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Product Liability: A Public Policy Approach to Contaminated Factor VIII Blood Products

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NOTES

PRODUCT LIABILITY: A PUBLIC POLICY APPROACH TO CONTAMINATED FACTOR VIII BLOOD PRODUCTS

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* Dedicated to my husband, Uday and to my family for their love and encouragement.

I. INTRODUCTION

Factor VIII is a protein within the human body that regulates the normal coagulation and clotting of blood.[1] Individuals suffering from a deficiency of the protein are prone to acute incidences of excessive bleeding which often can result in death.[2] This condition is known as hemophilia.[3]

In the early 1980s, a concentrated form of Factor VIII was marketed which was produced from the pooled plasma of 2000 to 30,000 donors per lot.[4] The commercial concentrate was much more effective than the previously available treatment, a cryoprecipitate of which each bag was produced from the plasma of one donor.[5] This advance in technology resulted in great benefits for hemophiliacs, including reduced hospital admissions and safer surgical treatment of other conditions.[6] In addition, hemophiliacs enjoyed greater independence because they could administer the concentrate to themselves at home.[7]

At the time this product was marketed, however, blood products were known to transmit hepatitis, a virus that causes liver disease.[8] The risk of contracting the disease from the concentrate was much higher than from previous products because of the exposure to thousands of donors with each treatment.[9] Despite the risk that one percent to ten percent of recipients would become infected with hepatitis, the product continued to be produced, prescribed, and used.[10]

In 1982, evidence began to appear indicating that hemophiliacs were at risk of contracting Acquired Immune Deficiency Syndrome (AIDS)[11]

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1. *See* Jane F. Desforges, *AIDS and Preventive Treatment in Hemophilia*, 308 NEW ENG. J. MED. 94, 94 n.1 (1983); Eric Nauenberg & Sean D. Sullivan, *Firm Behavior in the U.S. Market for Factor VIII: A Need for Policy?*, 39 SOC. SCI. & MED. 1591, 1591 (1994).

2. Nauenberg & Sullivan, *supra* note 1, at 1591.

3. *See id.* Approximately 20,000 American men are hemophiliacs. *Id.*

4. *See* THE AIDS KNOWLEDGE BASE §§ 1.12-4 to 1.12-5 (P.T. Cohen et al. eds., 2d ed. 1994).

5. *See* Desforges, *supra* note 1, at 95. The cryoprecipitate containing this protein was discovered in 1964. *See id.* at 94 n.2.

6. *See id.* at 94.

7. *See id.*

8. *See id.*; N.C. Hughes-Jones, *Risk Assessment and Factor VIII Concentrates*, 345 THE LANCET 502, 502 (1995) (stating that the transmission of infectious agents by transfusion is well known and the resultant mortality well documented).

9. *See* Desforges, *supra* note 1, at 94-95.

10. *See* Hughes-Jones, *supra* note 8, at 502.

11. *See* Smith v. Cutter Biological, Inc., 823 P.2d 717, 721 n.4 (Haw. 1991); Centers for Disease Control, *Pneumocystis Carinii Pneumonia Among Persons with Hemophilia A*, 31 MORBIDITY & MORTALITY WKLY. REP. 365, 365-67 (1982).

from blood products contaminated with the Human Immunodeficiency Virus (HIV).[12] Some contemporaneous medical articles encouraged hemophiliacs to continue using the products because the authors perceived only a slight risk.[13] Other articles urged a reevaluation of the safety of factor concentrates and suggested returning to single-donor cryoprecipitate.[14] However, Factor VIII concentrates continued to be produced in great quantities. In 1986, procedures including rejecting donors in high-risk categories, screening other donors, and heat-treating to inactivate the HIV were implemented[15] which almost completely eradicated the virus from the concentrates.[16] By that time, however, approximately seventy percent of hemophiliacs in the United States suffering from Factor VIII deficiency had been infected with HIV.[17]

AIDS, like herpes, smallpox, yellow fever, and hepatitis, is an infectious disease caused by a virus. ROBERT M. JARVIS ET AL., AIDS LAW IN A NUTSHELL 1 (1996) [hereinafter NUTSHELL]. The disease was first identified in 1981. NUTSHELL, *supra*, at 4. There was evidence as early as 1982 that hemophiliacs had contracted AIDS, and by 1984 there was a general consensus that it was transmissible through blood products. *See Smith*, 823 P.2d at 721 n.4. Other modes of transmission include sexual intercourse, use of infected syringes, blood and organ donations, child birth and breast feeding. NUTSHELL, *supra*, at 8-9. AIDS is an incurable and fatal disease, with possible symptoms ranging from fatigue, weight loss, skin irritation, and swollen lymph nodes to dementia, deterioration of the immune system, Kaposi's sarcoma, Pneumocystis Carinii Pneumonia, and tuberculosis. *Id.* at 15-17.

There are many legal issues surrounding AIDS, its victims, and health care providers. *See, e.g.*, DONALD H.J. HERMANN & WILLIAM P. SCHURGIN, LEGAL ASPECTS OF AIDS (1991) (discussing, *inter alia*, liability for sexual transmission and privacy and defamation issues); MARK S. SENAK, HIV, AIDS, AND THE LAW (1996) (discussing, *inter alia*, federal and state entitlement benefits available to and employment discrimination against persons with HIV or AIDS); Diane A. Tomlinson, *Physicians with AIDS and Their Duty to Patients*, 43 FLA. L. REV. 561 (1991) (discussing the duty of health care providers to disclose their HIV-positive status to their patients).

12. HIV is an RNA virus characterized by integration into host cells in animals and humans. HIV infection proceeds through depletion of T-lymphocytes or T-helper white blood cells, which are specialized infection-fighting cells. This breakdown leads to extreme weakening of the body's immune system. Hermann & Schurgin, *supra* note 11, § 1:05, at 1-7.

13. *See, e.g.*, Hughes-Jones, *supra* note 8, at 502 (quoting L. Fraser, *Need for Factor VIII Outweighs AIDS Risk*, GENERAL PRACTITIONER, Oct. 19, 1984, at 3).

14. *See, e.g.*, Desforges, *supra* note 1, at 95.

15. *See* Cohen, *supra* note 4, § 1.12-5; Paul M. Rowe, *U.S. Inquiry into HIV in Blood Products*, 344 THE LANCET 876, 876 (1994).

16. *See* Cohen, *supra* note 4, § 1.12-5.

17. *See* Centers for Disease Control, *Human Immunodeficiency Virus Infection in the United States*, 36 MORBIDITY & MORTALITY WKLY. REP. 801, 801-02 (1987).

Thousands of hemophiliacs in France, Switzerland, Canada, and other countries also have been infected by Factor VIII concentrates. In France, three senior health officials were imprisoned for distributing the HIV-contaminated clotting products. Kate Dunn, *HIV and Canada's Hemophiliacs: Looking Back at a Tragedy*, 148 CANADIAN MED. ASS'N J. 609, 609 (1993); *see also* Rowe, *supra* note 15, at 876. The Canadian government created a Commission

Recently, as patients have begun to discover their conditions through HIV testing or development of AIDS symptoms, they or their families also have begun to bring suits against the manufacturers of Factor VIII concentrates based on negligence, strict liability, breach of implied warranty, or other theories. However, most courts that have considered the strict liability and warranty claims[18] have barred them under so-called blood shield statutes[19] enacted in almost all states.[20]

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of Inquiry to investigate why so many hemophiliacs became infected, Hughes-Jones, *supra* note 8, at 502, and established a compensation scheme for the victims, *see* Dunn, *supra*, at 609. The U.S. National Academy of Sciences Institute of Medicine also has launched a similar investigation. Hughes-Jones, *supra* note 8, at 502; Rowe, *supra* note 15, at 876.

18. Strict liability claims for product-related injuries are usually brought under RESTATEMENT (SECOND) OF TORTS § 402A (1977), which provides:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
> (a) the seller is engaged in the business of selling such a product, and
> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
> (2) The rule stated in Subsection (1) applies although
> (a) the seller has exercised all possible care in the preparation and sale of his product, and
> (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Id.

19. For example, the California blood shield statute provides:

> 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.

CAL. HEALTH AND SAFETY CODE § 1606 (West 1995).

By defining acts related to blood injections and transfusions as "services" instead of as product sales, the statute renders RESTATEMENT (SECOND) OF TORTS § 402A inapplicable and therefore bars strict liability claims. Hermann, *supra* note 11, at 3-14.

20. *See* Andrew R. Klein, *A Legislative Alternative to "No-Cause" Liability in Blood Products Litigation*, 12 YALE J. ON REG. 107, (1995); *see also* Hermann, *supra* note 11, at 3-14. The few states that have not passed blood shield statutes usually hold that these products fall under the "unavoidably unsafe products" exception in comment k following § 402A. Hermann, *supra* note 11, at 3-12. That comment provides:

In traditional negligence claims,[21] the cause-in-fact element[22] poses an insurmountable obstacle for plaintiffs injured by mass-produced drugs like Factor VIII.[23] In products liability, this general negligence causation requirement translates into a showing that the defendant was the manufacturer of the product that actually caused the injury.[24] This is a problem for Factor VIII plaintiffs because of the nature of the disease, interchangeability of the products, use of the products of more than one manufacturer, and other reasons.

Some courts have adopted theories such as concert of action, alternative, enterprise, and market share theories of liability which relax

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> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. . . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use. . . .

RESTATEMENT (SECOND) OF TORTS § 402A comment k (1977).

This exception is a bit of a strict liability-negligence hybrid, requiring that appropriate warning be given before it applies. The application of this exception in Factor VIII cases is inappropriate because the claims are usually based on failure to warn, failure to exclude high-risk donors, and failure to screen other donors. Implementation of these procedures would have rendered the products safe with no reduction in effectiveness. In addition, other less dangerous treatments, albeit less effective and convenient, were known at the time.

21. The four elements of a successful traditional negligence claim are (1) a legal duty requiring the defendant to meet a certain standard to protect a person from an unreasonable risk of harm, (2) breach of this duty, (3) a causal connection between the defendant's conduct and the plaintiff's injury, which includes notions of cause-in-fact and proximate cause, and (4) actual loss or damage to the plaintiff's interest. W. PAGE KEETON ET AL., PROSSER AND KEETON ON TORTS § 30, at 164-65 (5th ed. 1984).

