An International Drug Administration: Curing Uncertainty in International Pharmaceutical Product Liability

Katherine A. Davis
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I. INTRODUCTION

"Given the properties of drugs, the idea of a drug that is both perfectly safe and effective, at least with our present knowledge, is but a dream remembered from imaginings of a Garden of Eden designed for the welfare of man."1

Despite the extensive efforts pharmaceutical companies expend researching, developing, and testing new drugs to ensure their "safety" and

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"effectiveness," there is no way to guarantee complete safety.\textsuperscript{2} Thus, the pharmaceutical industry faces an inherent dilemma: While pharmaceutical products have a high social value because they enable people to live longer, more productive, pain-free lives, these products also pose serious health risks to consumers. Pharmaceutical companies have no desire to create these risks,\textsuperscript{3} but they are present nonetheless; therefore, there needs to be an effective system to deal with injuries arising from pharmaceutical products.

The dangers posed by pharmaceutical products differ from those attributable to mistakes in the manufacturing process such as finding a piece of glass in a jar of mayonnaise.\textsuperscript{4} Such dangers can be labeled as "non-generic" because they endanger only a small percentage of a product's consumers.\textsuperscript{5} Little controversy arises over holding a manufacturer liable for consumer injuries caused by non-generic dangers because the manufacturer is clearly at fault. In contrast, the risks associated with pharmaceutical products are "generic" in nature because they are inherent in the products themselves rather than as a result of a manufacturing flaw or malfunction.\textsuperscript{6}

Holding manufacturers liable for injuries caused by generic risk products has proven quite controversial because the manufacturer does not appear to be as clearly at fault as with non-generic risk products. Nowhere has this controversy been more evident than in pharmaceutical product liability. While pharmaceutical companies make up only a small percentage of the manufacturing industry, in 1985 alone, the number of suits filed against pharmaceutical companies was more than double the amount of claims brought against the rest of the manufacturing industry.\textsuperscript{7}

The pharmaceutical industry, like so many other private industries, has expanded far beyond national borders. However, the laws governing the industry have not been as quick to venture outside their respective domains. The United States, the European Union,\textsuperscript{8} and Japan have become the primary players in the international pharmaceutical market.\textsuperscript{9} Together they

\textsuperscript{2} Opinions on the safety and effectiveness of pharmaceutical products can vary greatly depending on one's response to the question: safe and effective relative to what?

\textsuperscript{3} Basic common sense dictates that if you are trying to sell a product and make a profit, injuring your consumers is not a good way to encourage sales.


\textsuperscript{5} See id.

\textsuperscript{6} See id.

\textsuperscript{7} W. Kip Viscusi et al., A Statistical Profile of Pharmaceutical Industry Liability, 1976-1989, 29 SETON HALL L. Rev. 1418, 1421 (1994). This figure excludes asbestos claims. Id. at 1422.

\textsuperscript{8} The European Union was formerly known as the European Community, but for uniformity purposes, it will be referred to throughout this paper as the European Union.

account for seventy-five percent of the world’s pharmaceutical market and
ninety percent of all pharmaceutical research. As previously noted, phar-
maceuticals and product liability go hand in hand. The United States, the
European Union, and Japan have all developed their own product liability
standards based on their unique histories, traditions, philosophies, power
structures, and legal systems. Today, each regime, at least in theory, has
adopted the doctrine of strict liability. However, this standard has been
subject to such varied interpretation and application that, in practice, the
strict liability imposed in Toledo often bears little resemblance to the strict
liability found in Toulouse or Tokyo. To avoid the problems generated by
the inconsistencies and uncertainty in pharmaceutical product liability, a
new international, uniform system of liability should be established for in-
ternational pharmaceutical products.

This comment will demonstrate how discrepancies among product li-
ability standards and different interpretations of their application have cre-
ated fear and uncertainty in the pharmaceutical industry. This fear has
caused distortions in the market, increased costs for both manufacturers
and consumers, and chilled the research and development of new products.
To combat these problems, this comment proposes that the United States,
the European Union, and Japan work together to create a new international,
uniform system of product liability for pharmaceutical products. Harmo-
nizing the standard of liability for pharmaceuticals among these regimes has
proved inadequate to stop inconsistency and uncertainty. This comment
proposes the creation of an International Drug Administration (IDA), com-
prised of members from different countries that would serve as an interna-
tional regulatory agency promulgating registration and development
requirements for new drugs on the international market. A special subset of
the IDA would serve as an administrative tribunal for liability cases. The
IDA tribunal would provide a uniform system of product liability, compens-
ing consumers for injury but not punishing manufacturers without fault.

Part II of this comment will introduce the current liability standards for
pharmaceutical products in the United States, the European Union, and Ja-
pan, and will explain how these standards developed and how they differ
from each other. Part III will then illustrate how these differences translate
into uncertainty and how that uncertainty negatively affects the pharma-
cutical market. Part IV will introduce the concept of international regulation
of the pharmaceutical industry through an IDA. Finally, Part V will explain
how this IDA would act as an administrative tribunal for pharmaceutical
product liability claims. This system would eliminate inconsistency and
uncertainty in product liability and provide a better, more uniform system
of product liability for the pharmaceutical industry.

10 Id.
11 Companies have chosen to stop producing certain products rather than face uncertain
liability.
II. THE CURRENT STANDARDS OF PRODUCT LIABILITY IN THE UNITED STATES, THE EUROPEAN UNION, AND JAPAN: HOW THEY DEVELOPED, HOW THEY DIFFER, AND WHY

The underlying goal of any product liability system is to protect consumers by providing an incentive for manufacturers to create safe products. An effective system will provide fair compensation for consumer injury without unfairly punishing manufacturers. The United States, the European Union, and Japan have each struggled to achieve the goal of fairly redressing consumer injuries without crippling the pharmaceutical industry in the process.

A. The Doctrine of Strict Liability in the United States

The U.S. common law, viewed as the champion of the common person, has developed a consumer-friendly approach to product liability. In 1944, Justice Roger Traynor introduced the idea of a consumer-friendly product liability standard in Escola v. Coca Cola Bottling Co. In 1965, Justice Traynor’s consumer-friendly liability concept was officially adopted as the doctrine of strict liability in Section 402A of the Restatement (Second) of Torts. In response to a proposal to exclude prescription drugs from the purview of strict liability, the drafters adopted Comment k which created a general exemption for “unavoidably unsafe” products. The Re-
statement is not binding law, but rather a reflection of common law, and as such it has been subject to numerous judicial interpretations. Over the past three decades, courts have altered the legal product liability doctrine dramatically to make it easier for consumers injured by drugs and other "unavoidably unsafe" products to recover under strict liability.

In 1997, after thirty years of common law development of strict liability under Section 402A, the Restatement (Third) of Torts was adopted. Commentators have suggested that the new Restatement reflects a recent trend towards shortening the long arm of strict liability. Perhaps it will, but we must wait to see if the theory translates into practice or if judicial interpretation continues to be consumer-friendly.

Comment k: 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. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared and accompanied by proper directions and warnings, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason can not legally be sold except to physicians, or under prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. 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 or unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

RSTATEMENT (SECOND), supra note 14, § 402A cmt. k.

The doctrine of strict liability was designed to allow courts to move away from looking only at manufacturer fault and to focus on the defectiveness of products themselves. Brown v. Superior Ct., 751 P.2d 470, 474 (Cal. 1988). Originally, the drafters of Section 402A intended it to have a narrow focus and "apply only to products with latent manufacturing defects." Teresa Moran Schwartz, The Impact of the New Products Liability Restatement on Prescription Products, 50 Food & Drug L.J. 399, 400 (1995). However, the courts have extended the application of the strict liability doctrine to include claims based on inadequate warnings and design defects. Id.

17See, e.g., Reyes v. Wyeth Lab., Inc., 498 F.2d 1264 (5th Cir. 1974) (stating that a failure to warn consumers was a design defect that made product "unreasonably dangerous"); Cronin v. J.B.E. Olsen Co., 501 P.2d 1153 (Cal. 1972) (modifying strict liability under § 402A by rejecting requirement that product be "unreasonably dangerous" in favor of only having to show proximate cause); Barker v. Lull Eng'g Co., 573 P.2d 443 (Cal. 1978) (defining "design defect").


19See Schwartz, supra note 16, at 399.

For over-the-counter drugs, while the new Restatement abandons Section 402A's doctrinal label of strict liability, it follows 402A's underlying principle of consumer-friendly recovery.设计缺陷索赔在新《重述》中要求进行风险/效用平衡测试，其中受伤消费者必须证明一种“合理替代设计”存在，并且未能使用这种替代设计使产品“不合理的安全”。虽然这种测试似乎为原告设定了更重的负担，但“不合理的安全”等术语往往适合于解释。此外，法院和陪审团在判决和大陪审团的裁决中表明了对受伤原告的偏好。因此，《重述》为处方产品创造了特别的法律责任标准。制造缺陷和不足警告的标准基本上遵循普通法，只是对不足警告索赔有少数例外。然而，由于普通法未能提供设计缺陷案件中的一个稳定的标准，制作者发明了自己的新的“超级”过错标准。这新的标准基本上要求受伤消费者证明这种药物永远不应该被放在市场上，并且对任何类别的患者都没有好处。尽管《重述》(第三版)制止旨在至少遏制严格责任原则在产品责任案件中的扩展，但美国的药品责任法仍然对受伤消费者友好。
B. A Directive for Strict Liability in the European Union

In order to understand how the European Union's current product liability standard operates, it is important to discuss the structure and background of the European Union. In 1957, several European countries agreed to join together to form a single market of common trade policies. These nations agreed to harmonize their national laws to facilitate the free movement of goods, people, and capital among participating Member States. Each Member State remains an autonomous nation, while agreeing to be part of a supranational organization and allow one common decision-making body, the European Commission, to promulgate legislative proposals, including those governing trade policies. The Council of Ministers [hereinafter the Council] votes on proposals from the European Commission and largely enacts legislation through either Regulations or Directives. Once legislation in the form of a Council Directive, is adopted by the Council, Member States must implement the Directive’s policies through their respective national laws.

Historically, product liability laws varied tremendously throughout the European Union. Most Member States' liability laws originated from civil and common law principles of tort and contract, however, differing national legal traditions meant the methods by which products were found defective and manufacturers held liable varied greatly among Member States. In the mid 1970s, the European Union recognized that differences in Member States’ product liability laws hindered free trade.

28Treaty establishing the European Economic Community, Mar. 25, 1957, 298 U.N.T.S. 11 [hereinafter Treaty of Rome]. The fifteen Member States comprising the European Union are: Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, United Kingdom, Austria, Finland, and Sweden.

29Treaty of Rome, arts. 2, 3.

30Treaty of Rome, arts. 4, 5.

31Regulations are directly applicable to, and bind all Member States. Directives, on the other hand, are binding on Member States only as to the goals expressed in the Directive; Member States have discretion to determine the means by which the goals will be achieved. Treaty of Rome, art. 189.

32Treaty of Rome, art. 189.

33The standard of traditional fault liability was used by southern Member States. Patrick E. Thieffry, Strict Product Liability In The EEC: Implementation, Practice, And Impact On U.S. Manufacturers of Directive 85/374, 388 PLI/LIT 223, 227 (1990) (reprinted with permission from 25 TORT & INS. L. J. No. 1, (Fall 1989)). Fault liability with a reversal of the burden of proof was used by northern European Member States. Id. France, Luxembourg, and Belgium used strict de facto liability based on contracts theory. Id.

34For a detailed discussion of how different Member States historically handled product liability issues, see WILLIAM C. HOFFMAN & SUSANNE HILL-ARNING, GUIDE TO PRODUCT LIABILITY IN EUROPE (1994).

