

# PATIENT SAFETY OR PROFIT: WHAT INCENTIVES ARE BLOOD SHIELD LAWS AND FDA REGULATIONS CREATING FOR THE TISSUE BANKING INDUSTRY?

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## INTRODUCTION

Blood shield laws have been construed to grant tissue banks immunity from strict liability. Weak government oversight combined with blood shield laws create a disincentive for the organizations that recover and process tissue to focus on patient safety. The state of the industry and current Food and Drug Administration (FDA) regulations do not provide reasonable protection for recipient patients and donor families during this time of rapid expansion of the tissue banking industry. This industry is unique because the raw material used to create the products is donated by individuals giving their final gift who probably had no idea about the for-profit nature of the industry and the risks involved. Patient safety should be the primary concern because of the particularly dangerous nature of donated human tissue. Therefore, if the courts were to apply the reasonable alternative standard of strict liability, society's expectation of tissue banking could be achieved by forcing the industry to internalize the harm caused by unreasonable practices and create an economic incentive for tissue banks to implement processes that are in the interest of patient safety and donation in general.

This Note will observe the current state of the tissue banking industry and the possible adverse effects this structure could have on patient safety. To illustrate the disincentives created by the blood shield laws, this Note will present an overview of the impact of the blood shield laws on hemophiliacs in the nineteen-eighties and compare the plasma fractionation industry with the tissue banking industry. Finally, this Note will propose that the blood shield laws be amended to subject tissue banks to strict liability.

Parts I and II of this Note discuss the history and current state of the tissue banking industry along with FDA regulation. Parts III and IV provide an overview of blood shield laws and discuss cases analyzing the rationale applied to blood shield laws. Part V discusses two recent cases immunizing tissue banks from strict liability. Parts VI and VII describe how blood shield laws coupled with poor regulation failed to create incentives for the plasma fractionation industry to effectively consider patient safety. Parts VIII and IX discuss the risks associated with the tissue banking industry and how the

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imposition of strict liability could avert a medical disaster similar to the one suffered by hemophiliacs.

## I. THE TISSUE BANKING INDUSTRY

### A. *A Brief History of the Tissue Banking Industry*

To properly understand the tissue banking industry today, it is important to understand how the banking industry developed. The first tissue bank was established in the nineteen-forties by the United States Navy.<sup>1</sup> This bank only recovered and stored bone, skin, dura, fascia, and tendons.<sup>2</sup> Traditionally, the majority of tissue were located in hospitals and only served the local community.<sup>3</sup> These banks were created by physicians, researchers, or hospitals to meet their own demand for tissue.<sup>4</sup> In 1987, the tissue banking industry was described as a "cottage industry."<sup>5</sup> At that time, most tissue banks were still very small, only banking, at most, a few tissues, and serving the physicians who established the bank.<sup>6</sup> In the late eighties most of the large tissue banks were based out of major medical institutions that had transplantation programs that created demand for banked tissue.<sup>7</sup> Even though the tissue banking industry, at that time, was not-for-profit, it was recognized that it would be problematic if private companies became involved in tissue banking and processing.<sup>8</sup>

The traditional community tissue banks were comparable to blood banks. Blood banks are typically run by hospitals, the American Red Cross, or local non-profit organizations to serve the needs of a particular community. In the initial stages of development, tissue banks could be compared to blood banks in their structure and motivation; they were not-for-profit organizations motivated only to provide the tissue necessary to meet their particular demand. In 1987, the executive director of the largest freestanding tissue bank, Virginia based Lifenet, a not-for-profit tissue bank still in existence today, stated, "[w]e don't try to make the largest number of deposits, we try to take what is needed."<sup>9</sup> This statement indicates the respect for the gift and the motivation

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1. Timothy F. Kirn, *Tissue Banking in Midst of 'Revolution of Expansion' as More Uses Are Found for Various Transplants*, 258 JAMA 302, 303 (1987).

2. *Id.*

3. *Id.* at 302.

4. *Id.*

5. *Id.*

6. Timothy F. Kirn, *How Does Tissue Banking Work? Virginia Bank, While Not Typical, May Offer Some Insights*, 258 JAMA 304 (1987).

7. Kirn, *supra* note 1, at 302-03.

8. *Id.* at 304. The introduction of for-profit organizations into an area where altruism should dominate could easily pervert the entire donation process. Profiteering could overwhelm altruism and create a serious disincentive for individuals to choose to donate.

9. Kirn, *supra* note 6, at 304.

behind this organization—to take what is really needed. Due to the state of the tissue banking industry at the time the blood shield laws were enacted, it is not difficult to see why courts and legislatures were willing to bring tissue banks behind the statutory shield.<sup>10</sup>

### B. Accreditation

The American Association of Tissue Banks (AATB) is the only organization that accredits tissue banks in the United States. The AATB was created in 1976 to ensure quality standards, encourage donation, create a forum for scientific exchange, promote ethical standards throughout the industry, and ensure an adequate supply of transplantable human tissue.<sup>11</sup> It publishes standards and only offers accreditation to organizations that meet its standards.<sup>12</sup> However, accreditation is not required for a tissue bank to legally operate.

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10. Traditionally, blood banks have been community centered specializing in a very narrow area—the collection and distribution of blood. However, there are two different types of blood collection activities. COMM. TO STUDY HIV TRANSMISSION THROUGH BLOOD & BLOOD PRODUCTS, INST. OF MED., HIV AND THE BLOOD SUPPLY: AN ANALYSIS OF CRISIS DECISION MAKING 25 (Lauren B. Leveton et al. eds., 1995) [hereinafter HIV AND THE BLOOD SUPPLY]. First, whole blood is collected by several blood collection organizations throughout the United States. These organizations include the American Red Cross, community blood banks, and hospital blood banks. *Id.* at 26-28. The components collected from whole blood are red blood cells, platelet concentrate, and fresh frozen plasma. *Id.* at 27. The second blood collection activity is conducted by the for-profit plasma fractionation industry for collection and supply, manufacturing, and research. *Id.* at 26. These for-profit plasma collection organizations collect plasma through a process called plasmapheresis, which only extracts plasma from the donor, and purchase plasma collected by the banks that collect whole blood. *Id.* at 29-31. Plasma donors who donate through the organizations supported by the blood fractionation industry are compensated for their plasma. *Id.* at 31. However, whole blood donors are not compensated for their donation. *Id.* Due to the high demand for plasma and the uncomfortable and time consuming process of plasmapheresis, compensation for donors was legalized and many plasma collection centers up to the early nineteen-eighties were located in areas such as prisons with high infection rates of hepatitis. *Id.* at 30. Whole blood collection organizations most likely fit the public's perception of blood collection organizations. These organizations are only in existence to serve a vital function in the health care system—to maintain an adequate and safe supply of blood. These organizations do not exist to make a profit. Most likely, many whole blood donors would be opposed to donation if they knew their altruistic gift was used to generate a profit. In turn, blood shield laws protect these whole blood collection organizations from liability that could frustrate their purpose and severely limit the supply of a vital health care resource. However, plasma collection organizations cannot be easily placed in the same category as whole blood collection organizations. These organizations are controlled by the for-profit plasma fractionation industry. Additionally, plasma donors are most likely motivated by compensation. The motivation behind the two types of collection organizations is crucial when considering the impact of blood shield laws on each organization's decision making process.

11. AATB, About the American Association of Tissue Banks, at <http://www.aatb.org/aatbintr.htm> (last visited Apr. 19, 2005) (on file with the Indiana Health Law Review).

12. *Id.*

In January 2001, the Department of Health and Human Services (HHS), Office of Inspector General (OIG) found that the AATB accredited fifty-eight tissue banks but identified ninety banks that were not accredited.<sup>13</sup> At that time, the unaccredited tissue banks ranged from the very small to very large, including the largest processor of heart valves.<sup>14</sup> In its report, the OIG stated that there were no incentives for tissue banks to seek accreditation.<sup>15</sup> Some of the factors that discourage accreditation indicated in the report were the following: (1) hospitals and physicians regularly purchasing products from non-accredited banks; (2) accreditation can be cost prohibitive to some smaller banks; and (3) requiring inspection by a third entity may seem unduly burdensome to banks that are already subject to inspection by the FDA and the state in which they are located.<sup>16</sup> Accreditation by the AATB is not the standard throughout the industry. Historically, numerous tissue banks have not sought accreditation. In 1987, only three tissue banks were accredited out of over 400 banks in operation at that time.<sup>17</sup>

### C. *The Tissue Banking Industry Today*

The tissue banking industry has undergone a revolution in the past decade. First, the tissue banking industry has grown rapidly. For example, 350,000 human tissue products were transplanted in 1990; however, more than 800,000 tissue products were transplanted in 2002.<sup>18</sup> Second, many of the traditional community tissue banks no longer process tissue. Instead, most of the community banks send the tissue that they recover to for-profit tissue processors and collect a recovery fee.<sup>19</sup> The for-profit processing companies generate substantial revenue from “selling” the tissue processing service to hospitals and physicians who transplant the tissues.<sup>20</sup> Over the past several

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13. DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., OEI-01-00-00441, OVERSIGHT OF TISSUE BANKING 9 (2001).

14. *Id.*

15. *Id.*

16. *Id.*

17. Kirn, *supra* note 1, at 303.

18. *Tissue Banks: The Dangers of Tainted Tissues and the Need for Federal Regulation: Hearings Before the Comm. on Gov't Affairs*, 108th Cong. (2003) [hereinafter *Dangers of Tainted Tissues Hearings*] (statement of Jesse L. Goodman, Director of the FDA Center for Biologics Evaluation and Research).

19. See DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., OEI-01-00-00440, INFORMED CONSENT IN TISSUE DONATION: EXPECTATION AND REALITIES (2001) [hereinafter CONSENT IN TISSUE DONATION]; see also John J. Zodrow, *The Commodification of Human Body Parts: Regulating the Tissue Bank Industry*, 32 SW. U. L. REV. 407, 408-09 (2003).

20. Sandra Blakeslee, *Lack of Oversight in Tissue Donation Raising Concerns*, N.Y. TIMES, Jan. 20, 2002, § 1 (National Desk), at 1. Cryolife is the leader in processing heart valves but also produces several different tissue products. Its net revenues were \$87.7 million in 2001, \$77.8 million in 2002, and \$59.5 million in 2003. CRYOLIFE, INC., 2003 ANNUAL REPORT F-30 (2004), <http://www.cryolife.com/investornew.htm> (last visited Apr. 19, 2005) (on file with the

years, the large for-profit tissue processing companies have entered into partnerships with community tissue banks to increase the processing companies' access to tissues these banks recover.<sup>21</sup> These partnerships allow the tissue processing organizations reliable access to the raw materials they need to generate revenues.<sup>22</sup> However, these partnerships indicate the entire industry is shifting from a charitable institution into a business institution motivated by profits rather than purpose.<sup>23</sup>

This trend is likely to increase given the current state of the pharmaceutical industry shifting some of its focus toward the use of human tissue for research and possibly production of the next significant pharmaceutical break-

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Indiana Health Law Review). Lifecell, another tissue processing company, reported net revenues of \$26.6 million in 2001, \$32.9 million in 2002, and \$38.6 million in 2003. LIFECELL CORP., 2003 ANNUAL REPORT (2004), <http://www.lifecell.com/downloads/annual/2003%20Annual%20Report%20with%2010-K.pdf> (last visited Apr. 19, 2005) (on file with the Indiana Health Law Review). Osteotech, a tissue processing company focusing on bone and connective tissue, generated over \$94 million in net revenues in 2003, over \$83 million in net revenues in 2002, and over \$75 million in net revenues in 2001. Osteotech, Inc., Financial: Financial Highlights, at <http://www.osteotech.com/finhi.htm> (last visited Apr. 19, 2005) (on file with the Indiana Health Law Review). Regeneration Technologies, a tissue processing company founded in 1998, reported net revenues of \$69 million in 2002, \$75.5 million in 2003, and \$92.7 million in 2004. Regeneration Technologies, Inc., Investors: Financial Highlights, at <http://www.rtx.com/investors/financial.cfm> (last visited Apr. 19, 2005) (on file with the Indiana Health Law Review). In 2003, it is estimated that industry revenues would have reached the \$1 billion mark. Blakeslee, *supra* note 20, at 1.