22. The causation requirement may be stated as follows: "In order that a negligent actor shall be liable for another's harm, it is necessary not only that the actor's conduct be negligent toward the other, but also that the negligence of the actor be a legal cause of the other's harm." RESTATEMENT (SECOND) OF TORTS § 430. Restatement § 431 discusses one formulation of what constitutes legal cause: "The actor's negligent conduct is a legal cause of harm to another if (a) his conduct is a substantial factor in bringing about the harm, and (b) there is no rule of law relieving the actor from liability because of the manner in which his negligence has resulted in the harm." KEETON ET AL., *supra* note 21, § 41, at 266. Another formulation of legal cause is the "but for" or "sine qua non" rule, which states that "[t]he defendant's conduct is a cause of the event if the event would not have occurred but for that conduct; conversely, the defendant's conduct is not a cause of the event, if the event would have occurred without it. *Id.*

23. *See* Klein, *supra* note 20, at 108.

24. KEETON ET AL., *supra* note 21, § 103, at 713.

the causation requirements in products liability cases.[25] However, most courts have adhered to traditional negligence law in these cases, including Factor VIII cases, holding that the plaintiff's inability to show causation precludes any recovery.[26] In doing so, these courts have denied the HIV-positive plaintiffs even compensatory damages.

Intertwined with the legal issues in these cases are public policy issues that weigh heavily on courts in determining whether to adopt or expand theories of liability for new cases such as those involving Factor VIII. First, although courts want to serve justice in individual product liability cases and encourage development and distribution of safe and effective products, they fear that doctrinal expansion may greatly increase liability and litigation costs incurred by pharmaceutical companies, which could result in adverse social consequences including unavailability of important new or existing drugs, increased prices of drugs, and decreased international competitiveness of United States pharmaceutical companies.[27] Second, in the face of social, industrial,

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25. *See, e.g.*, Poole v. Alpha Therapeutic Corp, 696 F. Supp. 351 (N.D. Ill. 1988) (applying alternative liability to a Factor VIII case); Hall v. E.I. Du Pont de Nemours & Co., 345 F. Supp. 353 (E.D.N.Y. 1972) (developing and applying enterprise liability theory in a blasting cap case); Sindell v. Abbott Lab., 607 P.2d 924 (Cal. 1980) (developing and applying market-share liability theory in a diethylstilbesterol (DES) case), *cert. denied*, 449 U.S. 912 (1980); Abel v. Eli Lilly & Co., 343 N.W.2d 164, 175-76 (Mich. 1984) (applying concert of action theory and alternative liability theory in a DES case), *cert. denied*, 469 U.S. 833 (1984).

DES is a synthetic compound of estrogen, a female hormone. *Sindell*, 607 P.2d at 925. It was prescribed to prevent miscarriage in pregnant women from the early 1940s to the early 1970s. *Id.* It is now known to cause adenocarcinoma, which involves cancerous vaginal and cervical growths, in the daughters of women who took it. *Id.* It also causes adenosis, a condition involving precancerous vaginal and cervical growths which can spread to other parts of the body. These conditions did not manifest themselves until around 10 or 12 years after exposure to the drug. *Id.* The treatment for these conditions is radical surgery, and women with the condition must endure painful follow-up examinations twice a year. *Id.*

26. *See* Victor E. Schwartz & Liberty Mahshigian, *Failure to Identify the Defendant in Tort Law: Towards a Legislative Solution*, 73 CAL. L. REV. 941, 965 (1985).

27. This climate of fear was probably fostered by a tort insurance crisis in the mid-1980s, which involved a tripling of general product liability insurance premiums, resulting from the perception that there had been a tort litigation explosion. *See* 1 A.L.I. REPORTERS' STUDY, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY 3 (1991). General product liability premiums increased from $6.5 billion to $19 billion in just three years. *See id.* Although in retrospect the perception of a crisis seems to have been unfounded, courts remain apprehensive, and tort reformers continue to explore alternatives to tort law for dealing with product-related injuries. *See, e.g.*, Marc Galanter, *The Day After the Litigation Explosion*, 46 MD. L. REV. 3 (1986). *But see* Donald G. Gifford et al., *Litigation Trends in Florida: Saga of a Growth State*, 39 U. FLA. L. REV. 829 (1987) (stating that litigation did increase significantly in Florida); R. Kyle Gavin, Note, *The Constitutionality of Florida's Cap on Noneconomic Damages in the Tort Reform and Insurance Act of 1986*, 39 U. FLA. L. REV. 157, 192 (1987) (concluding that Florida's $450,000 noneconomic damages cap is constitutional and could impact the "insurance

and regulatory change, courts are uncertain of the appropriate relationship between tort law and other institutions, such as market forces and government regulation, in striking a balance among these interests.[28]

The purpose of this Note is to develop a systematic approach to product-related injury cases, specifically Factor VIII cases, that balances all of the interests at stake, including (1) providing compensation for injured plaintiffs, (2) encouraging drug safety and effectiveness, (3) ensuring availability of new and existing drugs, (4) keeping drug prices reasonable, and (5) maintaining international competitiveness of United States pharmaceutical companies.[29]

In order to examine the interconnected issues involved in achieving these goals, it is first necessary to consider each facet individually. To this end, part II provides background information on the pharmaceutical industry including the industry's decisionmaking process, which is the mechanism through which product liability law, market forces, and governmental regulation act to achieve the desired interests. Part III of the Note traces the historical development of the potentially applicable tort law theories in order to facilitate a better appreciation of their respective approaches in tackling product liability cases. Part IV evaluates the soundness of these theories in terms of the policies involved in Factor VIII cases and other similar cases, while part V formulates a practicable approach to Factor VIII and similar cases.

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crisis"); David J. Nye et al., *The Myth of a Liability Explosion: An Empirical Rebuttal*, 41 VAND. L. REV. 909 (1988) (observing that a claims explosion did not occur from 1981-1984).

28. *See generally* Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 HARV. L. REV. 773 (1990) (criticizing the current FDA regulation system and arguing in favor of FDA preemption of tort claims based on design defects or inadequate warnings).

29. Although maintaining international competitiveness of U.S. industries is a valid interest, it will receive little direct attention in this Note for two reasons. First, it appears that currently the industry has no real reason to complain about its economic competitiveness. It has been one of the most profitable industries in the United States for many years. U.S. DEP'T OF COMMERCE, A COMPETITIVE ASSESSMENT OF THE U.S. PHARMACEUTICAL INDUSTRY 26 (Theodore W. Schlie ed., 1986). In addition, as of 1982, 11 of the top 20 pharmaceutical companies worldwide were U.S. companies, with West Germany and Switzerland lagging far behind in second place with three of the top companies each. DEP'T OF COMMERCE, *supra*, at 2. Second, most economists agree that the competitive focus should be on maintaining a rising standard of living for Americans, and not necessarily obtaining certain international trade results, although the latter may be one way to achieve the former. STEVEN GARBER, PRODUCT LIABILITY AND THE ECONOMICS OF PHARMACEUTICALS AND MEDICAL DEVICES 12 (1993). However, because the introduction of new drugs into the market and the quality and reputation of drugs are important factors in a company's international competitiveness, the analyses and recommendations contained in this Note for encouraging innovation, availability, safety, and effectiveness of new drugs also will enhance international competitiveness.

II. BACKGROUND OF THE PHARMACEUTICAL INDUSTRY

The pharmaceutical industry is not a single market, but rather is comprised of a wide variety of markets and submarkets, ranging from biologicals and blood fractions to prescription and over-the-counter medicines to nontherapeutic care products.[30] Many pharmaceutical products are patented,[31] giving the patentee exclusive production and marketing rights for twenty years.[32]

Pharmaceutical companies engage in three main types of production. First, they create completely new drugs through innovative research with relatively unknown compounds and substances.[33] Second, aside from developing their own innovative products, companies also engage in production of "me too" drugs: when a chemical or biological compound or substance is determined to have valuable physiological effects, the developer's competitors experiment in making slight changes to the compound in an effort to find a patentable variation of it for the original use or other uses.[34] Third, generic versions of drugs are produced and sold after the patents on their brand-name counterparts expire.[35]

The pharmaceutical industry is one of the most profitable manufacturing industries in the United States.[36] Its high pricing of products needed for public health[37] and its very high and consistent profits, as

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30. *See* DEP'T OF COMMERCE, *supra* note 29, at 1.

31. *See id.*

32. 35 U.S.C. § 154(a)(2) (1994). However, at the time that Factor VIII concentrates were being produced, the patent term was 17 years. *See* 35 U.S.C. § 154 (1988).

33. *See id.* at 11; GARBER, *supra* note 29, at 24.

34. DEP'T OF COMMERCE, *supra* note 29, at 11-12; GARBER, *supra* note 29, at 24. The introduction of valuable new drugs to the market, whether developed through innovation or the "me too" strategy, is the most important factor in a company's long-term profitability. *Id.* at 21-22. Often, an overwhelming percentage of a company's profits come from just a handful of "blockbuster" drugs. *Id.* at 20. In addition, it appears that the first company to introduce a drug maintains the largest share of the market even after other companies begin to sell the same drug or a very similar drug. *Id.* at 22.

35. DEP'T OF COMMERCE, *supra* note 29, at 11.

36. *See id.* at 26.

37. Elevated price is a function of two factors. First, it is well documented that there is little or no price competition among pharmaceutical companies. *See* GARBER, *supra* note 29, at 19. Second, the demand for such products is inelastic, in other words, the demand does not vary with price. *Id.* There are several reasons for inelastic demand in this industry: (1) people with serious conditions will pay almost anything for effective drugs, (2) many products have no real substitute, (3) physicians prescribing the medications are not concerned or aware of the cost or of substitutes, and (4) patients are not overly concerned with cost because either public or private insurance will reimburse them for a substantial portion of the cost. *See id.* at 19 n.25. The combination of lack of price competition and inelastic demand can result in a profit-maximizing price that is several times the production cost. *Id.* at 19. In addition, unlike many other countries, the United States does not directly regulate the price of drugs. *Id.* at 17

compared to other industries, have drawn a great deal of criticism against the industry for purportedly engaging in anticompetitive behavior.[38] In addition to high prices and high profits, the industry has exhibited other anticompetitive characteristics.[39] Indeed, in the Factor VIII submarket itself, there has been evidence of oligopolistic trade practices.[40]

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n.18, 20.

