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Regulation of the Human Tissue Industry: A Call for Fast-Track Regulations

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Regulation of the Human Tissue Industry: A Call for Fast-Track Regulations

Self-regulation by an industry-dominated accrediting body will, in our opinion, never be as rigorous nor as aggressive as Government regulation and consequently will not . . . as effectively protect the patients.

—Steven Anderson, President of Cryolife, before the Subcommittee on Regulation, Business Opportunities, and Technology, 103rd Congress, 1993.¹

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1. Ironically, in 2002, Cryolife was in the center of controversy concerning its manufacturing processes. The Centers for Disease Control uncovered twenty-six cases of bacterial infections resulting from human tissue processed by Cryolife. *Feds Zap Implant Tissue Supplier*, cbsnews.com, Aug. 15, 2002, at <http://www.cbsnews.com/stories/2002/08/15/health/main518794.shtml>.

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I. INTRODUCTION

Twenty-three-year-old Brian Lykins arrived at St. Cloud Hospital in St. Cloud, Minnesota for a routine cartilage transplant to repair a damaged knee.² Three days following surgery, Brian was dead. Scientists from the Centers for Disease Control (CDC) later determined the cause of death to be *Clostridium Sordellii*, a rare and toxic bacteria that lives in soil and human intestines.³ The CDC's investigation traced the source of infection to the donor of the transplanted tissue—a dead human body.⁴ The transplanted tissue was processed by Cryolife, one of the largest human tissue banks in the United States.

Conventional tissue banks process human tissues from cadavers and distribute the tissues to surgeons for transplantation.⁵ These products serve a crucial role in medicine, and they have the potential for providing important new therapies.⁶ The tissue bank industry has

2. *What Killed Brian Lykins?*, cbsnews.com, May 15, 2002, at <http://www.cbsnews.com/stories/2002/05/14/60II/main509045.shtml>.

3. Upon death, the bacteria can migrate, usually to warm, anaerobic areas such as a knee or hip joint. See *Clostridia Facts*, cbsnews.com, May 15, 2002, at <http://www.cbsnews.com/stories/2002/05/15/60II/main509174.shtml>.

4. *What Killed Brian Lykins?*, *supra* note 2.

5. While it is illegal to buy or sell an organ for transplantation, reasonable payments associated with removal, transportation, implantation, processing, preservation, quality control, and storage of an organ are not prohibited. Human Tissue Intended for Transplantation, 58 Fed. Reg. 65,514, 65,514 (Dec. 14, 1993) (codified at 21 C.F.R. pts. 16, 1270).

6. Tissues processed by conventional tissue banks largely consist of bone, ligaments, tendons, fascia, cartilage, corneas, and skin that are used in the treatment of bone disease, orthopedic injuries, ligamentous and joint complaints, degenerative

experienced rapid growth over the past two decades. In 1990, surgeons performed 350,000 tissue transplants.⁷ Today, more than 800,000 tissues are transplanted every year.⁸ However, all human cellular and tissue-based products pose a potential risk of transmitting communicable diseases because of their nature as derivatives of the human body.⁹ The risk of infection can be marginalized if proper testing and sterilization procedures are followed.¹⁰

Although transplantation was generally thought to be a safe and effective surgical procedure, investigational reports conducted by the CDC following Brian Lykins' death exposed grave deficiencies within the tissue industry.¹¹ Some banks ran multiple tests on recovered tissue in hopes that the second test would find material healthy when the first did not;¹² accepted donors with non-metastasizing malignant tumors;¹³ and pooled material from multiple donors, risking contamination of the entire batch.¹⁴ The investigational report documented fifty-four bacterial infections resulting from tissue transplants.¹⁵ The death of Brian Lykins

skeletal disease, blindness due to corneal opacification, and burn wounds. *Id.* Scientists are hopeful that human tissues may provide therapies for cancer, AIDS, Parkinson's Disease, Hemophilia, anemia, diabetes, and other serious diseases. See Food and Drug Administration, Proposed Approach to the Regulation of Cellular and Tissue-Based Products (Feb. 28, 1997), available at <http://www.fda.gov/cber/gdlns/celltissue.pdf>.

7. *Tissue Banks: The Dangers of Tainted Tissues and the Need for Federal Regulation: Hearing Before the Senate Comm. on Governmental Affairs*, 108th Cong. 63 (2003) (statement of Jesse L. Goodman, Director, Center for Biologics Evaluation and Research).

8. *Id.*

9. Suitability Determination for Donors of Human Cellular and Tissue-Based Products, 64 Fed. Reg. 52,696, 52,698 (Sept. 30, 1999) (to be codified at 21 C.F.R. pts. 210, 211, 820, & 1271). Known risks include transmission of human immunodeficiency virus, hepatitis B and C viruses, human T-lymphotropic virus Type I, rabies, Creutzfeldt-Jakob disease, syphilis, group B streptococcus, and other sexually transmitted diseases such as gonorrhea, Chlamydia, Mycoplasma, Trichomonas, and herpes. *Tissue Banks: The Dangers of Tainted Tissues*, *supra* note 7 (statement of Jeanne V. Linden, Director, Blood and Tissue Resources, Wadsworth Center, New York State Department of Health).

10. See *Tissue Banks: The Danger of Tainted Tissues*, *supra* note 7 (statement of Jesse L. Goodman).

11. See discussion *infra* Parts III.A-B, IV.A.

12. *FDA Still Lacks Timetable for Tissue Bank Oversight*, Blood Weekly, June 5, 2003.

13. See *Tissue Banks: Is the Federal Government's Oversight Adequate?: Hearing Before the Subcomm. on Investigations of the Senate Comm. on Governmental Affairs*, 107th Cong. (2001) (testimony of Valerie J. Rao, M.D., Chief Medical Examiner, District Five, Leesburg, Florida).

14. *FDA Still Lacks Timetable*, *supra* note 12.

15. Anna Lumelsky, *Transplant Tissue: Cryolife Human Soft Tissue Implants Recalled*, 30 J. L. Med. & Ethics 474 (2002).

combined with the shocking report issued by the CDC left the question, "How could a medical industry in the United States of America be allowed to operate like this?"¹⁶

Though organs and blood have long been subjected to extensive FDA oversight, human tissues have fallen between the cracks of federal regulation.¹⁷ While "normally, when something [is] a matter of public health and safety, the federal government acts far more quickly," the implementation of a federal regulatory scheme governing human tissues has been a lethargic process.¹⁸ The FDA first acknowledged the need for extensive government oversight in its 1993 Interim Rule.¹⁹ However, the FDA did not propose a comprehensive regulatory approach to the regulation of human tissues until February of 1997.²⁰ Still, seven years later, the FDA still has not finalized all of the proposed regulations.²¹

In contrast, other countries have exercised government oversight over the human tissue industry for many years. Belgium enacted a comprehensive regulatory system in 1988.²² In 1994, France enacted

16. See *Tissue Banks: The Dangers of Tainted Tissues*, *supra* note 7 (testimony of Steve Lykins, father of Brian Lykins).

17. See *Human Tissue Intended For Transplantation*, 58 Fed. Reg. 65,514, 65,514 (Dec. 14, 1993).

18. *What Killed Brian Lykins?*, *supra* note 2 (quoting Senator Susan Collins). The FDA has also expressed frustrations regarding the length of time required to finalize human tissue regulations. Dr. Murray Lumpkin, the Principal Associate FDA Commissioner, stated, "We ourselves get frustrated with the time. But I think when you [are] looking at the issue as complex as this is, the different kinds of tissues we [are] involved with, the evolutionary nature of a very new technology that [is] coming along, even though five years sounds like a long time, it [is] also the time to get it right." *Id.*

19. *Human Tissue Intended For Transplantation*, 58 Fed. Reg. 65,514. The FDA published the Interim Rule to address an immediate need to protect the public health from the transmission of HIV infection and hepatitis infection through tissue transplants. This rule required only minimal testing, and the FDA announced that, in the near future, more extensive regulations would be proposed regarding infectious disease control for tissues. See discussion *infra* Part II.B.