21. See Blakeslee, *supra* note 20, at 1; Stephen J. Hedges, *Cadavers for Cash in Texas: 'People Make a lot of Money Selling Tissue'*, CHI. TRIB., May 22, 2000, at 10; Ronald Campbell et al., *Anatomy of an IPO: Making Charity Pay Investigations: A Flurry of Deals Builds Regeneration Technologies into a Tissue-Industry Giant*, ORANGE COUNTY REG. May 7, 2000, at A1.

22. See *supra* note 21.

23. The changes in the industry are dramatic indicating a real shift in the motivation from altruism to profit. The Chicago Tribune reported that in 1999 a county in Texas took bids from area tissue banks for the right to take tissues from bodies collected by the medical examiner. This contract went for \$180,000 annually. Hedges, *supra* note 21, at 10. This contract may appear significant, but it has been estimated that a human body is worth as much as \$220,000. Blakeslee, *supra* note 20, at 1. One interesting example of the shift from non-profit to for-profit is Regeneration Technologies, Inc. (RTI). RTI was a spin off of the University of Florida Tissue Bank and derives all its revenues from processing human tissues. Campbell et al., *supra* note 21, at A1. A top official at both RTI and the University of Florida Tissue Bank minimized concerns about profiting from donated tissue by stating, "[w]e're not talking about people profiteering or exploitation . . . [w]e're talking about something that is very accepted in our business system in this country—that there is a return on investment." *Id.* RTI states that it processes about one-third of all tissue donated in the United States. *Id.* RTI has also created strong partnerships throughout the industry by contracting for exclusive rights to donated tissue, buying or providing management services to tissue banks, and controlling non-profit groups within the industry. *Id.* Additionally, the not-for-profit tissue bank, from which RTI was created, was the largest shareholder in RTI at that time. *Id.* Another disturbing fact is that several states permit funeral homes to contract with tissue banks allowing tissue recovery technicians to harvest the tissue at the funeral home. Blakeslee, *supra* note 20, at 1. The actions of the industry appear to be turning a precious gift into a common commodity. See Zodrow, *supra* note 19, at 409.

through.<sup>24</sup> The tissue banking industry is driven by biotechnology innovation. The innovators in this industry patent their techniques for processing donated human tissue and aggressively market their products to hospitals.<sup>25</sup> This trend is not likely to change given the substantial revenues generated by selling processed human tissue.

Clearly, the tissue banking industry today has drastically changed. In the past, the industry resembled the blood banking industry serving the community motivated by an altruistic desire to bring a desperately needed resource to the community. This motivation does not appear to hold true for at least some organizations within the tissue banking industry today.<sup>26</sup> The appearance of for-profit companies in the industry casts a suspicious shadow on the motivations of the organizations and is not compatible with many of the assumptions families have when they consent to donation.<sup>27</sup> The only possible motivation for a private, for-profit company is profit. Clearly, there is money to be made in the tissue banking industry. Most likely, the incentives to generate revenue and profits from processing donated human tissue were not considered by the legislatures when enacting the blood shield laws; however, the motivations and disincentives created by the current regulations and blood shield laws must be considered in light of the industry today.

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24. See James Boxell, *UK: U.S. Deal Boosts Drug Company*, FIN. TIMES, Dec. 29, 2003, at 18; *Finance; Human Tissue Research Bank Closes Financing Round*, MEDICAL DEVICES & SURGICAL TECH. WK., Dec. 21, 2003, at 57; *Genomics Collaborative Inc.: Pact is Signed with Novartis to Supply Samples of Material*, WALL ST. J., Sept. 22, 2003, at C13.

25. Blakeslee, *supra* note 20, at 1.

26. During a Senate hearing, the questionable practices of one tissue bank operating in the Washington, D.C. area were highlighted by Williams Minogue, M.D. He stated that after the local organ procurement organization had ruled out a deceased individual for organ and tissue donation for transplantation purposes due to medical unsuitability, a second tissue bank obtained confidential patient information and approached the family to obtain consent for tissue donation. The family had specifically stated that they did not wish to donate for medical research, the only realistic donation option for the patient. The second tissue bank stated that they were pursuing the tissue for transplant even though the patient was out of the standard age range, had a history of cancer, showed evidence of a recent infection, and was dead for almost twenty-four hours (to ensure safety the maximum time between death and recovery of transplant tissue is twenty-four hours) when the second tissue bank contacted the family. The only plausible explanation for the second tissue bank's action was that it was attempting to recover the tissue for research but not disclosing this information to the family. The second tissue bank was recovering tissue for a for-profit tissue bank. These actions illustrate that some tissue banks allow profit motives to supercede the public's interest in donation. *Human Tissue Banks: Hearings Before the Subcomm. on Investigations of the Comm. on Governmental Affairs*, 106th Cong. (2001) [hereinafter *Human Tissue Banks Hearings*] (statement of William Minogue, M.D., Chairman, Board of Directors, Washington Regional Transplant Consortium).

27. CONSENT IN TISSUE DONATION, *supra* note 19, at ii (stating that in reality, contrary to most families' assumptions, tissue banking is commercialized, donated human tissue is viewed as a commodity after it is processed, and some donated tissue, particularly skin, is used for cosmetic purposes).

## II. FDA REGULATION OF THE TISSUE BANKING INDUSTRY

Current FDA regulations apply to any organization that recovers, screens, tests, processes, stores, or distributes human tissue.<sup>28</sup> However, the regulations that apply to drugs and medical devices do not apply to tissue banks, most importantly the requirement for pre-market approval.<sup>29</sup> Tissue banks are required to determine donor suitability by testing for certain infectious diseases, calculating hemodilution, and reviewing donor medical records.<sup>30</sup> Records containing information on the donated tissue must be kept up-to-date during every significant step of the donation process, and tissue must be properly quarantined until suitability for donation is determined.<sup>31</sup> Additionally, tissue banks are required to retain records of every recovered tissue for at least ten years beyond the date of transplantation or other disposition.<sup>32</sup> They are also required to have written procedures in place to ensure compliance with regulations and prevent the spread of infectious disease and cross-contamination during processing.<sup>33</sup> The records tissue banks keep must include the results of all tests, the identity and medical records of the donor, and information regarding the chain of custody or destruction of the donated tissue.<sup>34</sup> All tissue banks are required to allow FDA inspections of their facility.<sup>35</sup> The FDA also has retained complete power over tissue imported from foreign countries.<sup>36</sup> If the FDA finds a tissue bank in violation of any of the regulations, it may retain, recall, or destroy questionable tissue.<sup>37</sup> The FDA also requires tissue banks to register with the Center for Biological Evaluation and Research.<sup>38</sup> This is the extent of current FDA regulation of tissue banks.

Tissue products are exempt from the more stringent requirements on drugs and medical devices if they meet the following criteria: (1) the product is minimally manipulated; (2) the product is intended for a homologous use;<sup>39</sup> (3) the processor does not combine "another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent," with the tissue; and (4) the product does not have a systemic effect and is not dependent upon

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28. 21 C.F.R. § 1270.1 (2005).

29. *Id.*

30. 21 C.F.R. § 1270.21 (2005).

31. 21 C.F.R. § 1270.33 (2005).

32. *Id.*

33. 21 C.F.R. § 1270.31 (2005).

34. 21 C.F.R. § 1270.35 (2005).

35. 21 C.F.R. § 1270.41 (2005).

36. 21 C.F.R. § 1270.42 (2005).

37. 21 C.F.R. § 1270.43 (2005).

38. 21 C.F.R. § 1271.1 (2005).

39. "Homologous use means the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P [human cells, tissues, or cellular or tissue-based product] that performs the same basic function or functions in the recipient as in the donor." 21 C.F.R. § 1271.3(c) (2005).

metabolic activity of living cells for its primary function.<sup>40</sup> However, the product may escape this last condition if certain criteria are met.<sup>41</sup>

If a tissue product does not meet these specific requirements, the FDA requires that it be regulated as a drug or medical device;<sup>42</sup> however, it should be noted that most tissue products are not regulated as drugs or medical devices. Therefore, in most cases involving tissue products, the FDA's authority is limited to the prevention of communicable diseases.<sup>43</sup>

The regulations indicate the FDA is relying on the established tissue banking industry to police itself. The FDA actually rewrote language in the regulations practically allowing the industry to decide whether a product should be regulated as a drug or medical device.<sup>44</sup> In its revision the FDA stated, "[w]e agree that the establishment that manufactures the HCT/P [human cell, tissue, and cellular-tissue based product] should make the initial determination of whether the addition of a drug or device that is a sterilizing, pre-

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40. 21 C.F.R. § 1271.10 (2005).

41. *Id.* § 1271.10(a)(4)(ii)(a-c) (allowing systemic effect or dependence on metabolic activity if tissue used for autologous use, a first or second-degree relative, or reproductive use).

42. 21 C.F.R. § 1271.20 (2005).

43. *See* Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment, Registration and Listing, 66 Fed. Reg. 5447, 5449 (Jan. 19, 2001); *see also* Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement, 69 Fed. Reg. 68,612, 68,613 (Nov. 24, 2004) (to be codified at 21 C.F.R. pts. 16, 1270, 1271). Unless a HCT/P is categorized as a drug or medical device, the FDA only has the authority to regulate the product under section 361 of the Public Health Service Act. 42 U.S.C. § 264 (2005). This limits the FDA's authority to prevent communicable diseases. As a result of this limited authority, no pre-market approval is required by the FDA. Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment, Registration and Listing, 66 Fed. Reg. at 5449. If the HCT/P is classified as a drug or medical device, the FDA has the authority under section 352 of the Public Health Service Act to impose more comprehensive regulations, including pre-market approval. 42 U.S.C. § 262 (2005).

44. In response to the concerns expressed by these comments, we have rewritten the proposed language. Proposed § 1271.10(c) has been renumbered as § 1271.10(a)(3), and now reads: "The manufacture of the HCT/P does not involve the combination of the cell or tissue component with a drug or a device, except for a sterilizing, preserving, or storage agent, if the addition of the agent does not raise new clinical safety concerns with respect to the HCT/P."

The addition of a drug or a device to the cell or tissue component of an HCT/P may ordinarily be expected to add a therapeutic effect and may also raise safety concerns. For these reasons, the addition of a drug or a device to a cell or tissue makes it no longer appropriate to regulate the HCT/P solely under section 361 of the PHS Act. (As used, the terms drug and device are defined in section 201(g) of the act (21 U.S.C. 321(g)).