35Lucille M. Ponte, Guilt By Association In United States Products Liability Cases: Are The European Community And Japan likely to Develop Similar Cause-In-Fact Approaches To Defendant Identification?, 15 LOY. L. A. INT'L & COMP. L. J. 629, 648-49 (1993).
Recognition of the negative effects that this fragmentation had on free trade sparked discussion and debate on a new Directive. The European Union issued a proposal for a more unified approach to product liability in 1976, which was debated and negotiated before the Council for nine years. The hope was to create a more uniform product liability standard. These discussions resulted in the European Union's 1985 adoption of the "Directive on the Approximation of Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Provisions" (Directive).

The Directive embraces strict liability as the European Union's standard of product liability. Thus, the Directive requires only that a plaintiff show damage, defect, and a causal connection between the two. The plaintiff is not required to show fault, and privity of contract is no longer required to file a product liability claim. Moreover, the definition of "product" includes all moveables, even those incorporated inside another movable or immovable product. Safety and consumer expectations are central themes of the Directive. A consumer expectation test is used to determine whether a product is defective, and is an even more liberal test than the United States' standard, which requires a product to be "unreasonably dangerous." Under the Directive, a defect is established if a product is used as it was supposed to be used, but performs less safely than a consumer might reasonably expect.

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39 Id. art. 1, 1985 O.J. (L 210) at 30. The Directive provides: "producer shall be liable for damage caused by a defect in his product." Id.
40 Id.
41 Id. arts. 1, 3, 1985 O.J. (L 210) at 30.
42 The Directive does not clearly define the term "movable"; thus, whether a good is a movable product will be decided by the applicable national law, which may cause differences in interpretation of the Directive. Thieffry, supra note 33, at 230.
43 Directive, supra note 38, art. 2, 1985 O.J. (L 210) at 30. This means a victim will have a claim under the Directive even if the pharmaceutical product that caused the injury is incorporated within an immovable good that would not otherwise be considered a product.
44 Id. art. 6, 1985 O.J. (L 210) at 31:
A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:
(a) the presentation of the product;
(b) the use to which it could reasonably be expected that the product would be put;
(c) the time when the product was put into circulation.
45 See RESTATEMENT (SECOND), supra note 14, § 402A.
46 Directive, supra note 38, art. 6, 1985 O.J. (L 210) at 31.
The Directive affords producers several defenses to a liability claim.47 One such defense is similar to the “unavoidably unsafe” exception in the Restatement. A producer can avoid strict liability in the European Union by proving that, based on the scientific and technological knowledge available at the time the product was made and introduced to the market, it was impossible for the producer to know or discover the defect.48 Commonly referred to as the “state of the art” defense, it is used by producers to defend against claims of inadequate instructions or warnings for inherently unsafe products like pharmaceuticals.49 As in the United States, consumers can recover for personal injury, death, or harm to personal property.50 However, the Directive does not provide for pain and suffering compensation, and punitive damages do not play a role in European product liability.51

It should be remembered that Council Directives are only policy statements which supplement rather than replace existing national laws;52 Member States are required to accept a Directive’s stated policy goal, but the means by which they enforce that policy goal fall within the province of each individual Member State.53 Thus, this product liability system leaves room for differing national implementation of the same policy.54

C. The New Standard of Strict Liability in Japan

Unlike in the United States or the European Union, where formal mechanisms such as Restatements and Directives provide direction for shaping the future of product liability, “in Japan[,] informal, social forces are molding this developing area of law, and the present and changing law cannot be understood without first understanding the social forces”55 that have shaped Japanese law for centuries. Japanese law is a complex mixture.

47 A producer can avoid liability by proving: (1) that he or she did not place the defective product on the market; (2) that the defect probably did not exist at the time he or she did put the product on the market; (3) that the product was not intended to be commercially distributed; (4) that based on the scientific and technological knowledge available at the time the product was made and introduced to the market, it was impossible for the producer to know or discover the defect. Directive, supra note 38, art. 7, 1985 O.J. (L 210) at 31.
48 Id.
49 Thieffry, supra note 33, at 234.
50 Directive, supra note 38, art. 9, 1985 O.J. (L 210) at 31.
51 Thieffry, supra note 33, at 234.
52 Treaty of Rome, art. 189. Directives bind Member States as to the result to be achieved but leave up to each individual member state’s domestic agencies the means of achieving the end result. Id.
53 Id.
54 See infra Part II.D.
55 Sheinwold, supra note 37, at 275 (citing Hideo Tanaka, The Role of Law in Japanese Society: Comparisons with the West, 19 U.B.C. L. Rev. 375 (1985)).

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of tradition, civil law, and foreign influence. In its earliest stages, the
Japanese legal system adopted Chinese legal traditions designed to central-
ize the emperor’s authority. The Chinese system, heavily influenced by
Confucianism, blended well with the hierarchical, feudal society ruled
by the Samurai warriors that flourished as the emperor’s power diminished.
The combination of strict feudal hierarchy and Confucianism created a
Japanese tradition that stressed the importance of harmony and group
obedience to superiors. The individual per se was unimportant; what mat-
ttered was the group and the individual’s position in the group hierarchy.
The legal system encouraged conciliation and settlement since preservation
of the group, not individual rights was its focus. Confucianism collided
with democracy when Commodore Matthew C. Perry, flanked by the
United States Navy, ended Japan’s isolation from the Western world.
Western powers superimposed elements of their legal systems over the ex-
isting Japanese legal framework.

Although the legal framework currently reflects the influence of west-
ern ideas, the legal reality reveals the retention of Japanese culture and
tradition. Lawyers and judges represent only a tiny fraction of the popula-

56 Hideo Tanaka, The Role of Law in Japanese Society: Comparisons with the West, 19
57 Paul Lansing & Marlene Wechselblatt, Doing Business in Japan: The Importance Of
Unwritten Law, 17 INT’L LAWYER 647, 647 (1983). In addition, the adoption of Chinese le-
gal traditions sought to minimize the aristocracy’s power and rationalize land ownership.
Sheinwold, supra note 37, at 273.
58 There were two distinct warrior-controlled periods. The Shogunate Era which lasted
from around 1300-1600s and the Tokugawa Shogunate Period (also know as the Edo Era)
which lasted from 1600-1850s, and although there were differences between the two, during
both periods, Japan remained a strict hierarchical, feudal society. See Mark A. Behrens &
Daniel H. Raddock, Japan’s New Product Liability Law: The Citadel of Strict Liability
Falls, But Access to Recovery is Limited by Formidable Barriers, 16 U. PA. J. INT’L BUS. L.
669, 671-72 (1995) (discussing the historical origins and development of the Japanese legal
system).
59 This is what the Japanese refer to as Wa, or understanding one’s place in society and
accepting it. See id. at 672.
60 Lansing & Wechselblatt, supra note 57, at 648.
517, 519 (1983).
62 Commodore Perry opened Japan to the West in 1853. See Behrens & Raddock, supra
note 58, at 672-673.
63 At first more subtle pressure forced Japan to westernize its legal system. For example,
in order to counteract several unfavorable treaties, Japan adopted principles of German civil
code. These pressures intensified after World War II, when the United States urged (or some
would argue forced) Japan to incorporate the ideals of individual rights and an adversarial
judiciary system (as opposed to judge-led inquisitions) in a new Constitution. See B.J.
George, Jr., The Japanese Judicial System: Thirty Years of Transition, 12 LOY. L.A. L. REV.
64 Japan has adopted the strict liability standard used in the United States and the Euro-
pean Union.
tion in Japan, they are members of the small educational elite and are not accessible to the average consumer. Moreover, there are no sympathetic juries for consumers to appeal to, and discovery is extremely limited, making it difficult for consumers to prove exactly who the producer of a particular product is and whether or not a product is defective. Until July 1995, product liability in Japan was governed by tort and contract laws written in the nineteenth century. Product liability suits based in tort were governed by a negligence standard predicated on the injured consumer's ability to prove beyond a reasonable doubt that the manufacturer caused a defect in the product and that such defect resulted in the consumer's injury. Technically, claims could be made against producers for negligence in manufacturing, inadequate warnings, and design defects. However, the requirement of proving intent and negligence beyond a reasonable doubt, combined with Japan's restrictive discovery limitations, made winning anything but a straight manufacturing defect claim almost impossible.

Although very restrictive, Japanese contract law provided some recovery for damages caused by defective products. A producer had to deliver a product that was fit for the purpose for which it was sold and did not have any latent defects, or a consumer could recover damages for breach of contract. However, the courts restricted recovery, imposing a judicial requirement of proving negligence and limiting recovery to damages to the product itself.

It was not until Japan faced a series of tragic incidents involving product-related injuries that it began to move toward a more consumer-friendly method of recovery in product liability cases. After the Thalidomide inci-

65 Tanaka, supra note 55, at 376.
66 Lansing & Wechselblatt, supra note 57, at 652-653.
67 Bernstein & Fanning, supra note 12, at 69.
68 Minpo (Civil Code), Law No. 89 of 1896 and Law No. 9 of 1898 (Japan); Shoho (Commercial Code), Law No. 48 of 1899 (Japan).
69 Minpo, supra note 68, art. 709.
70 Id. A 1990 survey by the Japan Federation of Bar Associations showed that out of 250 instances in which attorneys were consulted about potential product liability cases, only thirty claims were brought to court. Behrens & Raddock, supra note 58, at 680 n.61 (citing Tadashi Saito, Product Liability Reform in Japan, 3A JAPAN ECON. INST. REP. 7 (1994)).
71 Unlike the United States and the European Union, Japan strictly enforced a privity requirement. See Minpo, supra note 68, arts. 415, 570.
72 Id. art. 415.
73 Id. art. 570.
74 Behrens & Raddock, supra note 58, at 683-84. If a seller can show that the defect was caused by some factor which he or she could not control or foresee and that he or she took reasonable measures to inspect and prevent defects, the seller is not held liable. Id. Moreover, a consumer cannot recover for personal injuries or damage caused to other property. Id.
75 Id. at 686. For example, in the Marinaga Dairy case, 12,000 infants were poisoned by powdered milk that had been contaminated with arsenic. See Younghuee Jin Ottley & Bruce L. Ottley, Product Liability Law in Japan: An Introduction to A Developing Area of Law, 14
dent, the Japanese began researching better methods of addressing the problem of defective products and injured consumers. However, it was not until a new, more consumer-oriented government won power in 1993, that Japan adopted its first product liability law. Japan’s new product liability law, approved nine years after the European Union adopted its product liability Directive, took effect in July 1995.

Japan’s new product liability law embraces the doctrine of strict liability, and the law’s goal of protecting consumers by relieving them of the burden of proving fault is a big step forward for Japanese consumers. However, Japan’s product liability law is short, vague, and some have labeled it a “watered-down” version of the United States and European Union standards. Unlike the United States’ standard that allows anyone in the chain of distribution to be held strictly liable, Japan extends liability only to the manufacturer of a product. Japan’s new law, however, does utilize a consumer expectation test similar to the test in the European Union for determining if a product is defective. The most noticeable difference between Japan’s new law and the standards in the United States and the European Union is that Japan’s law does not specifically address how this new strict liability standard will be applied to “unavoidably unsafe products” like pharmaceuticals.

Japanese consumers are limited in the damages they can claim. Consumers in Japan cannot recover for pain and suffering as they can in the

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United States and some European Union nations. However, Japanese consumers can recover damages for death, personal injury, and property damage. Moreover, in cases where a direct causal connection can be shown, consumers can apparently recover for consequential economic losses such as lost wages or profits suffered while the injured consumer was out of work.\(^4\)

As with the Restatement and the Directive, Japan’s new law provides a “state of the art defense.” This defense applies when, given the scientific and technical knowledge available at the time a product was made and introduced into market, the manufacturer could not have known or discovered the defect.\(^5\) However, there is no indication of how this defense will be applied.