20. See FDA, Proposed Approach, *supra* note 6.

21. The proposed regulations were published in three parts: 1) establishment of registration and listing, 2) suitability determination of donors, and 3) current good tissue practices. At the time of this writing, the "Current Good Tissue Practices" regulations have not been finalized. The FDA has recently published the "Eligibility Determination of Donors" final rule, but it will not go into effect until May 25, 2005. The "Establishment Registration and Listing" regulations, although finalized on January 19, 2001, did not go into full effect until January 21, 2004 due to the delays in enacting the other two parts of the regulatory system. See discussion *infra* Part II. D.

22. 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, 353 (2000).

comprehensive regulatory legislation.²³ Even two states—New York and Florida—have developed comprehensive human tissue programs.²⁴ The absence of a federal comprehensive regulatory system has concerned many leaders within the tissue industry as well as members of Congress.²⁵ In a hearing before the Senate Governmental Affairs Committee, Chairwoman Susan Collins sharply criticized the FDA for its failure to exercise any substantial oversight. She stated, “The FDA still has not kept its commitment to addressing this public health risk. The result of bureaucratic inertia has been tragedy.”²⁶

The FDA presented its comprehensive regulatory plan approximately seven years ago. The long delay in FDA enactment of human tissue regulations is illustrative of a serious problem afflicting all administrative agencies: “ossification” of the rulemaking process.²⁷ Today, the *minimum* time period between the proposal of major regulations and the final enactment is five years. While ossification affects every administrative agency in the United States government, it has been particularly detrimental to FDA regulation of the human tissue industry. This article contends that the dynamic nature of science and technology requires Congress to consider implementing a fast-track program for FDA regulations.

Section II will trace the evolution of human tissue regulation. Section III will look at recent developments on Capitol Hill concerning human tissue regulation. Section IV analyzes the threat of contaminated human tissues and the support for federal oversight. Section V will discuss the informal rulemaking procedure, noting the benefits as well as the drawback of the current rulemaking system. Section VI proposes the creation of a fast-track rulemaking system that will function to streamline the FDA rulemaking process.

II. THE EVOLUTION OF HUMAN TISSUE REGULATIONS

During the late 1980s and early 1990s, reports surfaced concerning the spread of communicable diseases through tissue transplants. The most infamous report occurred in 1991. Lifenet, a

23. *See id.* at 355.

24. John J. Zodrow, *The Commodification of Human Body Parts: Regulating the Tissue Bank Industry*, 32 Sw. U. L. Rev. 407, 431 (2003).

25. *See* discussion *infra* Parts III.A–B, IV.B.

26. *FDA Still Lacks Timetable for Tissue Bank Oversight*, *supra* note 12.

27. Professor E. Donald Elliot coined the term “ossification.” He used it to characterize the effects of additional procedural, analytical, and substantive requirements imposed on the informal rulemaking procedure by the three political branches. *See* E. Donald Elliot, Remarks at the Symposium on *Assessing the Environmental Protection Agency After Twenty Years: Law, Politics, and Economics*, at Duke University School of Law (Nov. 15, 1990); *see also* discussion *infra* Part V.B.

human tissue bank, mistakenly distributed five organs and fifty-four tissue products taken from a HIV-positive donor.²⁸ Three organ recipients died, and at least another three of the patients contracted HIV from tissue transplants.²⁹

Public concern over the transmission of HIV and other communicable diseases forced the federal government to address the growing concerns. "The Assistant Secretary for Health 'convened a Public Health Service Work Group to evaluate the need for, and type of, federal oversight that should be developed for human tissue.'³⁰ The Work Group recommended that an investigation into the needed level of mandatory oversight for tissue transplantation should take place.³¹ The Work Group suggested that the FDA should assert jurisdiction.³²

A. *Early Human Tissue Legislation*

Growing public concern over the transmission of communicable diseases through tissue transplants did not escape attention from Congress. Senator Paul Simon (D-IL) introduced the Human Tissue Transplantation Act of 1992 amid the growing concerns of human tissue contamination.³³ The bill established a National Council on Tissue Transplantation which would develop a record keeping system to facilitate the tracking of potentially contaminated tissue and publish voluntary standards governing the procurement, processing, and distribution of human tissue. The bill also required all tissue banks to register with the Department of Health and Human Services (HHS). Tissue banks would have to obtain a license and pay license fees to fund the regulatory program. Furthermore, the Secretary of HHS was directed to issue mandatory professional standards if the voluntary standards published by the Council were not adequately protecting the public health.

The bill received a cold reception by the human tissue industry. The American Association of Tissue Banks (AATB) and the American Red Cross agreed that tissue transplantation must be federally regulated.³⁴ The registration of human tissue banks,

28. Marc O. Williams, *The Regulation of Human Tissue in the United States: A Regulatory and Legislative Analysis*, 52 Food & Drug L. J. 409, 413 (1997).

29. *Id.*

30. Zodrow, *supra* note 24, at 413 (quoting 62 Fed. Reg. 40,429, 40,430 (July 29, 1997)).

31. Human Tissue Intended for Transplantation, 62 Fed. Reg. 40,429, 40,430 (July 29, 1997) (codified at 21 C.F.R. pts. 16, 1270).

32. *Id.*

33. S. 2908, 102d Cong., 2d Sess. § 7(a)-(b) (1992).

34. *See* Williams, *supra* note 28, at 421-24.

establishment of donor screening and testing procedures, and the establishment of a tracking system were widely supported. However, the AATB and the Red Cross opposed the bill. They argued that mandatory standards—rather than the proposed voluntary professional standards—were needed.³⁵

The Human Tissue Transplantation Act of 1992 did not become law. However, Senator Simon made a second attempt the following year. Abandoning the National Council on Tissue Transplantation, the Human Tissue for Transplantation Act of 1993 centralized rulemaking authority in the Secretary of DHHS.³⁶ The 1993 Act required the Secretary to enact regulations concerning donor screening, donor testing, record keeping, and good tissue practices. Tissue banks would be required to register with the Secretary.

Unlike the 1992 Act, the 1993 Act was popular. The American Academy of Orthopaedic Surgeons stated, “[This] legislation takes necessary steps to ensure the safe screening of human tissue without impeding with undue regulation the scientific developments in the field of biological implants and without compromising the availability of human tissue.”³⁷ Despite widespread support throughout the industry, the 1993 Act never received a floor vote and consequently died.

B. FDA's 1993 Interim Rule

Following the recommendation of the Public Health Service Work Group, the FDA exercised jurisdiction over the human tissue industry with the publication of an interim rule on December 14, 1993. The Interim Rule for Human Tissue Intended for Transplantation addressed an immediate need to protect the public health from the transmission of HIV infection and hepatitis infection through tissue transplants.³⁸ The interim rule required a minimal level of infectious disease testing, donor screening, and record keeping to help prevent the transmission of AIDS and hepatitis through human tissue intended for transplantation.³⁹ Although the rule established a rudimentary regulatory program that was far less comprehensive than the Congressional proposals, it was nevertheless

35. *Id.*

36. S. 1702, 103d Cong., 2d Sess. § 7(a)–(b) (1993).

37. See Williams, *supra* note 28, at 425 (citing *Regulation of Human Tissue Banks: Hearing Before the Subcomm. on Regulation, Bus. Opportunities, and Tech. of the House Comm. on Small Bus.*, 103d Cong., 1st Sess. 32 (1993) (statement of Bernard A. Rineberg, President, American Academy of Orthopaedic Surgeons)).

38. See Human Tissue Intended For Transplantation, 58 Fed. Reg. 65,514 (Dec. 14, 1993).

39. *Id.*

viewed as a positive step by most of the tissue industry.⁴⁰ The FDA found its legal authority for the interim rule in Section 361 of the Public Health Safety Act (PHS Act). The PHS Act authorizes the Department of Health and Human Services "to make and enforce such regulations as judged necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or from State to State."⁴¹ The Act also provides statutory authority to conduct inspections, as well as the authority to destroy any tissues found to be infected or contaminated.⁴²

C. 1997 Final Rule

In response to comments received after conducting three separate workshops designed to promote and encourage communication between the FDA and the human tissue industry, the FDA clarified and modified the provisions of the interim rule in its final rule, which went into effect on January 26, 1998.⁴³ The final rule requires facilities engaged in the recovery, screening, testing, processing, storing, or distributing of human tissues to perform a minimum level of medical screening and infectious disease testing.⁴⁴ Facilities also must keep records documenting such screening and testing and make the records available for FDA inspection.⁴⁵ If these records are not properly kept, the final rule allows the FDA to retain, recall, or destroy the tissue.⁴⁶

More significant was what the final rule did not include. The final rule did not require mandatory registration. Adverse reactions—a noxious and unintended response to any human cellular or tissue-based product for which there is a reasonable possibility that the response may have been caused by the product—were not required to be reported to the FDA. The final rule also did not proffer regulations governing the individual steps of the manufacturing process. Industry leaders considered these provisions essential to any comprehensive regulatory scheme.