However, we recognize that the use of certain sterilizing, preserving, and storage agents do not raise the same concerns. For this reason, we have excepted sterilizing, preserving, and storage agents, but only if the addition of the agent does not raise new clinical safety concerns with respect to the HCT/P. Examples of substances that would generally be acceptable include: (1) Cryoprotectants (e.g., DMSO); (2) chemicals used for sterilization (e.g., ethylene oxide); and (3) storage solutions. *We encourage the development of industry standards that describe the safe use of sterilization, preserving, and storage agents.*

Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing, 66 Fed. Reg. at 5459 (emphasis added).

servicing, or storage agent to an HCT/P raises new clinical safety concerns.”<sup>45</sup> The FDA’s stance gives the tissue banking industry free reign to determine what is in the best interest of patient safety without any check on the decision-making process employed by a company who stands to profit from an innovative processing technique that most likely required substantial investment to develop. Clearly, there is an incentive for a tissue processing company to determine the addition of an agent does not present a new safety concern thereby requiring time consuming and costly FDA pre-market approval.

The FDA has established regulations that set manufacturing standards for the tissue banking industry.<sup>46</sup> These regulations require tissue manufacturers “to follow current good tissue practice (CGTP), which governs the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps; recordkeeping; and the establishment of a quality program.”<sup>47</sup> Interestingly, the proposed regulations—the foundation of the current regulations—were based entirely on the current practices of the industry.<sup>48</sup>

If a tissue product is not classified as a drug or medical device, the proposed rule does not require pre-market approval for any processing technique. It only requires that the manufacturers not pool<sup>49</sup> human tissue during the manufacturing process and that they validate the process to ensure that it “does not cause contamination or cross-contamination” and “prevents the introduction, transmission, or spread of communicable disease.”<sup>50</sup> However, the process validation is carried out by the manufacturer.<sup>51</sup> Although these regulations give the FDA increased oversight of tissue processing, the FDA still relies on the industry to police itself. The FDA provides no incentive to develop new technology in order to prevent risks that are considered accept-

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45. *Id.*

46. Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement, 69 Fed. Reg. at 68,612.

47. *Id.*

48. *Id.* at 68,615 (stating “[t]he proposed requirements were based on current good industry practice”).

49. Pooling refers to placing tissue or human cells from two or more donors in contact with on another or mixing them in a single receptacle during manufacturing. Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement, 69 Fed. Reg. at 68,632. Pooling of human tissue during processing is thought to be an unacceptable practice and may pose a risk to patient safety. See Letter from Theodore Malinin, M.D., Professor of Orthopaedics and Rehabilitation and Director, Tissue Bank, University of Miami School of Medicine, to Dockets Management Branch, Docket No. 97B-484P, Food & Drug Administration (May 7, 2001), [http://www.fda.gov/ohrms/dockets/dailys/01/May01/050801/97n\\_484p-c000019.pdf](http://www.fda.gov/ohrms/dockets/dailys/01/May01/050801/97n_484p-c000019.pdf) (last visited Apr. 19, 2005) (on file with the Indiana Health Law Review).

50. Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement, 69 Fed. Reg. at 68,684 (to be codified at 21 C.F.R. § 1271.220).

51. *Id.* at 68,684, 68,660 (to be codified at 21 C.F.R. § 1271.230).

able within the industry. These acceptable risks could end up being highly detrimental to patient safety.

### III. BLOOD SHIELD LAWS

Forty-eight states have enacted statutes that grant blood banks immunity from strict liability.<sup>52</sup> Some states explicitly grant immunity to blood banks in order to shield the industry from strict liability.<sup>53</sup> Many states characterize a blood related transaction as the rendering of a service as opposed to the sale of a good; therefore, a plaintiff cannot pursue an action in strict liability.<sup>54</sup> Due to blood shield laws, the blood banking industry enjoys a comfort that most manufacturers do not enjoy in American society, which is immunity from strict liability. The treatment of the blood banking industry is the exception to the rule of product liability. As discussed *infra* Part V.A.-B., courts and legislatures appear to be willing to place tissue banks in the same category.

### IV. BLOOD SHIELD LAW RATIONALE ANALYZED BY COURTS

Although few courts have addressed whether tissue banks should be granted immunity from strict liability, several courts have determined whether pharmaceutical companies producing blood clotting factors from blood plasma should be granted immunity from strict liability. These courts faced the situation of determining whether hemophiliacs who contracted HIV through blood clotting factors could bring a strict liability claim. Due to the latency period between infection and the manifestation of symptoms of HIV and the immunity granted to the plasma fractionation industry, the plaintiffs in these cases found it almost impossible to receive compensation for their injuries.<sup>55</sup> However, a plaintiff's only effective means of redress for her injury was a claim in strict liability. The majority of American courts refused to allow these plaintiffs to bring a claim in strict liability, thereby denying any means of relief for the pain and suffering caused by diseases contracted through the use of products manufactured and sold by several for-profit pharmaceutical companies.

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52. AMERICAN LAW OF PRODUCTS LIABILITY (THIRD) § 20:3 (2004).

53. See, eg., ARK. CODE ANN. § 20-9-802 (Michie 2005); 42 PA. CONS. STAT. § 8333 (2004); WYO. STAT. ANN. § 35-5-110 (Michie 2004).

54. See, eg., ALA. CODE § 7-2-314(4) (2005); ALASKA STAT. § 45.02.316(e) (Michie 2004); ARIZ. REV. STAT. § 36-1151 (2004); CAL. HEALTH & SAFETY CODE § 1606 (West 2005); FLA. STAT. ANN. § 672.316(6) (West 2004); LA. REV. STAT. ANN. § 9:2797(A) (West 2004); N.Y. PUB. HEALTH LAW § 580(4) (McKinney 2005); WASH. REV. CODE § 70.54.120 (2004).

55. See HIV AND THE BLOOD SUPPLY, *supra* note 10, at 223-24; George W. Conk, *Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?*, 109 YALE L.J. 1087, 1111-17 (2000).

*A. Immunity Granted To Commercial Entities Under Blood Shield Laws*

The vast majority of courts throughout the United States have been unwilling to impose strict liability on pharmaceutical companies by construing the statutes broadly, allowing commercial entities immunity under blood shield laws. A California appellate court stated public policy supported immunity because it was impossible to test for hepatitis or screen donors to completely remove the risk of infection.<sup>56</sup> While making a reference to penicillin and cortisone, the court determined that blood clotting factors were unavoidably dangerous and that a court should be hesitant to impose strict liability because it could deter pharmaceutical companies from producing and selling enormously beneficial medical products.<sup>57</sup>

The rationale given in *Fogo* is typical of courts in late nineteen-seventies and early nineteen-eighties when faced with a case involving a hemophiliac who was infected with a blood borne disease by clotting factors. Many courts believed the risk of hepatitis and HIV infection was an unavoidable risk associated with the use of blood clotting factors. However, blood clotting factors were dangerous to anyone exposed to an infected product. The resulting infection was more than a potential side effect, it was an inevitable result.<sup>58</sup> The spread of a communicable disease is hardly analogous to the potential side effects of a drug; however, courts used this rationale to support immunity for pharmaceutical companies producing blood-clotting factors.

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56. *Fogo v. Cutter Lab., Inc.*, 137 Cal. Rptr. 417, 422 (Cal. Ct. App. 1977). Although this statement had some merit at that time, the process used to create clotting factors greatly increased the chances hemophiliacs would contract a blood borne disease such as hepatitis or HIV. See HIV AND THE BLOOD SUPPLY, *supra* note 10, at 81.

57. *Fogo*, 137 Cal. Rptr. at 422. The court quoted Prosser to support its unavoidably unsafe determination:

There are a number of cases involving hepatitis resulting from blood transfusions. So far as the transfusion itself is concerned, it has been regarded by most courts as a service, and not a sale, so that in the absence of negligence there is no liability of the hospital which gives it. But a blood bank which supplies the blood is certainly to be regarded as a seller; and [t]he general refusal to hold it strictly liable has gone on the basis of the unavoidability of the danger . . . . But strict liability, whether on warranty or in tort, does not require negligence; and the question becomes one of whether the defendant is to be held liable for marketing the thing at all. The argument that industries producing potentially dangerous products should make good the harm, distribute it by liability insurance, and add the cost to the price of the product, encounters reason for pause, when we consider that two of the greatest medical boons to the human race, penicillin and cortisone, both have their dangerous side effects, and that drug companies might well have been deterred from producing and selling them.

WILLIAM PROSSER, LAW OF TORTS UNSAFE PRODUCTS, § 19 at 661-62 (4th ed. 1971).

58. In 1987, the Centers for Disease Control and Prevention (CDC) reported that approximately seventy percent of hemophilia A patients and thirty-five percent of hemophilia B patients had tested positive for HIV antibodies. *Human Immunodeficiency Virus Infection in the United States*, 36 MORBIDITY & MORTALITY WKLY. REP. 801 (1987).

When a hemophiliac was infected with HIV after he received tainted clotting factors, a Georgia district court determined that allowing an action in strict liability would defeat the purpose of the blood shield law.<sup>59</sup> In another case involving a hemophiliac who contracted AIDS from clotting factors, an Illinois district court based its decision on the legislative determination that the blood shield laws were important to the health and welfare of the people of Illinois because strict liability would inhibit the "exercise of sound medical judgment and restrict the availability of important scientific knowledge, skills and materials."<sup>60</sup> The court determined that the plaintiff's interest in a remedy for her injury was outweighed by society's interest in maintaining an adequate blood supply.<sup>61</sup> Finally, the court found that it was immaterial that the producers of the clotting factors were commercial producers because the blood shield laws were drafted broadly to include any entity engaged in the production and distribution of blood products.<sup>62</sup> Along these same lines, a Pennsylvania court ruled, as a matter of first impression, that the Pennsylvania blood shield laws were applicable to commercial entities after a patient contracted hepatitis B and C from contaminated platelets; it specifically declared that public-policy was not against allowing immunity for commercial industries.<sup>63</sup> The court reasoned that there may never realistically be a test that can completely eliminate the risk of viral infections from blood clotting factors; therefore, the imposition of strict liability on commercial producers of blood clotting factors would discourage blood banking and frustrate the purpose behind the blood shield law.<sup>64</sup>

Continuing the trend, a Minnesota district court adopted the view that clotting factor producers were unable to completely remove the risk of HIV infection from clotting factors even by exercising due care.<sup>65</sup> Interestingly, the court determined the clotting factors lengthened and improved the quality of hemophiliacs' lives<sup>66</sup> while minimizing the plaintiff's statement that approximately seventy-five percent of hemophilia A patients, who represent nearly half the patient population for clotting factors, were infected with HIV in 1982.<sup>67</sup> The court rationalized its decision on the policy ground that imposing strict liability on such a small market would dramatically increase the cost of the product and threaten its availability.<sup>68</sup>

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59. *Jones v. Miles Lab., Inc.*, 705 F. Supp. 561, 563 (N.D. Ga. 1987).

60. *Poole v. Alpha Therapeutic Corp.*, 698 F. Supp. 1367, 1370 n.3 (N.D. Ill. 1988).

61. *Id.* The court buttressed its position by noting that immunity was accepted throughout the nation. *Id.*

62. *Id.*

63. *Weishorn v. Miles-Cutter*, 721 A.2d 811, 814 (Pa. Super. Ct. 1998).

64. *Id.*

65. *Doe v. Travenol Lab., Inc.*, 698 F. Supp. 780, 784 (D. Minn. 1988).

66. *Id.*

67. *Id.* at 784 n.8.

68. *Id.* at 784.