38. DEP'T OF COMMERCE, *supra* note 29, at 26; *see also* Naomi Sheiner, Comment, *DES and a Proposed Theory of Enterprise Liability*, 46 FORDHAM L. REV. 963, 975-76 (1978) (citing *Senate Subcomm. on Monopoly, Select Comm. on Small Business, Competitive Problems in the Drug Industry*, 92d Cong., 2d Sess. 33-34 (Comm. Print 1972)). Sheiner notes:

> In a 1972 report to Congress, it was emphasized that the drug industry was "practically unique" in that "[l]osses, or even low profits, are practically unheard of among large drug companies." Although the pharmaceutical manufacturers justify their profits by the extreme risk inherent in the development of new drugs, critics have recognized an inherent contradiction in the coexistence of high risks and consistently high, industrywide profits. Such risks would result in at least "occasional losses" to some firms.

Sheiner, *supra*, at 975-76 (footnotes omitted); *see also* Nauenberg, *supra* note 3, at 1592 (stating that "[m]arket performance results suggest that the industry generates high profit margins, selectively restricts supply, and practices price discrimination"). The classic explanation for implicit collusion is that "firms recognize the mutual benefit of sustaining a monopoly price without explicit collusion. The threat of a price war reducing profits to zero is sufficient to deter the incentive to cut prices in an attempt to capture the market for oneself." *Id.* at 1594.

39. Besides high profits and lack of price competition, another measure of a market's competitiveness is firm concentration ratios, which indicate the potential for coordination and collusion. *See* Nauenberg, *supra* note 3, at 1592. A firm concentration ratio indicates the percentage of market share occupied by a certain number of firms. *See id.* At first glance, the pharmaceutical industry may appear competitive because the overall firm concentration levels for the entire industry are fairly low. *See* DEP'T OF COMMERCE, *supra* note 29, at 3 (stating that the "U.S. drug industry is highly competitive, with no firm accounting for more than 8 percent of total sales"). However, firm concentration ratios within submarkets provide a more realistic view of competition because it is within submarkets that collusion is most likely to take place. Nauenberg, *supra* note 3, at 1592. These firm concentration ratios can prove to be very high. For example, "[t]he unweighted average of the four-firm concentration ratio for eighteen therapeutic markets was 68% in 1968 with values ranging from 46% for digestive enzymes to 93% for diabetic therapies and 95% for antiarthritic medications." *Id.*

In addition, pharmaceutical firms use "frivolous patent litigation and petitions to the Food and Drug Administration (FDA) to limit competition and market entry." Lars Noah, *Sham Petitioning as a Threat to the Integrity of the Regulatory Process*, 74 N.C. L. REV. 1, 2 (1995) (proposing changes in agency procedures to combat these tactics).

40. Factor VIII concentrates have been supplied by four manufacturers since the 1970s including Miles Inc. (Cutter Laboratories), Rhone-Poulenc Rorer (Armour Pharmaceuticals), Green Cross (Alpha Therapeutics), and Baxter Healthcare (Hyland), New York Blood Center, and, until recently, the American Red Cross. Nauenberg, *supra* note 3, at 1592. "Thus, strictly from a four-firm concentration ratio perspective, the market is highly concentrated." *Id.* On

A. *Decisionmaking in the Pharmaceutical Industry*

Industrial decisionmakers are primarily concerned, of course, with maximizing profits.[41] Profits are the difference between revenues received and costs incurred.[42] When a company is considering a proposed course of action, for example, placing a new drug on the market or withdrawing a drug already on the market, it must estimate the costs associated with the action. These costs may be broken down into two categories.[43] Direct costs are those that can be directly traced and accounted for, such as the amount paid in court judgments and settlements.[44] Although companies generally carry insurance to cover

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another scale of market concentration, the Hirschmann-Herfindahl Index, the Factor VIII submarket is at the 95th percentile for concentration, which means that only 5% of U.S. industries are more concentrated. *Id.*

In addition, in the late 1980s the Factor VIII submarket behaved contrary to the economic law of supply and demand, which states that in a normal market the quantity of a good supplied in the market tends to meet the quantity of the good demanded, resulting in market equilibrium in which there is neither a surplus or shortage of the good. *See* ROY J. RUFFIN & PAUL R. GREGORY, PRINCIPLES OF MACROECONOMICS 78-79 (3d ed. 1988). In 1987, when it was known that many hemophiliacs had been infected with HIV from contaminated Factor VIII concentrates, the industry began to produce intermediate purity factor concentrates which had been pasteurized to render the virus inactive. *See* Nauenberg, *supra* note 3, at 1593. These products were followed in 1988 by high purity products, which were even safer and more effective therapies produced through a monoclonal antibody purification process. *See id.* at 1594. Because the high purity products were very expensive, there remained a great demand for the intermediate purity products by hemophiliacs who already had been infected with HIV. *See id.* Only a small portion of this demand was met by the Factor VIII manufacturers, leaving a very large percentage of an approximately $182 million market unclaimed. *See id.* The most likely explanation for this is inter-product collusion resulting in exclusion of the less profitable intermediate purity product:

> Inter-product collusion is not based on coordinated price decisions among players in the cartel but rather on the joint determination of production and price decisions by members. In the market for Factor VIII, the manufacturers of high purity products are also the manufacturers of intermediate purity products all of which are still under patent protection. Given this protection, manufacturers did not fear entry by other firms when they coordinated a decrease in production of intermediate purity product simultaneous with the introduction of high purity product. These high purity products were significantly more refined than their predecessors, a difference which could justify assignment of higher prices. Given all of these contingencies, it may have been possible for manufacturers to coordinate production and substitute the more profitable high purity product for the intermediate purity product.

Id. at 1594.

41. *See* GARBER, *supra* note 29, at 16.
42. *Id.* at 34.
43. *See id.* at 34-35.
44. *See id.* at 35.

at least a portion of these costs, there is a trend toward self-insurance.[45] In addition, when a commercial insurance company pays an adverse judgment, future premiums often increase.[46] Indirect costs are less tangible, including loss of reputation resulting in a drop in stock prices or closer regulatory scrutiny.[47] These indirect costs cannot be insured against externally.[48]

Estimating direct and indirect costs is somewhat speculative. The main determinants are risk and uncertainty.[49] Risk is the cost that a company estimates it will incur as a result of a certain action.[50] Uncertainty is the variance in the range of possible risk; it is an estimate of how wrong the company could be about its risk figure.[51] Because any reasonable amount of risk can be insured against, industrial decisionmakers and insurers have the most difficulty with the uncertainty element.[52]

B. *Forces Affecting the Decisionmaking Process*

At least three outside influences significantly affect decisionmaking within the pharmaceutical industry: market forces, governmental regulation, and the potential for product liability. Each of these influences comprises a system that may be used to achieve the goals regarded as valuable by courts that have decided the outcomes of mass tort cases.

1. Market Forces

Ideally, market forces should allow consumers to make informed choices about how much risk they are willing to accept and at what

45. *See id.*
46. *See id.*
47. *See id.*
48. *See id.* at 56.
49. *See id.* at 61; 1 A.L.I., *supra* note 27, at 86.
50. *See* GARBER, *supra* note 29, at 61; 1 A.L.I., *supra* note 27, at 86.
51. *See* GARBER, *supra* note 29, at 61; 1 A.L.I., *supra* note 27, at 86.
52. *See* 1 A.L.I., *supra* note 27, at 86.

price.[53] However, in practice this system is far from perfect because consumers do not have complete information.[54]

Market forces affect economic decisionmaking in the pharmaceutical industry in the same way that they affect it in other industries. The potential for profitability, primarily determined by demand, drives the decision of whether to introduce a new product into the market. Withdrawal of a product already on the market depends partly on whether the continued demand of a defective product will result in continued profitability despite the costs that will be incurred as a result of the defect.[55] Generally, the profit-maximizing price is primarily determined by what consumers are willing to pay and by price competition.[56] However, in the pharmaceutical industry there is very little price competition.[57]

2. Governmental Regulation

Governmental regulation is often cited as one of the most significant factors in the pharmaceutical industry's decisionmaking.[58] The goal of

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53. *Id.* at 203-04.

> It is important to remember that however attractive safety may be in the abstract, making products safer is costly and may detract from their performance. Cars could be made almost collision-proof if their exteriors were of thick steel or ceramic, but then they would both be very expensive and perform like tanks. To the extent that consumers prefer less safety, lower cost, and higher performance over the reverse of these attributes, a well functioning market will supply comparatively hazardous cars. A commitment to market solutions implies a commitment to accepting the possibility of a consumer choice "against" safety.

Id. at 204.

There are two primary justifications for allowing consumers to make such a choice. First, a utilitarian theory holds that legal rules should produce the best state of affairs in society, in other words, maximize the utility of people. Utilitarians generally believe that individuals can best determine how to maximize their own utility. *Id.* at 205-06. Second, the moral philosophy of Immanuel Kant asserts that individuals are to be treated as ends in themselves, not as means to an end. Thus, treating people with the requisite respect under this philosophy would include permitting people to make their own choices, including market choices. *Id.* at 206.

54. *Id.* at 205.

55. *See* GARBER, *supra* note 29, at 138.

56. A company also must be careful that its prices are not too unreasonable or else it may lose the goodwill of consumers, prescribing physicians, and third-party payors, which can result in decreased demand when there are substitutes. GARBER, *supra* note 29, at 20. Price-setting is not seriously affected by occasional congressional threats of price regulation probably because companies perceive that their individual pricing schemes will not affect a congressional decision to regulate prices. *See id.* at 31.

57. *See supra* note 37.