40. See *Zodrow*, *supra* note 24, at 415.

41. See *Human Tissue Intended For Transplantation*, 58 Fed. Reg. 65,514, 65,516 (Dec. 14, 1993).

42. *Id.*

43. See *Human Tissue Intended for Transplantation*, 62 Fed. Reg. 40,429 (July 29, 1997).

44. *Id.* at 40,429.

45. *Id.*

46. *Id.*

D. FDA's Proposed Rules

Although the final rule fell short of establishing a comprehensive regulatory system, the FDA eased criticism with the publication of *The Proposed Approach to Regulation of Cellular and Tissue-Based Products*.⁴⁷ This document set forth a road map for future regulations. The FDA acknowledged that human tissue regulation under the 1993 interim and 1997 final rules was extremely fragmented.⁴⁸ In light of the development of new products, combined with a growing awareness of infectious disease concerns, the current piecemeal approach to tissue regulation was no longer adequate.

The proposed regulations were published in three parts: 1) establishment of registration and listing, 2) suitability determination of donors, and 3) current good tissue practices. They are designed to instill public confidence in the safety of human tissue transplants while also ensuring that the availability of new products will not be encumbered by over-regulation.⁴⁹ Tissues will be regulated based on the potential health risk posed by the particular tissue.⁵⁰

1. Establishment Registration and Listing

The lack of a registration system had prevented the FDA from acquiring information regarding the full size of the cell and tissue industry and the scope of its products.⁵¹ Therefore, on May 14, 1998, the FDA published a proposal: *Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products*. This set of regulations would require facilities engaged in the recovery, screening, testing, processing, storing, or distributing of human tissues to register with the FDA and list their products.⁵²

The FDA initially planned to enact all three of the proposed regulations together, thus creating a comprehensive regulatory program in part 1271.⁵³ Nevertheless, on January 19, 2001, the FDA finalized the proposed rule.⁵⁴ The FDA stated, "We are taking this

47. See FDA, *Proposed Approach*, *supra* note 6.

48. *Id.*

49. *Id.* at 7.

50. *Id.* at 6.

51. *Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products*, 63 Fed. Reg. 26,744, 26,746 (May 14, 1998) (codified at 21 C.F.R. pts. 207, 807, 1271).

52. *Id.* at 26753.

53. *Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing*, 66 Fed. Reg. 5447, 5448 (Jan 19, 2001) (codified at 21 C.F.R. pts. 207, 807, 1271).

54. *Id.* Substantially the rule did not change. However, President Clinton's "plain language initiative," which required federal agencies to publish government

action because of recent concerns raised about the safety of tissue, which have led us to believe that accelerating the collection of basic information about the rapidly growing tissue industry is vital.”⁵⁵ However, despite pressure from Congress and the public to enact any finalized regulations as soon as possible, the FDA decided to delay the effective date of the final rule to January 21, 2004.⁵⁶ The FDA cited its desire to enact all of the proposed regulations within a relatively short time period, creating a comprehensive regulatory program in part 1271.

2. Suitability Determination of Donors

The FDA envisioned replacing the donor screening and testing requirements established by the 1993 Interim Rule in the near future with more extensive requirements.⁵⁷ Six years later, the FDA published its second proposal: Suitability Determination for Donors of Human Cellular and Tissue-Based Products.⁵⁸ On May 25, 2004, the “Suitability Determination for Donors” regulations were finalized, although this rule will not be effective until May 25, 2005.⁵⁹

Once in effect, the donor suitability regulations will expand government oversight in two ways. First, the regulations will increase the number of products covered by the screening and testing requirements.⁶⁰ Second, the regulations will expand the mandatory

documents that are easier to understand, has resulted in substantial editorial changes from the proposed rule. *Id.* at 5447–49.

55. *Id.* at 5448.

56. Originally all facilities to be regulated under Section 361 of the Public Health Service Act were required to register with the FDA by January 21, 2003. This deadline has been pushed back to January 21, 2004. *See* Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing, 68 Fed. Reg. 2689 (Jan. 21, 2003) (codified at 21 C.F.R. pt. 1271).

57. *See* Human Tissue Intended For Transplantation, 58 Fed. Reg. 65,514, 65,516 (Dec. 14, 1993).

58. *See* Suitability Determination for Donors of Human Cellular and Tissue-Based Products, 64 Fed. Reg. 52,696 (Sept. 30, 1999) (to be codified at 21 C.F.R. pts. 210, 211, 820, 1271).

59. *See* Eligibility Determination of Donors of Human Cells, Tissues, and Cellular and Tissue-based Products, 69 Fed. Reg. 29,786 (May 25, 2004) (codified at 21 C.F.R. pts. 210, 211, 820, 1271). The title of the proposed rule was changed from “Suitability Determination for Donors of Human Cellular and Tissue-Based Products” to “Eligibility Determination of Donors of Human Cells, Tissues, and Cellular and Tissue-based Products” in the final rule.

60. For instance, the FDA is proposing to require donors of reproductive cells and tissue to be tested. *Neisseria gonorrhoea* and *Chlamydia trachomatis* have both been transmitted through artificial insemination procedures. *Id.* at 52,698.

testing and screening requirements to include additional diseases.⁶¹ In certain situations, however, human tissues that would normally be subjected to FDA regulation are exempted. Human tissues intended for autologous use would not require testing.⁶² Likewise, the FDA would not compel reproductive cells to be tested if the recipient is a sexually intimate partner of the donor.⁶³ Nevertheless, while the FDA does not obligate facilities to test these human tissues, such testing is recommended as a general safety measure.⁶⁴

3. *Good Tissue Practices*

Although the donor-suitability rule will require facilities to screen and test donor tissues for certain communicable diseases, additional measures must be taken to further reduce the public health risk associated with tissue transplantation. Errors in product labeling and record keeping, substandard cleaning of facilities and equipment, and improper processing procedures could contaminate human tissues during the manufacturing process. Thus, on January 8, 2001, the FDA proposed its third rule: Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement.⁶⁵ As of this writing, the “Current Good Tissue Practices” regulations have not been finalized.

The term “good tissue practices” envelopes a multitude of steps within the manufacturing process. Generally, “current good tissue practices” requires facilities engaged in the recovery, screening, testing, processing, storing, or distributing of human tissues to comply with minimum industry standards and procedures in order to prevent tissue contamination and to preserve tissue function and integrity.⁶⁶ Under the proposed rule, facilities must: 1) maintain current processing methods;⁶⁷ 2) establish a quality program;⁶⁸ 3) maintain a sanitary work

61. The current regulations only require testing for Human Immunodeficiency Virus Type 1, Human Immunodeficiency Virus Type 2, Hepatitis B, and Hepatitis C. The new regulations will require tissues to be tested and screened for: syphilis, Creutzfeldt-Jakob Disease, human T-cell lymphotropic virus type I and II, Cytomegalovirus, Neisseria gonorrhoea, and Chlamydia trachomatis. *Id.* at 52,697–98.

62. Autologous use means the implantation, transplantation, infusion, or transfer of a human cellular or tissue-based product back into the individual from whom the cells or tissue comprising such product were removed. *Id.* at 52,609.

63. *Id.* at 52,707.

64. *Id.* at 52,706–07.

65. See Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement, 66 Fed. Reg. 1508 (Jan. 8, 2001) (to be codified at 21 C.F.R. pt. 1271).