Although the new law holds manufacturers liable for product-related injuries regardless of fault, it contains few substantive provisions and leaves key issues undefined and controversial questions unanswered.\(^6\) Questions as to the scope of this law will have to be answered through judicial interpretations on a case-by-case basis.\(^7\) However, it may be some time before these answers become available because Japan has a long tradition of non-litigation. In the fifty years since World War II ended, less than 150 product liability cases have been decided in Japanese courts.\(^8\) Moreover, judicial interpretation will shape Japanese strict liability according to Japan’s unique culture and traditions. Unlike the United States or the European Union, the concept of a natural hierarchy remains strong in Japan.\(^9\) The recognition of this hierarchy and one’s place in it promotes the Japanese belief in harmony, and this desire for harmony creates a strong tradition of not challenging one’s superiors either in business or government.\(^10\) An injured consumer who sues a manufacturer for product liability challenges not only the product and its maker but the Japanese way of life.\(^11\)

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\(^4\) Id. This provision would go further than either the U.S. Restatement or the European Directive, but again, we will have to wait and see how the Japanese courts interpret it.

\(^5\) Id. art. 4.

\(^6\) Behrens & Raddock, supra note 58, at 689.

\(^7\) While Japan is a civil law country and does not rely as heavily on judicial precedent, judicial interpretations, especially in an area of law in which already few suits are brought, is important. If courts interpret the law narrowly and make it difficult for plaintiffs to recover, fewer plaintiffs will bother even to attempt to recover for injuries under the new law, and Japan’s new standard of strict liability will essentially be meaningless.

\(^8\) Bernstein & Fanning, supra note 12, at 49 n.23.

\(^9\) Id. at 62; Lansing & Wechselblatt, supra note 57, at 653.

\(^10\) Bernstein & Fanning, supra note 12, at 52; Lansing & Wechselblatt, supra note 57, at 652; Tanaka, supra note 55, at 384-5.

\(^11\) Bernstein & Fanning, supra note 12, at 52.
D. The Same Standard?

Instituting a strict liability standard has not created uniformity in product liability systems among the United States, the European Union, and Japan. While the form and goal of strict liability may appear the same, in reality strict liability means different things under each regime. Each uses its own history, culture, and legal traditions, to formulate and interpret its own variation of strict liability. In the United States, it is not just thirty years of strict liability that suggests individual consumers will find courts sympathetic to their fight against large manufacturers, it is 200 years of U.S. history predicated on pragmatic equality and individual empowerment. The early American frontier provided enough land for all the new settlers; therefore, unlike Europe and Japan, there was no need for feudalistic land-based hierarchies. Instead of land-based birth rights relegating people to certain places in society, the law provided for equality and individual rights. In this way, U.S. law became the great leveler.

In the United States, law empowered the common person, mandating that “all men were equal in the eyes of the law” and that “no man was above the law.” As the champion of the common person, law helped individuals assert their rights against those more powerful than themselves. These principles lie at the heart of the legal system in the United States. It is this mentality that provides the foundation for large jury awards in product liability cases. Juries see an ordinary consumer battling to win justice against a powerful manufacturer that appears to act as it were above the law. The jury helps the common person by granting large compensatory damages and shows the manufacturer that it is not above the law by awarding large punitive damages. Regardless of the liability standard, the U.S. tradition of “cheering for the underdog” will continue to encourage judges and juries to find for individuals in their fights against large manufacturers in product liability cases.

The multinational structure of the European Union and the individualistic nature of the implementation of Council Directives have a significant impact on the application of the product liability standard that currently exists within the European Union. Each Member State has its own unique traditions. The Directive itself cannot provide a cause of action for product

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92 Id. at 68.
93 Id. at 59.
94 See e.g., United States Const. art. I § 9 (prohibiting the United States from granting titles of nobility).
95 See Bernstein & Fanning, supra note 12, at 59. Law told people where they belonged and what their rights were in the United States whereas in feudal societies, the land-based aristocracy told people where their place was in society. Id.
96 See id. See also The Declaration of Independence (U.S. 1776) (“We hold these truths to be self-evident that all men are created equal”).
97 See Bernstein & Fanning, supra note 12, at 59.
liability because European Union Directives are not self-executing. The product liability Directive must be enacted through individual Member State legislation. Moreover, since the Directive does not require uniform compliance, even in those Member States where it has been enacted, substantive differences remain in several areas. For example, Member States can decide whether to extend the definition of "product," allow the "state of the art" defense, cap damages for personal injury caused by the same defect in identical products, and choose whether compensation will be allowed for pain and suffering. Germany, for example, created a separate provision governing pharmaceutical products that does not allow the "state of the art" defense. Greece narrowed the definition of "producer" while other states have broadened it to include suppliers or importers of a product. Going even further, the United Kingdom inserted a negligence standard into the "state of the art defense," which caused the European Union Commission to start proceedings against the United Kingdom for non-compliance with the strict liability standard.

Although in form the European Union and the United States have officially adopted strict liability as their product liability standard, the application of strict liability varies widely between the two regimes. Jury trials, for example, are favored by consumers in the United States because juries are thought to be more sympathetic to consumers and give higher awards. However, England is the only European Union member which uses jury tri-

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58 See Directive, supra note 38, art. 19, 1985 O.J. (L 210) at 33 ("Member States shall bring into force ... the laws, regulations, and administrative provisions necessary to comply with this Directive").
59 Treaty of Rome, art. 189; see also Directive, supra note 38, art. 19, 1985 O.J. (L 210) at 33.
60 See Directive, supra note 38, art. 15, 16, 1985 O.J. (L 210) at 32 (explicitly granting member states discretion to define "product producer" and defenses to liability).
61 For example, Member States can include agricultural products in the definition of "product." Id. art. 15(1), 1985 O.J. (L 210) at 32.
62 See id. art. 15(2), 1985 O.J. (L 210) at 32.
63 Id. art. 16, 1985 O.J. (L 210) at 32.
64 HOFFMAN & HILL-ARNING, supra note 34, at 8-9.
67 Id. at 39; see, e.g., Portugal's Decree Law No. 383/89 of 6 November 1989, art. 2 (reprinted in English in HOFFMAN & HILL-ARNING, supra note 34, at 197).
68 See United Kingdom's Consumer Protection Act 1987 (1987 Ch. 43) Part 1, § 4(1)(e) (reprinted in HOFFMAN & HILL-ARNING, supra note 34, at 204). While this section does not explicitly mention a "reasonable person" standard, this negligence standard was employed by law makers to describe this provision. See HOFFMAN & HILL-ARNING, supra note 34, at 78 n. 4.
als. Moreover, because most Member States do not allow compensation for pain and suffering, the damage awards in the European Union remain significantly lower than damage awards in the United States where pain and suffering are compensable in a product liability suit. Additionally, most Member States have placed caps on other compensatory damages, and punitive damages are not allowed. The United States and the European Union both aim to compensate consumers without requiring a showing of manufacturer fault. However, they use different philosophies, methods and legal traditions to pursue that goal.

The Japanese goal of harmony negates the need for the law to serve as the social equalizer and protector of individual rights as it does in the United States and the European Union. Instead, Japanese citizens view the law as an authority over them that will, if necessary, relieve genuine injury. However, relief is not focused solely on monetary redress and punitive action as it seems to be in the United States and the European Union. Conciliation is stressed. For example, a simple apology or an agreement to establish safety guidelines for the future have been used as alternatives to litigation. In fact, there is a general dislike of lawsuits and lawyers who are seen to detract from social harmony.

Around the same time that Japan passed its new consumer-friendly product liability law, governmental agencies asked members of the Japanese business community to organize associations within their respective industries to “deal with” product liability claims and settle them out of court. As a result, the Federation of Pharmaceutical Manufacturers’ Association of Japan was created to help settle product liability claims in the pharmaceutical industry out of court. Considering the unique culture and

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109 See Hoffman & Hill-Arning, supra note 34.
110 For a discussion of the more “positive environment” for product liability suits in Europe, see Sheinwold, supra note 37, at 257-8.
111 Capping damages means limiting them to a certain maximum amount.
112 Hoffman & Hill-Arning, supra note 34, at 4.
114 Bernstein & Fanning, supra note 12, at 70. Conciliation procedures are an important consideration as well. See Tanaka, supra note 55, at 384-85.
116 Bernstein & Fanning, supra note 12, at 65 (citing Norie Huddle et al., Island of Dreams: Environmental Crisis in Japan 177 (1975)).
117 Lansing & Wechselblatt, supra note 57, at 653.
119 Id.
legal traditions in Japan, the application and scope of strict liability could take a different direction in Japan than the strict liability standard in either the United States or the European Union. However, the pharmaceutical industry will have to wait to see what that direction will be because Japan’s product liability law is so new.

There is little certainty provided by a uniform standard applied non-uniformly. The only thing certain about product liability among the United States, the European Union, and Japan is that it is uncertain. Product liability standards and applications of those standards are always changing; sometimes these changes are subtle, and sometimes they are quite radical. Although recent radical changes in product liability standards in Japan have seemingly created a uniform standard of strict liability among the major players in the pharmaceutical market, subtle differences in the construction, interpretation, and application of that standard pull them worlds apart.

These three regimes use their individual beliefs and traditions to form their own conception of strict liability and determine how that standard will translate into consumer recovery. No matter what the standard is, however, there will never be uniformity in consumer recovery if each regime individually decides how to apply and enforce that liability standard, and interpretations will always vary. Thus, as long as pharmaceutical product liability cases continue to be decided domestically, uncertainty will always remain, and it is that inevitable inconsistency and uncertainty which creates problems in the international pharmaceutical market.

III. PROBLEMS IN THE PHARMACEUTICAL MARKET CAUSED BY UNCERTAINTY IN PRODUCT LIABILITY

A. The Economics of Uncertainty

Product liability law has undoubtedly had some beneficial effects on the safety of certain pharmaceutical products. It helped eliminate the harmful intrauterine contraceptive, the Dalkon Shield, from the market, and more recently it helped foster the removal of the weight loss drug, Phen

120 For example, judicial interpretations regarding “unavoidably unsafe” products in the United States. See supra Part II. A.

121 For example, Japan changing from contract and tort liability to a strict liability standard codified in its new product liability law. See supra Part II. C.

122 Liability exposure forced A.H. Robbins Company to remove its intrauterine contraceptive device, the Dalkon Shield, from the market after research demonstrated that it increased a woman’s chance of developing pelvic inflammatory disease and caused sterility. Gregory C. Jackson, Pharmaceutical Product Liability May be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation, 42 Am.U. L. Rev. 199, 208 (1992).
Phen, from the market. However, when consumer compensation and protection is replaced by punishment, liability exposure often hinders rather than helps pharmaceutical safety as manufacturers discontinue products and halt research. International pharmaceutical companies sell their products worldwide; thus, they have no way of knowing where a consumer injury will occur and therefore, no way of foreseeing the forum in which they will face prosecution. Even though the three major players in the international pharmaceutical market, the United States, the European Union and Japan, have all formally adopted the doctrine of strict liability for product-related injury suits, how that standard will be interpreted and applied and what damages will be allowed within these different fora remain uncertain.

Uncertainty breeds fear, and in the pharmaceutical market, the uncertainty surrounding product liability cases has bred a fear of devastating liability. This fear has had serious ramifications on the pharmaceutical market.

Basic economics and simple common sense explain why this uncertainty and fear negatively affect the international pharmaceutical market. As Judge Richard Posner points out, individuals make determinations of whether to engage in an activity by deciding if participating in that activity is worth paying the price that participation requires, or if avoiding the activity, and thus, the expense is a better option. Judge Posner also points out that there are other factors that contribute to an individual’s decision-making process such as concern for the well-being or wishes of others.