58. *See* Garber, *supra* note 29, at 31.

governmental regulation of pharmaceuticals is to ensure, to the extent possible, safe and effective drugs and products for public welfare.[59] Food and Drug Administration (FDA) regulations require several phases of testing before a new drug, product, or process will be approved.[60] This process takes an average of two and a half years, leaving a company only a fraction of the patent period to make a return on its investment through exclusive marketing before the patent expires and other companies can compete in producing and selling the product.[61] This testing process may result in safer or more effective drugs, but it also results in delayed access to needed products.[62] The FDA also can require or encourage a company to withdraw an existing product from the market.[63] The expense of compliance with FDA regulations is generally reflected in higher prices on products. Despite having what may seem like burdensome regulations, the FDA is often criticized for not having strict enough regulations and not enforcing those it does have.[64]

3. Product Liability Law

Product liability is one area within the broader law of torts. At least four functions or goals of tort law have been recognized. First, perhaps the simplest function of tort law is to enhance corrective justice; that is, tort law serves to restore the relationship between two parties that existed until one of the parties unjustly injured the other, thereby altering the relationship between them.[65] A second goal is the redress of social grievances against wrongdoers.[66] Third, tort law serves to reallocate risk and compensate victims.[67] This function stems from the idea that it is better for large numbers of people to bear small additional costs than for a few individuals to suffer severely harsh losses.[68] A

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59. *See id.* at 27.

60. *See id.* at 27-28. For example, to gain FDA approval to begin marketing a new drug, a company must perform clinical trials, file applications, and produce extensive documentation. *Id.* at 27. Only then will the FDA determine whether there is evidence of safety and effectiveness sufficient to justify marketing the drug. *Id.* The FDA is the "primary authority" in pharmaceutical regulation, empowered by the 1962 amendments to the federal Food, Drug, and Cosmetic Act. *Id.*

61. *See id.* at 28.

62. *See id.* at 31-32.

63. *See id.* at 89.

64. *Id.* at 33; DEP'T OF COMMERCE, *supra* note 29, at 47.

65. 1 A.L.I., *supra* note 27, at 24-25.

66. *Id.* at 26-27.

67. *Id.* at 28-30.

68. *Id.* at 28.

fourth goal of tort law is to prevent future injuries by providing monetary disincentives to harmful behavior.[69]

To achieve these goals, the product liability system requires individual plaintiffs to bring suits to redress their injuries. The successful plaintiff can win compensatory damages, damages for pain and suffering, and possibly punitive damages. The direct and indirect costs incurred by defendant manufacturers as a result of these suits affect the industry's decisionmaking process.[70]

Decisionmakers base their predictions of cost, risk, and uncertainty on their own perceptions of the potential for liability.[71] Predictions of substantial liability potential can result in failure or delay in introducing a new drug into the market, withdrawal of a drug already on the market, and high prices.[72] If a company determines that estimated costs outweigh the benefits, in other words, that it would not make a profit in introducing a product into the market, it would most likely decide not to market it at all.[73] This has the positive effect of preventing injuries that may be caused by the product.[74] However, it also has the negative consequence of rendering the product unavailable to consumers who would be willing to accept the risk in exchange for the benefit the product would provide.[75]

A new drug may be delayed in order to permit the manufacturer to do more testing so that better estimates of potential costs can be made. This results in a delay in availability of products, but the additional testing and consideration also may lead to modifications in the product that enhance safety. Unfortunately, sometimes modifications that increase safety also decrease effectiveness.[76]

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69. *Id.* at 30-31.

70. *Id.* at 65. Direct costs include those paid in court judgments and settlements, and in defending against law suits. *See* GARBER, *supra* note 29, at 91. Indirect costs of product-related injuries are more difficult to define. *See id.* Adverse product liability judgments play an important role in triggering FDA action and often provide the impetus for FDA hearings. *Id.* at 92. In addition, doctors may be less willing to prescribe a certain manufacturer's drug due to the publicity surrounding product liability actions and their own potential for liability. *See id.* Finally, loss of law suits may cause stock prices to drop because of tarnished reputation or fear of future losses.

71. GARBER, *supra* note 29, at 101. Different companies often have different perceptions of identical liability situations depending on their past experience and the degree of risk averseness of the decisionmakers. *Id.* at 94. Some objective factors that may lead to a prediction of substantial liability are widespread use of the product, high background injury rates, and the potential for jury sympathy. *Id.*

72. *Id.* at 81.

73. *Id.* at 71.

74. *See id.* at 86-87.

75. *See id.*

76. *Id.* at 124. A decrease in dosage level is a simple example of increased safety at the

Many product withdrawals involve products with potential liability problems.[77] The cause of withdrawal, however, is difficult to isolate and in reality is probably a combination of market forces, regulation, and liability perceptions.[78] Withdrawal of a product already on the market has the same social advantages and disadvantages as failure to introduce a product into the market.

Product liability affects prices because estimates of future costs are usually built into the price of a product.[79] If the price of a product is substantially increased, it sometimes exceeds the financial reach of people who need it. While a price increase due to a threat of product liability may reduce potential injuries through market forces, because a high price for a risky product may deter many people from using it, the alternative may be the use of a less effective product.[80]

C. *Relative Merits of the Institutions*

Market forces successfully deal with product-related injuries because they are adaptable to product changes, and they can act to prevent injuries.[81] However, that success is limited because market forces only treat risks perceived in the market,[82] and a completely informed consumer is an ideal unlikely to be realized.[83]

Governmental regulation does not adequately deal with all of the product defects that can arise because of the generalized applicability of governmental regulations and limited resources for enforcement.[84] However, for defects it can regulate, an agency with expertise in this area would be in the best position to determine the type and severity of sanction which would best deter future product defects.[85] A major problem with governmental regulation as a sole force acting in the area of product-related injuries is that it provides no compensation to the

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expense of effectiveness. *Id.* at 124 n.3.

77. *Id.* at 87.

78. *Id.*

79. *Id.* at 111. However, contrary to the layperson's expectation, past liability costs (also called "sunk" costs) are not always recouped by increasing prices of future products if price increases would conflict with the primary goal of maximizing profits. *Id.* Nevertheless, past liability costs may be relevant to future prices because they may indirectly affect current estimates of future liability costs. *Id.*

80. *Id.* at 121.

81. 1 A.L.I., *supra* note 27, at 257.

82. *Id.* at 255-56.

83. *Id.* at 262.

84. *Id.* at 257-58.

85. *See id.* at 256.

victim, thereby failing to achieve one of the most valuable goals of tort law.[86]

Tort law itself also does not apply to all risks. If traditional negligence standards are applied, only those defects for which liability and causation can be shown in individual cases can be addressed by tort law.[87] This counteracts the advantages of tort law, which include providing compensation to injured plaintiffs, adapting well to changes in products, and dealing more justly (on a case-by-case basis) with very specific or odd risks than broad-sweeping regulations aimed at more generalized defects.[88]

Hence, it is apparent that none of these systems by itself achieves all of the desired public goals, and all of them have mixed effects on the pharmaceutical industry and society. Therefore, none of these systems is sufficiently superior to justify choosing one exclusively over the others. In addition, although some commentators have proposed legislative solutions such as compensation schemes, such schemes also are not perfect in securing all of the values reflected within the body of tort law.[89] Moreover, they have not yet been enacted. In a historically common law area such as product liability, courts should not refrain from doing justice in individual cases in the hope that future legislative action will resolve the issues.

For the present, it seems that the approach to product-related injuries such as those inflicted by Factor VIII concentrates should consist of some combination of market forces, governmental regulation, and product liability law.[90] First, the advantages of these institutions complement each other. Second, if these institutions act with awareness of and in cooperation with each other, they can produce synergistic effects which enhance the functions of each in achieving the desired goals. The purpose of the remainder of this Note is to show that the rationales behind existing product liability theories that relax the causation requirement apply to Factor VIII and similar cases. Addition-

86. *Id.* at 257-58.

87. *Id.* at 257.

88. *Id.* at 256.

89. *See, e.g.*, Klein, *supra* note 20, at 107 (arguing in favor of a compensation scheme for victims of contaminated blood products which would be funded partly by the industry and partly by the government). *But see Sindell*, 607 P.2d at 938 n.30 (stating that in principle it did not "see any justification for shifting the financial burden for such damages from drug manufacturers to the taxpayers. . . ."). *See also* Schwartz, *supra* note 26, at 966 (arguing for a legislative compensation scheme in mass tort cases in which the defendant who caused the injury cannot be identified, which would apportion compensation and administration costs among all manufacturers).

90. 1 A.L.I., *supra* note 27, at 258. "[T]he tort liability system will continue to be needed as an umbrella institution to complement the market and regulation." *Id.* at 204.

ally, the Note proposes a modified theory of product liability that both advances the goals of tort law and fosters beneficial interplay of market forces and governmental regulation.

III. THEORIES OF LIABILITY

A. *Concert of Action*

The theory of concert comes from the aiding and abetting concept in criminal law.[91] Its purpose is to deter dangerous group schemes and conduct.[92] The classic model for concert is that of an innocent bystander being injured by one of two cars racing each other at excessive speeds.[93] Under concert, the injured person may sue either or both of the drivers.[94] It is not required that there be an express agreement among the defendants; rather, a "tacit understanding" will suffice to create liability.[95] Each defendant may be held jointly and severally liable for the injury caused by one of them.[96]

In the area of products liability, one court has applied the concert theory to a claim for injuries caused by diethylstilbesterol (DES).[97] However, most courts have rejected concert claims in DES cases on the ground that parallel practices and mutual reliance on tests and marketing techniques fall short of a "tacit agreement."[98] Likewise, no court has allowed recovery under this theory in a Factor VIII case.

