extremely useful products, like bones that are tooled into special shapes or ground into powders and pastes.²⁴

B. Entry of For-Profit Tissue Banks

An increasing number of for-profit companies are now competing with non-profits for this processing business. This stiff competition can result in use of medically questionable tissue by firms that have a financial interest in producing as much material as they can.²⁵ As stated by Dr. William Minogue, board chairman for the Washington Regional Transplant Consortium, "These organizations often operate from profit motives that supersede the public interest."²⁶ Indeed, for-profit entities need access to human tissue in order to generate revenue and are under shareholders' pressure to increase their market position to maximize profits. These companies are not required to take the overall donation interests of the public into account and, unlike

²⁰Ellen Beck, *FDA Told To Do More Tissue Bank Inspections*, UNITED PRESS INTERNATIONAL, May 24, 2001.

²¹See Hedges and Gaines, *supra* note 18.

²²See Blakeslee, *supra* note 1.

²³*Prepared Testimony of George F. Grob Deputy Inspector General for Evaluation and Inspections U.S. Department Of Health and Human Services Before the Senate Committee on Governmental Affairs Permanent Subcommittee on Investigations*, FEDERAL NEWS SERVICE, May 24, 2001.

²⁴See Blakeslee, *supra* note 1.

²⁵See Laura Meckler, *Congress Examines Tissue Bank Operators*, DAYTON DAILY NEWS, May 25, 2001.

²⁶*Id.*

OPOs, their boards have no requirements to represent the public interest.²⁷

C. Standards of Practice

Unfortunately, standards of practice have not kept pace with market growth and development.²⁸ As a result, for-profit corporations influencing tissue donation with questionable practices can hinder the overall organ and tissue donation process, and bring about serious negative consequences.

Local tissue and organ banks compete and even pay for access to hospitals, morgues and hospices where they can find families willing to donate a deceased loved one's remains.²⁹ In several states, funeral homes have gone into partnership with tissue banks.³⁰ If a family agrees to donate tissue, technicians trained by the tissue bank remove tissue at the funeral home. The level of training varies, but critics of the practice say many such technicians cannot identify problems like undiagnosed tuberculosis or cancer in donor bodies.³¹ The altruism of donation is further clouded by the complicated relationships that have developed between the non-profit and for-profit companies in the tissue business.³² Though donor families give a relative's tissue to a non-profit tissue bank, some of those groups turn around and sell the tissue to for-profit companies. It is not unusual for the non-profit and the for-profit to have supply agreements, processing contracts and formal partnerships.³³

²⁷ See Minogue, *supra* note 12.

²⁸ See Grob, *supra* note 23.

²⁹ See Hedges and Gaines, *supra* note 18.

³⁰ *Unregulated Tissue Donations Concern Federal and State Officials*, DEATH CARE BUSINESS ADVISOR, Feb. 21, 2002.

³¹ *Id.*

³² See Hedges and Gaines, *supra* note 18.

³³ *Id.*

III. FDA REGULATION

As the industry continues to advance, problems stemming from a lack of regulatory oversight grows more acute. Over the last decade, the FDA has responded to the increasing pressure and advanced regulatory standards in an industry where it once declined to regulate at all. Currently, the FDA regulates the tissue industry through the Center of Biologics Evaluation and Research (CBER). However, it has taken the FDA many years to decide upon the appropriate regulatory paradigm. Only until very recently, has the FDA developed comprehensive protection of the public through guidance to the tissue industry.

A. Early Regulatory Decisions

Prior to 1993, the FDA regulated most cellular and tissue-based products on a case-by-case basis.³⁴ When regulation of a certain tissue-based product was deemed necessary, the FDA did so under existing regulatory schemes. This ad-hoc approach led to fragmented and sometimes inconsistent results. For example, the FDA regulated some products as medical devices – such as dura mater and heart valves – and subjected them to all applicable medical device provisions, including pre-market notification.³⁵ However early tissue banking operations involving products such as eye and bone tissue were not regulated.³⁶ The FDA had no *general* policy as to which tissue products would be subject to any particular regulatory requirement.

³⁴See Martha A. Wells, *Overview of FDA Regulation of Human Cellular and Tissue-Based Products*, 52 Food & Drug L. J. 401 (1997).

³⁵See Isabel P. Dunst & Robert P. Brady, *Human Cellular and Tissue Products: Regulation, Coverage, and Reimbursement*, J. BIOLAW & BUS., Winter 1999, at 6.