However, considering that the individuals in this case are pharmaceutical companies engaged in making and marketing a product for a profit, it seems plausible, if not likely, that economic and cost considerations will be paramount in companies’ decisions to produce and sell their products. For any activity, there are certain factors that will affect the activity’s price; therefore, accurate information on those factors is essential in determining the

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123 Research has linked the use of Phen Phen to heart valve problems. See Dana Canedy, H.M.O.’s Move To Restrict Use Of Diet Pills By Members, N.Y. TIMES, Sept. 11, 1997, at D5. The FDA recently revoked its approval of this drug. See Sheryl G. Stolberg, F.D.A. Warns About Herbs For Weight Loss, N.Y. TIMES, Nov. 7, 1997, at A1.

124 Uncertainty is exacerbated by the fact that an injured consumer can usually file suit in either the jurisdiction where the injury occurred or the jurisdiction where the manufacturer is located; this can lead to “forum shopping” where a consumer will file suit where it will be best for him or her in terms of relief or expense. Lasagna, supra note 75, at 337.

125 Richard Posner is a Judge on the United States Court of Appeals for the Seventh Circuit and is regarded as one of the United States’ most eminent scholars on economic legal theory. Judge Posner has been criticized for applying his economic theory selectively, in favor of conservatism, and for failing to recognize the limits of economic theory when confronted with real markets that may prove inefficient or incomplete. See e.g., George M. Cohen, Posnerian Jurisprudence and Economic Analysis of Law: The View From the Bench, 133 U. PA. L. REV. 1117 (1985).


127 Id.
actual price of an activity. Among other things, when determining what the price of manufacturing a product for the international market will be, pharmaceutical companies will need to look at the cost of making the product, the liability risks associated with that product, and the costs of covering those liability risks. Uncertainty in liability risks and the costs of covering those risks makes it difficult for pharmaceutical companies to make accurate calculations about the costs of manufacturing and marketing a drug.

Common sense suggests that corporations weigh the consequences of their actions before making decisions. The reality in the pharmaceutical market is that, with no way to accurately anticipate a product's liability risks, and with the only weighable consequence being the potential for extremely large liability exposure, the safest course of action for pharmaceutical companies is to keep a product off the market or increase prices to such a level that pharmaceutical companies can cover the costs that result from uncertain liability risks. This reality has created distortions in the international pharmaceutical market, increased both manufacturing and consumer costs, and chilled research and development of new pharmaceutical products. The best way to illustrate the negative effects that uncertain liability has on the pharmaceutical market is by example. This part of the comment will primarily use examples from the pharmaceutical market where the effects of liability fears speak for themselves. These examples are not used to suggest that all drugs are potential horror stories waiting to occur. Many drugs are manufactured and marketed without incident. These examples are used merely as concrete illustrations of the real problems that uncertain product liability exposure has created in the pharmaceutical market.

B. Distortions in the Market

In an industry in which the costs of bringing a drug to the market are rapidly increasing, the fear of unknown and potentially devastating liability has caused pharmaceutical companies to stop manufacturing and marketing certain products. This coerced halt in production creates three negative consequences. First, the loss of a product means certain maladies will go untreated. Second, a reduction in the number of manufacturers producing a product can create shortages and pose serious health risks. Third, the fear that initiated the halt in manufacturing creates a stigma that remains long after the immediate danger has passed and binds the actions of pharmaceutical companies long into the future.

128 Id.
129 For example, when deciding how to cut costs, corporations routinely consider the effects that laying off workers will have on their public image and their profits or, when planning a merger, corporations consider how the announcement of the merger will affect the price of their stock.
1. Bendectin Example

In 1956, the William S. Merrell Company (hereinafter Merrell Co.) introduced a drug called Bendectin that relieved the nausea and vomiting associated with pregnancy.\textsuperscript{130} It remains the only drug to ever receive approval to be marketed in the United States for the treatment of “morning sickness”.\textsuperscript{131} Bendectin initially enjoyed huge success and was sold in twenty-two countries and prescribed to twenty-five percent of the pregnant women in the United States.\textsuperscript{132} However, in 1969, a mother filed the first lawsuit claiming Bendectin caused birth defects.\textsuperscript{133} In this case, as in the many suits that followed, the claim for relief was based on the argument that the mother had used Bendectin during her pregnancy and had given birth to a deformed baby; therefore, Bendectin must have caused the defect.\textsuperscript{134}

If Bendectin did cause birth defects, then even if the manufacturer did not know such a result would occur, a fair liability system would compensate injured consumers and promote the product’s removal from the market to ensure future consumer safety. However, the evidence shows that Bendectin did not cause birth defects. Numerous studies\textsuperscript{135} were conducted to determine if Bendectin was in fact a teratogen.\textsuperscript{136} A study by Robert Brent reflects the conclusion revealed in the vast majority of studies. As Brent’s study points out, birth defects occur in one to seven percent of all infants even when a teratogen is not present.\textsuperscript{137} Based on the fact that around thirty million infants were exposed \textit{in utero} to Bendectin, Brent concluded that with a birth defect rate of three percent, chance alone and not Bendectin could account for 900,000 birth defects among the exposed infants.\textsuperscript{138} Moreover, no study ever proved that Bendectin was a teratogen, and both the Food and Drug Administration (FDA) and the majority of courts con-

\textsuperscript{131}Jackson, supra note 122, at 207.
\textsuperscript{132}Lasagna, supra note 75, at 338.
\textsuperscript{133}See Mekdeci v. Merrell Nat’l Lab., 711 F.2d 1510 (11th Cir. 1983) (mother claimed that her son’s birth defect was caused by Bendectin which she had taken during her pregnancy).
\textsuperscript{134}See id; Lasagna, supra note 75, at 338. As is the case with any birth defect, the parents wanted to know why this happened. The Mekdeci chose Bendectin as the cause even though an investigation revealed that Bendectin was only one of seven medications Mrs. Mekdeci took during her pregnancy. MICHAEL GREEN, \textit{BENDECTIN AND BIRTH DEFECTS: THE CHALLENGES OF MASS TOXIC SUBSTANCES LITIGATION} 2 (1996).
\textsuperscript{135}Sanders, supra note 130, at 395 (table of Bendectin Epidemiological studies).
\textsuperscript{136}A teratogen is an agent that causes medical defects. Lasagna, supra note 75, at 338.
\textsuperscript{138}Id.
cluded that there was no increased risks of birth defects associated with Bendectin.139

The FDA never asked for the removal of Bendectin; Merrell Co. had followed the FDA regulations, passed the necessary research tests, and satisfied the scientific experts. In fact, a 1980 FDA hearing on the safety of Bendectin largely exonerated the drug.140 So why has Bendectin disappeared from the market? Two words provide the answer—product liability. Despite the overwhelming evidence that showed Bendectin was not a teratogen,141 parents of children with birth defects who were searching for answers as to why the defects occurred were spurred on by the media storm generated by plaintiffs’ lawyers.142 These lawyers, armed with a few studies that supported only the possibility that Bendectin could be a teratogen continued to fuel the litigation fires.143 In 1983, Merrell Co. faced a seemingly endless barrage of liability suits and an unfavorable ratio between Bendectin’s profits on sales and the cost of fighting these liability suits.144 Thus, Merrell Co. voluntarily removed Bendectin from the market not because of any danger it posed to consumers but because of the financial danger the company faced from liability exposure. At a 1983 press conference announcing the removal of Bendectin from the market, Merrell Co.’s President made it clear that Bendectin’s “removal was a result of business, rather than medical, concerns.”145 At the same press conference, Dr. Charles Flowers, Vice President of the American College of Obstetricians and Gynecologists, commented that the loss of Bendectin would create a “significant therapeutic gap.”146 The removal of Bendectin means that “morning sickness” remains untreated for thousands of women in the United States.


140 Green, supra note 134, at 159.

141 None of the 39 epidemiological studies conducted clearly concluded Bendectin was a teratogen, and although six of the studies indicated at least one significant correlation between Bendectin and some adverse affect, the other 33 studies found no such statistical relationship. See Sanders, supra note 130, at 395.

142 Green, supra note 134, at 159. The proliferation of litigation was a product of lawyers who used national media to capitalize on the possibility of an explosion of suits involving Bendectin. Id.

143 Lasagna, supra note 75, at 338.

144 See id.

145 Green, supra note 134, at 180.

146 Id.
2. Vaccine Example

Vaccination is the world's preventative method of fighting disease. Vaccines have arguably one of the highest social values of any pharmaceutical product since they do not just respond to pain or sickness but actually prevent disease. Vaccines are responsible for the complete elimination of smallpox from the planet and the near disappearance of polio, measles, rubella, mumps, diphtheria, and tetanus from countries like the United States that have standard immunizations. However, overwhelming product liability concerns have caused many pharmaceutical companies to stop manufacturing vaccines.

Even in a perfect market, vaccines do not provide much of a profit when balanced against the large investment required for their production. Vaccine production is very complex. Manufacturing one vaccine can take six to twelve months. In addition, because vaccine production requires special facilities, companies cannot use these facilities to manufacture other products. Moreover, the market for vaccines is often unpredictable. Foreign markets are unpredictable because different countries have different rules and requirements regarding distribution, marketing and suppliers. Developing countries, which could provide the largest market because they have the greatest need for vaccination, are often unable to pay for the necessary vaccines. Finally, if a vaccine works properly, then the disease it attacks will be eliminated, and the market will disappear. For many companies, adding the burden of uncertain, potentially large liability expenses to the list of profit killers already facing vaccine manufacturers has raised the risks too much to merit the expense of making vaccines.

A liability system should protect consumers and provide them with compensation for actual injuries, but it should not unfairly punish producers. Although the volume of suits for vaccination-related injuries remains relatively low when compared to other drug-related injury suits, the damages sought in these cases far exceed the profits available to cover liability awards. For example, the amount of damages claimed in lawsuits filed against manufacturers of the diphtheria-tetanus-pertussis (DTP) vaccine

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147 See Peter W. Huber, Liability: The Legal Revolution and Its Consequences 166 (1988).
148 Lasagna, supra note 75, at 341.
149 Id. at 341-342. These two realities often create inventory and cash flow problems for vaccine manufacturers. Id.
150 Id. at 342.
151 Id.
153 See Jackson, supra note 122, at 205.
was more than double the gross annual sales of the vaccine. In the 1980s, a manufacturer of a whooping cough vaccine was named the defendant in a new suit each week. The manufacturer faced $2 billion in damages awards, with the punitive damages alone totaling 200 times the annual revenue derived from the vaccine.

These huge potential liability awards make liability insurance essential, but at the same time make insurers wary of providing coverage and often raise insurance premiums out of the economic reach of most manufacturers. For example, in 1976, fear of a swine flu epidemic prompted the U.S. Congress to launch an emergency vaccination program. Pharmaceutical companies quickly developed a vaccine, but the insurance companies refused to provide coverage fearing large liability. The vaccine manufacturers, also realizing the potential devastating affect of projected liability costs, refused to sell the vaccines without insurance. Only when Congress agreed to insure pharmaceutical companies against liability did the vaccination process proceed. More recently, the Center for Disease Control (CDC), the sole distributor of the vaccine for Japanese encephalitis, announced that the vaccine would no longer be available because the manufacturer did not have appropriate liability insurance, and there was no mechanism to absolve the manufacturer from liability in case of injury. The losers in these conflicts are the consumers who lose access to valuable vaccines.