66. *Id.*

67. Since advancements in technology are inevitable, the FDA is not proposing

environment;⁶⁹ 4) perform routine maintenance on equipment;⁷⁰ 5) develop a record-keeping system;⁷¹ 6) establish a product tracking system;⁷² 7) meet certain labeling requirements;⁷³ 8) report adverse reactions and product deviations;⁷⁴ and 9) document and review all complaints.⁷⁵

III. APPREHENSION ON CAPITOL HILL: CONGRESS THREATENS THE USE OF FORCE

A. May 2001 Senate Hearings

On May 24, 2001, the Senate Governmental Affairs Permanent Subcommittee on Investigations convened to examine the current state of the human tissue industry. Deputy Inspector General George Grob for the Department of Health and Human Services (HHS)

specific processing methods. Rather, the FDA would insist that facilities maintain up-to-date processing methods that evolve with changing industry standards. *Id.* at 1516.

68. A quality program would function to ensure the effectiveness of the implemented processes and procedures. *Id.* at 1512–14.

69. An unsanitary facility has the potential of exposing otherwise healthy human tissue to additional contamination risks. *Id.* at 1514–15.

70. In addition to performing adequate cleaning and disinfecting procedures, facilities would also be obliged to perform scheduled calibrations of equipment according to established procedures. *Id.* at 1515.

71. In order for the FDA to make certain facilities are complying with FDA regulations, facilities must also maintain records detailing the procedures used in their manufacturing processes. *Id.* at 1518.

72. The need for a product tracking system became apparent in the wake of the Lifenet debacle. After discovering that the donor tissue was infected with HIV, investigators attempted to contact all recipients of the donor tissue. The investigators, however, could not account for all of the contaminated tissue; some of the hospitals did not have records of even receiving the tissue. Several of the recipients of the contaminated tissue were not warned or advised to seek medical treatment due to the lack of a tracking system. *Id.* at 1518–19.

73. Labeling procedures would prevent product mix-ups. The label must contain the name of the distributing facility, a description of the product, and an expiration date. Also, storage temperature, warnings, and instructions for use must be included on the label or within the packaging. *Id.* at 1517, 1521.

74. Facilities must report adverse reactions to the FDA if the reaction: is fatal; is life-threatening; causes permanent damage to body function or structure; or requires medical or surgical intervention. Product deviations—events that represent a deviation from current good tissue practice, applicable standards, or established specifications—must be reported to the FDA if they could reasonably lead to a reportable adverse reaction. *Id.* at 1520–21.

75. A complaint is any communication that alleges: a product has transmitted a communicable disease; a product's function or integrity is impaired; or any other problem that may have resulted from non-compliance with good tissue practices. *Id.*

testified that growth of the industry has outpaced the development of regulations, making current federal oversight insufficient.⁷⁶ Dr. Valerie Rao, a medical examiner from the state of Florida, substantiated Mr. Grob's testimony. Dr. Rao's investigation painted a grave picture of the state of the human tissue industry. One company failed to perform routine blood or bone marrow aspiration cultures used to detect possible diseases. The company also did not require an autopsy and, consequently, did not know the donor's cause of death. They would accept donors with non-metastasizing malignant tumors of the breast, colon, cervix, and lung.⁷⁷

Following the testimony before the committee, Chairwoman Susan Collins (R-ME) called for the FDA to increase its inspection of human tissue banks and impose sanctions where appropriate.⁷⁸

B. May 2003 Senate Hearings

On May 14, 2003, the Senate Governmental Affairs Committee held a hearing to address public concerns over the safety of human tissue transplants. Dr. Jeanne Linden, Director of Blood and Tissue Resources for New York State Department of Health, testified before the senate panel describing New York's regulatory system governing human tissue banks.⁷⁹ In 1991, the state of New York established mandatory standards overseeing testing and screening of human tissue. The state mandates that tissue facilities develop a recordkeeping system in order to facilitate product tracking. Adverse reactions must be reported, and tissue banks must seek a license from the New York State Department of Health. Upon implementation of the comprehensive regulatory scheme, New York uncovered many dangerous practices within the human tissue industry. Dr. Linden presented some of the more egregious cases:

[T]wo semen bank operators were using only themselves as donors, but, through the use of fictitious names, led physicians and recipients to believe that more than a dozen donors were available through the program. Testing and record keeping at this bank were virtually nonexistent. Another reported incident concerned a hematopoietic stem cell bank that transplanted the wrong component—the ABO-incompatible red cells that had been removed from the bone

76. Zodrow, *supra* note 24, at 430–31.

77. *Tissue Banks: Is . . . Oversight Adequate?*, *supra* note 13 (testimony of Valerie J. Rao).

78. Zodrow, *supra* note 24, at 430.

79. See *Tissue Banks: The Dangers of Tainted Tissues*, *supra* note 7, at 17–24 (testimony of Jeanne V. Linden).

marrow, rather than the marrow itself. Had the marrow not been retrievable, the patient . . . could have died as a result of a severely impaired immune system.⁸⁰

Dr. Linden declared that these cases demonstrate the importance of implementing a comprehensive regulatory system that ensures proper labeling, record-keeping, and tissue tracking procedures are followed.⁸¹

Dr. Jesse Goodman, the Director for Biologics Evaluation and Research, also testified before the Committee setting forth the current state of FDA regulation.⁸² Dr. Goodman stated that, while the goal of the FDA is to prevent the spread of communicable diseases and enhance public confidence in human tissue products, the FDA “[seeks] to accomplish these goals in a manner that will not discourage the development of new products.”⁸³ Both Republicans and Democrats chastised the FDA for its failure to expeditiously enact a comprehensive regulatory framework. Despite governmental hearings in 2001 exposing the dangerous practices within the tissue industry, two years and several tragedies later “[t]he FDA still has not kept its commitment to addressing and minimizing this public health risk through effective regulation.”⁸⁴ The FDA, refusing to give a timeline for implementation of its proposed rules, responded, “[these] are complex rules and we want to do them right.”⁸⁵ Senator Mark Pryor—acknowledging that he was completely unaware of the dangers associated with human tissue transplants when he received an Achilles tendon transplant—told Dr. Goodman, “I [am] not satisfied with your answers.”⁸⁶

C. *Brian Lykins Human Tissue Transplant Safety Act of 2003*

Senator Collins introduced the Brian Lykins Human Tissue Transplant Safety Act of 2003 immediately following the May 14, 2003 hearing.⁸⁷ “It is obvious to me that without a statutory deadline

80. *Id.* at 56.

81. *Id.* at 58.

82. *Id.* at 26–38 (testimony of Jesse L. Goodman).

83. *Id.* at 64.

84. This was the statement of Senator Collins at the May 2003 Hearings. *Senate Panel Criticizes FDA on Tissue Bank Regulations*, CongressDaily/A.M., May 15, 2003.

85. *Id.*

86. *Id.*

87. S. 1063, 108th Cong., 1st Sess. (2003). Senator Collins introduced the bill for herself, Senator Richard Durbin (D–Ill), Mr. Coleman, and Senator Mark Pryor (D–Ark). *Id.*

[the] FDA will continue to delay and delay," stated Senator Collins.⁸⁸ The bill would require any entity engaged in the recovery, screening, testing, processing, labeling, packaging, or distribution of human cellular or tissue-based products to register with the Commissioner of Food and Drugs.⁸⁹ The bill mandates the Commissioner of Food and Drugs to issue regulations within ninety days of enactment specifying procedures for donor eligibility screening and testing, good tissue practices, and inspection and enforcement. Furthermore, the commissioner may conduct inspections of any human tissue facility in order to ensure compliance with the statute or regulations promulgated under the statute. If products are deemed noncompliant, the commissioner may order the recall or destruction of tissue.⁹⁰

In effect this bill would require the FDA to enact its proposed regulations. Nevertheless, the proposed legislation has not become law at the time of this writing.