³⁶D. Michael Strong, *Tissue Banks: Drafting New Rules for Grafting*, BUS. & SOC'Y REV., Sept. 22, 1991.

B. 1993 Interim Rule

In the early 1990s, two events spurred FDA into action. First, AIDs-tainted body parts distributed by LifeNet, a reputable Virginia organ recovery agency, killed 3 people in 1991.³⁷ Around the same time, FDA receive reports of tainted foreign tissue being imported into the United States without adequate testing and screening.³⁸

In response to these serious problems, on December 14, 1993, the FDA promulgated its Interim Rule on Human Tissue Intended for Transplantation.³⁹ The Agency did so under Section 361(a) of the Public Health Service (PHS) Act of 1944, which authorizes “regulations . . . necessary to prevent the introduction, transmission or spread of communicable diseases...” In accordance with that authority, the FDA required all tissue banks perform serological tests to screen for viruses such as hepatitis and HIV.⁴⁰ The importation of tissue from abroad also became prohibited unless it has been shown to meet all FDA requirements.⁴¹ The regulations also outlined criteria for tissue donor selection, and authorized the FDA to inspect any facility that recovers, processes or distributes tissue for transplant. A tissue bank that refuses to allow FDA inspection may be prosecuted under Section 368 of the PHS Act.⁴²

The rules were effective immediately and included “conventional” banked tissue, such as skin, bone, and eye. Excluded from the rule was vascularized organs, human milk, reproductive tissue, and bone marrow. Also excluded were products regulated as drugs, biological or medical devices.⁴³

³⁷ See Bill Sizemore, *Body Parts: Big Business Medical Advances and a Growing Willingness to Donate Organs Have Bolstered the Largely Unregulated Trade of Human Parts*, THE VIRGINIAN-PILOT, Apr. 29, 2001.

³⁸ Christopher Joyce, *FDA Will Regulate Importation of Human Tissue*, NPR – Weekend Edition, Dec. 11, 1993.

³⁹ 58 Fed. Reg. 65513

⁴⁰ See Antonio Pereira, M.D., *Overview of FDA Regulation of Bone as a Tissue*, PPT Slide Presentation, Aug. 2, 2000; also see FDA (visited March 17, 2002) <<http://www.fda.gov/cber/summaries/pereira080200.htm>>.

⁴¹ See Joyce, *supra* note 38.

⁴² *Prepared Statement of Bob Rigney Chief Executive Officer of The American Association of Tissue Banks (AATB) Before the Senate Committee on Governmental Affairs, The Permanent Subcommittee of Investigations*, FEDERAL NEWS SERVICE, May 24, 2001.

⁴³ See Pereira, *supra* note 40.

C. 1997 Final Rule

On July 29, 1997, the FDA issued its final regulations (21 CFR 1270) that were broader in scope than its interim rule. The final regulations cover *all* facilities that are engaged in the recovery, screening, testing, processing, storage or distribution of human tissues. It required that specified minimum required medical screening and infectious disease testing be performed. Records documenting such screening and testing for each human tissue must be available for inspection by the FDA. For human tissue that is imported, the importer must notify the director of the FDA district that has jurisdiction over the port of entry through which the tissue is imported or offered for import. All imported tissue must be quarantined until the FDA releases it.⁴⁴

The 1997 final rule also requires tissue banks to permit inspection by authorized FDA inspectors of its facilities, equipment, processes, products and all records necessary to determine compliance with the regulation. These inspections can be made without notice; the frequency of the inspections is left to the agency's discretion. Upon finding that human tissue may be in violation of the FDA's regulations, the agency may serve the tissue bank with an order for recall and/or destruction, or it may take possession of and/or destroy the tissue in question.⁴⁵

FDA has not extended its regulation to Organ Procurement Organizations (OPOs), nor has it covered hospitals or other clinical facilities that only receive and store human tissue for transplantation within the same facility. However, hospitals or clinics that participate in recovery, screening, testing, processing, or distribution of human tissue in addition to storage for transplantation are covered by the rule.⁴⁶

The Final Rule was made effective on July 29, 1997.

⁴⁴ See Rigney, *supra* note 42.

⁴⁵ *Id.*

⁴⁶ *Id.*

D. Proposed Rules

The scope of FDA's current regulation (21 CFR Part 1270) is limited to donor screening and testing to prevent transmission of HIV and Hepatitis.⁴⁷ However the FDA recognizes that, stricter standards for tissue donor suitability should be imposed. Unlike organ transplants which are life-saving, tissue transplants are, for the most part, life-enhancing. Therefore, if tissue donor evaluation and recovery practices are unsafe, a recipient can be subjected to unnecessary risk.