Although the arguments in favor of immunity are persuasive in light of society's interest in maintaining an adequate blood supply, the courts failed to address whether the pharmaceutical companies could have taken steps to reduce the risk of infection. Every court focused on the fact that the risk of HIV and hepatitis could not be completely prevented and ended their analysis of the risk at that point. However, if the courts had been willing to investigate the industry more closely, they may have been more inclined to construe the blood shield laws narrowly and allow relief.

*B. Immunity Not Applicable to Commercial Entities  
Under Blood Shield Laws*

Some courts have been unwilling to construe the blood shield laws broadly, thereby denying for-profit pharmaceutical companies immunity under blood shield laws. The Indiana Court of Appeals refused to grant immunity to pharmaceutical companies that supplied tainted clotting factors to a patient who eventually died of AIDS.<sup>69</sup> Adopting the principle of strict construction in this situation, the court determined that the legislature would have explicitly included pharmaceutical companies in the statute if it had intended to grant commercial entities immunity.<sup>70</sup> The court concluded that commercial producers of clotting factors were not in the same class as blood banks even though the manufacturing of factors involved storage of blood.<sup>71</sup> In turn, the court held that the pharmaceutical company's activities constituted the sale of a good rather than the rendition of a service; therefore, the company was subject to strict liability.<sup>72</sup>

A district court in Maryland refused to grant immunity from strict liability narrowly construing Maryland's blood shield statute. The court also determined that the risk of HIV infection from clotting factors was not a reasonable danger.<sup>73</sup> The court addressed numerous public policy grounds supporting immunity but ultimately determined that blood containing an undetectable disease was a defective product.<sup>74</sup> The defendant argued that allowing a claim in strict liability could dramatically decrease the supply of clotting factors.<sup>75</sup> The court dismissed this plea stating that the arguments in favor of strict liability apply to clotting factors just as they do to all other

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69. *JKB v. Armour Pharm. Co.*, 660 N.E.2d 602 (Ind. Ct. App. 1996).

70. *Id.* at 605.

71. *Id.*

72. *Id.*

73. *Doe v. Miles Lab., Inc., Cutter Lab. Div.*, 675 F. Supp. 1466, 1479 (D. Md. 1987). The court commented on the alarmingly high rate of infection: "It is estimated that up to 95% of severe hemophiliacs test positive for exposure to the HTLV-III virus. The nearly complete exposure by the group most in need of coagulant-factors and the inevitably fatal nature of the disease for those who actually develop it are stark facts." *Id.* (citation omitted).

74. *Id.*

75. *Id.* at 1479-80.

products: first, the court could not find a good reason to shift costs of the injury from the manufacture to the victims; second, the court recognized that it was a rational business decision to keep costs down and strict liability is the incentive for businesses to prevent accidents; third, the manufacturers of products are in the best position to spread the costs of injury; fourth, the court believed it was a better allocation of resources for the price of blood to reflect its actual costs.<sup>76</sup> Finally, the court stated it did not have the authority to create a subsidy for a particular product by shifting the costs of accidents to the consumer or the state without a clear expression by the legislature.<sup>77</sup>

The Washington Supreme Court stated that the legislature, when enacting blood shield laws, did not intend to grant statutory immunity from strict liability to pharmaceutical companies producing blood clotting factors.<sup>78</sup> The court focused its attention on the fact the legislature only considered whole blood when enacting the blood shield law, an abrogation of the common law.<sup>79</sup> Again, a court, operating under strict construction, refused to construe the statute broadly enough to allow immunity for commercial manufactures.

All of the courts which refused to grant statutory immunity faced statutes similar to the one in *Condos*.<sup>80</sup> However, they chose to construe the statutes very narrowly realizing the implications of their decisions. These courts were willing to recognize the differences between blood banks and commercial producers and impose strict liability on entities primarily motivated by profit, not patient safety or purpose.

### C. Restatement's Rationale for Limiting Strict Liability to Blood Banks

Courts in the past have relied on the Restatement (Second) of Torts<sup>81</sup> position, placing blood products in the same class as prescription drugs and vaccines and labeling them as unavoidably unsafe. The position taken by the Restatement (Second) of Torts is that some products cannot be made safe given the current state of human knowledge.<sup>82</sup> As an example, the Restatement acknowledges that many drugs and vaccines may cause serious side effects, however, these side effects are justified because the disease itself can lead to death.<sup>83</sup> These unsafe products are not considered unreasonably dan-

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76. *Id.* at 1480.

77. *Id.*

78. *Rogers v. Miles Lab., Inc.*, 802 P.2d 1346, 1347 (Wash. 1991) (stating that blood clotting factors are unavoidably unsafe and manufacturers should not be held strictly liable if proper warnings were included).

79. *Id.* at 1349.

80. *Condos v. Musculoskeletal Transplant Found.*, 208 F. Supp. 2d 1226 (D. Utah 2002). In *Condos*, the court ordered a strict liability claim against a tissue bank dismissed even though the blood shield law did not explicitly grant immunity to tissue banks. *Id.* See *infra* Part V.A.

81. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

82. *Id.*

83. *Id.*

gerous if properly produced and accompanied by appropriate warnings.<sup>84</sup> This comment also states that experimental drugs should not be considered unreasonably dangerous “because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk.”<sup>85</sup> The Restatement’s position is clear that strict liability should not be applied to drugs and vaccines. The consequences are considered “unfortunate” but reasonable because these products are considered useful and desirable.<sup>86</sup> The Restatement (Second) takes the position that a product that cannot be made safe is not unreasonably dangerous under a products liability standard if the product is useful and desirable and proper warnings are given.

In a more recent publication, the American Law Institute (ALI)<sup>87</sup> has expressed a slightly different rationale for the unique treatment of drugs and medical devices. The Restatement (Third) of Torts: Products Liability states that a product is not reasonably safe if the risks of the product known to medical professionals would significantly outweigh the benefits, thereby preventing the health care provider from using the product on any class of patient.<sup>88</sup> The ALI places drugs and medical devices in a unique category outside of standard consumer products.<sup>89</sup> This distinction is rightful. It recognizes that drugs and medical devices are very unique in that they may be harmful to one patient but lifesaving to another; therefore, drugs and medical devices should be employed only under a physician’s care who can thoughtfully weigh the risks and benefits to each particular patient.<sup>90</sup> Implicit in the physician’s and patient’s consideration of the risks and benefits is full disclosure of the known risks and benefits of the drug or medical device. The ALI states that courts have given considerable deference to regulatory agencies when considering drug design.<sup>91</sup> This deference rests on three assumptions: first, it is in the interest of public policy for drugs and medical devices to be available to patients at a reasonable cost; second, when health care providers are informed about the drugs and medical devices by the manufacturers, the proper drug or medical device will be prescribed to the patients who can truly

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84. *Id.*

85. *Id.*

86. *Id.*

87. The ALI publishes the Restatement.

88. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c) (1998).

A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.

*Id.*

89. *Id.* § 6 cmt. b.

90. *Id.*

91. *Id.*

benefit from the drug or medical device; third, “governmental regulatory agencies adequately review new prescription drugs and devices, keeping unreasonably dangerous designs off the market.”<sup>92</sup>

The ALI then goes to state its rationale for the relaxed standard for drugs and medical devices:

The requirement for establishing defective design of a prescription drug or medical device . . . is that the drug or device have so little merit compared with its risks that reasonable health-care providers, possessing knowledge of risks that were known or reasonably should have been known, would not have prescribed the drug or device for any class of patients. Thus, a prescription drug or medical device that has usefulness to any class of patients is not defective in design even if it is harmful to other patients.<sup>93</sup>

Many of the blood shield laws used the product service distinction to provide immunity from strict liability; however, in recent years this distinction has become disfavored by many courts.<sup>94</sup> The product service distinction does not provide sufficient guidance for a court when faced with considering patient safety if a medical product is not regulated by the FDA in the same manner as drugs and medical devices. As discussed in *supra* Part II., tissue products do not have to be preapproved by the FDA before release. This pre-market approval is a costly and time consuming regulatory process, but it is primarily focused on patient safety.<sup>95</sup> The regulatory process imposed on drugs and medical devices is a balance between the cost and availability of drugs and medical devices and the reasonable expectation of patient safety by consumers of these products. Certainly, if the FDA’s regulatory standards were less stringent, more drugs and medical devices would be available at a reduced cost. However, this decreased cost and increased availability would come at

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92. *Id.* The third assumption rests on infirm ground when viewed in the context of tissue bank regulation. As discussed in *supra* Part II, the FDA does not require HCT/P to go through the pre-market approval process. Tissue products must only meet minimal standards that protect patients from known risks of infectious disease. This assumption is based on the presumption that the FDA will weigh the risks and benefits and ensure the health care community will be adequately informed about HCT/Ps. However, in the context of tissue bank regulation the manufacturer of a tissue product is allowed to decide if a HCT/P “raises new clinical safety concerns.” Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing, 66 Fed. Reg. 5447, 5459 (Jan. 19, 2001).

93. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 cmt. b (1998).

94. See David B. Harrison, Annotation, *Application of Rule of Strict Liability In Tort To Person or Entity Rendering Medical Services*, 100 A.L.R.3D 1205 (2004).

95. See 1 JAMES T. O’REILLY, FOOD AND DRUG ADMINISTRATION § 18:8 (2d ed. 2004).

the expense of patient safety.<sup>96</sup> This trade off for increased patient safety is accepted for drugs and medical devices, but when the FDA considered increasing regulation over the tissue banking industry, it faced opposition from the industry stating that increased regulation was unnecessary to ensure patient safety and would decrease availability.<sup>97</sup> Although the detriment suffered by patients through FDA regulation of drugs and medical devices is accepted, the tissue banking industry does not believe it is in the same class as drug and medical device manufacturers and therefore should not be strictly regulated.<sup>98</sup> Interestingly, the regulatory process imposed upon drug and medical device manufacturers is one of the main presumptions employed by the ALI to rationalize the relaxed standards of strict liability for these unique manufacturers.

Nevertheless, patients are still at risk of severe injury or death from receiving a defective tissue graft just as they are from receiving a defective

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96. For example, the explosively popular weight loss drug Redux was marketed and sold in Europe years before it received approval by the FDA for distribution in the United States. See Robert Langreth, *Medicine: Obesity Drug Appears Close to Approval*, WALL ST. J., Jan. 29, 1996, at B1. However, this approval had tragic consequences for numerous patients. See David S. Cloud & Richard B. Schmitt, *Probe Aims to Determine if Diet-Drug Clearance Merits Criminal Inquiry*, WALL ST. J., Sept. 9, 1999, at A3; Laura Johannes & Steve Stecklow, *Redux Panel Was in the Dark*, WALL ST. J., Dec. 11, 1997, at A1; Edward R. Silverman, *Diet Pill Revolution Stalls Amid Concerns*, THE STAR-LEDGER, Sept. 10, 1997, at 1. Eventually, Redux was recalled and removed from the U.S. market amid concerns that prolonged use could damage heart valves. See Alison R. McCabe, Note, *A Precarious Balancing Act--The Role of the FDA as Protector of Public Health and Industry Wealth*, 36 SUFFOLK U. L. REV. 787 (2003). This event demonstrates the value society places on patient safety. The general public is willing to make the trade off between increased cost and decreased availability to increase patient safety. The tissue banking industry should be provided with the correct incentives to mirror society's expectations of patient safety and corporate responsibility.