As vaccine manufacturers decide that the benefits of producing vaccines do not outweigh the risks, the number of vaccine manufacturers decreases. Today, only a single supplier remains for many vaccines. This modern trend toward monomanufacturers not only distorts the market, but also poses a threat to consumers. The price of vaccines may rise to such a level that not everyone will be able to afford these lifesaving products. Moreover, anytime a product has only one supplier, the danger of shortages arises. In the case of pharmaceutical products, a shortage can create serious

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154 Lasagna, supra note 75, at 342.
155 Huber, supra note 147, at 166-67.
156 Id.
158 Id., supra note 147, at 133.
159 Id. at 133-34.
160 Id.
161 Encephalitis is a mosquito-born viral infection.
162 Lasagna, supra note 75, at 343.
163 There used to be three to six manufacturers producing vaccines for measles, mumps, rubella, and polio, but as of 1986 these vaccines each have only one producer. See H.R. Rep. No. 99-908, at 7 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6348.
164 Id. at 4, reprinted in 1986 U.S.C.C.A.N. 6344, 6345 (noting that decline in number of vaccine manufacturers has caused decline of immunization against some preventable diseases coupled with increase of disease).
public health risks. For example, in 1984, liability concerns caused Wyeth and Connaught Laboratories to stop selling the DTP vaccine to the public, making Lederle Lab the sole manufacturer of this vaccine in the United States. When Lederle had production problems, concerns over a shortage of DTP vaccine caused the CDC to recommend that people stop vaccinating children over the age of one so that vaccine supplies could be saved for more vulnerable infants. The shortage proved to be less serious than originally thought, but the reality for dangerous shortages in the future is clear.

3. Thalidomide Example

Perhaps the most infamous drug in the history of pharmaceutical product liability is Thalidomide. This sedative-hypnotic drug, introduced by the West German manufacturer, Chemie Grunenthal, in 1957, quickly became the most popular sleeping pill in West Germany. Eventually, fourteen different pharmaceutical companies were producing Thalidomide and selling it under different trade names in over forty-five different countries. However, after a 1961 report by German and Australian doctors associated Thalidomide with certain birth defects, the drug disappeared from almost every world market. Liability concerns undoubtedly played a role in the disappearance of Thalidomide, and those liability fears continue to affect the pharmaceutical market today.

Doctors continued to research the drug, and have discovered that Thalidomide has many significant, beneficial medical uses. It has unique anti-inflammatory and immunosuppressant properties that make it effective in treating many painful and debilitating medical conditions including: lep-

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165 Lasagna, supra note 75, at 343.
166 Id. at 344.
167 Id.
168 Sanders, supra note 130, at 313; Green, supra note 134, at 64.
169 Lasagna, supra note 75, at 344.
170 Sanders, supra note 130, at 313.
171 Green, supra note 134, at 72.
172 This comment does not mean to suggest that a drug that causes medical defects should remain on the market simply to stabilize the pharmaceutical industry. Harmful products should be removed. However, drugs that are on the market have usually undergone years of extensive testing. See 21 U.S.C. §355(b) 1994 (requiring extensive testing of pharmaceutical products before their approval by the FDA). Thus, these products should be presumed to be safe and allowed to remain on the market unless there is substantial evidence that the drug is in fact harmful.
rosy, discoid lupus, and rheumatoid arthritis. Researchers have also discovered that Thalidomide may prove invaluable in fighting AIDS. Until recently, researchers and manufacturers made no attempt to reintroduce Thalidomide into the general market, but instead sold directly to physicians and health clinics who routinely used Thalidomide to treat these and other recurring medical conditions. In 1985, Chemie Grunenthal, stopped all production and distribution of Thalidomide due to liability concerns. Since 1985, only one small Brazilian pharmaceutical manufacturer has continued to produce Thalidomide. It has been difficult for physicians and health clinics to obtain this valuable drug and there is uncertainty about future supplies. As with Bendectin, the public continues to think of Thalidomide as one of the “most notorious drug[s] in history.” Few companies are willing to face the liability exposure that manufacturing such a drug would involve.

The “side effects” of liability fears created by Thalidomide reach much further than one product. Thirty years later, the liability fears generated by Thalidomide have resulted in the pharmaceutical industry rejecting pregnant women as consumers. Most pharmaceutical companies issue blanket warnings against pregnant women using their products. While sometimes these warnings are merited, in many cases there is no documented reason

174 Squires, supra note 173.
176 Lasagna, supra note 75, at 346-47. Doctors at the University of North Carolina at Chapel Hill have conducted research on the affects of Thalidomide in helping cure ulcers related to AIDS. Their initial research showed 55% of those taking Thalidomide to treat those ulcers were healed completely. See Ready, supra note 173.
177 Lasagna, supra note 75, at 346.
178 Id. at 347.
179 Id.
180 See Ready, supra note 173.
181 Thirty-five years after Thalidomide was removed from the world market, one company has obtained a patent and plans to market the drug under the name Silced as a treatment for leprosy See Sheryl G. Stolberg, 37 Years Later, A Second Chance For Thalidomide, N.Y. Times, Sept. 23, 1997, at 6.
182 See Today Show (NBC television broadcast, Nov. 20, 1996) (interview with obstetrician, Dr. Laura Riley, discussing what drugs pregnant women should and should not take); see also Huber, supra note 147, at 155. As one pharmaceutical company executive put it, “Who in their right mind would work on a product today that would be used by pregnant women?” See id.
183 For example, Accutane is a drug used to treat severe cystic acne, but animal research showed it to be teratogenic in animals; therefore, it was marketed with the warning that women should not use it at any time before or during pregnancy. Jackson, supra note 122, at 208-09. The fear of liability is so high that Hoffman La Roche, Accutane’s manufacturer, added a pregnancy prevention kit to its product that included an instructional video tape and informed consent forms. Id. Similarly, officials at the FDA announced they would only ap-
to restrict a product from use by pregnant women. Manufacturers are simply frightened by the possibility of liability suits involving birth defects in light of the Thalidomide and Bendectin incidents. Little to no research has been done to determine what, if any, effects these drugs will have on pregnancy and the birth of a child. These warnings and restrictions are more a way of limiting liability exposure since, by restricting the product to non-pregnant women, companies can avoid birth defect claims and the devastating stigma associated with claims like those in the Thalidomide and Bendectin cases.

C. Increased Costs

Some pharmaceutical products remain on the market despite large liability exposure; however, the uncertainty of product liability increases the costs of both manufacturing and purchasing these products. The cost of introducing a new drug to the market has sky-rocketed in the last ten years. In the United States, bringing a new drug to the market takes an average of twelve years and costs over $230 million. Moreover, for every 10,000 drugs tested, only one will be approved by the FDA and introduced to the market. The situation in the European Union is no better as it may take as long as fourteen years, at similar costs, to develop a new drug. While manufacturers can estimate the costs of developing a product, they cannot predict liability expenses. Pharmaceutical companies now spend millions of dollars researching, developing, and testing new products in the hopes of avoiding liability exposure. This amount pales in comparison, however, to the rising litigation expenses pharmaceutical companies incur in fighting multi-million dollar lawsuits and paying explosive jury awards and out-of-court settlements. Companies not only have to pay liability awards but also have to incur expenses for in-house counsel and outside trial attorneys. They then have to expend more money on marketing and advertising to counteract the negative publicity generated by liability suits.

prove Thalidomide to treat leprosy if the drug contained “elaborate restrictions” to keep it away from pregnant women. Stolberg, supra note 123.

184 Jackson, supra note 122, at 208-09.
185 Kanusky, supra note 9, at 682-83.
186 Jackson, supra note 122, at 230-31.
188 Jackson, supra note 122, at 230-31.
189 See, e.g., Grundberg v. Upjohn Co., 813 P.2d 89 (Utah 1991), reh’g denied (plaintiff filed a $21 million lawsuit against the manufacturer of Halcion and eventually received a multi-million dollar settlement).
190 A 1991 Senate staff report revealed that pharmaceutical manufacturers spend billions on marketing and advertising and that, in fact, they spend more on marketing and advertising than on research. STAFF OF SENATE SPECIAL COMM. ON AGING, 102D CONG. 1ST SESS., THE
Moreover, to protect against potentially devastating liability awards, pharmaceutical companies must purchase liability insurance at premiums that have sky-rocketed in recent years. Insurance premiums have increased because it is difficult—almost impossible—to calculate the quantifiable risks associated with pharmaceutical production in today’s litigation and liability climate. Thus, to insure against these incalcuable risks, insurers will charge disproportionately high premiums. Further, pharmaceutical manufacturers who need capital to help finance the production of new, innovative products may face serious credit concerns. As with insurance companies, uncertainty makes creditors nervous, so they will charge higher interest rates to protect against their own losses. All of these concerns will increase the cost manufacturers must expend to bring products to the market.

As the costs of manufacturing a product increase, manufacturers must either decide to stop making a product, as with Bendectin, or must spread their costs across the market by increasing the product’s price, as with vaccines, or accept a lower profit margin. Thus, as liability expenses raise manufacturing costs, drug prices are rising at alarming rates. A Senate report revealed that during the first six months of 1991, the general yearly rate of inflation was 3.3% while the annual inflation rate of prescription drugs was 11.2%.

The experience of Chemie Gruenthal, the West German manufacturer of Thalidomide, presents a good example of the many ways in which product liability affects a company’s costs. This example is not intended to imply that the costs incurred by Gruenthal were unwarranted or that the victims of Thalidomide were unfairly compensated. It is merely one of the best-documented examples of the interplay between product liability and cost. First, the removal of Thalidomide from the market hit Gruenthal hard because, at the time of its removal, Thalidomide represented 50% of Gruenthal’s sales. Second, after three years of highly publicized litigation in Germany, Gruenthal agreed to settle for $30 million to be paid directly by the company, and another $20 million to be paid by the German government. This $50 million represented only the damages paid in Germany. More damages would be sought and won by consumers in England and later in the United States. Finally, there is no way to measure the financial losses stemming from the bad publicity of having the company’s name associated with one of the most notorious drugs in history.

Sometimes the risks are so high, that an insurer may refuse to provide coverage at all. For example, insurers refused to provide coverage for the new swine flu vaccine, even when Congress had requested mass production and distribution of this vaccine. See Christoph Ann, Innovations in the Crossfire: A Policy Sketch for Unknowable Risks in European and United States Liability Law, 10 Tul. Eur. & Civ. L.F. 173, 183 (1995).

1. Halcion Example

An examination of recent events involving the drug Halcion illustrates the many ways that increased liability fear has increased costs. Halcion, the trade name for the drug triazolam, is a prescription sedative and is the most widely-used drug for treating insomnia in the world. In the late 1980s, a young woman filed a $21 million lawsuit against Halcion’s manufacturer, the Upjohn Company. The plaintiff, who shot and killed her eighty-three year old mother, claimed that she had acted while in a Halcion-induced intoxication that caused depression, psychosis, depersonalization, aggressive assaultive behavior, and homicidal compulsions. Despite the fact that the Supreme Court of Utah has found that FDA-approved prescription drugs like Halcion are “unavoidably unsafe” products and are exempted from strict liability, Upjohn feared that a jury would award damages anyway. Thus, despite having “unavoidably unsafe” liability protection, Upjohn chose to make an out-of-court multi-million dollar settlement rather than face the risk of an even higher jury award.