To address identified regulatory deficiencies, the FDA is in the process of revising 21 CFR Part 1270. The proposed regulatory approach would address a broader scope of products, include more comprehensive requirements to prevent the transmission of communicable disease, and would apply tiered requirements based on the characteristics of such products. Three proposed regulations currently comprise the new regulatory regime being considered:

a. Registration Proposed/Final Rule

In 1998, the FDA published the proposed rule "*Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products*." The proposed rule required cell and tissue establishments to register with the FDA and submit a list of their human cellular and tissue-based products. Final rules for this measure was issued on January 19, 2001 and made effective April 4, 2001 for establishments previously regulated – bone, skin, corneas, tendon; reproductive establishments have until January 2003 to register. In compliance with the new regulation, at least 387 tissue banks have registered with the FDA as of August 2001.⁴⁸ This number is far in excess of the 154 tissue banks identified by the Office of Inspector General

⁴⁷See Grob, *supra* note 23.

⁴⁸See Martha A. Wells, *Update on the Implementation of FDA's Establishment Registration and Product Listing Regulation*, Slide Presentation, Aug. 28, 2001; or see <<http://www.fda.gov/cber/summaries/wellsaatb.htm>>.

in a report published in early January 2001.⁴⁹ Part of the reason lies in the fact that some tissue banks have multiple sites registered. Additionally, many banks that are not required to register – for example, if they supply tissue *only* for research – have nonetheless registered. Finally, there are at least 71 eye banks included in the count and eye banks were not covered by the Inspector General’s report.⁵⁰

b. Donor Suitability Proposed Rule

Proposed rule for “*Suitability Determination for Donors of Human Cellular and Tissue-Based Products*” was issued on September 30, 1999. The proposed regulation would require tissue banks to test for communicable disease: HIV 1/2, Hepatitis B/C, Treponema Pallidum, HTLV I/II, CMV, Chlamydia Trachomatis, and Neisseria Gonorrhoea. Also required will be donor screening for risk factors and clinical evidence of disease for: HIV, Hepatitis B/C, CJD, Chlamydia trachomatis, and Neisseria gonorrhoea.

c. Current Good Tissue Practices (CGTP) Proposed Rule

Issued on January 8, 2001, the proposed new rule for “*Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products*” outlines the following key elements:

1)

Establishment of a quality program, which would evaluate all aspects of the firm’s operations, to ensure compliance with GTP;

2) Maintenance of an adequate organizational structure and sufficient personnel;

3) Establishment of standard operating procedures for all significant steps in manufacturing;

4) Maintenance of facilities, equipment and the environment;

⁴⁹See OIG, *Oversight of Tissue Banking*, Jan. 200; located at <<http://www.fda.gov/cber/tissue/ovrst0101.pdf>>.

⁵⁰See Wells, *supra* note 48.

- 5) Control and validation of manufacturing processes;
- 6) Provisions for adequate and appropriate storage;
- 7) Record keeping and management;
- 8) Maintenance of a complaint file;
- 9) Procedures for tracking the product from donor to recipient, and from recipient to donor.⁵¹

Not included in the FDA's 3-tiered requirements are organs, bone marrow, xenografts, blood, and secreted/extracted products.⁵²

IV. OTHER REGULATORY BODIES

A. Private Accreditation

a. American Association of Tissue Banks

The American Association of Tissue Banks (AATB) is a scientific, not-for-profit, peer group organization founded in 1976 to facilitate the provision of transplantable cells and tissues of uniform high quality in quantities sufficient to meet national needs.⁵³ The Association is not affiliated with, supported by, or chartered by the Government. At the core of its mission is public health – the AATB is dedicated to ensuring that human tissues intended for transplantation are safe and free of infectious disease, of uniform high quality,

⁵¹ *FDA Proposes New Rules for "Good Tissue Practice"*, FDA TALK PAPER, Jan. 5, 2001; also see <<http://www.fda.gov/bbs/topics/ANSWERS/ANS01062.html>>.

⁵² See Jesse L. Goodman, FDA and Tissues in the Year 2000, PPT Slide Presentation, Oct. 3, 2000; also see FDA (visited March 17, 2002) <<http://www.fda.gov/cber/summaries/goodman92000.htm>>.