IV. A CALL FOR QUICK, EFFECTIVE RULEMAKING

A. *A Matter of Life and Death*

The consequences of receiving a contaminated human tissue transplant are grave. Numerous deaths have occurred resulting from Creutzfeldt-Jakob Disease-infected human tissue transplants.⁹¹ A 1997 report linked forty-two deaths to CJD-infected dura mater grafts in Japan.⁹² Over 114 deaths have been reported worldwide.⁹³ Human tissues contaminated with bacteria and fungi also pose serious health risks. Jay James, a San Francisco stockbroker, received a bacterially-infected human tissue implant in his knee.⁹⁴ James underwent five more operations to cure the clostridium infection in his knee. Alan Minvielle suffered a similar fate.⁹⁵ Minvielle, a man who once

88. *Tissue Banks: The Dangers of Tainted Tissues*, *supra* note 7, at 4 (statement of Senator Susan M. Collins).

89. S. 1063, 108th Cong., 1st Sess. (2003).

90. *Id.*

91. Creutzfeldt-Jakob Disease (CJD) is a disorder that causes a rapid decrease of mental function and movement. Complete dementia occurs within six months of the onset of symptoms. Death follows shortly, usually within seven months of the first symptoms.

92. *Creutzfeldt-Jakob Disease Associated with Cadaveric Dura Mater Grafts—Japan, January 1979–May 1996*, 46 *MMWR* 1066 (1997), available at <http://wonder.cdc.gov/wonder/PrevGuid/m0049829/m0049829.asp>.

93. Joanne Laurier, Human Organs: The Next Futures Market, at <http://www.wsws.org/articles/2002/apr2002/body-a26.shtml> (last visited Jan. 3, 2004).

94. See *What Killed Brian Lykins?*, *supra* note 2.

95. *Id.*

competed in marathons, now can barely walk. Yet, the consequence of receiving a fungal or bacterially-infected tissue can be much worse. A five-year-old girl from New Mexico died of a rare fungus infection after receiving a human tissue transplant.⁹⁶ Brian Lykins died suddenly from a clostridia infection.⁹⁷

While the highly publicized death of Brian Lykins increased awareness both on Capitol Hill and within the human tissue industry, the government has had difficulty quantifying the potential risk of infection resulting from contaminated tissues.⁹⁸ An investigation by the CDC following Lykins' death uncovered fifty-four more cases of infection resulting from contaminated tissues.⁹⁹ Yet when asked how serious is the problem of tissue contamination, Dr. Daniel Jernigan, the lead CDC investigator, stated, "We don't really know."¹⁰⁰ Under current regulations, tissue banks are not required to report adverse reactions or product deviations to the FDA.¹⁰¹ Cases of tissue contamination generally can slip under the radar unless a facility voluntarily reports an adverse reaction or a civil lawsuit is brought by or on behalf of the recipient.

The overall risk posed by transplanted human tissues is thought to be quite low despite the difficulty quantifying the risk of disease transmission.¹⁰² Nevertheless, human tissues still pose a major health risk. A single contaminated donor can lead to a public health epidemic. Nine patients across eight states received tissue implants from the same cadaveric donor of the clostridia-infected tissue received by Brian Lykins.¹⁰³ In the mid-1980s tissue from a single HIV-infected donor was implanted in fifty-six separate recipients.¹⁰⁴

96. *FDA Orders Recall of Cadaver Tissue Processed by Cryolife*, 9 No. 11 Andrews Med. Devices Litig. Rep. 3 (Aug. 23, 2002).

97. *See What Killed Brian Lykins?*, *supra* note 2.

98. Following the death of Brian Lykins, the attendance at a conference held by the Third World Congress of Tissue Banking and the AATB was three times larger than expected. *See Jill Burcum, State Case May Bring Tissue-Bank Changes; Industry Delegates Bridle at Publicity, but Say the Result is Likely to be Safer Implant Material*, Star. Trib. (Minneapolis-St. Paul), Aug. 26, 2002, at 1A.

99. *Id.*

100. *See What Killed Brian Lykins?*, *supra* note 2.

101. *Cf.* Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement, 66 Fed. Reg. 1508 (Jan. 8, 2001). *See also What Killed Brian Lykins?*, *supra* note 2 (Dr. Daniel Jernigan stated, "This particular problem, especially with these rare kinds of bacteria, [is] not reportable. So in the past, we [have] not heard about them.").

102. *See Tissue Banks: The Dangers of Tainted Tissues*, *supra* note 7 (statement of Jesse L. Goodman).

103. *Id.* (statement of Jeanne V. Linden). One of the recipients of the tissue developed an infection. However, cultures tested negative for *Clostridium Sordellii*, and he eventually recovered after undergoing an antibiotic treatment. *Id.*

104. *See Williams*, *supra* note 28, at 413.

Due to poor record-keeping and the absence of a product tracking system, the tissue bank could locate and notify only thirty-four of the recipients.¹⁰⁵ Some potentially infected recipients could have unknowingly transmitted the disease to others.

B. Impetus to Federal Regulation

The serious and sometimes deadly nature of these viral, bacterial, and fungal diseases requires measures aimed at the prevention of the introduction and transmission of the pathogens. Likely due to the absence of government oversight, the industry has attempted to self-regulate.¹⁰⁶ Private organizations such as the American Association of Tissue Banks and the Eye Bank Association of America offer stringent accreditation programs that provide uniform industry standards aimed at preventing the introduction and spread of pathogens.¹⁰⁷ Many facilities have willingly adopted these standards. But since membership in these private organizations is voluntary and because there are additional costs with maintaining higher quality standards, some facilities choose not to participate in these accreditation programs. Even when a facility does participate in the accreditation program, the private associations have no enforcement power other than dismissal from the organization.

The filing of civil lawsuits has likely encouraged voluntary adherence to proper testing and tissue processing procedures also. However, the tort system alone is not sufficient to prevent the spread of communicable diseases. Whereas agency rules are prospective and generally create clear requirements that make it easy for regulated entities to know and understand their obligations, case-by-case adjudications are retroactive in nature.¹⁰⁸ A plaintiff may only bring a lawsuit after a harm. This may prove to be too little too late if the transmitted disease is terminal or in the case of a catastrophic epidemic.¹⁰⁹ Furthermore, the additional costs associated with

105. *Id.* The tissue bank, LifeNet Transplantation Services, became aware of the problem on April 26, 1991, when the Colorado Department of Health reported that an elderly Denver woman who had received a hip joint from the donor had tested positive for the virus. In prior reports, a Medical College of Virginia patient who received the infected donor's heart died in 1986, and two recipients of the donor's kidneys died in 1988 and 1990. None of these cases were brought to the attention of the transplant network until early May 1991. *Id.*

106. See Human Tissue Intended For Transplantation, 58 Fed. Reg. 65,514 (Dec. 14, 1993).

107. See American Association of Tissue Banks, at <http://www.aatb.org>; Eye Bank Association of America, at <http://www.restoresight.org>.

108. See generally Richard E. Levy & Sidney A. Shapiro, *Administrative Procedure and the Decline of the Trial*, 51 U. Kan. L. Rev. 473, 481 (May 2003). (discussing the benefits of regulations).

109. See *supra* Section IV.A.

maintaining higher quality standards may entice some tissue facilities to ignore the risk of a lawsuit in order to increase their short-term profitability.¹¹⁰

The failure of even a relatively small percentage of tissue banks to adhere to uniform industry standards could have a profound effect on the industry. Tissue banks worry that the publicity resulting from cases of disease transmission could lead to a decrease in organ donations.¹¹¹ Even worse, public confidence in these products could diminish. Self-regulation and tort-based regulation have proven to be insufficient in protecting the public health.¹¹² Consequently, members within the human tissue industry have welcomed federal oversight. The president of the AATB encouraged "immediate compulsory registration of all tissue banks to determine the scope of tissue banking" and the "[establishment of] uniform donor selection requirements to ensure the lowest possible risk of disease transmission to patients."¹¹³ The national head of the American Red Cross Tissue Services stated, "The American Red Cross feels strongly that appropriate, enforceable federal standards are needed to ensure the continued safety of the people who depend upon human tissue to sustain or improve the quality of their lives and to foster continued public support for the collection and use of transplantable tissue."¹¹⁴

V. PROMULGATING HUMAN TISSUE REGULATIONS UNDER THE ADMINISTRATIVE PROCEDURE ACT

The FDA took an initial step in preventing the introduction and transmission of pathogens with the promulgation of its 1993 Interim rule. Yet, seven years since introducing its comprehensive regulatory

110. For instance, Cryolife maintained two inventories of tissue for release: one for patients in the state of New York and the second for patients in other states. *See Tissue Banks: The Dangers of Tainted Tissues*, *supra* note 7, at 19 (statement of Jeanne V. Linden).