As Upjohn’s costs increase as a result of fighting the suit and paying the settlement award, so will Upjohn’s prices. However, there are other less obvious costs as well. As a result of this case, the United Kingdom removed Halcion from its market. This reaction reduced market exposure that will translate into lost profit for Upjohn, which will likely compensate for that loss by increasing the price of the drug in the remaining markets. Moreover, the negative publicity created by this case and the removal of Halcion from the British market will likely force Upjohn to increase its marketing and advertising expenditures, again adding to the cost of the product and likely resulting in a price increase. Finally, consumers in the United Kingdom will have to spend more money to get the product from other markets as it is no longer readily available to them. The reality is that Halcion is widely-used and relied upon by consumers, thus, it is unlikely that Upjohn will stop producing it. It is more likely that Upjohn will

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198 Jackson, supra note 122, at 201.
199 Grundberg, supra note 189.
200 Id. at 90.
201 Jackson, supra note 122, at 200.
202 See generally Posner, supra note 126.
203 Id. at 201.
204 Ann, supra note 192, at 181.
205 See Jackson, supra note 122, at 201.
206 See generally Posner, supra note 126. Having weighed the costs and benefits of participating in the activity of selling Halcion and deciding to continue, Upjohn will then look to maximize its profits which means raising prices to balance out rising costs. See Ann, supra note 192, at 180-81.
continue to produce and sell Halcion and will pass its increased costs on to the consumer by raising prices so as to maintain its profit margin.\footnote{207}{See for example the case of the DTP vaccine \textit{infra} Part III.C.2.}

2. Vaccine Example

In addition to the detrimental effect uncertain liability has had on the availability of vaccines, increased litigation costs have raised the price of certain vaccines.\footnote{208}{See Gina Kolata, \textit{Litigation Causes Huge Price Increases in Childhood Vaccines}, 232} These increased costs are attributable to higher premiums paid by manufacturers for liability insurance and, in some cases, excise taxes imposed on manufacturers for each dose of vaccine administered.\footnote{209}{Lasagna, \textit{supra} note 75, at 343-44; Jackson, \textit{supra} note 122, at 205.} For example, the DTP vaccine, recently a favorite target for liability claims, cost only eleven cents in 1982, but four years and several liability suits later, the price of DTP exploded to $11.40 with eight dollars of that price going to pay for liability insurance.\footnote{210}{Jackson, \textit{supra} note 122, at 237 n. 38 (citing Kolata, \textit{supra} note 208).}

Another factor in the increased price of DTP and other childhood vaccines is the tax imposed per dose on manufacturers of these vaccines.\footnote{211}{Lasagna, \textit{supra} note 75, at 344. The National Childhood Vaccine Injury Act imposes a tax on certain childhood vaccines.\footnote{212}{42 U.S.C. § 300aa-1 to -34 (1994).} This tax helps finance a trust fund which compensates children injured by certain vaccines without forcing them to resort to common law adjudication.\footnote{213}{The vaccines covered by the Act include: diptheria and tetanus toxoids (DT); measles, mumps, and rubella (MMR); diptheria, tetanus, and pertussis (DTP); polio; and any combination thereof. 26 U.S.C. § 4132 (1994).} The DTP vaccine has a $4.56 tax per dose while the tax for the measles-mumps-rubella vaccine is $4.44 per dose; for polio, twenty-nine cents per dose, and for diphtheria-tetanus six cents per dose.\footnote{214}{Jackson, \textit{supra} note 122, at 224. The author notes that this fund, while providing victims with a more certain and efficient source of relief than tort action, also serves to preempt such action, as the Act contains an award cap, and victims must exhaust all remedies under the Act before they can bring any action in tort. \textit{Id.}} The tax is based on a calculation of the estimated risk of each vaccine. In some cases manufacturers pass on the entire cost to consumers by raising prices.\footnote{215}{Lasagna, \textit{supra} note 75, at 344.}
D. Chilling Research and Development

The costs of bringing a new product to the market are significant in terms of both time and money. It can take up fourteen years to receive the necessary regulatory approval to market a product in a particular country.\(^{217}\) During this time, a pharmaceutical company expends a great deal of money and resources to research, develop, and test a new product. Pharmaceutical companies must balance the costs of bringing a new product to the market with the potential profits that a new drug will generate.\(^{218}\) Companies can estimate potential profits by calculating the importance of a drug to society, the size of the market for that drug, and the availability of other drugs with similar effects.\(^{219}\) These potential profits must be weighed against not only manufacturing costs, but also regulatory fees, liability insurance costs, litigation expenses, and liability payments. Although companies can estimate regulatory costs, uncertainty in product liability today makes it impossible to accurately predict the liability costs.\(^{220}\) With the increasing exposure to potentially devastating liability, many pharmaceutical companies have decided that researching and developing new products is not worth the risk.

1. Drugs and Pregnancy

Concerns over liability exposure have inhibited research into developing new contraceptives.\(^{221}\) In the early days of contraceptive research, as pharmaceutical companies and medical researchers struggled to find better methods of birth control, product liability played a valuable role in protecting consumers. In the case of the birth control pill, many women took the pill without adequate information and warnings.\(^{222}\) Liability pressures encouraged further research into the drug, resulting in health officials urging a lowering of estrogen levels and an increase in warnings about the pill's side effects.\(^{223}\) Liability exposure also helped remove the Dalkon Shield from

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\(^{217}\) Kanusky, supra note 9, at 683.

\(^{218}\) Posner, supra note 126, at 274. For example, in light of the potential liability associated with vaccines, many manufacturers have been reluctant to invest their time and effort in developing an AIDS vaccine. Smith, supra note 152, at 207.

\(^{219}\) Lasagna, supra note 75, at 336-37.

\(^{220}\) Id. at 337.

\(^{221}\) Jackson, supra note 122, at 204. The chilling effect product liability concerns have on contraceptive research is illustrated by the fact that, in the United States, once a leader in contraceptive research, as liability awards sky-rocketed, research expenditures for contraceptives decreased 90% between 1973 and 1983. See Huber, supra note 147, at 155.

\(^{222}\) Shapo, supra note 157, at 88-141. Professor Shapo makes the argument that women were in essence being used as guinea pigs to test the harmful effects of the pill because they were allowed and even encouraged to use the product to confirm the reports of negative side effects of the drug. Id.

\(^{223}\) Id. In 1969, the Chairman of the British Committee on Safety of Drugs spoke out to encourage women not to take contraceptive pills containing estrogen levels higher than fifty micrograms. See id. at 108. The FDA followed suit by sending recommendations to physi-
the market, after research demonstrated that this intrauterine contraceptive device increased pelvic inflammatory disease and caused sterility. Liability expenses, including approximately $3 billion in damage awards forced A.H. Robbins to remove this unsafe product from the market and declare bankruptcy.

However, the protection that liability exposure has provided to consumers has become harmful in some ways. For example, some scholars have suggested that the chilling effect of potential liability on the oral contraceptive market after the Bendectin and Thalidomide incidents, led to the hasty development of unsafe intrauterine devices like the Dalkon Shield. Moreover, while liability exposure originally encouraged further research that helped bring problems to light, it now has virtually halted research on oral contraceptives and has dissuaded the development of other contraceptives, especially chemical ones, which are viewed as posing a greater risk of birth defects. In fact, no truly new chemical contraceptives have been developed in the United States since 1968, and the chemical formula for steroidal oral contraceptives has not changed since 1976. The possibility of birth defects and the fear of liability that stems from that possibility, illustrated by the Bendectin and Thalidomide incidents, led one pharmaceutical company president to comment, “Who in his right mind would work on [developing] a product today that would be used by pregnant women?” Practitioners, echoing this sentiment, have pointed out that virtually no research has been done to determine what drugs are safe for pregnant women and their unborn children.


Id. at 208.

Id.


See HUBER, supra note 147, at 155.

The Thalidomide injuries made it clear that drugs taken by a pregnant woman can cross the placenta.

See HUBER, supra note 147, at 155, 168. The chemical composition of oral contraceptives has remained unchanged despite the fact that oral contraceptives, the most convenient and effective form of birth control, currently cannot be used by many women because of side effects such as nausea, dizziness, etc.

Id. at 155.

Today Show, supra note 182.
This lack of research has resulted in some women being told not to have children and others having to suffer through pregnancy without the use of any medication. Women with diabetes or other medical conditions requiring regular medication have often been told not to have children because of potential dangers posed to their unborn children by their medication.\textsuperscript{233} Moreover, pregnant women are often warned not to take any medication, including aspirin, during pregnancy because the medical community simply does not know what dangers, if any, these products pose to unborn babies.\textsuperscript{234} In the current litigation climate, the sentiment expressed by that pharmaceutical company president will continue to inhibit research into the effects drugs have on unborn children.

2. AIDS

Discomfort during pregnancy and increases in unwanted pregnancies, especially among teenagers, are important concerns, but so, especially today, is the chilling effect liability fears have had on the development of vaccines and drugs to help fight human immunodeficiency virus (HIV), the virus that causes acquired immune deficiency syndrome (AIDS).\textsuperscript{235} Knowing that any AIDS vaccine will likely have some side effects\textsuperscript{236} and fearing the potential liability arising from those side effects, manufacturers have been reluctant to expend the large amount of money necessary to research and develop these vaccines.\textsuperscript{237} Moreover, even if an effective AIDS vaccine is developed, private pharmaceutical companies will have to find insurers before they would dare market the product.\textsuperscript{238} Finding insurers may prove difficult in the present liability climate especially given the example of the swine flue vaccine episode.\textsuperscript{239} The use of drugs and vaccines that may help alleviate the painful conditions associated with AIDS or help prevent the spread of the disease have also been inhibited by liability fears. For example, Thalidomide has proven helpful in eliminating severe ulcers in AIDS patients but due to liability fears associated with it, this ‘drug of infamy’ as of yet has remained available only for experimental research.\textsuperscript{240} A

\textsuperscript{234}i Id.
\textsuperscript{233}i Id.
\textsuperscript{235}i Deborah M. Barnes, \textit{Will an AIDS Vaccine Bankrupt the Company That Makes It?}, 233 \textit{Science} 1905 (1986) (noting that pharmaceutical companies may be less willing to invest money in production of AIDS vaccine in legal climate where lawsuits against manufacturers are richly rewarded); Donald P. Francis & John C. Petricciani, \textit{The Prospects for and Pathways Toward a Vaccine for AIDS}, 313 \textit{New Eng. J. Med.} 1586, 1587 (1985) (recognizing liability concerns as major reason why companies may be reluctant to invest large amounts of money in developing AIDS vaccine).
\textsuperscript{236}i Most vaccines have some side effects.
\textsuperscript{237}i Smith, supra note 152, at 207.
\textsuperscript{238}i See HUBER, supra note 147, at 230; see supra Part II.C.
\textsuperscript{239}i See supra Part III.B.2.
\textsuperscript{240}i See Ready, supra note 173 (discussing some experimental uses of Thalidomide).
vaccine might help prevent mothers who are HIV-positive from transferring the virus to their children in utero.241 However, there is the possibility that using such a vaccine during pregnancy may cause birth defects.242 Fear of potential liability suits arising from birth defects have caused companies like MicroGeneSys to postpone tests of this vaccine in HIV-infected women.243 Concerns over liability exposure have caused other companies like Genentech temporarily to stop even general research on vaccines that may prevent HIV and AIDS.244

3. Orphan Drugs

The next casualty of uncertain liability could be "orphan drugs." Orphan drugs are drugs used to treat rare diseases, such as AIDS, Parkinson's disease, and certain types of cancer.245 The market for these drugs is small, and profits are relatively low. Moreover, because the United States has become a market in which pharmaceutical companies face crippling product liability awards, manufacturers stopped selling certain drugs aimed at fighting these conditions.246 To counter the disincentive to manufacture orphan drugs and sell them in the United States, in 1983, the U.S. Congress passed the Orphan Drug Act,247 which was designed to encourage the development and availability of orphan drugs. It offered monetary incentives to pharmaceutical companies that would "adopt" and sponsor the development of an orphan drug.248 Although critics have noted that determining the safety of orphan drugs presented unique problems due to a lack of qualified persons to participate in clinical trials,249 Congress did not provide special protection from state law-governed orphan drug liability claims.250 Nearly one-fifth of the forty-two orphan drugs developed between 1983 and 1989 have already faced liability claims.251 Orphan drugs are already higher-risk products with lower-profit potential. Despite governmental support, the

242 Id.
243 Id. The company eventually will conduct the tests but only after moving them from Tennessee to Connecticut where a new law offers substantial legal protection to companies conducting such tests. Id.
244 Id. Genetech later resumed the research program after the California legislature passed a law protecting companies from liability if subjects received adequate warnings of the test's risks. Id.
246 See Huber, supra note 147, at 159. Thalidomide is one example and botulinum, a substance used to control eye-twitching disease, is another. See id.
248 See Asbury, supra note 245.
249 Since these diseases are rare, the pool of possible testers is low. Id.
250 See id.
251 Id.
continued threat of uncertain liability may cause orphan drug sponsors to remove their products from the market and stop researching the development of new products to treat rare diseases.