⁵³ See AATB (visited March 13, 2002) <<http://www.aatb.org>>.

and available in quantities sufficient to meet national needs.⁵⁴

To ensure that tissue banking activities are performed in a professional manner, the AATB initiated a program of Inspection and Accreditation of tissue banks in 1986.⁵⁵ Accreditation addresses not only donor screening and testing practices, but operational and organizational aspects, such as qualifications of tissue bank personnel and banks' safety practices, equipment testing, facilities, labeling, and quality assurance programs.⁵⁶ To comply with antitrust laws, the AATB does not differentiate between for-profit and not-for-profit tissue banks. Indeed, the current list of AATB accredited tissue banks includes both for-profit and not-for-profit entities.⁵⁷

Seeking accreditation is purely voluntary and currently only 58 tissue banks are accredited.⁵⁸ The remaining banks are under no obligation to meet the standards or policies set by the association, and for many banks there is no incentive to seek accreditation.⁵⁹

Despite the relatively low participant ratio, the safety record established by the AATB's accredited members demonstrate great promise. During the past seven years, tissue banks accredited by the AATB have distributed more than four million allografts to surgeons without a single reported case of disease transmission from donor to recipient.⁶⁰

b. Eye Bank Association of America

The Eye Bank Association of America (EBAA) is a not-for-profit organization of eye banks dedicated to the restoration of sight through the promotion and advancement of eye banking.⁶¹ Established in 1961 by the American Academy of Ophthalmology's Committee on Eye Banks, the EBAA is the oldest national

⁵⁴ See Rigney, *supra* note 42.

⁵⁵ See AATB (visited March 13, 2002) <<http://www.aatb.org/aatbaccr.htm>>.

⁵⁶ See Grob, *supra* note 23.

⁵⁷ See Rigney, *supra* note 42.

⁵⁸ See Grob, *supra* note 23.

⁵⁹ *Id.*

⁶⁰ See Rigney, *supra* note 42.

⁶¹ See EBAA (visited March 16, 2002) <<http://www.restoresight.org>>.

association of transplantation organizations in the United States.⁶² The EBAA developed medical standards in 1980 and since then, has continuously reviewed and revised those standards to reflect medical and technological advancements.

The EBAA currently represents 92 U.S. eye bank organizations (or 99 percent of the entire domestic eye banking community), and provides 97 percent of all corneal tissue for transplantation.⁶³ All eye banks are non-profit 501(c)(3) organizations whose mission is to procure and provide donated human eye tissue for sight restoring transplantation procedures.

Like the AATB, the EBAA routinely inspects its member organizations to ensure compliance with the association's prescribed standards.

B. States

New York and Florida are the only two States that operate oversight programs requiring that tissue banks be licensed and inspected. A few states, including California, Georgia and Maryland, require that banks be licensed, either as tissue banks or as laboratories.⁶⁴

a. New York

New York's Tissue Resource Program was established in 1990.⁶⁵ Pre-dating FDA's 1993 interim rules, the New York program is the first comprehensive oversight program for tissue banks in the country and maintains

⁶²See EBAA (visited March 16, 2002)<http://www.restoresight.org/general/about_ebaa.htm>.

⁶³See EBAA (visited March 16, 2002)<<http://www.restoresight.org/newsroom/newsroom.htm>>.

⁶⁴Office of Inspector General, *Oversight of Tissue Banking*, January 2001 at 5.

⁶⁵Following enactment of the State's Public Health Law Article 43-B.

the most rigorous standards by far. Under New York regulations,⁶⁶ all tissue banks seeking licensure within the state are required to establish a very rigid organizational structure, tissue tracking and mandatory blood testing of tissue donors.⁶⁷

In addition to meeting FDA requirements to screen and test for HIV and hepatitis, New York requires banks to test for HTLV and syphilis. New York also requires tissue banks to meet specific standards for each type of tissue – musculoskeletal, cardiovascular, and skin – that the bank procures, processes, or stores. These standards relate to donor qualifications, tissue retrieval processes, laboratory testing, and disposal of unused tissue.⁶⁸

Licensure requires an initial application and on-site survey. Tissue banks do not pay a fee for licensure, but they must provide an annual report of statistics on procurement, processing and distribution.⁶⁹

b. Florida

Licensing of tissue banks in Florida State is conducted by Florida's Agency for Health Care Administration. To obtain a license from the State, tissue banks must submit a \$1,000 non-refundable application fee. There is also an annual fee of 0.25% of gross Florida revenues, with a minimum of \$1,000 and a maximum of \$35,000.⁷⁰ Applicants must disclose the bank's ownership, as well as information on equipment and donor selection and testing criteria. Florida requires tissue banks to comply with current FDA regulations.