B. *Alternative Liability*

The alternative liability theory was adopted by the California Supreme Court in *Summers v. Tice*, the facts of which provide an excellent demonstration of the theory.[99] In that case, the plaintiff was injured by one of two defendants when both defendants negligently shot

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91. *Smith*, 823 P.2d at 726.
92. Sheiner, *supra* note 38, at 979.
93. *Id.*
94. *Id.*
95. KEETON ET AL., *supra* note 21, at 46.
96. *Id.* There are two analytical approaches to such a problem which render the resulting joint and several liability just. Sheiner, *supra* note 38, at 978. The first treats all defendants vicariously liable for the injuries caused by one of them on the basis of agency principles. *Id.* at 979-80. The second approach asserts that the negligence involved is formulation of and participation in the plan itself; therefore, the actions of all possible defendants are true causes of the injury. *Id.*
97. *See* Abel v. Eli Lilly & Co., 343 N.W.2d 164 (Mich. 1984).
98. *See, e.g.*, *Sindell*, 607 P.2d at 924.
99. 199 P.2d 1 (Cal. 1948).

in the general direction of the plaintiff while all three were hunting.[100] The plaintiff did not know and could not prove which of the defendants actually caused the harm.[101] The court found that both defendants were wrongdoers and acted tortiously toward the plaintiff.[102] Therefore, the court decided that, as a matter of fairness, the burden of proof should be shifted from the innocent plaintiff to each of the tortious defendants to show that the defendant was not responsible.[103] The *Restatement (Second) of Torts* embodies this principle.[104]

In applying the theory of alternative liability, one issue that often arises is whether *Summers* or the *Restatement* requires that the defendants' negligent acts occurred simultaneously. Some courts have held that simultaneity is a requirement, relying on the facts of *Summers* itself.[105] However, other courts have disagreed, holding that simultaneity is not a *sine qua non* for application of the theory.[106] In addition, comment (h) following the *Restatement* provision expresses that modification of the provision may be appropriate in the future to meet as yet unanticipated circumstances.[107]

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100. *Id.*
101. *Id.* at 4-5.
102. *Id.*
103. *Id.* at 5.
104. RESTATEMENT (SECOND) OF TORTS § 433(b)(3) (1977). This section provides:

> Where the conduct of two or more actors is tortious, and it is proved that harm has been caused to the plaintiff by only one of them, but there is uncertainty as to which one has caused it, the burden is upon each such actor to prove that he has not caused the harm.

Id.
105. *See Sindell*, 607 P.2d at 929.
106. *Id.* at 928. The court in *Sindell* recognized that simultaneity is but one circumstance which precludes a plaintiff from explaining which defendant was responsible, but not the only circumstance precluding such a determination. *See id.*
107. THE RESTATEMENT (SECOND) OF TORTS § 433(b)(3) cmt. (h) (1965) provides:

> The cases thus far decided in which the rule stated in Subsection (3) has been applied all have been cases in which all of the actors involved have been joined as defendants. All of these cases have involved conduct simultaneous in time, or substantially so, and all of them have involved conduct of substantially the same character, creating substantially the same risk of harm, on the part of each actor. It is possible that cases may arise in which some modification of the rule stated may be necessary because of complications arising from the fact that one of the actors involved is not or cannot be joined as a defendant, or because of the effect of lapse of time, or because of substantial differences in the character of the conduct of the actors or the risks which they have created. Since such cases have not arisen, and the situations which might arise are difficult to forecast, no attempt

Another issue that arises is whether the defendants must be in a better position than the plaintiff to identify which one of them caused the harm. This issue was addressed in *Sindell v. Abbott Laboratories*, an influential case involving product liability theories decided by the California Supreme Court.[108] In *Sindell*, the plaintiff's mother had taken DES for the purpose of preventing miscarriage while pregnant with the plaintiff.[109] The plaintiff developed injuries in her adulthood as a result of the in vivo exposure.[110] The plaintiff could not identify the individual defendant responsible for the injury-causing drug.[111] The defendant manufacturers argued that application of the alternative liability theory (burden-shifting) requires that the defendants be in a better position to make the causation determination than the plaintiff.[112] However, the *Sindell* court stated that neither *Summers* nor the *Restatement* section embodying the *Summers* principle required such a showing.[113]

A third issue that arises in the application of the alternative liability theory is whether all possible defendants must be joined.[114] In *Summers*, there were two possible defendants, and both were joined.[115] Although there was only a fifty percent chance that either defendant was the real cause-in-fact, shifting the burden to the defendants could be justified on the ground that, because both possible defendants were joined, the probability that one or the other of them was responsible was one hundred percent.[116] Therefore, the question is whether shifting the burden is justified when there is a chance that the responsible tortfeasor has not been joined and will escape liability.[117] There is a split among the courts as to resolution of this issue as well.[118] In *Sindell*, the court refused to allow recovery on the basis of alternative liability in a DES case because the number of possible defendant manufacturers was around 200, and therefore they could not all be joined.[119]

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is made to deal with such problems in this Section. The rule stated in Subsection (3) is not intended to preclude possible modification if such situations call for it.

Id.

108. 607 P.2d 924 (Cal. 1980).
109. *Id.* at 925.
110. *Id.* at 926.
111. *Id.* at 926, 931.
112. *Id.* at 929.
113. *Id.*
114. *See id.* at 930-31.
115. *Summers*, 199 P.2d at 2.
116. Sheiner, *supra* note 38, at 986.
117. *See Sindell*, 607 P.2d at 924.
118. *See id.*
119. *Id.* at 931.

C. *Enterprise Liability*

The theory of enterprise liability was first postulated in *Hall v. E.I. Du Pont de Nemours & Co.*[120] The plaintiffs were several children injured in separate explosions of blasting caps occurring in ten different states over a four-year period.[121] The defendants were several blasting cap manufacturers and their trade association.[122] No individual manufacturer was linked to any individual injury; rather, the principal cause of action was the industry's failure to warn and to take safety precautions, which resulted in an unreasonable risk of harm.[123] In *Hall*, the plaintiffs presented evidence that (1) each defendant followed an industry safety standard, (2) manufacturers cooperated in the production of the blasting caps, and (3) a trade association researched and designed some of the safety features, including labeling.[124] In light of this evidence, the court concluded that the defendant manufacturers could be found to have jointly controlled the risk, and therefore determined that the plaintiff needed only to show, by a preponderance of the evidence, that one of the defendants was responsible for the injury-causing cap in order for the burden to shift to the defendants to absolve themselves from liability.[125]

In *Sindell*, the plaintiff argued a cause of action under the rationale of *Hall* based on "'concerted promulgation and adherence to industry-wide testing, safety, warning and efficacy standards'" by the DES manufacturers.[126] In addition, a law review comment cited several times in the *Sindell* opinion[127] urged that an industry-wide theory of liability be applied to DES cases on the basis that promulgation and adherence to the industry-wide standard was the tortious act resulting in manufacture of the injury-producing drug, much as the concerted plan is the tortious act in a concert of action claim.[128] Thus, the conduct of each defendant was a substantial element contributing to the injury, which would satisfy the causation requirement.[129] Nevertheless, the court refused to adopt the enterprise theory for the case before it.[130]

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120. 345 F. Supp. 353 (E.D.N.Y. 1972).
121. *Id.* at 359.
122. *Id.*
123. *Id.* at 359, 386.
124. *Id.* at 373-76.
125. *Id.* at 380.
126. *Sindell*, 607 P.2d at 934.
127. *See id.* at 927-37 (citing Sheiner, *supra* note 38).
128. Sheiner, *supra* note 38, at 997-98.
129. *Id.* at 997.
130. *Sindell*, 607 P.2d at 935.

The *Sindell* court distinguished *Hall* on the basis of the total number of manufacturers.[131] In *Hall*, there were six manufacturers comprising the whole of the industry, whereas in *Sindell* there were at least 200 manufacturers of DES.[132] Apparently the court heeded *Hall*'s warning against applying the theory where there are a large number of manufacturers.[133] In rejecting this theory, the *Sindell* court also noted that the FDA is heavily involved in regulating the testing, manufacturing, and labelling of drugs.[134] Therefore, the court reasoned, it would be inequitable to hold a manufacturer liable for injuries caused by a drug it did not produce just because it followed the industry standard.[135]

D. *Market Share Liability*

The theory of market share liability was enunciated in *Sindell*.[136] It evolved primarily from alternative liability,[137] but contains one key difference. Rather than imposing joint and several liability on each individual manufacturer, it allocates damages according to the percentage market share held by each manufacturer.[138] The rationale is that a manufacturer's market share is an estimate of the probability that it caused an individual plaintiff's injury and that the aggregate amount of damages paid in all such cases would approximate the total damages caused by the manufacturer.[139]

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131. *Id.*

132. *Id.*

133. *Id.*; *see also Hall*, 345 F. Supp. at 378 (stating that enterprise liability would be "manifestly unreasonable if applied to a decentralized industry composed of thousands of small producers").

134. *Sindell*, 607 P.2d at 935.

135. *Id.*

136. *Id.* at 936. The court acknowledged the duty of courts to be flexible and willing to go beyond traditional negligence law when justice requires, stating:

> In our contemporary complex industrialized society, advances in science and technology create fungible goods which may harm consumers and which cannot be traced to any specific producer. The response of the courts can be either to adhere rigidly to prior doctrine, denying recovery to those injured by such products, or to fashion remedies to meet these changing needs.

Id.

137. *See id.* at 936-37.

138. *Id.* at 937. To illustrate, suppose that a plaintiff sues several defendants for an injury caused by a defective product, but she cannot identify which manufacturer produced the particular product. If manufacturer A sold 30% of all such products during the relevant time period, and the plaintiff were awarded $100,000 in damages, then manufacturer A would owe $100,000 X .30 = $30,000. *See id.* n.28.

139. *Id.* at 937.

In order to apply the market share theory, the *Sindell* court required that a "substantial share" of the market be joined.[140] As such, the defendant manufacturer's argument that the manufacturer who actually caused the injury would likely escape liability loses much of its force.[141] The court did not quantify what constitutes a "substantial share," but it is apparent that something less than seventy-five percent of the market would have sufficed, since the court explicitly rejected the cited law review comment's proposal that seventy-five to eighty percent should be required.[142]

The court noted that a defendant may absolve itself by showing that "it could not have made the product which caused the plaintiff's injuries."[143] The example the court gave was that of an actual DES manufacturer in the *Sindell* case who was dismissed from the suit on showing that it had not produced any DES before the time that the plaintiff was born.[144]

Although the court acknowledged that the market is difficult to define, that any determination of market share would likely not be mathematically accurate, and that the correlation between market share and probability of liability is not perfect, the court left such issues to be determined at trial by the factfinder.[145] The court only espoused the basic tenets of the market share liability theory, which would be enough to permit a plaintiff to proceed beyond a defendant's summary judgment motion based on a plaintiff's inability to show causation as to a particular defendant under a traditional negligence cause of action.

Since the California Supreme Court first adopted market share liability in *Sindell*, the highest courts of four other states as well as some lower courts have adopted it in some form.[146] The Wisconsin

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140. *Id.*

141. *See id.*

142. *Id.*

143. *Id.*

144. *Id.*

145. *Id.* at 937-38. The *Sindell* court found support in *Summers* for leaving these issues to the factfinder, stating:

> [T]he difficulty of apportioning damages among the defendant producers in exact relation to their market share does not seriously militate against the rule we adopt. As we said in *Summers* with regard to the liability of independent tortfeasors, where a correct division of liability cannot be made "the trier of fact may make it the best it can."