IV. MOVING TOWARD INTERNATIONAL PHARMACEUTICAL REGULATION AND AN INTERNATIONAL DRUG ADMINISTRATION

A. Introduction

No matter what the product liability standard is, there will never be uniformity in consumer recovery if regimes individually apply and enforce that liability standard, as interpretations will always vary. Thus, as long as the United States, the European Union, and Japan continue to decide pharmaceutical product liability cases individually, uncertainty will remain. It is this inevitable inconsistency and uncertainty that creates problems in the international pharmaceutical market.

The United States, the European Union, and Japan all have governmental agencies that are responsible for regulating the manufacture and distribution of pharmaceutical products. These agencies govern nearly every aspect of the design, testing, manufacture, labeling, and distribution of pharmaceutical products. The regulation processes in these regimes are already similar, and in the recent past, these three regimes have begun working together to coordinate the regulation requirements for new drug approvals. These efforts at harmonization have laid the foundation for a new type of international regulatory agency, and provide an excellent model for the creation of a new international drug administration.

1. Background on Regulation in the United States

In the United States, no pharmaceutical product may be marketed in interstate commerce until it has been approved by the FDA. In order to receive that approval, a pharmaceutical company must go through several steps. First, the company must develop and test its product using the standards of good laboratory procedures promulgated by the FDA. Second, the company must file an Investigational New Drug Application (IND). The IND will provide the procedures the company must follow during its clinical testing phase when the components of the drug are analyzed and the

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252 These agencies are: the FDA, the European Agency for the Evaluation of Medicinal Products, and the Pharmaceutical Affairs Bureau, respectively.
253 Kanusky, supra note 9, at 665.
254 See supra Parts IV.B. and C.
255 See Kanusky, supra note 9, at 668.
safety and effectiveness of the drug are studied.\textsuperscript{258} Third, the company must file a New Drug Application (NDA) which details the results of the clinical testing.\textsuperscript{259} Finally, the FDA must review the application and approve it if there is substantial evidence that indicates the drug will have its predicted effect.\textsuperscript{260} Even after a drug receives approval, it is still subject to FDA regulations that require companies to report all adverse drug reactions\textsuperscript{261} and, in some cases, continue clinical testing to determine the cause of those adverse reactions.\textsuperscript{262} Moreover, pharmaceutical manufacturers in the United States must submit to inspections of their manufacturing facilities by the FDA at least once every two years.\textsuperscript{263}

2. Background on Regulation in the European Union

The European Union's equivalent to the FDA is the European Agency for the Evaluation of Medicinal Products (hereinafter the Agency).\textsuperscript{264} The Agency is responsible for coordinating the evaluation of a drug's quality, safety, and efficacy and approving new products for the market.\textsuperscript{265} After an application is submitted to the Agency, the CPMP, a division of the Agency, takes responsibility for formulating the opinion of the Agency.\textsuperscript{266} The CPMP reviews the documentation regarding a drug's quality, safety, and efficacy and may require further testing or inspections of a manufacturing facility before granting approval.\textsuperscript{267} If the Agency denies approval, no Member State may market the product.\textsuperscript{268} As in the United States, even after a drug receives approval, manufacturers and Member States must ensure adverse drug reactions are reported to the Agency.\textsuperscript{269}

\textsuperscript{258}See Kanusky, supra note 9, at 670-71.
\textsuperscript{259}21 U.S.C. § 355(b) (1994). A company can file an Abbreviated New Drug Application if it is marketing a generic version of a pre-existing product that is already FDA approved. Kanusky, supra note 9, at 671.
\textsuperscript{260}21 U.S.C. § 355(d).
\textsuperscript{261}See 21 C.F.R. § 314.80 (1997).
\textsuperscript{262}See 21 C.F.R. § 312.85.
\textsuperscript{263}See 21 U.S.C. § 360(h).
\textsuperscript{264}The Agency was formed in 1995, when the Committee for Proprietary Medicinal Products (CPMP) joined with the Committee for Veterinary Medicinal Products. See Council Reg. No. 2309/93 (EEC), art. 49, 1993 O.J. (L 214) 2.
\textsuperscript{265}Id. art. 51. Before 1995, the Agency did not grant product approval itself. Each Member State in which a product was to be marketed had to approve a product. See Kanusky, supra note 9, at 680. Companies could either file a multi-state application whereby a special application was sent to all Member States for approval, or a concertation application whereby a single application was sent to one Member State who acted as a reporter and fielded questions from other Member States. For a discussion of the old system, see id., at 680-81.
\textsuperscript{266}Council Reg. No. 2309/93/EEC, arts. 4 and 5, 1993 O.J. (L 214) 2.
\textsuperscript{267}Id. arts. 7, 8.
\textsuperscript{268}Id. art. 12.
\textsuperscript{269}Id. arts. 20, 22, 23.
3. Background on Regulation in Japan

In Japan, the sale and distribution of pharmaceutical products are governed by the Pharmaceutical Affairs Bureau, a division of the Japanese Ministry of Health and Welfare (hereinafter the Bureau). The Bureau requires not only that new drugs be approved, but that manufacturing facilities be licensed. Pharmaceutical companies must use Bureau-approved laboratory practices in pre-clinical testing and must report their testing methods and results. Companies must also report information on the chemical components of a drug as well as details on the development and conditions of use of the drug in other countries. The process is not complete until the full Bureau has reviewed the application and the Ministry of Health and Welfare grants approval. Once a drug has been approved, manufacturers are still subject to regulations on labeling and packaging; they must report adverse drug reactions, submit the drug to be re-evaluated when necessary, and allow their manufacturing facilities to be periodically re-examined.

B. The Basis for Harmonization

The United States, the European Union, and Japan all utilize similar processes for the approval of new drugs, and in the last fifteen years the regulatory agencies of these regimes and others have begun working together to transform those similarities into a more uniform system of pharmaceutical regulation. Initially, these harmonization efforts were small in scope and were structured as bilateral agreements. For example, in 1990, the FDA and the Agency agreed on a list of good laboratory and manufacturing practices that would govern pharmaceutical companies seeking approval in either the United States or any Member State of the European Union. In 1991, the United States, the European Union, and Japan

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271 Id. § 6.08[2] (referencing §§ 12 and 14 of the Law). Foreign manufacturers may apply directly to the Minister of Health and Welfare, but the process for manufacturer approval remains the same. Id. § 608[2][C] (referencing §§ 19-2 and 19-4 of the Law).

272 See id. § 608[2][A].

273 Id.

274 See id. § 608[1].

275 Id. § 608[6][B].

276 Id. § 6.08[3].

277 Kanusky, supra note 9, at 687.

278 It was still the CPMP at that point.

279 FDA and European Commission Discussing GMP Memorandum of Understanding, Pink Sheet, Apr. 9, 1990, at T&G 4, available in Lexis, GENMED Library, FDC file. The United States had also made such an agreement with Japan. Id.
helped co-sponsor a conference to create uniform regulations governing excipients, the substances used to give drugs appropriate form and consistency.\textsuperscript{280}

The most dramatic effort at harmonizing pharmaceutical regulation began in 1991, with the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (hereinafter ICH). The ICH focused on creating uniform regulation requirements among the United States, the European Union, and Japan.\textsuperscript{281} The ICH represents a unique harmonization commitment because it is backed by both the pharmaceutical industry and the regulatory agencies of these three regimes.\textsuperscript{282} Moreover, the ICH was not just a one-time conference; it is an on-going effort at unity.\textsuperscript{283}

C. The ICH: A Model For an International Drug Administration

The ICH provides a unique international, representative perspective on the pharmaceutical market and offers an excellent framework from which to structure a new International Drug Administration. The ICH is a representative body, comprised of several groups including the pharmaceutical regulatory agencies from the United States, the European Union, and Japan and pharmaceutical manufacturers from each regime.\textsuperscript{284} There are three ICH committees: the Secretariat, the Steering Committee, and the expert working group.\textsuperscript{285} The International Federation of Pharmaceutical Manufacturers serves as the Secretariat,\textsuperscript{286} while two members from each organizing group plus two representatives from the Secretariat comprise the Steering Committee.\textsuperscript{287} There are also three expert working groups on safety, quality, and efficacy.\textsuperscript{288}

The five-phase process used by the ICH to promulgate new uniform regulation requirements provides an effective method of gathering input from each country and interest group. First, the Steering Committee selects

\textsuperscript{280} See William J.C. Currie, European Registration: Today, Tomorrow, and Beyond, 30 J. CLINICAL PHARMACOLOGY 386, 387 (1990).
\textsuperscript{283} The ICH has held three meetings. The first was in Europe in 1991, the second in the United States in 1993, and the third in Japan in 1994. Kanusky, supra note 9, at 691.
\textsuperscript{286} See STEERING COMMITTEE, INTERNATIONAL CONFERENCE ON HARMONIZATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE, ICH PROCEDURES, Annex 1, para. 6 (Mar. 1992) (on file with the Northwestern Journal of International Law & Business) [hereinafter STEERING COMMITTEE].
\textsuperscript{287} Id., at para. 2.
a topic for discussion, and then a small working group generates a statement of suggested policies, guidelines, recommendations, and points to consider. Second, the working group sends this statement to each regime's regulatory agency for review. Third, a chosen Reporter analyzes the comments made by the regulatory agencies and amends the statement which it gives back to the working group for review before sending it to the Steering Committee for approval. Fourth, a larger expert working group reviews and revises the statement one final time before the fifth phase in which the Steering Committee recommends the statement for adoption by the regulatory agencies of the United States, the European Union, and Japan. While ICH regulations are not binding, they represent "a firm political commitment on the part of the concerned governments."

D. An International Drug Administration

Although not officially labeled as such, the organizing groups of the ICH effectively act as a type of international regulatory agency for pharmaceutical products. The United States, the European Union, and Japan should use the framework of the ICH and expand their harmonization efforts to form an International Drug Administration (IDA). A multilateral treaty among these parties establishing the IDA would make their previous "political commitment" into a more formal obligation. The IDA would have the official responsibility of promulgating uniform international requirements for the registration and development of new pharmaceutical products.

As the international regulatory agency, the IDA would facilitate the introduction of new products to the international market by requiring pharmaceutical companies to file a single multi-nation new drug application with the IDA. The IDA would then coordinate the registration process. It would act as a reporter for the company, respond to individual member questions, and issue the final approval or denial. Once a new product is approved, pharmaceutical companies would report adverse drug reactions to the IDA. This would facilitate the collection of more complete, accurate

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289 STEERING COMMITTEE, supra note 286, at para. 8.
290 THE SECOND INTERNATIONAL CONFERENCE ON HARMONISATION, CLOSING REPORT, Annex 6, at 17 (Oct. 27-29, 1993).
291 Id.
292 Id.
293 Id.
294 Kanusky, supra note 9, at 695.
296 This would be like a combination of the European Union's old multi-state and concertation applications. See supra Part IV.A.2.
297 This procedure is similar to the process currently used in the European Union.
data and enable the IDA to recognize products that have reached unacceptable safety levels which require their removal from the market. Each regime would have access to the same information at the same time. A multinational application process would lower the cost of bringing a new drug to market. It would reduce current wasteful repetition caused by having to file separate applications in each regime. It would eliminate the expense of having to make small but expensive alterations in manufacturing practices, facilities, reports, and testing procedures for each regime. Moreover, with truly uniform research, development, testing, and safety standards, it will be easier for manufacturers to know and satisfy these necessary requirements. Finally, all products will have the same safety standards and present the same liability risks regardless of where they are manufactured, which will provide certainty.