111. *See* Jill Burcum, *supra* note 98. Doug Prete, senior vice president for quality and compliance for Lifenet tissue bank in Virginia Beach, Virginia, stated that the industry's biggest concern following the highly publicized death of Brian Lykins is how the publicity affects donor families. *Id.*

112. History has shown that the tort system and self-regulation efforts alone are not sufficient to protect the public health from potentially deadly diseases transmitted through human tissues. *See generally What Killed Brian Lykins?*, *supra* note 2 (Jay James brought a lawsuit against Cryolife, the supplier of the clostridium-infected tissue, in 1998. Cryolife settled out of court. Three years later, Brian Lykins died after receiving a similar tissue from Cryolife with the same clostridium infection.); *see also Tissue Banks: The Dangers of Tainted Tissues*, *supra* note 7 (testimony of Dr. Jeanne Linden concerning egregious practices within the human tissue industry).

113. *See* Human Tissue Intended For Transplantation, 58 Fed. Reg. 65,514, 65,515 (Dec. 14, 1993).

114. *Id.*

plan and eleven years since acknowledging the need for more extensive regulations governing the human tissue industry, the FDA has not finalized all of the proposed human tissue regulations despite support from both the industry and Congress. Human tissue banks today are still operating with little government oversight.¹¹⁵ What is taking the FDA so long?

The FDA's mission to protect the public health has become increasingly more complex with the onslaught of new, rapidly expanding technologies.¹¹⁶ Advances in gene therapy,¹¹⁷ bioinformatics,¹¹⁸ and other biotechnologies are pushing the envelope of modern science. The FDA is struggling to keep up with these technological advances.¹¹⁹ Once the FDA does attempt to address new problems facing the public health through the promulgation of regulations, the FDA is confronted with a plethora of procedural requirements that severely slow the rulemaking process.¹²⁰ These additional requirements mandate the FDA to balance the protection of public health with the potential social,

115. The "Current Good Tissue Practices" regulations have not been finalized; the "Eligibility Determination of Donors" final rule will not go into effect until May 25, 2005; and the "Establishment Registration and Listing" regulations, although finalized on January 19, 2001, have only been in full effect since January 21, 2004. See *Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement*, 66 Fed. Reg. 1508 (Jan. 8, 2001); *Eligibility Determination of Donors of Human Cells, Tissues, and Cellular and Tissue-based Products*, 69 Fed. Reg. 29786 (May 25, 2004); *Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing*, 68 Fed. Reg. 2689 (Jan. 21, 2003).

116. See Food and Drug Admin., *FDA's Mission Statement*, at <http://www.fda.gov/opacom/morechoices/mission.html> (last visited Jan. 10, 2005).

117. Gene therapy is a technique for correcting defective genes responsible for disease development. Most studies replace an abnormal gene with a normal gene. The death of eighteen-year-old Jesse Gelsinger in 1999 after participating in a gene therapy trial was a major setback. Gelsinger's death forced the FDA to reevaluate its oversight process. See Human Genome Project Information, *Gene Therapy*, at http://www.ornl.gov/sci/techresources/Human_Genome/medicine/genetherapy.shtml (last visited Jan. 10, 2005).

118. Bioinformatics involves the use of mathematical, statistical, and computing methods that aim to solve biological problems using DNA and amino acid sequences and related information. See *Bioinformatics Frequently Asked Questions*, at <http://bioinformatics.org/faq/#definitions> (last visited Jan. 10, 2005).

119. See Alison R. McCabe, *A Precarious Balancing Act—The Role of the FDA as Protector of Public Health and Industry Wealth*, 36 Suffolk U. L. Rev. 787, 792-98. (2003) (stating that the FDA is ill-equipped to monitor these promising areas of medicine); Judith A. Cregan, *Light, Fast, and Flexible: A New Approach to Regulation of Human Gene Therapy*, 32 McGeorge L. Rev. 261, 281-82 (2000) (addressing concern that the FDA lacks the expertise and resources to regulate the biotechnology industry).

120. See *Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement*, 66 Fed. Reg. 1508.

environmental, and economic impact of its rules. During the 1960s and early 1970s, administrative rules could be promulgated in six months.¹²¹ Today, major rules proposed by administrative agencies take a minimum of five years from proposal to enactment.¹²² The FDA's comprehensive regulatory program governing human tissues—first introduced in 1997—is following this trend. Professor E. Donald Elliot characterizes this tendency as the “ossification” of the rulemaking process.¹²³

A. *The Birth of the Administrative State*

Early federal regulation was promulgated through legislation followed by judicial enforcement. Following the Great Depression, President Roosevelt sought to expand the federal bureaucracy, believing traditional procedures were too lethargic. Congress lacked the capacity and expertise to handle growing public welfare concerns. While courts also functioned to regulate social behavior through common law causes of action, such adjudications react to societal ills. Rules, on the other hand, allow the government to look prospectively, preventing societal ills before they come to pass. Roosevelt envisioned “administratively organized communities of highly trained professionals” to relieve the legislative and judicial branches.¹²⁴ The administrative agencies would have expertise in their respective field, allowing it to efficiently promulgate and enforce regulations intended to improve society's general welfare.

Roosevelt's vision did not have universal appeal.¹²⁵ The administrative agencies lacked political accountability; unelected bureaucrats directed the agencies. Critics argued that rulemaking through administrative agencies violated due process.¹²⁶ However, criticism was quieted in 1947 with the enactment of the Administrative Procedure Act (APA).¹²⁷ The APA sought the middle ground by mandating specific administrative procedures, balancing the efficiency of administrative rulemaking with procedural checks.

121. See Thomas O. McGarity, *Some Thoughts on “Deossifying” the Rulemaking Process*, 41 Duke L.J. 1385 (1992).

122. See Richard B. Stewart, *Administrative Law in the Twenty-First Century*, 78 N.Y.U. L. Rev. 437, 447 (2003).

123. See Elliot, *supra* note 27.

124. See Levy & Shapiro, *supra* note 108, at 477 (citing Sidney A. Shapiro, A *Delegation Theory of the APA*, 10 Admin. L.J. 89, 97 (1996) (quoting Joel D. Schwartz, *Book Review*, 97 Harv. L. Rev. 815, 820 (1984))).

125. *Id.*

126. *Id.*

127. *Id.*

The 1970s witnessed a boom in agency rulemaking.¹²⁸ Agencies began to use informal rulemaking—a form of rulemaking that allows an agency to enact rules without the need for formal hearings or adjudication. Unlike formal rulemaking, the informal rulemaking process does not require trial-type proceedings. Rather, the agency conducts a “paper hearing.” The agency must put the public on notice of potential rulemaking, accept written comments from the interested public, and explain the final rule in a concise general statement of their basis and purpose.¹²⁹ Informal rulemaking is designed to allow an agency to intelligently and efficiently create rules while improving the legitimacy of agency rulemaking by allowing the President, Congress, and the general public to actively participate in the rulemaking process.¹³⁰ Legal scholars and federal agencies agreed: Informal rulemaking was an “ideal vehicle” for developing new comprehensive regulations.¹³¹

B. Ossification of the Rulemaking Process

The informal rulemaking process was originally a model of governmental efficiency; Professor Kenneth Culp Davis even called informal rulemaking “one of the greatest inventions of modern government.”¹³² However, such optimism has soured. Efforts by all three political branches to exert control over administrative agencies has stricken the informal rulemaking process with additional procedural, analytical, and substantive requirements. Agencies now must run the gauntlet in order to promulgate rules.

Additional analytical requirements imposed by Congress and the President have resulted in paralysis by analysis.¹³³ Agencies now must provide “impact statements” before promulgating rules. For instance, Executive Order 12866 requires agencies to assess all costs and benefits of available regulatory alternatives.¹³⁴ Congress, through

128. Justice Scalia referred to the 1970s as the “era of rulemaking.” See McGarity, *supra* note 120 (citing Antonin Scalia, *Back to Basics: Making Law without Making Rules*, Regulation, July/August 1981, at 25).