97. See Letter from Jamie M. Grooms, Regeneration Technologies, to Dockets Mgmt. Branch, Docket No. 97N-484P, Food & Drug Admin. (May 7, 2001), [http://www.fda.gov/ohrms/dockets/dailys/01/May01/050801/97n\\_484p-c000015.pdf](http://www.fda.gov/ohrms/dockets/dailys/01/May01/050801/97n_484p-c000015.pdf) (last visited Apr. 19, 2005) (on file with the Indiana Health Law Review); see also Letter from Thomas L. Craig, President, Orthopedic Surgical Mfrs. Ass'n to Dockets Mgmt. Branch, Docket No. 97N-484P, Food & Drug Admin. (May 7, 2001), [http://www.fda.gov/ohrms/dockets/dailys/01/May01/050801/97n\\_484p-c000016.pdf](http://www.fda.gov/ohrms/dockets/dailys/01/May01/050801/97n_484p-c000016.pdf) (last visited Apr. 19, 2005) (on file with the Indiana Health Law Review); Letter from Margery Moogk, Director, Northwest Tissue Ctr., to Dockets Mgmt. Branch, Docket No. 97N-484P, Food & Drug Admin. (May 7, 2001), [http://www.fda.gov/ohrms/dockets/dailys/01/May01/050801/97n\\_484p-c000014.pdf](http://www.fda.gov/ohrms/dockets/dailys/01/May01/050801/97n_484p-c000014.pdf) (last visited Apr. 19, 2005) (on file with the Indiana Health Law Review); Letter from Joel C. Osborne, Director of Quality Assurance and Regulatory Affairs, Musculoskeletal Transplant Found., to Dockets Mgmt., Docket No. 97N-484P, Food & Drug Admin. (May 7, 2001), [http://www.fda.gov/ohrms/dockets/dailys/01/May01/050801/97n\\_484p-c000022.pdf](http://www.fda.gov/ohrms/dockets/dailys/01/May01/050801/97n_484p-c000022.pdf) (last visited Apr. 19, 2005) (on file with the Indiana Health Law Review); Letter from James C. Vander Wyk, Ph.D., Vice-President, Regulatory Affairs and Quality Assurance, CryoLife, Inc., to Dockets Mgmt. Branch, Docket No. 97N-484P, Food & Drug Admin. (May 7, 2001), [http://www.fda.gov/ohrms/dockets/dailys/01/May01/050801/97n\\_484p-c000021.pdf](http://www.fda.gov/ohrms/dockets/dailys/01/May01/050801/97n_484p-c000021.pdf) (last visited Apr. 19, 2005) (on file with the Indiana Health Law Review).

98. See Letters *supra* note 97.

drug.<sup>99</sup> Patient safety is a prime concern for the general public. The current state of regulation of the tissue banking industry does not provide the proper incentives. Additionally, the immunity the tissue banking industry enjoys poses a significant threat because manufacturers of tissue products are not motivated to protect patients in the same way as drug and medical device manufacturers.<sup>100</sup>

## V. CASES DEFINING TISSUE BANK LIABILITY

### A. *Condos v. Musculoskeletal Transplant Foundation*

In *Condos*,<sup>101</sup> one of two reported cases<sup>102</sup> that have addressed the issue whether strict liability applies to tissue banks, the transplantee contracted hepatitis C virus after a bone graft was implanted.<sup>103</sup> The transplantee brought suit against the tissue bank that distributed the graft and the company that processed the tissue. One of the transplantee's basis for recovery was a claim in strict liability; however, the court dismissed the transplantee's strict liability claim.<sup>104</sup> The court based its decision to dismiss the strict liability claim on statutory and public policy grounds.<sup>105</sup>

The court determined that the Utah Blood Shield Statute (UBSS) instructed it to construe the distribution and processing of blood and blood products as a service.<sup>106</sup> Interestingly, the statutory language does not clearly

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99. See *Dangers of Tainted Tissues Hearings*, *supra* note 18 (statement of Jesse L. Goodman, M.D., Director of the FDA Center for Biologics Evaluation and Research); *CDC Response to Infections Related to Human Tissue Transplantation: Hearings Before the Committee on Governmental Affairs*, 108th Cong. (2003) [hereinafter *CDC Response to Infections Hearings*] (statement of Steven L. Solomon, M.D., Acting Director, Division of Healthcare Quality Promotion, CDC's National Center for Infectious Diseases); *Human Tissue Banks Hearings*, *supra* note 26 (statement of Kathryn C. Zoon, Ph.D., Director, Center for Biologics Evaluation and Research, Food & Drug Admin. Dep't of Health & Human Servs.); Anna Lumelsky, *Transplant Tissue: Cryolife Human Soft Tissue Implants Recalled*, 30 J.L. MED. & ETHICS 474 (2002); *Septic Arthritis Following Anterior Cruciate Ligament Reconstruction Using Tendon Allografts--Florida and Louisiana, 2000*, 50 MORBIDITY & MORTALITY WKLY. REP. 1081 (2001); *Public Health Dispatch: Update: Unexplained Deaths Following Knee Surgery--Minnesota, 2001*, 50 MORBIDITY & MORTALITY WKLY. REP. 1080 (2001); Claudia Kalb, *Nasty Infections; As the Government Cracks Down on Tissue Banks, Patients Worry About Safety and Consider Their Options*, NEWSWEEK, Aug. 26, 2002, at 48.

100. See generally Conk, *supra* note 55, at 1087 (arguing the Restatement approach to strict liability as applied to medical products should be revised to provide the necessary incentives to protect against a medical disaster).

101. *Condos v. Musculoskeletal Transplant Found.*, 208 F. Supp. 2d 1226 (D. Utah 2002).

102. See *id.*; *Cryolife, Inc. v. Super. Ct. of Santa Cruz County*, 2 Cal. Rptr. 3d 396 (Cal. Ct. App. 2003).

103. See *Condos*, 208 F. Supp. 2d at 1227-28.

104. *Id.* at 1230.

105. *Id.* at 1228-30.

106. *Id.* at 1230.

indicate it applies to tissue products.<sup>107</sup> The court construed the statutory text stating:

This statement recognizes that medical transfusions and transplants are essentially medical services, even though a tangible item is involved in the process. Accordingly, the Court finds that human bone tissue is not a “product” subject to products liability law, and that the distribution of human tissue, including reasonable payments for related services, does not constitute a “sale” for purposes of strict liability.<sup>108</sup>

The court quickly dismissed the transplantee’s argument that the absence of language expressly granting immunity implied tissue products should be subject to strict liability.<sup>109</sup> Although the court appeared to refrain from making unnecessary implications from the statutory language, the court’s construction practically rewrote the statute to shield tissue banks from strict liability even though the statutory language did not include tissue products.

Although the statutory text did not fully support the court’s decision, the court believed that public policy strongly supported its decision to dismiss the strict liability claim.<sup>110</sup> It stated that the transplantee’s public policy argument had some merit.<sup>111</sup> The court recognized that the transplantee is in a particularly vulnerable position and that strict liability was created to protect the consumer in our complex society.<sup>112</sup> The court appeared to give some weight to public policy considerations of a person in the transplantee’s position and may have ruled differently if it had not given so much weight to the statute. However, the court deferred to the legislature stating, “this Court is not in a position to decide state tort law policy, especially in light of the clear legislative policy indications to the contrary.”<sup>113</sup>

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107. The relevant section of the UBSS states:

The procurement, processing, distribution, or use of whole human blood, plasma, blood products, and blood derivatives for the purpose of injecting or transfusing them into the human body together with the process of injecting or transfusing the same shall be construed to be the rendition of a service by every person participating therein and shall not be construed to be a sale.

UTAH CODE ANN. § 26-31-1 (1998).

108. *Condos*, 208 F. Supp. 2d at 1230.

109. *Id.* at 1229. The court reasoned, “[p]laintiffs’ argument under the UBSS is not persuasive. No court has ever applied strict liability to the distribution of human tissue . . . [The UBSS] cannot reasonably be read as an implied acknowledgment that other human tissue is a ‘product’ subject to strict liability.” *Id.*

110. *Id.* at 1230.

111. *Id.* at 1229.

112. *Id.* The *Condos* court stated, “Strict liability was created because of the limitations in negligence remedies and to protect consumers in an increasingly complex society. Patients are helpless to prevent harm caused by infected human tissue distributed to hospitals for implantation or transfusion.” *Id.* (citation omitted).

113. *Id.*

The *Condos* court then addressed policy statements in the Restatement of Torts<sup>114</sup> and the policy indicated by the Utah Legislature through the Uniform Anatomical Gift Act (UAGA).<sup>115</sup> The UAGA prohibits the sale of human tissues,<sup>116</sup> but allows for “reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transportation, implantation of a part, and administration of a procurement entity, including educational and other efforts to encourage anatomical gifts.”<sup>117</sup> The court interpreted the UAGA in relation to the situation as follows: “Clearly, the Utah legislature does not consider the manner in which MTF distributes human bone tissue to hospitals to be a ‘sale.’ MTF and Osteotech are careful to only charge for the services they provide and properly disclaim any ownership of the bone tissue in their operating contracts.”<sup>118</sup>

The court in *Condos* was careful to place the weight of its opinion on statutory construction rather than on public-policy grounds.<sup>119</sup> However, the court failed to realize the importance of its decision in two respects. First, it failed to realize that it was the first court to rule on whether strict liability applied to tissue banks. Second, it failed to address the issue that Osteotech is a private company that processes tissue to generate a profit.<sup>120</sup> Implicit in the court's decision is the acknowledgment that the Utah Legislature and the courts will permit private companies to profit from an individual's final gift and shield those profits from plaintiffs who are injured by the products but never given the opportunity to make their case.

### B. *Cryolife, Inc. v. Superior Court*

In *Cryolife*, the plaintiff was a transplant patient who received a cadaveric patellar tendon graft supplied by Cryolife.<sup>121</sup> Two months after the surgical procedure, the surgical graft was removed from the plaintiff due to a bacterial infection.<sup>122</sup> The plaintiff brought a cause of action in strict liability

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114. “Human blood and human tissue, even when provided commercially, are not subject to the rules of this Restatement.” *Id.* (quoting RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 19 (1998)). Additionally, the authors of the Restatement state that this view is consistent with jurisdictions throughout the United States. *Id.* § 19 cmt. c.

115. UTAH CODE ANN. § 26-28-10 (2005).

116. *Id.* § 26-28-10(1).

117. *Id.* § 26-28-10(2).

118. *Condos*, 208 F. Supp. 2d at 1230.

119. *Id.*

120. See *Osteotech, Inc., Financial: Financial Highlights*, at <http://www.osteotech.com/finhi.htm> (last visited Apr. 19, 2005) (on file with the Indiana Health Law Review). In 2003, Osteotech's gross profits were \$52.3 million—fifty-five percent of its revenue. *Id.* It appears that the court was willing to accept that a charge generating a fifty-five percent profit is reasonable for the processing of human tissue under the UAGA.