⁶⁶Part 52 of Title 10 of New York Codes, Rules and Regulations

⁶⁷See IIAM General Information (visited March 14, 2002)<<http://www.iiam.org/geninfo/backgrnd.htm>>.

⁶⁸Office of Inspector General, *Oversight of Tissue Banking*, January 2001 at 6.

⁶⁹*Id.*

⁷⁰*Id.*

V. ENFORCEMENT ISSUES

A. Regular Inspection and Enforcement

For nearly 8 years after the FDA's initial regulation of tissue in 1993, the tissue bank industry enjoyed a clean safety record in that no new cases of disease transmission through human tissue were identified. However, the death of Brian Lykins in November 2001 reinforced the point that despite significant regulatory advancements in the current system, the need for continued vigilance and monitoring remain.

In a 2001 study published by the Office of Inspector General⁷¹, several problems with current FDA oversight was identified:

1)

Some tissue banks have never been inspected by the FDA;

2) FDA lacks a prescribed cycle for reinspection of tissue banks;

3) The number and location of tissue banks are unknown;

4)

current scope of FDA's regulations are limited.⁷²

Even prior to Brian Lykin's infection by *clostridium sordelli*, FDA inspectors uncovered serious deficiencies in tissue banks' screening and testing practices.⁷³ A natural assumption would be that similar problems

⁷¹OIG report did not address eye or reproductive tissue.

⁷³See Grob, *supra* note 23.

exist at tissue banks not yet inspected by FDA inspectors. However, at the time of the Inspector General's study, only 118 tissue banks had ever been inspected by the FDA, and of that number, 68 were inspected only once.⁷⁴ Due to limited resources, the agency has established a priority list for follow-up inspections, focusing on banks with the most serious deficiencies.⁷⁵

Since the Inspector General's office issued their report, the FDA has begun inspecting all known tissue banks.⁷⁶ The initiative was facilitated when the FDA's Registration Rule became effective on April 4, 2001. Prior to requiring registration, the FDA had no effective method of locating, much less inspecting, all the tissue banks in operation.

B. Resource Restraints

Despite the acknowledged need to conduct adequate inspections of registered tissue banks, the FDA does not have enough money to regularly inspect all tissue banks.⁷⁷ FDA has indicated that because regulation of tissue banks is an unfunded mandate, it has had to borrow resources from other programs to carry out these inspections.⁷⁸

FDA officials budgeted \$4.35 million on inspections for 2001, but acknowledged the agency does not have enough money to inspect U.S. tissue banks as often as the agency would like.⁷⁹ The agency's goal for fiscal year 2001 was to inspect those tissue banks identified by the Office of Inspector General as never inspected and any other banks the new registration requirements bring to its attention.⁸⁰ According to Kathryn C. Zoon, the FDA's director of research, the ideal would be an inspection every two years. But due to lack of

⁷⁴Office of Inspector General, *Oversight of Tissue Banking* 7-8, January 2001 at 7-8.

⁷⁵See Grob, *supra* note 23.

⁷⁶*Id.*

⁷⁷See Laura Meckler, *Congress Examines Tissue Bank Operators*, DAYTON DAILY NEWS, May 25, 2001.

⁷⁸See Grob, *supra* note 23.

⁷⁹See MacDonald, *supra* note 3.

⁸⁰See Beck, *supra* note 20.

funding, the agency focuses on banks where problems were found in the past.⁸¹

Re-inspections are conducted by the FDA based on levels of risk.⁸² Tissue banks cited for violations and ordered to take corrective action are at the top of the re-inspection list, followed by tissue banks where voluntary corrective action was requested.⁸³

a. User Fees

To address budgetary shortages, the FDA has, in the past, attempted to introduce user fees to support the agency's cost of oversight. However, this measure was met with great resistance from the AATB, EBAA, and other non-profit organizations within the industry. Speaking before the Subcommittee on Regulation, Business Opportunities, and Technology on Capitol Hill, the National Head of Tissue Services of the American Red Cross, Randolph May, reiterated his organization's strong resistance to the idea of user fees. He noted that user fees were only introduced by the FDA after extensive negotiations with the for-profit pharmaceutical industry who were losing millions from the growing backlog of new drug applications awaiting review by the FDA.⁸⁴ When user fees were finally approved, it was not without significant benefit to the pharmaceutical industry: "There was a clear quid pro quo, in that in exchange for the user fees, the FDA would agree to hire 600 new inspectors and expedite the processing of new drug applications."⁸⁵ By contrast, Mr. May notes that the U.S. tissue banking industry is mostly comprised of tissue banks that are small, not-for-profit, community-based operations. These tissue banks depend on the public perception that donating the tissue of a deceased loved one is a humanitarian service, not a commercial activity. The fear is that the imposition of user fees for tissue banking would jeopardize this perception.⁸⁶

⁸¹ See MacDonald, *supra* note 3.