129. 5 U.S.C. § 553 (2000).

130. *Id.*

131. See McGarity, *supra* note 121, at 1385.

132. *Id.* (citing Kenneth C. Davis, *Administrative Law Treatise* § 6.15, at 283 (1st ed. Supp. 1970)).

133. Stewart, *supra* note 122, at 477.

134. When regulation is deemed necessary, the agency is to adopt regulatory approaches that maximize net benefits. Agencies should consider potential economic, environmental, public health, and public safety benefits. Once the rule is finalized, it must be submitted to the Office of Management and Budget for approval before its issuance, further delaying the effective date of any proposed regulations. See Current Good Tissue Practice for Manufacturers of Human

legislation such as the Regulatory Flexibility Act and the Unfunded Mandates Reform Act, has inflicted even more analytical requirements. The Regulatory Flexibility Act requires agencies to analyze a rule's potential impact on small entities and analyze regulatory options that would minimize the impact.¹³⁵ The Unfunded Mandates Reform Act requires agencies to perform a cost/benefit analysis if a regulatory proposal will cost either the private sector, state, or local governments \$100 million any given year.¹³⁶

Most of the blame for ossification of the rulemaking process has fallen at the feet of the judiciary. A reviewing court examines an agency's decisionmaking process to ensure the agency has carefully and thoughtfully considered all relevant issues before it. If "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise," the reviewing court may set the agency action aside by declaring the rule arbitrary and capricious.¹³⁷

Although the Supreme Court has asserted that the standard of review is narrow, in application, judicial scrutiny has been quite substantial.¹³⁸ While the court does not make the ultimate decision, it insists that the agency take a "hard look" at all relevant factors.¹³⁹ The effects of this "hard look" are profound. Agencies must develop and maintain a rulemaking record in order to survive judicial scrutiny.¹⁴⁰ They must respond to all significant comments and provide extensive reasons for its decisionmaking. Consequently, interested parties, especially those with abundant resources, can inundate an agency with numerous written comments, attacking every facet of an agency's proposed rule.¹⁴¹ Agencies are left to guess

Cellular and Tissue-Based Products; Inspection and Enforcement, 66 Fed. Reg. 1508 (Jan. 8, 2001).

135. *Id.*

136. *Id.*

137. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43, 103 S. Ct. 2856, 2867 (1983).

138. 5 U.S.C. § 706 (2000). The reviewing court shall hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. *Id.*

139. See Harold Levant, *Environmental Decisionmaking and the Role of the Courts*, 122 U. Pa. L. Rev. 509, 514 (1974).

140. See McGarity, *supra* note 121.

141. For instance, in 1996, the FDA received 700,000 pieces of commentary concerning proposed tobacco regulations. A single comment submitted by the tobacco industry consisted of 2,000 pages with an astounding 45,000 pages of supporting documents. The FDA was forced to provide 200,000 pages of factual

which issues the reviewing court will consider relevant and the corresponding depth of analysis required. As a result, agencies now are spending an inordinate amount of time preparing supporting documents, responding to public comments, and preparing the record for *all* possible attacks upon judicial review.¹⁴² Consequently, the promulgation of a major rule now takes approximately five years to complete.¹⁴³ Agencies have determined that “any faster action would simply invite reversal on judicial review.”¹⁴⁴

C. Alternatives to Informal Rulemaking

1. The Good Cause Exception

Under certain circumstances agencies may abandon informal rulemaking altogether. Notice-and-comment rulemaking procedures are not required “when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.”¹⁴⁵ Numerous reports citing the transmission of communicable diseases through human tissue transplants seem to establish a serious and immediate threat to the public health that would exempt human tissue regulations from notice-and-comment procedures. However, courts have held that the good cause exception to the APA’s notice-and-comment requirement is to be “narrowly construed and only reluctantly countenanced.”¹⁴⁶

Such stringent judicial review has likely neutralized the applicability of the good cause exception to human tissue regulations. In a 1995 hearing concerning the detention of certain human tissue

materials to support its basis and purpose of its rule.

142. See McGarity, *supra* note 121.

143. See Stewart, *supra* note 122.

144. Jerry L. Mashaw & David L. Harfst, *Regulation and Legal Culture: The Case of Motor Vehicle Safety*, 4 Yale J. on Reg. 257, 284 (1987).

145. 5 U.S.C. § 553(b)(B) (2000). In *National Nutritional Foods Ass’n v. Kennedy*, 572 F.2d 377 (1978), the court interpreted the terms “impracticable,” “unnecessary,” and “contrary to public interest.” “Impracticable” means a situation in which the due and required execution of an agency’s functions would be unavoidably prevented if it had to comply with the notice-and-comment rulemaking procedures. “Unnecessary” means unnecessary so far as the public is concerned. Rules that are minor and attract little public interest would qualify as “unnecessary.” “Contrary to public interest” supplements the terms “impracticable” or “unnecessary”. If the informal rulemaking procedures would severely inhibit the agency from carrying out its functions or there is little or no public interest, the “contrary to public interest” exception may apply. *Id.*

146. *New Jersey Dep’t of Env’tl. Prot. v. EPA*, 626 F.2d 1038, 1045 (D.C.Cir.1980).

products by the FDA, Judge Motz expressed doubt that the FDA had any basis for issuing the 1993 interim rule without first accepting public comment. Judge Motz stated, "There certainly is a substantial question as to whether or not the adoption of the "interim rule" by emergency measure was appropriate I have grave doubts as to whether or not any emergency existed."¹⁴⁷ After weeks of negotiations, the FDA and the tissue bank reached a compromise, thus the validity of the interim rule was never officially challenged in court.¹⁴⁸

2. *Nonlegislative Rules*

Agencies have turned to less formal regulatory processes—policy statements, guidance documents, and interpretative rules—that do not require public participation in order to avoid informal rulemaking.¹⁴⁹ Such rules can be promulgated quickly with few resources. Agencies can hurdle the analytical and procedural quagmires associated with informal rulemaking and simply publish an interpretative rule or a general statement of policy.

A serious drawback to nonlegislative rulemaking is their lack of enforceability. Nonlegislative rules such as guidance documents and policy statements generally are not binding on the public.¹⁵⁰ Interpretive rules, while binding on the public, must work within the rubric of existing rules.¹⁵¹ Nonlegislative rulemaking should continue to be used as supplements to existing rules, but they are not a practical option for creating new, extensive regulations.

147. Richard A. Merrill, *Human Tissues and Reproductive Cloning: New Technologies Challenge FDA*, 3 Hous. J. Health L. & Pol'y 1 (2002) (citing Transcript of Temporary Restraining Order Hearing Before the Honorable J. Frederick Motz, United States District Court Judge at 5, 89, Biodynamics Int'l, Inc. v. United States, No. JFM-95-919 (D. Md. 1995)).

148. *Id.*

149. For instance, the FDA, while unable to finalize its proposed regulations, has published a guidance document reminding human tissue manufacturers that product testing should include bacteria and fungi as well as other known transmittable viruses. Guidance for Industry: Validation of Procedures for Processing of Human Tissues Intended for Transplantation, 67 Fed. Reg. 11,343 (Mar. 13, 2002).

150. See McGarity, *supra* note 121.

151. *Stinson v. United States*, 508 U.S. 36, 113 S.Ct. 1913 (1993); see also Richard J. Pierce, Jr., *Seven Ways to Deossify Agency Rulemaking*, 47 Admin. L. Rev. 59 (1995) (discussing attempts by the Court to give interpretative rules greater deference in order to limit the scope of the duty to engage in reasoned decisionmaking).