121. *Cryolife, Inc. v. Super. Ct. of Santa Cruz County*, 2 Cal. Rptr. 3d 396, 398 (Cal. Ct. App. 2003). Cryolife is a “tissue bank in the business of harvesting, preserving and distributing products derived from human tissue for medical use.” *Id.*

122. *Id.*

pleading the following: the tissue product was not fit for its intended use; CryoLife had failed to warn either the plaintiff or the health care provider of the risks associated with the use of this tissue product; the tissue product was defective; the tissue was inadequately tested and treated; Cryolife misled the plaintiff and health care providers about the safety of the product;<sup>123</sup> and Cryolife had maliciously denied that an infection could be caused by the tissue graft.<sup>124</sup> The trial court refused to dismiss the strict liability claim.<sup>125</sup> When Cryolife appealed the trial court's decision, the appellate court dismissed the plaintiff's strict liability claim.<sup>126</sup>

The appellate court based its decision to dismiss on statutory and public policy grounds.<sup>127</sup> The court looked to California's blood shield law to determine if the legislature had granted immunity from strict liability to tissue banks.<sup>128</sup> Interestingly, this section of the statute does not include a reference to tissue banks. However, another section of the California Health and Safety Code grants tissue banks immunity,<sup>129</sup> but this statute is phrased differently than the statute addressing blood products. The statute addressing tissue banks reads:

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123. Cryolife has not been a particularly good corporate citizen when it comes to the safety of their products. In August 2002, the FDA stated:

After determining that Cryolife failed to take adequate corrective measures to address possible infectious disease contamination of tissue, and after reviewing information provided by the firm in response to FDA's warnings, FDA issued the present order for retention, recall and/or destruction of allograft tissues other than allograft heart valves, and is issuing this Web Notification to physicians regarding FDA's recommendations for both allograft heart valves and other allograft tissues. FDA's concerns described in the order relate specifically to bacterial and fungal contamination of soft tissues, such as cartilage and tendons.

CTR. FOR DEVICES & RADIOLOGICAL HEALTH, FOOD & DRUG ADMIN., FDA PUBLIC HEALTH WEB NOTIFICATION: HUMAN TISSUE PROCESSED BY CRYOLIFE, INC. (Aug. 21, 2002), at <http://www.fda.gov/cdrh/safety/humantissue.html> (last visited Apr. 19, 2005) (on file with the Indiana Health Law Review). For a brief overview of this recall see Lumelsky, *supra* note 99.

124. *Cryolife*, 2 Cal. Rptr. 3d at 398.

125. *Id.* at 400.

126. *Id.* at 408.

127. *Id.* at 400-05

128. CAL. HEALTH & SAFETY CODE § 1606 (West 2005). California's blood shield law states:

The procurement, processing, distribution, or use of whole blood, plasma, blood products, and blood derivatives for the purpose of injecting or transfusing the same, or any of them, into the human body shall be construed to be, and is declared to be, for all purposes whatsoever, the rendition of a service by each and every person, firm, or corporation participating therein, and shall not be construed to be, and is declared not to be, a sale of such whole blood, plasma, blood products, or blood derivatives, for any purpose or purposes whatsoever.

*Id.*

129. In California, a tissue bank is defined as "any place, establishment, or institution that collects, processes, stores, or distributes tissue for transplantation into human beings." CAL. HEALTH & SAFETY CODE § 1635(d) (West 2005).

The Legislature hereby declares its intent that the collection, processing, storage, or distribution of tissue for the purpose of transplantation, as regulated by this chapter, shall be deemed a service by those persons engaged in these activities. Therefore, the collection, processing, storage, or distribution of tissue for the purpose of transplantation, as regulated by this chapter, shall not be subject to the requirements of Division 2 (commencing with Section 2101)<sup>130</sup> of the Commercial Code.<sup>131</sup>

Clearly, the language in the section addressing tissue banks is very different from the blood product sections. The plaintiff claimed that the differences in the statutory language indicated that the legislature only intended to prevent application of the Commercial Code and not grant immunity to tissue banks.<sup>132</sup>

However, the court did not find the plaintiff's argument persuasive.<sup>133</sup> The court stated the rationale behind the blood shield law was that the supplying of blood was incidental to the services provided by a hospital and there is strong public policy in favor of maintaining an adequate supply of blood.<sup>134</sup> The court then addressed the section that applied to tissue banks:

The statute is unequivocal in its plain language, placing no limits on the circumstances in which a tissue bank will be deemed to have provided a service. . . . “[I]f statutory language is ‘clear and unambiguous there is no need for construction, and courts should not indulge in it.’”<sup>135</sup>

The court construed the plain meaning of the statute as follows: “Therefore, by expressly excluding the application of the sales and warranty provisions of the Commercial Code to ‘the collection, processing, storage, or distribution of tissue for the purpose of transplantation,’<sup>136</sup> the Legislature implicitly excluded such tissue-related activities from the application of the doctrine of strict liability.”<sup>137</sup>

Although the statute did exclude tissue banks from the Commercial Code, the statute did not explicitly provide immunity from strict liability. The court decided not to rest its entire opinion on statutory construction. The court analyzed other statutory sections and court decisions to provide additional

130. Division 2 of the Commercial Code concerns the sale of goods.

131. CAL. HEALTH & SAFETY CODE § 1635.2 (West 2005).

132. *Cryolife*, 2 Cal. Rptr. 3d at 402.

133. *Id.*

134. *Id.*

135. *Id.* (quoting *Tiernan v. Trustee of Cal. State. Univ. & Colleges*, 33 Cal. 3d 211, 218 (Cal. 1982)).

136. CAL. HEALTH & SAFETY CODE § 1635.2 (West 2003).

137. *Cryolife*, 2 Cal. Rptr. 3d at 403.

support for its decision. First, the court stated that the Uniform Anatomical Gift Act (UAGA)<sup>138</sup> “also demonstrate[s] the Legislature’s broad intent that the provision of human tissue not be considered a sale of goods or products.”<sup>139</sup> The court looked to the section in the UAGA that allowed payment for tissue related services.<sup>140</sup> Second, the court stated that it was a crime<sup>141</sup> to knowingly sell human tissue for the purpose of transplantation.<sup>142</sup> Third, the court analogized tissue banking to the services provided by a pharmacist.<sup>143</sup> In a case involving a strict liability claim against a pharmacist, the California Supreme Court concluded that the pharmacists had statutory immunity from strict liability similar to that granted by the blood shield law even though pharmacists sell a product and are compensated for their service.<sup>144</sup> The court placed significant weight in this analogy stating:

When the Legislature enacted section 1635.2 in 1991 as part of a regulatory scheme for tissue banks, it had to know that tissue banks are paid for their activities in connection with providing human cadaver tissue for medical use. By expressly deeming such activities to constitute a service, the Legislature must have intended a tissue bank to be immune from strict liability, just like a pharmacy.<sup>145</sup>

Finally, the court cited *Condos*<sup>146</sup> and the Restatement<sup>147</sup> as additional authority in accord with its opinion.<sup>148</sup>

Next, the court found that public policy supporting blood shield laws also supported immunity for tissue banks.<sup>149</sup> The court explained its position stating:

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138. CAL. HEALTH & SAFETY CODE §§ 7150-7157 (West 2005). The Uniform Anatomical Gift Act provides, “[a] person may not knowingly, for valuable consideration, purchase or sell a part for transplantation, therapy, or reconditioning, if removal of the part is intended to occur after the death of the decedent . . . .” *Id.* § 7155(a).

139. *Cryolife*, 2 Cal. Rptr. 3d at 403.

140. *Id.* “However, payment for tissue-related services is allowed, including ‘the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of a part.’” *Id.* (quoting CAL. HEALTH & SAFETY CODE § 7155(b)) (West 2003).

141. CAL. PENAL CODE § 367f(c)(1) (West 2005).

142. *Cryolife*, 2 Cal. Rptr. 3d at 403.

143. *Id.*

144. *See* *Murphy v. E.R. Squibb & Sons, Inc.*, 221 Cal. Rptr. 447 (Cal. 1985).

145. *Cryolife*, 2 Cal. Rptr. 3d at 404 (footnote omitted).

146. *Condos v. Musculoskeletal Transplant Found.*, 208 F. Supp. 2d 1226 (D. Utah 2003).

147. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 19 (1998).

148. *Cryolife*, 2 Cal. Rptr. 3d at 404.

149. *Id.* at 405. “[W]e see no reason that the public policy rationale for exempting blood products from strict liability should not also apply to human tissue products, such as the allograft at issue in the case at bar.” *Id.*

In our view there is a legitimate state interest in manufactured blood products. We concur in the perception that “legislatures have determined that the production and use of human blood *and its derivatives* for therapeutic purposes should be encouraged; and for this purpose those who provide these products, and who are themselves free from fault, should not be required to bear the economic loss which might otherwise be imposed under the rules of strict liability which are applicable to sellers of commercial products generally.” The California statutory provisions we have discussed reflect a similar legitimate state interest in human tissue products used for therapeutic purposes.<sup>150</sup>

The court in *Cryolife* found it easy to analogize the activities engaged in by tissue banks to the activities of pharmacists and blood banks. However, the court failed to realize the true differences between blood banks and pharmacists as compared to tissue banks. Tissue banks do not provide a product incidental to a professional service. Rather, tissue banks actually process human tissue to create a product they market and sell to health care providers. If the court had taken a legitimate look into the tissue banking industry, it would have found real differences that set tissue banking apart from professionals that merely provide a product incidental to a service. Nevertheless, it still stands in question whether the rationale supporting blood shield laws would logically apply if a court effectively considered the activities of the tissue banking industry.

## VI. PLASMA FRACTIONATION INDUSTRY AND PATIENT SAFETY

Coagulant factors, produced by the plasma fractionation industry,<sup>151</sup> are used to treat severe cases of hemophilia.<sup>152</sup> Coagulant factors and tissue products are direct derivatives from the human body. In turn, these blood products produce similar risks to patient safety when compared to tissue products due to the numerous diseases that are blood-borne, particularly hepatitis and HIV. As is evident, the regulation of the fractionation industry is analogous to the regulation of the tissue banking industry in that the FDA depended on the industry to police itself. However, this regulatory approach

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150. *Id.* (quoting *Hyland Therapeutics v. Super. Ct.*, 175 Cal. App. 3d 509, 516 (Cal. Ct. App. 1985)).

151. The plasma fractionation industry acquires plasma from whole blood collectors and plasma collection centers. After collection, the plasma is sent to a laboratory where it is further separated into proteins through a process called fractionation. HIV AND THE BLOOD SUPPLY, *supra* note 10, at 29-31.

152. For a primer on hemophilia see Hemophilia Association, Information, at <http://www.hemophiliaz.org> (last visited Apr. 19, 2005) (on file with the Indiana Health Law Review).

coupled with immunity from strict liability devastated the hemophiliac population while allowing only minimal compensation for their injuries.

Currently, blood clotting factors used to treat severe hemophiliacs are processed using heat treatment or chemical detergents to inactivate the HIV virus.<sup>153</sup> However, viruses were not always inactivated in blood clotting factors released to the public. Instead, the plasma fractionation industry did not attempt to deactivate any virus in their clotting factors until it was too late to prevent the hemophiliac population from being devastated by HIV.<sup>154</sup>

Although it may appear that the HIV outbreak in hemophiliacs was the impetus for the development of viral inactivation technology, it is important to look at the development of technology that could have prevented the spread of hepatitis in hemophiliacs.<sup>155</sup> Technology that would have deactivated the hepatitis virus would have also prevented the spread of AIDS to many hemophiliacs.<sup>156</sup> Disturbingly, hepatitis was considered a reasonable risk,<sup>157</sup> but in a relatively short period of time, this reasonable risk of being infected by a blood borne pathogen became devastatingly unreasonable requiring action that could have been taken years before to eliminate this risk. The patients who receive tissue products are likely heading down this same path. Is it reasonable to make the same mistake twice?