⁸² See Beck, *supra* note 20.

⁸³ *Id.*

⁸⁴ *Testimony October 15, 1993 S. Randolph May, Ph.D. National Head Tissue Services American Red Cross House Small Business Subcommittee: Regulation of Human Tissue Banks*, FEDERAL DOCUMENT CLEARING HOUSE CONGRESSIONAL TESTIMONY, Oct. 15, 1993.

⁸⁵ *Id.*

⁸⁶ *Id.*

Mr. Randolph May's arguments have been repeated by many others in the industry and the FDA has acknowledged these important points. However, the agency notes that its resources are limited and they must balance the benefits to be gained by allocating resource to tissue regulation against using those resources to address other risks. Indeed, enacting a statute without the necessary resources to establish the program and sustain it over time will not accomplish much. The FDA argues that user fees should be strongly considered as a funding mechanism and bear the majority of the cost. It points out that standard setting and other functions of a federal oversight program would provide real value to the tissue banking community in terms of public credibility and a level playing field, and it is fair to ask that community to bear the cost.⁸⁷

b. Possible Solutions

To date, the FDA has chosen not to impose user fees on the industry; though the possibility remains. The entry of for-profit companies into the tissue banking business has undercut at least part of the argument that the industry is filled with small not-for-profit organizations and the industry cannot sustain the cost of user fees. One must merely look to the \$173.3 million in revenue brought in by the four leading for-profit tissue companies in 1999.⁸⁸ As previously mentioned, in 1998, the revenue of the 10 largest not-for-profit organizations was \$230 million. Not only does the entry of for-profit organizations place increasing stress on the FDA's resources, but the amount of revenue they generate does more to undercut the public image that tissue donation is a humanitarian service and not a commercial activity than any user fees. On the other hand, there should be some incentive for tissue banks and for-profit enterprises to invest in the development of new and useful innovations in technology. In addition, the FDA recognizes the concern that user-fee costs would likely be passed on to consumers.⁸⁹

Perhaps the answer lies in a combination of user fees and greater collaboration with the States and private

⁸⁷ *Testimony October 15, 1993 Kathryn Zoon PhD Director of Center for Biologics Evaluation & Research FDA House Small Business Subcommittee: Regulation of Human Tissue Banks*, FEDERAL DOCUMENT CLEARING HOUSE CONGRESSIONAL TESTIMONY, Oct. 15, 1993.

⁸⁸ See Hedges and Gaines, *supra* note 18.

⁸⁹ See Zoon, *supra* note 81.

organizations such as the AATB and the EBAA. Experienced private entities, including professional societies and voluntary standard-setting or accrediting organizations, can provide valuable service to the agency, often at a lesser cost than it would take for the agency itself to carry out similar tasks.

VII. CONCLUSION

The need for greater regulatory oversight in the tissue banking industry has never been greater. Tissue donation has become a near billion-dollar-a year national industry and the entry of for-profit companies underscore the need for federal oversight to protect public health and safety. However, until FDA's CGTP and Donor Suitability proposed rule is finalized, tissue banks have no external requirements for quality and handling of tissue if they are not accredited by AATB, the EBAA, or licensed by New York or Florida. As such, it is imperative that the FDA work quickly to finalize their proposed rules.

In the meantime, organ procurement organizations look on with more than benign interest at the developments within the tissue banking industry. Their worry is that negative public image directed at the human tissue industry will be shared unfairly by their industry as the general public does not differentiate between tissue donation and organ donation.

At the crux of the problem of insufficient regulatory oversight, is the limited resources the FDA has at its disposal. Given the non-profit nature of much of the industry, and its reliance on donations of cadaveric tissue from generous families, user fees do not seem entirely appropriate. However, the FDA still has other avenues, such as professional societies and the States, that it can leverage to help ensure industry compliance with its newly proposed regulations.