D. *Efficiency or Accountability?*

The balance between accountability and efficiency varies greatly between the available rulemaking procedures. The additional procedural, analytical, and substantive requirements imposed on informal rulemaking have imposed a significant level of accountability on the bureaucracy. By making an agency analyze and consider all significant issues raised by public comments, the court ensures the administrative agency is making an informed decision and remains politically neutral. The agency must give the same credence to a comment submitted by a single individual as it does to a comment submitted by a powerful special interest group. Analytical requirements imposed by both Congress and the President work to prevent tunnel vision by forcing agencies to consider economic, environment, public health, and public safety effects of its proposed rules. Such analysis can forewarn Congress and/or the President of potential over-regulation. They may choose to influence the agency through the notice-and-comment procedure, or they may exercise other political powers to obstruct such rulemaking. However, this increase in accountability has its expense. The additional procedural, analytical, and substantive requirements have stripped informal rulemaking of its principal attribute: efficiency.

Conversely, alternatives to informal rulemaking such as nonlegislative rules and the good cause exception allow an agency to quickly promulgate regulations. Yet, several commentators question whether an abandonment of the notice and comment procedure is a step forward or a step backward. Unelected bureaucrats can promulgate nonlegislative rules with little or no procedural checks. A wholesale shift to these less formal devices could result in unaccountable government and lead to arbitrary decisionmaking.¹⁵² In addition, the quality of rules is likely to decline. Leaders within the affected industry are not given the opportunity to offer recommendations and voice concerns.

VI. STREAMLINING THE FDA RULEMAKING PROCESS WITH THE CREATION OF A REGULATORY FAST-TRACK SYSTEM

A. *Striking the Balance Between Efficiency and Accountability*

Human tissues serve a crucial role in medicine, and they have the potential for providing many important new therapies.¹⁵³ Yet *contaminated* tissues pose a direct and serious threat to the public

152. See McGarity, *supra* note 121.

153. See *supra* note 6.

health.¹⁵⁴ The informal rulemaking process has been too lethargic to respond to the emerging health risks posed by human tissues, subjecting the general public to unnecessary health risks due to regulatory lag. Likewise, an alternative such as the good cause exemption is not a viable option. The narrow construction of the good cause exception casts serious doubt as to whether human tissue regulations could survive judicial scrutiny notwithstanding Judge Motz's clearly erroneous assessment of the seriousness of human tissue contamination. Plus, rapid advancements in biotechnology have challenged the expertise of the FDA.¹⁵⁵ When promulgating regulations governing such a complex field as human tissues, industry involvement in the rulemaking process is vital.

Ideally, political accountability and efficiency would coexist within the rulemaking process. However, these characteristics are inversely proportional: an increase in efficiency usually results in a decrease in accountability and vice versa.¹⁵⁶ Since human tissues call for both quick rulemaking and a certain level of industry involvement, the FDA needs a rulemaking procedure that strikes a balance between accountability and efficiency. Using section 112 of the Food and Drug Modernization Act as a model, Congress should develop a regulatory fast-track system that allows the FDA to circumvent many of the procedural, analytical, and substantive hurdles that severely slow the informal rulemaking process while maintaining an appropriate level of political accountability.

B. A Model: The Drug Fast-Track System under the Food and Drug Modernization Act of 1997

Since the enactment of The Federal Food, Drug, and Cosmetic Act of 1938, the FDA has required new drugs to obtain pre-market approval.¹⁵⁷ Manufacturers had to prove by substantial evidence that its new drug met certain safety and efficacy standards prior to

154. See *discussion supra* Section IV.A.

155. See *discussion supra* notes 117–119.

156. Agency rulemaking with no procedural or substantive checks would make the rulemaking process extremely efficient, yet the agency would not be accountable to the public for its actions. Conversely, requiring an agency to consider all factors and subjecting its decisionmaking to substantial judicial scrutiny would result in a high level of political accountability. However, efficiency would undoubtedly suffer.

157. A new drug is "any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof." The Federal Food Drug and Cosmetic Act of 1938 § 201(p)(1), 52 Stat. 1040, 1041–42 (1938).

entering the market.¹⁵⁸ The drug approval process was quite long. A pharmaceutical company had to submit an investigational new drug application and then undergo three phases of clinical studies. The time from development of a new drug to its approval by the FDA could take as long as fifteen years.¹⁵⁹

In order to expedite the drug approval process, Congress enacted the Food and Drug Modernization Act of 1997 (FDMA).¹⁶⁰ Section 112 of the FDMA created a fast-track system for the approval of potentially life-saving drugs. Under section 112, the sponsor of a new drug requests designation of its product as a "fast track product."¹⁶¹ If the drug "is intended for the treatment of a serious or life-threatening condition and demonstrates the potential to address unmet medical needs for such a condition," the Secretary is required to designate the drug as a fast track product and expedite its review.¹⁶²

C. A Regulatory Fast-Track System

Congress, through the passage of the Modernization Act, determined that potentially life-saving drugs should be made available to the general public quickly. Human tissue regulations, like certain drugs, are potentially life-saving. The risks of transmitting communicable diseases through tissue transplants can be significantly reduced when facilities employ the proper testing and tissue processing procedures.¹⁶³ The FDA should have a rulemaking procedure available to expedite potentially life-saving regulations.

Under a regulatory fast-track system, The Secretary, at the request of any interested party, would designate regulations as "fast track regulations" if they would significantly reduce a serious or life-threatening public health risk and no other current regulations adequately protect against this risk.¹⁶⁴

Fast-track regulations would be exempt from judicial review and all analytical and procedural requirements imposed by Congress. Congressional initiatives such as the Regulatory Flexibility Act and

158. See Deborah G. Parver, *Expediting the Drug Approval Process: An Analysis of the FDA Modernization Act of 1997*, 51 Admin. L. Rev. 1249, 1253 (1999).

159. *Id.*

160. Food and Drug Association Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (1997).

161. *Id.* § 112 (a)(1), 111 Stat. at 2309.

162. *Id.* § 112 (a)(1)-(a)(2), 111 Stat. at 2309.

163. See *Tissue Banks: The Dangers of Tainted Tissues*, *supra* note 7 (statement of Jesse L. Goodman).

164. The characterization of a regulation as a "fast-track regulation" would undoubtedly have to be exempt from judicial review. Failure to allow for such an exemption would destine the regulatory fast-track system to the same fate as the Good Cause Exception, discussed *supra* Part V.C.1.

the Unfunded Mandates Reform Act require agencies to perform time and resource-consuming impact statements. The judicial branch has severely delayed the informal rulemaking process through the application of the hard-look doctrine. When the public health is at risk, the need for quick rulemaking outweighs the possible benefits achieved by these additional requirements. Attempts to turn the court's "hard look" into a "soft look" would likely subject the fast-track procedure to new judicial doctrines that would inevitably slow the proposed rulemaking process. By removing judicial review completely, the FDA would not be forced to spend such an inordinate amount of time developing and maintaining its rulemaking record.

Removal of judicial review and the additional requirements imposed by Congress would make the fast-track procedure efficient but largely unaccountable. Thus the FDA still must accept comments on its proposed rulemaking and respond to all relevant public comments in its final rule. Maintaining the notice-and-comment will serve two functions. First, industry involvement in the rulemaking process will improve the quality of regulations. Second, requiring the FDA to accept public comment will facilitate ex-post political oversight of agency decisionmaking. The responses to public comments in the final rule will create a rulemaking record—albeit smaller than the rulemaking record currently required by the hard-look doctrine. If the FDA over-regulates, the regulated industry will certainly react. Then, Congress or the President can review agency decisionmaking via the rulemaking record and use their respective powers to influence subsequent agency decisionmaking if the FDA is in fact being over-zealous.

VII. CONCLUSION

Human tissues play a crucial role in medicine. Human tissue transplants are generally safe as well as effective. Yet, their nature as a derivative of the human body makes implanted tissues a potential source of infection. Although the FDA proposed a comprehensive regulatory program in 1997, six years later the rules have not been finalized. Currently human tissue banks operate under little or no government oversight. While many facilities have voluntarily adopted good tissue practices, some have not. Federal regulations would significantly reduce the risk of transmittal. Congress should implement a regulatory fast-track system in order to streamline the FDA rulemaking process so that rules necessary for the protection of the public health may be enacted within a

reasonable time period. Under the proposed fast-track procedure, the FDA would still be required to accept public comments on its proposed rulemaking. But many of the additional analytical, procedural, and substantive requirements imposed on the informal rulemaking process would be removed so that fast-track regulations could be promulgated quickly.

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