The processing techniques used by the plasma fractionation industry greatly increased the risk that a hemophiliac would contract a virus from clotting factors.<sup>158</sup> The plasma fractionation industry knew of the substantial risk of hepatitis infection to hemophiliacs consuming their products shortly after clotting factors were introduced.<sup>159</sup> However, no steps were taken at that time to eliminate or reduce this risk even though blood derivative products had been heat treated since the nineteen-forties to destroy viruses.<sup>160</sup> In 1983, the plasma fractionation industry finally began to implement viral inactivation techniques; however, according to the Institute of Medicine, viral inactivation technology could have been developed before 1980 and prevented many cases of HIV in hemophiliacs.<sup>161</sup>

In 1976, research had begun on the feasibility of using chemical solutions to inactivate the hepatitis virus in clotting factors while maintaining

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153. HIV AND THE BLOOD SUPPLY, *supra* note 10, at 81.

154. *See Id.* at 81-96; *Human Immunodeficiency Virus Infection in the United States*, *supra* note 58, at 801.

155. *See* HIV AND THE BLOOD SUPPLY, *supra* note 10, at 81.

156. *Id.* at 5.

157. *Id.* at 93.

158. *Id.* at 5. "In fact, the methods used to manufacture AHF concentrate can also inadvertently concentrate certain viruses, present in the original plasma donation, within the final product preparation. The fact that AHF concentrate is prepared from pooled plasma from thousands of donors greatly increases its risks for transmitting disease." *Id.* at 81.

159. *Id.*

160. *Id.*

161. HIV AND THE BLOOD SUPPLY, *supra* note 10, at 95.

therapeutic value.<sup>162</sup> These studies proved to be unconvincing, and hepatitis still remained the major risk for hemophiliacs using clotting factors in 1978.<sup>163</sup> By the early nineteen-eighties, several companies within the plasma fractionation industry were developing heat treating methods to inactivate viruses. "There was, however, little if any communication between the different manufacturers regarding the results of the ongoing experiments, because of antitrust laws, regulations, and the normal business consideration of competitive advantage."<sup>164</sup> The manufactures in the plasma fractionation industry were for-profit organizations driven by a desire to gain a competitive advantage over their rivals. The competitive atmosphere coupled with the view that hepatitis was an "acceptable risk for individuals with hemophilia because it was considered a medically manageable complication of a very effective treatment for hemophilia" proved to be very dangerous for hemophiliacs.<sup>165</sup>

Although the manufacturers were developing technology to inactivate the viruses, one major concern in the implementation of the technology was the "potential additional cost of implementing the process."<sup>166</sup> The regulatory framework, including FDA regulations and blood shield laws, placed the decision and motivation to develop viral inactivation method in the hands of the for-profit plasma fractionation industry.<sup>167</sup> Is it really rational to place patient safety in the hands of organizations that stand to gain if they produce a product that is just "safe enough" to pass their own standards?

"[T]he impelling motive and decision to develop viral inactivation methods depended almost entirely on the plasma fractionation industry."<sup>168</sup> The FDA's role in the development of viral deactivation technology for clotting factors was very small. First, the FDA considered the transmission of hepatitis to be an acceptable risk and did not believe it was urgent that this technology be developed.<sup>169</sup> Second, the FDA, at that time, did not have the appropriate expertise to develop viral inactivation methods believing the expertise resided within the manufactures of the products "and that innovations would eventually emerge."<sup>170</sup> Third, even if the FDA wanted to pursue viral inactivation methods, the FDA had very limited personnel for regulatory oversight and limited internal facilities and support in the early nineteen-eighties.<sup>171</sup>

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162. *Id.* at 86 (citations omitted).

163. *Id.*

164. *Id.* at 88.

165. *Id.* at 93.

166. *Id.* at 89.

167. HIV AND THE BLOOD SUPPLY, *supra* note 10, at 93-4.

168. *Id.*

169. *Id.* at 94.

170. *Id.*

171. *Id.*

Due to the FDA's limited role and resources, the FDA looked to the industry to develop viral inactivation technology. However, the industry did not have the proper incentives in place:

[T]he factors that influenced the pace of viral inactivation technologies developed by industry included interest in gaining competitive advantage and concerns over yield and cost. While these concerns are understandable from the perspective of a manufacturer, in the absence of active encouragement by the FDA these concerns probably inhibited expeditious progress in inactivation technologies. Further, with the primary responsibility for the development of viral inactivation methods left to industry, inherent limitations were placed on the free exchange of scientific and technical information that might expedite product development efforts. *Operating in a competitive market, manufacturers are not inclined to share the details of their research efforts; and the FDA is legally barred from sharing a company's research findings among competitors.* Companies interacting among each other could be in violation of antitrust laws and face potential criminal charges, fines, and sanctions. Furthermore, the very nature of the competitive world of business is one that normally would cause a company to preserve manufacturing processes and research results for its own benefit, to enable the marketing of products at a competitive advantage.<sup>172</sup>

The Institute of Medicine stated that the "heat treatment processes to prevent the transmission of hepatitis could have been developed before 1980, an advance that would have prevented many cases of AIDS in individuals with hemophilia."<sup>173</sup> The Institute believed the plasma fractionation industry was not properly encouraged to develop heat treating technology before HIV ravaged the hemophiliac population. It stated that "[s]trong incentives to maintain the status quo and a weak countervailing force concerned with blood product safety, combined to inhibit rapid development of heat-treated products by plasma fractionation companies."<sup>174</sup> One strong incentive that was completely removed was the threat of civil litigation through strict liability. Strict liability could have proved to be a strong incentive for the plasma fractionation industry to develop viral inactivation methods before HIV

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172. *Id.* at 94-5 (emphasis added).

173. HIV AND THE BLOOD SUPPLY, *supra* note 10, at 95.

174. *Id.* at 96.

devastated hemophiliacs. However, strict liability was never a viable option for hemophiliacs except in a few isolated circumstances.<sup>175</sup>

The story of HIV and hemophiliacs clearly indicates that the legislatures failed to create the proper incentives for for-profit organizations. The legislatures also failed to implement a regulatory system capable of properly addressing the unique risks associated with products derived from the human body. To add insult to injury, the legislatures provided immunity from strict liability for the manufactures of these uniquely dangerous products. The blood shield laws and regulatory system combined to prove devastating to hemophiliacs by failing to place the proper incentives on patient safety. This approach allowed pharmaceutical companies to maximize profits at the expense of patient safety.

## VII. THE CONSEQUENCES OF BLOOD SHIELD LAWS

Because of the enactment of blood shield laws in forty-eight states, injuries related to blood products cannot be pursued under a theory of strict liability.<sup>176</sup> Blood shield laws are intended to protect the general public by ensuring an adequate supply of blood.<sup>177</sup> As a consequence of these laws, hemophiliacs, infected with HIV by blood products, have found it nearly impossible to obtain compensation from the plasma fractionation industry.<sup>178</sup> This statutory immunity coupled with scant regulation exposed a weakness in this system in the early nineteen-eighties—"its ability to deal with a new threat that was characterized by substantial uncertainty."<sup>179</sup>

The system demonstrated its weakness in its inability to properly address patient safety. This weakness exacerbated the infected hemophiliac's poor position. In turn, severe hemophiliacs were left with a failed regulatory system and no remedy or recourse for their injuries. However, Congress did address the injuries suffered by hemophiliacs in the nineteen-eighties through the Ricky Ray Hemophilia Relief Fund Act of 1998.<sup>180</sup> The Act provides \$100,000 for each eligible individual.<sup>181</sup> The Act provides very broad coverage, most likely a result of the substantial uncertainty during the relevant

175. See *supra* Part IV.A.

176. HIV AND THE BLOOD SUPPLY, *supra* note 10, at 223-24.

177. See *Id.*

178. See *Id.*

179. *Id.* at 2.

180. 42 C.F.R. §§ 130.1-130.50 (2005).

[T]his statute provides for compassionate payments to certain individuals with blood-clotting disorders, such as hemophilia, who contracted human immunodeficiency virus (HIV) due to contaminated antihemophilic factor within a specified time period, as well as to certain persons who contracted HIV from these individuals. In the event the individual eligible for payment is deceased, the Act also provides for payments to certain survivors of this individual.

*Id.* § 130.1.

181. *Id.* § 130.3.

time period.<sup>182</sup> Congress did not make it difficult for hemophiliacs to qualify for the program; an individual is covered by the Act with the submission of a simple affidavit, no extensive medical evaluation or medical record documentation is required.<sup>183</sup> The Act was unfunded for two years, until 2000, when Congress finally appropriated \$105,000,000 to fund the compensation program.<sup>184</sup>

As noted by the debates on the House and Senate floor, the majority of our representatives believed that hemophiliacs should be compensated for their loss due to the inaction by federal agencies.<sup>185</sup> However, in the end, hemophiliacs were given meager compensation for the losses they suffered due to no fault of their own. The question is did our regulatory agencies and legislatures learn anything?

#### VIII. THE TISSUE BANKING INDUSTRY POSES THE SAME RISKS TO PATIENT SAFETY AS THE PLASMA FRACTIONATION INDUSTRY

Three factors indicate the tissue banking industry has the potential to harm recipients in a similar way the plasma fractionation industry injured hemophiliacs. First, the FDA lightly regulates the tissue manufacturing industry relying on the organizations that the FDA is policing to set the proper standards.<sup>186</sup> Second, courts are unwilling to motivate the tissue banking industry to develop new technology to enhance patient safety. As *Condos*<sup>187</sup> and *Cryolife*<sup>188</sup> demonstrate, courts are willing to immunize tissue banks from strict liability using the same rationale that prevented hemophiliacs from receiving compensation after the regulatory system failed to properly address

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182. *Id.* § 130.10. "An individual who has any form of blood-clotting disorder, such as hemophilia, who was treated with antihemophilic factor at any place defined in § 130.2(o), . . . at any time during the time period from July 1, 1982, to December 31, 1987." *Id.*

183. *Id.* § 130.20.

In all instances in which medical documentation is referred to, medical documentation may be submitted in the following forms: (a) Copies of relevant portions of medical records, records maintained by a physician, nurse, or other licensed health care provider, test results, prescription information, or other documentation deemed credible by the Secretary; or (b) An affidavit, signed under penalty of perjury, by a physician, nurse practitioner or physician assistant, verifying that the medical criteria necessary for a petitioner to be eligible for payment under the Act are satisfied. Such an affidavit must include the physician's, nurse practitioner's or physician assistant's State of practice, and license, certification or registration number, as applicable.

*Id.*

184. See Consolidated Appropriations Act, H.R. 4577, 106th Cong. § 150 (2001).

185. See 144 CONG. REC. 3377 (1998); 144 CONG. REC. 12912 (1998).

186. See *supra* Part II.

187. *Condos v. Musculoskeletal Transplant Found.*, 208 F. Supp. 2d 1226 (D. Utah 2002).