Id. at 937.

146. In Martin v. Abbott Lab., 689 P.2d 368 (Wash. 1984), the Washington Supreme Court found the *Sindell* market share theory "conceptually attractive" but rejected it in favor of a

modified version which it reasoned would more appropriately and specifically characterize liability and apportion damages. *Martin*, 689 P.2d at 380. This theory became known as market-share alternate liability theory. *Id.* at 381-82.

First, the *Martin* court noted that *Sindell* had not defined what a substantial share of the market would be. *Id.* at 381. This was important because the *Martin* court also perceived that *Sindell* had been unclear as to whether the defendants representing a substantial share, but less than 100% of the market, would be liable for 100% of the damages, in other words, whether the percentage of the market that had been left unaccounted for would be reallocated. *Id.* at 380-81. If damages are reallocated, "[t]he lower the percentage of the market that is required to be joined, the higher will be the distortion," because a larger percentage of the market remains unallocated. *Id.* at 381. The court illustrated what it called "inherent distortion" of liability with a hypothetical example similar to the following: Assume that a plaintiff is awarded damages of $100,000, and she has joined DES manufacturers comprising 60% of the relevant market. Would a defendant manufacturer with 20% of the market be responsible for $20,000 or for $20,000 + (20/60 X 40,000) = $33,333? *See id.*

Instead, the *Martin* court proposed that each defendant that could show its market share would be liable for only that percentage of the damages. *Id.* at 383. Any defendants unable to prove their individual market shares would be responsible for equal shares of unaccounted for damages. *Id.*

The Washington approach differs from the California approach in other ways. A Washington plaintiff is not required to join a substantial share of the market, but rather only one defendant. *Id.* at 382. The *Martin* court perceived no reason for the substantial share requirement since an individual defendant's liability is based only on the defendant's market share. *Id.* The Washington plaintiff would need to allege that the plaintiff's mother used DES and that DES is the cause of the plaintiff's injuries, that the defendant manufactured or marketed the type of DES taken by the plaintiff's mother, and that the defendant's conduct constituted a breach of a legal duty owed to the plaintiff. *Id.* In showing that the defendant manufactured the type of DES taken by the mother, the plaintiff would need to prove by a preponderance of the evidence that the defendant manufactured DES like the DES the mother took with respect to dosage, color, size, or other physical characteristics. *Id.*

In addition, the *Martin* court limited the defendant's liability by allowing the defendant to exculpate itself by showing that it did not distribute the drug in the plaintiff's market area. *Id.* As in *Sindell*, the court stated that a defendant may absolve itself by proving that it did not market DES during the time period that plaintiff's mother could have ingested the drug. *Id.* at 380, 382.

In Hymowitz v. Eli Lilly, 539 N.E.2d 1069 (N.Y. 1989), the highest court of New York applied the market share theory to a DES case. *Hymowitz*, 539 N.E.2d at 1077. Unlike in *Martin*, the *Hymowitz* court explicitly selected the national market as the relevant one. *Id.* The court expounded several reasons for this choice, including unreliability of smaller than national scale markets, difficulty in establishing different market figures for every case depending on different geographical markets, and a need to reduce the burden on litigants. *Id.* In so holding, the court attempted to "apportion liability so as to correspond to the over-all culpability of each defendant, measured by the amount of risk of injury each defendant created to the public-at-large." *Id.* at 1078. Since the court viewed the culpable act as that of marketing the product in a general sense, this approach prevented what the court perceived as a windfall to a defendant who sells in a different geographical region than where the injury occurred. *Id.*

The Florida Supreme Court adopted Washington's market-share alternate theory with a few modifications in another DES case, Conley v. Boyle Drug, 570 So. 2d 275 (Fla. 1990). In *Conley*, the court stated that the relevant market should be drawn as narrowly as the evidence

Supreme Court rejected concert of action, alternative, enterprise, and

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allows to increase the likelihood that liability will be allocated to only those defendants who could have produced the injury causing DES. *Id.* at 284. In addition, the court stated that the theory should be restricted to negligence cases and therefore not permitted in strict liability, warranty or fraud causes of action. *Id.* at 286. Finally, the plaintiff should be required to show that she made a good faith effort to identify the manufacturer that actually caused her injury. *Id.* In adopting market-share alternate liability in this DES case, the *Conley* court distinguished Celotex Corp. v. Copeland, 471 So. 2d 533 (Fla. 1985), an asbestos case in which the same court had previously refused to adopt a market share theory.

In King v. Cutter Lab., 685 So. 2d 1358 (Fla. 2d DCA 1996), the court held that Factor VIII is more similar to asbestos than to DES and certified to the Florida Supreme Court the question whether market-share alternate liability as adopted in *Conley* should apply to Factor VIII cases in Florida. *Id.* at 1360. Although there are some similarities between the asbestos cases and Factor VIII cases, there is one very important difference. Injury due to asbestos exposure is cumulative, therefore every exposure causes injury. In *Celotex*, although the plaintiff could not identify all of the manufacturers of asbestos, he was able to identify some of them. *Celotex*, 471 So. 2d at 537. In contrast, in Factor VIII and DES cases, one product is responsible for the injury, and it cannot be identified. This is a crucial distinction in terms of the policy reasons behind suspending the causation requirement. Without an alternate form of liability in asbestos cases, the plaintiff still has a remedy: traditional negligence. *See id.* at 539. Indeed, in *Celotex* the court concluded:

> [W]e do not find it necessary to accept or reject the market theory approach; rather, we find that, since Copeland has identified several of the named defendants as having manufactured the products that caused his injury, this case neither requires nor justifies the major policy change necessary to adopt the market share theory in Florida.

Id.

In the same year as *Celotex*, the Hawaii Supreme Court adopted the market-share alternate theory with a few modifications in a Factor VIII case. *See Smith*, 823 P.2d at 729. The *Smith* court stated that the plaintiff should use due diligence to join all manufacturers, but such joinder was not absolutely required. *Id.* Rather, the court merely noted that rules as to how many defendants the plaintiff is required to join are not important as long as the plaintiff knows that the percentage he can receive depends on the percentage of the market represented by the defendants. *Id.* In addition, the court agreed with the *Hymowitz* court that the national market was the most appropriate for determining market shares. *Id.* at 728. Having determined that the national market would be used, the *Smith* court acknowledged that probably the only way for a defendant to exculpate itself is by showing that it did not have the product on the market during the relevant time period. *Id.* at 729.

The approach used by the *Smith* court, like that of the *Hymowitz* court, is a hybrid of sorts. The court based liability, at least to some extent, on the enterprise theory, stating "[a]s we are faced here with a minimal number of manufacturers of the product, we believe that culpability for marketing the product is a better policy." *Id.* at 728. However, it apportioned damages on the basis of market share. *Id.* at 729. The court implied that both concert of action and enterprise theories of liability may be applicable, but explicitly stated that it did not want to impose joint and several liability. *Id.* at 726-27.

market share theories of liability in a DES case and instead developed its own approach based on a comparative fault scheme.[147]

IV. ANALYSIS: WHY THE CAUSATION REQUIREMENT SHOULD BE RELAXED

A. *Public Policy*

There are strong policy reasons why manufacturers of Factor VIII concentrates should be held liable for the damage caused by their products. As a result of the contaminated Factor VIII concentrate products, the victims contracted AIDS, perhaps the most feared disease of this decade. AIDS is accompanied by a host of devastating symptoms[148] and often elicits social prejudice toward its victims.[149] Unlike heart disease and cancer, for which there are partially successful life-saving treatments or surgeries, AIDS is a death sentence for every person who contracts it.[150] Although there are medications that can extend the life of the victims, these are relatively new and are very expensive.[151] Recovery in product liability suits can provide the means to obtain these drugs and medical care, and can ease financial suffering that results from inability to work.

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147. Collins v. Eli Lilly Co., 342 N.W.2d 37 (Wis. 1984). In *Collins*, the court held that a plaintiff could recover all of her damages from one defendant if the plaintiff could show that the plaintiff's mother took DES, that DES was the cause of her injuries, that the defendant produced the type of DES taken by the plaintiff's mother, and that the defendant breached a duty to the plaintiff in producing and marketing the DES. *Id.* at 50. However, if the plaintiff joined more than one defendant, the damages would be apportioned by the jury on the basis of comparative fault where the percentage fault would be a function of a number of factors, including market share, the extent to which the company tested the product, and whether the company marketed the product after it was aware of the risks. *Id.* at 53.

148. *See supra* note 12 and accompanying text.

149. *See* Michael M. Merson, *Returning Home: Reflections on the USA's Response to the HIV/AIDS Epidemic*, 347 THE LANCET 1673, 1673 (1996).

150. AIDS is currently the leading cause of death for 25-44 year-olds in America. *Id.*

151. *Id.* at 1674:

> [F]ew Americans seem to realise [sic] the difficulties that many HIV-positive persons have in gaining access to these expensive drugs. There seems to be an all too common scenario. AIDS patients lose their job either because they can no longer work or are fired. In losing their job they lose their health insurance. . . . They then spend their remaining assets and savings to purchase the drugs and the care they need.

Id.

Because blood shield statutes preclude strict liability claims, victims have no remedy except through a negligence cause of action.[152] Plaintiffs usually cannot recover under negligence in Factor VIII concentrate cases because they cannot show causation, in other words, which defendant caused the plaintiff's harm.[153] However, the individual causation requirement would be suspended if one of the four theories discussed in the previous section apply. The problem is that courts have been reluctant to expand these doctrines for fear that it would affect drug innovation, availability, and prices and international competitiveness of the pharmaceutical industry.

It cannot be denied that these are valid concerns. However, research indicates that doctrinal expansions such as strict liability and market share theories do not seriously affect the pharmaceutical industry's decisionmaking process.[154] While these doctrines may remove barriers to bringing suit resulting in a rise in litigation, there is evidence that for every suit brought there are many injuries caused by negligence for which people do not bring suit.[155] In thinking about reform, it should be remembered that the primary goal of tort law is to encourage people injured by another's negligence to bring suit in order to obtain corrective justice, provide just compensation, and deter future product-related injuries.[156]

Moreover, it is not a general rise in the number of suits brought but rather an increase of extremely large awards, including pain and suffering and punitive damages, that inject the most uncertainty into the decisionmaking process.[157] As previously discussed, it is uncertainty, rather than risk, that most influences industrial decisionmakers and insurers, resulting in adverse social consequences.[158]

In addition, the strict causation requirement in traditional negligence law has been cited as a shortcoming in product liability law as a system for achieving the interests at stake in product-related injury cases, because it limits the number of product defects that can be addressed by courts.[159] Finally, doctrinal expansion in product liability law can enhance the function of market forces and governmental regulation in achieving the same interests.

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152. *See* Klein, *supra* note 20, at 109-10.
153. *See, e.g., King*, 685 So. 2d at 1359.
154. 1 A.L.I., *supra* note 27, at 20.
155. *Id.* at 51.
156. *Id.* at 24, 28, 31.
157. *Id.* at 66, 99.
158. *See supra* pt. II.
159. 1 A.L.I., *supra* note 27, at 257.

B. *Legal "Fit"*

In order for there to be liability under the concert of action theory, the defendants must have had a "tacit agreement" to engage in tortious acts.[160] Although the Factor VIII manufacturers likely engaged in parallel practices with respect to testing and marketing,[161] the *Sindell* court and other courts have held that this alone does not rise to the level of concert of action, partly because the conduct itself is not tortious.[162] However, there is also evidence of anticompetitive behavior within the pharmaceutical industry, and indeed within the Factor VIII concentrate submarket itself.[163] At the very least such conduct would undermine market forces, preventing people from making informed choices about risk, price, and alternatives. Such practices could potentially violate antitrust law.[164] Thus, such conduct, in addition to the parallel practices in safety and marketing, may rise to a level that would satisfy the concert theory. If so, liability would attach because of the conspiracy itself, and it would not matter which individual member of the group actually caused the harm.[165]

Under the alternative theory of liability, the burden of proof shifts to the defendant manufacturers to exculpate themselves after the plaintiff shows that all defendant manufacturers were negligent and that the plaintiff cannot show which manufacturer caused the harm.[166] In Factor VIII cases, it is known that all manufacturers had HIV-contaminated Factor VIII concentrates on the market.[167] In addition, all of the manufacturers engaged in basically the same inadequate procedures in

160. *See supra* pt. III.

161. *See* Sheiner, *supra* note 38, at 980 (suggesting that the pharmaceutical industry's production and marketing strategies involve cooperative conduct which supports application of the concert of action theory).

162. *Sindell*, 607 P.2d at 932.

163. *See supra* notes 37-40 and accompanying text.

164. *See* E. THOMAS SULLIVAN & JEFFREY L. HARRISON, UNDERSTANDING ANTITRUST AND ITS ECONOMIC IMPLICATIONS 125 (2d ed. 1994). Section 1 of the Sherman Act makes unlawful "[e]very contract, combination . . . or conspiracy in restraint of trade." 15 U.S.C. § 1 (1994). This provision requires some kind of concerted action or meeting of the minds, but "conscious parallelism" without express agreement may constitute an antitrust violation if certain other "plus factors" are present. SULLIVAN & HARRISON, *supra*, at 128-29. Three of these "plus factors" are present in Factor VIII cases: (1) each defendant had a "substantial profit motive for concerted action," (2) the defendant engaged in "unanimity of action," and (3) compliance with the concerted plan would benefit individual defendants only if all of the defendants also cooperated. *Id.* at 129.

165. *See supra* pt. III.

166. *See supra* pt. III.

167. *King*, 685 So. 2d at 1360.

manufacturing the plasma concentrate.[168] Therefore, the manufacturers were all potentially negligent with respect to the users of their products.

The second requirement for application of the alternative theory is also met in Factor VIII cases because the plaintiffs can rarely show which defendant caused the harm for three reasons. First, Factor VIII products were interchangeable.[169] The plaintiff usually would get the concentrate from a hospital or doctor, and he would be given whichever manufacturer's concentrates were available. Second, although many of the manufacturers' names were on the plasma bags, the plaintiff may not remember the names because it is often a long period of time between when the product was used and when the plaintiff realizes that he is infected and brings suit.[170] Indeed, sometimes it is the family of the victim that brings suit after the victim is deceased.[171] Third, if the plaintiff used the products of more than one manufacturer, he cannot show which one caused the harm even if he knows which manufacturers' products he used.[172] Because hemophiliacs have to repeat treatments often, many of them used different manufacturers' products.

As previously discussed, there is some question as to whether application of the alternative liability theory requires that (1) the defendants are in a better position to determine which of them caused the plaintiff's injury and (2) all of the potential defendants are joined.[173] In *Sindell*, the California Supreme Court explicitly stated that neither *Summers* nor the *Restatement* section 433(b) requires that the defendants be in a better position to determine which defendant caused the harm.[174] Therefore, it should not matter if the defendant manufacturers of Factor VIII concentrates did not have better access to information than the plaintiff. Rather, the policy is simply that as between an innocent plaintiff and negligent defendants, the latter should bear the burden of persuasion.[175]

As to the second issue, the majority of courts considering application of alternative liability theory have required joinder of all possible

168. Ray v. Cutter Lab., 754 F. Supp. 193, 196 (M.D. Fla. 1991); Brief of Amicus Curiae Academy of Florida Trial Lawyers in Support of Appellant at 9, King v. Cutter Lab., 685 So. 2d at 1358.

169. *Ray*, 754 F. Supp. at 196.

170. *Id.*

171. *See, e.g., King*, 685 So. 2d at 1359.

172. *Ray*, 754 F. Supp. at 196.

173. *See Sindell*, 607 P.2d at 929-31.

174. *Id.* at 930.

175. *See supra* pt. III.

defendants.[176] However, strict adherence to this requirement may not preclude recovery in Factor VIII cases because there are so few potential defendants,[177] especially if those who could not have supplied the injury-causing drug in the plaintiff's geographical region are omitted. Alternatively, relaxation of this requirement in Factor VIII cases would result in less unfairness to defendants than in DES cases because there are very few Factor VIII manufacturers in contrast to the 200 to 300 DES manufacturers.

Under enterprise liability theory, the plaintiff must show that the defendants jointly controlled the risk.[178] This theory is partly based on the concert of action theory, but it was specifically adopted in a product liability setting. Although it has not been widely accepted, both DES and Factor VIII courts continue to consider it in their analysis of which of the possible theories should apply.[179] In *Sindell*, the sole reason given by the court for rejecting the enterprise theory in that DES case was that the *Hall* court, which developed the theory, had cautioned against applying it in cases in which the enterprise consisted of a large number of manufacturers.[180] The *Hall* court's concern was that the more manufacturers there are, the less likely it seems that all manufacturers could have known of the risk and participated in setting and executing the inadequate safety standard.[181] However, in Factor VIII cases, the enterprise is much smaller than the DES enterprise. In fact, there have been only about six manufacturers of Factor VIII concentrates, about the same as the number of blasting cap manufacturers in *Hall*.[182] The existence of a small number of manufacturers, combined with the collusive and parallel practices in the market discussed herein with respect to the concert theory, favors the application of enterprise liability in Factor VIII cases.

Under market share theory, the primary issue in Factor VIII cases is whether the products were "fungible" within the meaning of *Sindell* and other cases that have applied the market share theory.[183] Arguably, the Factor VIII product is fungible according to the dictionary definition,

176. *See Smith*, 823 P.2d at 725.

177. *See, e.g.*, Poole v. Alpha Therapeutic Corp., 696 F. Supp. 351, 355 (N.D. Ill. 1988) (applying alternative liability in a Factor VIII case in which plaintiff had joined all potential defendants).

178. *See supra* pt. III.

179. *See, e.g., Sindell*, 607 P.2d at 924.

180. *Id.* at 935.

181. *Hall*, 345 F. Supp. at 378.

182. *Id.* at 359.

183. *See Sindell*, 607 P.2d at 936.

which gives "interchangeable" as a synonym.[184] Like DES, Factor VIII products were interchangeable with respect to their function: the products were produced by similar processes, any patient could have been given any manufacturer's product, and each product performed the same function in the same way.[185]

However, defendants in these cases argue that the products were not uniform with respect to risk because a product was only defective if the source plasma was contaminated with HIV.[186] There are two reasons why this distinction should not be dispositive. First, it seems that all of the manufacturers followed basically the same preparation procedures.[187] If a particular concentrate product was not contaminated with HIV, it was the result of chance, not the result of better procedures followed by some manufacturers and not by others.[188] Thus, barring a claim because of the plaintiff's inability to show causation by any one manufacturer results in a windfall for all manufacturers. Second, it is important to note that the claims in these cases are usually for negligence in failure to exclude high-risk donors, failure to screen other donors, and failure to warn, as opposed to claims for manufacturing or design defects.[189] The known nonuniformity of source plasma, which resulted from some donors being infected but not others, is precisely the factor that placed a duty on the defendants to exclude high-risk donors, screen other donors, and warn of the risk involved in using the concentrate. Thus, the fact that the infectiousness of the source plasma was nonuniform actually enhances the negligence claims.

However, probably due to fear of doctrinal expansion, most courts have given the term "fungible" a very narrow reading, which almost limits the theory to DES cases only.[190] Unfortunately, this interpreta-

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184. MERRIAM WEBSTER'S COLLEGIATE DICTIONARY 473 (10th ed. 1993).

185. *See Ray*, 754 F. Supp. at 196.

186. *See, e.g., King*, 685 So. 2d at 1360.

187. *Ray*, 754 F. Supp. at 196.

188. *See* Brief of Amicus Curiae Academy of Florida Trial Lawyers in Support of Appellant at 9, *King*, 685 So. 2d at 1358.

189. *See Smith*, 823 P.2d at 717.

190. *See, e.g., King*, 685 So. 2d at 1359-60. *But see* Fibreboard Corp. v. Kerness, 625 So. 2d 457 (Fla. 1993). In *Fibreboard*, the Florida Supreme Court stated,

> [The defendant] nevertheless argues that we should apply *Conley* only to DES (diethylstilbestrol) cases. We decline to adopt a rule of law based on the type of product at issue. There is no basis in logic for a special rule based on particular types of products; such a rule would be arbitrary by its very nature.