188. *Cryolife, Inc. v. Super. Ct. of Santa Cruz County*, 2 Cal. Rptr. 3d 396 (Cal. Ct. App. 2003).

the unique risks associated with clotting factors.<sup>189</sup> Third, tissue products are manufactured from donated human tissue that carry the same risk as clotting factors in that they are derived from the human body and considered unavoidably dangerous but medically necessary.<sup>190</sup> If these factors are not properly addressed, tissue recipients could face the same fate as hemophiliacs but on a much larger scale.<sup>191</sup>

IX. PATIENT SAFETY CAN BE ENHANCED WHILE ENSURING AN ADEQUATE SUPPLY OF DONATED HUMAN TISSUE BY IMPOSING STRICT LIABILITY ON TISSUE PROCESSORS

A. *Proper Incentives Must be Created to Enhance Patient Safety*

Blood shield laws should be reformed to heighten awareness for patient safety throughout the tissue banking industry for several reasons. First, tissue processing cannot effectively remove all contaminants which would make the products safe.<sup>192</sup> The unique nature of a human-based product makes the tissue product recipients susceptible to communicable diseases that go undetected by tissue processors. Second, the risk of infection or death is real. Several patients have either died or become seriously ill after receiving a tissue graft.<sup>193</sup> Third, for-profit tissue companies are under constant pressure to maximize profits and increase their market share; therefore, these tissue processors' decision-making is heavily influenced by market considerations and profit

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189. Hemophiliacs were eventually allowed meager compensation for their injuries related to clotting factors. See *supra* notes 181, 184, and accompanying text discussing the Ricky Ray Hemophilia Relief Fund Act. However, Congress did not feel the need to compensate individuals who were infected with HIV through means other than clotting factors. One possible distinction that can be drawn is that clotting factors were produced by for profit companies that may not have been properly motivated by the regulatory scheme to adequately consider patient safety.

190. See *supra* Part V.

191. Hemophilia Association, Information: Hemophilia A, at <http://www.hemophiliac.org> (last visited Apr. 19, 2005) (on file with the Indiana Health Law Review) (stating that about 17,000 people throughout the United States have hemophilia). However, an estimated 800,000 tissue grafts were transplanted in 2002. *Dangers of Tainted Tissues Hearings*, *supra* note 18 (statement of Jesse L. Goodman, Director of the FDA Center for Biologics Evaluation and Research). If an undetectable, untreatable disease were to strike the tissue graft recipient population, the impact would be devastating due to the growing use of cadaveric tissue grafts.

192. Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement, 66 Fed. Reg. 1508, 1509 (proposed Jan. 8, 2001).

193. See *id.* at 1540-42; *CDC Response to Infections Hearings*, *supra* note 99 (statement of Steven L. Solomon, M.D., Acting Director, Division of Healthcare Quality Promotion, CDC's National Center for Infectious Diseases); *Dangers of Tainted Tissues Hearings*, *supra* note 18 (statement of Jesse L. Goodman, Director of the FDA Center for Biologics Evaluation and Research); Lumelsky, *supra* note 99, at 474; *Unexplained Deaths Following Knee Surgery ---Minnesota, November 2001*, *supra* note 99, at 1080; *Septic Arthritis Following Anterior Cruciate Ligament Reconstruction Using Tendon Allografts*, *supra* note 99, at 1081; Blakeslee, *supra* note 20, at 1.; Kalb, *supra* note 99, at 48.

rather than patient safety and society's concept of donation. If the tissue donation process is influenced in a way that is contrary to public interest, society's concept of organ and tissue donation will be negatively impacted further exacerbating the already critical organ shortage.<sup>194</sup> These concerns must be addressed to ensure that human tissue products continue to be readily available.

### *B. Strict Liability is a Practical Incentive*

For-profit organizations can only be motivated by either government regulation or civil liability because their existence is defined by profit or the promise of profit. The FDA has demonstrated its unwillingness or inability to regulate the industry without practically allowing the industry to craft its own regulations. Additionally, the FDA could not possibly keep pace with this rapidly developing industry. A practical alternative to increased and costly regulation is the imposition of strict liability using the reasonable alternative test. If an unreasonable practice leads to injury, imposing strict liability on the tissue banking industry is a rational way to disgorge profits from the industry thereby creating an economic incentive to make changes in the interest of patient safety.

Because for-profit organizations are already entrenched in the tissue banking industry, new laws that would forbid or limit for-profit companies from participating in the tissue banking industry would certainly face fierce opposition, making enactment extremely costly and nearly impossible. However, strict liability is a practical solution because eliminating the statutory shield, an abrogation of common law, only requires legislatures to revise existing laws or, in some states, courts to construe blood shield laws narrowly.

### *C. The Rationale Behind Strict Liability and the Alternative Safer Design Analysis*

The rationale behind strict liability is that the consumer of a product expects and relies on the manufacturer to produce a safe product. Along with

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194. See CONSENT IN TISSUE DONATION, *supra* note 19; *Human Tissue Banks Hearings*, *supra* note 26 (statement of William Minogue, M.D., Chairman, Board of Directors, Washington Regional Transplant Consortium). Dr. Minogue stated:

To ensure that people remain willing to donate, they must trust the donation system. The organ and tissue recovery process affects people when they are most vulnerable. This circumstance can easily give rise to misunderstanding, causing suspicions that their loved one is being nudged toward premature death so that organs and tissues can be taken for the benefit of others. The public must have every confidence that no one will directly profit from the death of their loved ones and that the donation system will work to protect them and their loved ones from abuse or misuse.

*Id.*

this reliance comes the expectation that the consumer will be compensated for injuries that result from an accident caused by the product. In turn, the cost of accidents caused by the products are incorporated into the cost of the product and distributed throughout the entire consumer population. Therefore, the cost of the product represents its true cost. The most important aspect of strict liability is that the manufacturer, which directly bears the cost of the accident, is in the best position to anticipate, prevent, or remedy any injury or risk associated with the product. This is the special responsibility assumed by all manufacturers in society.<sup>195</sup> It is engrained in the conscience of society that the manufacturer of a defective product should be held liable for the injury caused by a defect. Tissue based products offer a unique challenge to strict liability because they are inherently dangerous; however, tissue products can be designed in a way that significantly reduces the inherent risks.<sup>196</sup>

The Restatement (Third) of Torts: Products Liability states a product is defectively designed “when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller . . . , and the omission of the alternative design renders the product not reasonably safe . . . .”<sup>197</sup> The reasonable alternative standard allows the design of a product to be considered with the state of technology in the industry at the time the product was manufactured. The reasonable alternative standard also allows the manufacturer to escape liability if an alternative design was not feasible but still serves the fundamental purpose of the tort system, which is:

[T]o identify socially unreasonable conduct and to compensate the victims of such conduct: “The issue in every products case is whether the product qua product meets society’s standards of acceptability[;] . . . whether . . . we as a society will live with it in its existing state or will require an altered, less dangerous form. Stated succinctly, the question is

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195. RESTATEMENT (SECOND) OF TORTS § 402A cmt. c (1965); *See, e.g.*, *East River S.S. Corp. v. Transamerica Delaval, Inc.*, 476 U.S. 858 (1986); *Castro v. QVC Network, Inc.*, 139 F.3d 114 (2d Cir. 1998); *Greenman v. Yuba Power Prods., Inc.*, 59 Cal. 2d 57 (Cal. 1963); *Puckett v. Oakfabco, Inc.*, 979 P.2d 1174 (Idaho 1999); *McCathern v. Toyota Motor Corp.*, 23 P.3d 320 (Or. 2001); *Green v. Smith & Nephew AHP, Inc.*, 245 Wis. 2d 772 (Wis. 2001).

196. *See CDC Response to Infections Hearings, supra* note 99 (statement of Steven L. Solomon, M.D., Acting Director, Division of Healthcare Quality Promotion, CDC’s National Center for Infectious Diseases).

197. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(b) (1998); *See, e.g.*, *McCourt v. J. C. Penney Co.*, 734 P.2d 696 (Nev. 1987); *Micallef v. Miehle Co., Div. of Miehle-Goss Dexter, Inc.*, 348 N.E.2d 571 (N.Y. 1976); *Lancaster Silo & Block Co. v. Northern Propane Gas Co.*, 427 N.Y.S.2d 1009 (N.Y. App. Div. 1980); *Ford Motor Co. v. Nowak*, 638 S.W.2d 582 (Tex. App. 1982).

whether the product is a reasonable one given the reality of its use in contemporary society."<sup>198</sup>

#### *D. Strict Liability Applied to Tissue Banks*

The application of the reasonable alternative standard would not impose upon tissue manufactures an absolute duty not to injure. Instead, the manufacturers would be required to act ethically in the light of the state of the technology at the time the product is manufactured and marketed.<sup>199</sup> The reasonable alternative standard shifts some risk to the manufacturers forcing them to consider patient safety when designing and marketing products. Therefore, the risk associated with tissue transplantation is equitably distributed thereby meeting the expectations of society.

Additionally, the supply of human tissue grafts would not be decreased by implementing the reasonable alternative standard. Some tissue manufacturers claim their processing techniques sterilize tissue without damaging the integrity of the graft.<sup>200</sup> Therefore, the tissue banks that are able to produce a reasonably safe product would gain access to more tissue as less credible tissue processors fail to obtain liability insurance and cease operations. In turn, the industry as a whole would become more efficient and increase the availability of a scarce resource, donated human tissue.

Patient safety and increased access to tissue products are not the only benefits that could be derived from strict liability on tissue manufacturers. First, imposing liability on manufacturers of tissue products will force the bad seeds out of the industry and reward the organizations that meet their ethical obligations. In turn, donation is likely to increase if the public believes their gift is being used in the most beneficial and respectful manner. If unethical companies are forced out of the industry, the issues concerning informed consent and questionable behavior by recovery agencies will be addressed by ethical processors refusing to conduct business with recovery agencies acting in bad faith.

Second, for-profit tissue processing companies will be forced to carefully evaluate their decision making process because a jury of average American citizens is not likely to accept profits as a justification for the unethical, wasteful, or undesirable use of donated human tissue. It is almost unconscionable to think our friends and family are asked to donate in a time of great sorrow and allow organizations to reap tremendous profits from a

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198. Conk, *supra* note 55, at 1117 (quoting William A. Donaher et al., *The Technological Expert in Products Liability Litigation*, 52 TEX. L. REV. 1303, 1307 (1974)).

199. *Id.* at 1123-24.

200. See Regeneration Technologies, Inc., Safety & Testing: BioCleanse™ Tissue Sterilization Process, at <http://www.rtx.com/safety/biocleanse.cfm> (last visited Apr. 19, 2005) (on file with the Indiana Health Law Review).

loved one's death with almost absolute immunity from liability. Finally, the government would not run the risk of subsidizing an industry that made poor decisions during a time of crisis.

#### X. CONCLUSION

Tissue based products have inherent risks that must be controlled to meet society's expectation of patient safety and ensure that society's image of donation is not tarnished. The fact that several large organizations processing human tissue exist to profit from donation indicates these organizations are moving away from their roots and becoming corporate giants consumed by profit. This shift is contrary to society's belief that donation is motivated by altruism and not profit. As evidenced, tissue products present a real risk of severe infection or death. Despite this risk, courts and the FDA are unwilling to scrutinize the industry and impose appropriate incentives for patient safety on the tissue banking industry. Removing the statutory barrier created by blood shield laws and imposing strict liability on the tissue banking industry would provide the appropriate incentives on the industry without unduly burdening supply or innovation.

However, if the safety concerns are not addressed and the injuries from donated tissue increase, a medical disaster could occur similar to the hemophiliac HIV epidemic in the nineteen-eighties, but on a much larger scale. A medical disaster involving human tissue grafts would have a detrimental effect on society's image of donation. If the public became informed of the for-profit nature of the tissue banking industry and the poor incentives created for patient safety in the context of a medical disaster, donor families are likely to believe they have been exploited by the for-profit tissue banking industry while the government stands in defense of the industry's profit. Thus, strict liability should be used as a conduit to carry society's expectations of donation into the tissue banking industry.