Id. at 458.

tion severely and unnecessarily limits the scope of product liability law as a system for redressing injuries caused by product defects.

Based on the foregoing analysis, any one of these four theories may be an appropriate basis for liability in Factor VIII cases.[191] Having discussed the policy reasons for relaxing or shifting the causation burden and the legal avenues through which this can be achieved, it is now necessary to focus on other aspects of the approach to these cases which will help to protect the other values at stake.

V. PROPOSALS

The following recommendations apply to Factor VIII and similar cases regardless of which of the above four theories are used to determine liability.

A. *Market Share versus Joint and Several Liability*

Market share and joint and several liability both accomplish certain goals, but a modified market share approach is preferable for apportioning damages. The proposed approach involves a comparative fault scheme. The market share percentage should be one element of a comparative fault calculation. The other element should be the relative

191. Some defendants would argue that the manufacturers were not negligent toward the particular plaintiff who has brought suit, and that under the reasoning of Palsgraf v. Long Island R.R., 162 N.E. 99 (N.Y. 1928), "negligence in the air, so to speak, will not do." *Palsgraf*, 162 N.E. at 99 (quoting POLLOCK, TORTS 455 (11th ed.)). There are two flaws in this reasoning. First, it confuses the negligence elements of causation and breach of duty. It is circular to say that a particular defendant could not have breached a duty toward the plaintiff because the plaintiff cannot prove that it was that particular defendant who caused the injury. Rather than intermingling causation issues, purely deductive reasoning can and should be used to determine if there has been a breach of duty: If a drug manufacturer has breached a duty by manufacturing a defective product, then it has breached a duty to all potential users of the product. If the manufacturer has breached a duty to all the potential users, then it necessarily has breached a duty to one of those users. Second, reliance on *Palsgraf* in this situation is misplaced. In *Palsgraf*, the plaintiff was standing on the defendant railroad's platform after buying a train ticket. *Palsgraf*, 162 N.E. at 99. As one of the defendant's guards was helping a passenger to board a moving train, the passenger's package of fireworks fell from his arms and exploded, causing some platform scales to fall and injure the plaintiff. *Id.* Justice Cardozo, writing for the majority, said that the defendant railroad was not liable because, while the guard's conduct may have been negligent with respect to the passenger, it was not negligent with respect to the plaintiff. *Id. Palsgraf* has been widely interpreted as standing for the proposition that a duty is owed only to foreseeable plaintiffs. *See generally* JAMES A. HENDERSON, JR. ET AL., THE TORTS PROCESS 365-72 (4th ed. 1994). The consumers of a manufacturer's products are like the train's passengers in *Palsgraf*, not merely bystanders. Thus, pharmaceutical consumers are foreseeable plaintiffs.

degree of negligence of each manufacturer, for example, what safety precautions were taken by each manufacturer with respect to the others.[192] This approach takes into account the fact that if one defendant was more careful than the others, then the probability that it caused the harm would likely be less than the percentage of its market share. The jury could determine these percentages by means of a special interrogatory form as in other comparative fault cases.

This is a "carrot" approach, providing pharmaceutical companies with an incentive to engage in more socially advantageous conduct. Because there is a negligence factor involved in calculating damages, there would be an incentive to invest in additional safety precautions, resulting in safer products.[193] This approach also would reduce uncertainty for decisionmakers and insurers because the manufacturer would know the approximate percentage of its market share and could estimate potential liability costs.

Furthermore, if individual companies have sufficient incentive to produce safer products than their competitors, there will be less collusion and more competition in the market.[194] Market forces will act more closely to expectation, perhaps resulting in lower prices and greater availability of products according to demand and competition rather than according to unethical and perhaps illegal mutual agreements among pharmaceutical manufacturers.[195]

Finally, because adherence to regulations by each defendant would be a factor in the comparative negligence calculation, this scheme would provide an additional incentive for companies to comply with regulations.[196] This would enhance the role of governmental regulation in ensuring safe and effective products for the public. Thus, the market share approach would promote the harmonious interaction of the relevant institutions to the benefit of consumers.

Conversely, joint and several liability is the "stick" approach. Because one manufacturer could be held totally liable for all damages

192. This can be implemented in two ways. The Wisconsin approach, in which market share percentage and other negligence factors are all considered together by the jury in calculating a single comparative fault percentage, is one possibility. *See supra* note 149 and accompanying text. The second possible approach is to have the jury calculate the comparative negligence percentage separately from market share, and then assign a certain weight to each of these elements in determining the overall comparative fault and corresponding damages. A court might prefer the latter for limiting jury discretion in Factor VIII cases because the jury is likely to be very sympathetic.

193. *See supra* pt. II.

194. *See supra* note 29.

195. *See supra* pt. II.

196. *See* GARBER, *supra* note 29, at 125.

caused by the others, joint and several liability acts as a deterrent against engaging in the conduct that triggers its application. However, joint and several liability may inject too much uncertainty into the decisionmaking processes of both the pharmaceutical and insurance industries, resulting in decisions based on fear rather than facts. Unwarranted predictions of substantial liability might lead to unavailability and high prices of drugs.[197]

In addition, because some companies are not amenable to suit due to personal jurisdiction or successor liability problems, only a few of the companies involved may be held liable for all of the damages under joint and several liability. This can result in companies going bankrupt, leaving virtual monopolies and even less competition.[198] Therefore, the joint and several approach is less preferable than the market share approach.

B. *Pain and Suffering Awards*

Pain and suffering awards should be limited. This proposal can be justified for three reasons. First, the possibility of large pain and suffering awards is a primary source of uncertainty for decisionmakers and insurers, resulting in poor decisions with adverse social consequences.[199] Second, it is generally acknowledged that monetary awards do not really alleviate pain and suffering caused by an injury beyond what compensatory damages would provide, such as medical care. Third, the plaintiff's injury often has been caused by a product which provided relief for an ailment that the plaintiff suffered prior to the use of the product. This is certainly true in Factor VIII cases. Thus, the pain and suffering award should reflect the difference between the plaintiff's level of pain and suffering and quality of life subject to the adverse effects of the product and the level the plaintiff would have experienced due to the previous ailment without the drug.

However, in Factor VIII cases all of the hemophiliacs infected by the concentrates eventually die because there is no cure for AIDS. Therefore, it is difficult to judge the relative value of the new treatment because it requires comparing life with the possibility of pain and suffering without this drug to no life at all after use of the negligently manufactured drug. The jury must deal with this philosophically nebulous dilemma as it deals with similar decisions regarding damages for the loss of life.

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197. *See supra* pt. II.
198. *See* GARBER, *supra* note 29, at 114.
199. *See* 1 A.L.I., *supra* note 27, at 99, 201.

C. *Punitive Damages*

Punitive damages also should be limited. The purposes of punitive damages are to punish wrongful behavior and deter similar future behavior.[200] Also referred to as exemplary or vindictive damages, punitive damages are those awarded in excess of the actual loss of the plaintiff when the loss is exacerbated by malicious, wanton, or reckless behavior on the part of the defendant.[201] These damages perform their deterrent function by increasing the risk estimates and uncertainty in decisionmaking.[202] However, punitive damages may deter more than is socially beneficial or reasonable.

It must be remembered that often even drugs that cause harmful side effects to some users also give relief to a great number of others. Many people would accept a risk of harm knowingly in order to obtain relief from an existing ailment, especially if their existing ailment is serious. It is important to allow individuals to make informed choices about the use of drugs or products rather than to preempt those choices by deterring pharmaceutical companies from producing the drugs or products altogether. Therefore, in addition to the traditional consideration of the extent of a defendant's knowledge about the risks involved in using a product, the following factors should be considered in determining whether punitive damages are appropriate.

First, in determining whether punitive damages should be awarded, the jury should consider whether adequate warning was given and to what extent the defendant's behavior prevented market forces from acting. Second, the positive effects of the drug or product and whether there was a viable alternative should also be taken into account. If the overall social benefit to be derived from a drug is greater than the accompanying social detriment, the manufacturer should be able to put the product on the market with proper warning for consumers to make their own decisions. In addition, society probably would not condone a manufacturer's withholding a life-saving drug, even a risky one, where there is no alternative. Third, if modifications to the drug would have made it safer, the extent to which such modifications would have reduced its effectiveness for the intended purpose also should be considered.

In Factor VIII cases, some of these factors militate in favor of punitive damages. First, one of the allegations is that manufacturers

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200. 1 LINDA L. SCHLUETER & KENNETH R. REDDEN, PUNITIVE DAMAGES § 2.2(A), at 28 (3d ed. 1995).

201. *Id.* at 25.

202. *See supra* note 54.

failed to provide adequate warning.[203] Second, there is evidence of collusion in the market, which would prevent market forces from acting correctly.[204] Third, modifications that would have made the concentrate safer, such as excluding high-risk donors and screening other donors, would not have made the concentrate less effective. On the other hand, the fact that very little was known about AIDS and its modes of transmission at the time the drug was introduced and for some time thereafter indicates that the manufacturers probably were not acting maliciously.[205] In addition, the concentrate provided great benefits for hemophiliacs over the cryoprecipitate alternative, and it is likely that at least some hemophiliacs would have accepted what was perceived at the time as a slight risk in order to obtain the relief and freedom that the concentrate afforded them. Therefore, punitive damages may be appropriate in Factor VIII cases, but they should be limited.

VI. CONCLUSION

Balancing conflicting interests is one of the most difficult and imperfect of tasks performed by courts and legislatures. However, the complete sacrifice of a few innocent persons for the benefit of many has never been an acceptable way to meet this challenge. In Factor VIII cases, courts must balance the interests of HIV-infected hemophiliacs, the pharmaceutical industry, and the public that depends on the availability of pharmaceutical products. As argued in this Note, this can be achieved by using a market-share liability approach which factors in the relative negligence of manufacturers and limits the available damages. This approach promotes socially beneficial outcomes by influencing the industrial decisionmaking process and enhancing the function of market forces and governmental regulation. In this way, tort law can meet the challenges posed by a progressive society while protecting the values it has secured for individuals for over a century.

203. *See, e.g., Smith*, 823 P.2d at 724.
204. *See supra* note 29.
205. *See supra* note 12 and accompanying text.