V. AN INTERNATIONAL DRUG ADMINISTRATION: A UNIFORM CURE FOR UNCERTAINTY IN PHARMACEUTICAL PRODUCT LIABILITY

A. The IDA: Providing An International Tribunal For Product Liability

The IDA should not only govern pharmaceutical regulation but also serve as an international administrative tribunal for product liability claims. In essence, this new system of liability would be a mixture of safety regulation, tort, and workmen's compensation. The IDA would set safety standards to be followed, and if injuries occurred despite these standards, it would offer a way to compensate consumers for their injuries. In this way, the IDA would truly serve as a "guardian" of the public health, protecting citizens from the dangers associated with pharmaceutical products through both regulation and redress.

Trying to create a new uniform system of product liability is not without its complexities. An argument could be made that cultural differences between the three regimes will make it difficult, if not impossible, to define and determine awards; tort law has been described as a "cultural mirror" in which judicial decisions often reflect the social norms of an individual country. However, this cultural divide is exactly the problem that the IDA would address. Under the current system of product liability, cultural and political differences and the fact that judicial decisions often reflect these differences create uncertainty. Creating an informed multinational, multicultural, forum in which to address liability concerns will provide a consensus view and interpretation. Allowing the IDA tribunal to utilize

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300 See supra Part II.D.
more of a workmen’s compensation mentality of no fault compensation will minimize areas of dispute because the approach limits the amount of interpretation usually required in a tort action. Injured consumers will not have to prove negligence or intent or get bogged down in various standards. All that will be needed is proof of injury.

An argument could be made that this system will raise preemption questions, especially in the United States where recent U.S. Supreme Court decisions reveal that FDA regulations do not always preempt state tort actions. However, since the IDA would be formed through a multilateral treaty that would bind each signatory as a nation, it would avoid the preemption questions surrounding domestic federal regulations. A final argument that could be raised is that the United States, the European Union, and Japan would be unwilling to cede their authority regarding product liability to an international body. The reality is that these regimes would not be giving up their right and authority to protect their citizens. This system would operate only when companies followed IDA regulations and injuries occurred despite their adherence to those regulations. Companies which failed to follow IDA procedures would be subject to suit in domestic fora just as companies which fail to follow federal regulations in the United States may face state tort claims as well as federal suits. As with any treaty or international organization, there will be measures and complexities that will need to be worked out, but nations are realizing the need for international cooperation and collaboration more each day. For example, under the dispute settlement mechanisms of the General Agreement on Tariffs and Trade (GATT), nations agree to bring their concerns over trade violations before an international body.

\[301\] See Medtronic Inc. v. Lohr, 518 U.S. 470 (1996) (in a case involving the Medical Device Amendments (MDA), state law defective design claims were not preempted despite federal approval; claims of manufacturer’s negligence were not preempted; claims of defective labeling and marketing were not preempted).

\[302\] For example, the European Union will establish a new currency known as the Euro that will be used by all Member States except Britain, Denmark, and Sweden, which have opted initially not to use the single currency and Greece, which has not yet met the European Commission’s criteria for inclusion. See Barry James, 11 Countries Approved for Euro in a Historic Moment for EU, Common Currency Moves Closer, INT’L HERALD TRIB., Mar. 26, 1998, at News available in LEXIS, World Library, IHT File; Angus MacKinnon, Brussels Set to Give Green Light to 11-state Single Currency, AGENCE FRANCE PRESSE, Mar. 24, 1998 available in LEXIS, News Library, AFP File.

1. The Tribunal Composition

The membership of the IDA, like the ICH, should include representatives from both government and industry, but membership should be extended to include consumer representation so that the IDA will have a knowledgeable, representative, global perspective on the pharmaceutical market. The IDA should have a specialized division responsible for dealing with product liability concerns. It should assess the risks associated with each product, make judgments about the safety requirements appropriate for each product, and serve as an international tribunal that reviews product liability claims. This IDA tribunal would serve as a better method of addressing product liability claims than the current system. It would provide a knowledgeable, fair forum that reflects the international composition of the pharmaceutical market and provides the certainty and stability that current pharmaceutical product liability lacks and so desperately needs.

The IDA tribunal members will have the necessary scientific and technical background to fully understand pharmaceutical product liability: they will be familiar with the products; they will have studied the research and tests; they will know the inherent risks associated with each pharmaceutical product; and, they will understand the technical medical questions that arise in pharmaceutical product liability cases. Armed with that knowledge, the IDA will be a fair judge of pharmaceutical product liability. The IDA tribunal as a representative body will be able to understand and empathize with each section of the pharmaceutical market. It will not be guided to decisions based only on sympathy for the consumer, nor will it be driven solely by the economic interests of industry or government. It will provide government, manufacturer, and consumer perspectives in reaching a decision; thus, no one faction will determine outcomes based on its own interests. The IDA will provide an international perspective that reflects the international scope of the pharmaceutical market.

The IDA tribunal will provide much-needed certainty in pharmaceutical product liability. Both pharmaceutical companies and consumers will know the forum in which their case will be decided before an injury occurs. It will not matter where a product was made or bought, and there will be no "forum shopping" as consumers search for the more friendly jurisdiction. Most importantly, the IDA tribunal will provide one international standard

\[3^{04}\text{See supra Part IV. C., expanding on current ICH composition.}\]

\[3^{05}\text{This would resolve the concerns raised in supra Part I.D.}\]

\[3^{06}\text{One of the problems that the IDA would stop, and which is of great concern to foreign pharmaceutical companies, is that in the United States, juries are thought to base their decisions on sympathy for an injured plaintiff.}\]

\[3^{07}\text{See supra Part III.A. Pharmaceutical companies will no longer fear selling products in the United States because, if injuries occur, they will not have to face a product liability suit in the United States where liability awards have proven exorbitant. See supra Part III.D.3.}\]
of recovery for pharmaceutical product liability. There will no longer be the uncertainty that results when each nation interprets and applies standards according to its own history, culture, and legal tradition. Instead of having a standard that is uniform in name only and subject to multiple interpretations by various "triers of facts" there will be one standard formulated from a multinational perspective, and one tribunal acting as judge.

2. The System of Product Liability Under the IDA Tribunal

Taking aspects of each regime's current liability traditions, the IDA can create a truly effective system for pharmaceutical liability. The IDA tribunal should serve less as a civil litigation forum and more as a review board. It should be patterned after the Japanese tradition of rejecting adversarial court battles in favor of conciliatory agreements that redress actual harm and non-litigation associations that provide compensation without legal action.\(^\text{308}\)

Recognizing the unique nature of pharmaceutical products, and the importance of balancing their high social value against their inherent risks\(^\text{309}\), the goal of the tribunal should be to compensate consumers for actual harm, not to punish pharmaceutical companies for injuries beyond their control. To achieve this goal, the IDA should start by adopting a standard of no-fault compensation.\(^\text{310}\) Under this standard, the tribunal will decide only if a product caused the consumer's injury. If the product is the proximate cause of injury, then the consumer will be compensated.

Despite the many differences in application of the current product liability standard, all three regimes have agreed that consumers, injured by a product, should receive compensation for their injuries.\(^\text{311}\) Injured consumers should receive compensation to cover personal injury or death, and enough money to pay their medical expenses. A limited amount of compensation for pain and suffering seems appropriate when the IDA, using its knowledge of the effects caused by a drug, determines what a reasonable amount of pain and suffering compensation should be. However, punitive damages should not be allowed because they are designed not to compensate the injured consumer but to punish the pharmaceutical manufacturer.

\(^{308}\) See supra Part II.C.

\(^{309}\) This goal is similar to what the Restatement (Second) of Torts § 402A tried to do in Comment k.

\(^{310}\) This goal is similar to the standard used in countries like New Zealand, Sweden, and Finland which utilize a no-fault insurance system created by agreement between the pharmaceutical industry and insurance companies. See Jackson, supra note 122, at 225-26 (discussing this no-fault insurance system). A similar standard is also utilized by the National Childhood Vaccine Injury Act and workman's compensation system. Id. at 223. These examples could be models for the structure of an IDA compensation scheme.

\(^{311}\) This belief was the impetus for adopting the strict liability standard. See supra Parts III. A., B., and C.
Pharmaceutical companies should not be punished as long as they have followed IDA regulations and have done everything they can to make their products safe and effective so that injury results, not from any fault of the company, but from the inherent dangers of pharmaceutical products.\textsuperscript{312}

The United States, the European Union, and Japan would not give up the right to protect their citizens from fraud, negligence, or recklessness, but rather, would provide a more effective method of compensation for no-fault injuries. Companies that do not follow IDA regulations; that are negligent or reckless and fail to maintain appropriate manufacturing and laboratory practices; or, that defraud the IDA by falsifying their applications or doctoring their research results will still be subject to the laws of the injured consumer's country.

Compensation awards will be paid out of a trust fund financed by pharmaceutical companies operating on the international market. There are two methods of financing this trust. The first is an excise tax, similar to that used in the National Childhood Vaccine Injury Act, imposed on pharmaceutical manufacturers for each product they sell.\textsuperscript{313} The tax would fluctuate based on the number and severity of claims filed with the IDA, and there would be a cap on the tax to prevent it from rising too high.\textsuperscript{314} The second method would be to impose a standard fee on pharmaceutical manufacturers.\textsuperscript{315} The fee would be a fixed percentage, based on annual pay-outs from the fund.\textsuperscript{316} The fee could be announced a year in advance, which would enable manufacturers to better predict their costs and plan for the future. Thus, manufacturers who incur greater liability expenses pay the same amount as manufacturers who have lower costs. The ability to accurately predict costs and operate free from uncertainty will reduce prices and encourage manufacturers to research new products and develop orphan drugs.

B. Benefits of an IDA Tribunal System of Product Liability

The current system of pharmaceutical product liability is inefficient and inequitable and has created: uncertainty and fear in the pharmaceutical industry, market distortion,\textsuperscript{317} increased costs,\textsuperscript{318} and a chill in the develop-

\textsuperscript{312}See supra Part I.
\textsuperscript{313}This parallels the National Childhood Vaccine Injury Act. See supra Part III.C.2 and accompanying notes.
\textsuperscript{314}With a more stable, certain system of liability and reasonable liability expenses, the tax will probably not increase to the extreme levels that are currently causing vaccine prices to soar. See supra Part III.C.2.
\textsuperscript{316}Id.
\textsuperscript{317}See supra Part III.B.
ment of new products. The IDA tribunal system would encourage efficient, equitable liability recovery. It would eliminate uncertainty and fear in pharmaceutical product liability, stabilize the market, and protect consumers.

No-fault compensation based on actual injury and with restrictions on non-compensatory damages creates certainty and stability by providing relief to injured consumers without unjustly punishing manufacturers. It avoids enormous multi-million dollar awards that increase costs and create liability fears that cause pharmaceutical companies to stop manufacturing and marketing current products and halt or slow research and development of new products.

While awards under this no-fault compensation system would be smaller, the payments would be more immediate and meritorious claims would not be unnecessarily reduced by the fees generated by lengthy legal battles. Under the current system, after an award is granted, actual compensation can be delayed for years by continued litigation. Moreover, the costs of this continued litigation has to be deducted from the actual award and may significantly reduce actual compensation to the consumer. Immediate payments will allow injured consumers to keep up with medical expenses incurred from the injury, and with an administrative tribunal system, excessive court costs and delays can be avoided.

Using a trust fund financed equally by pharmaceutical companies to pay liability awards stabilizes the market, encourages safety, and provides an incentive for development. The fund spreads liability risks and costs evenly among manufacturers. The fixed rate of payment allows pharmaceutical companies to more accurately predict their costs and will help keep consumer prices reasonable and stable. As the fee to finance the trust is based on annual pay-outs from the fund, the fewer claims brought that require pay-outs, the less money each company must contribute each year. Fewer expenditures means more profits, and this gives manufacturers another incentive to produce safe products that will not incur liability awards from the IDA. Moreover, when companies pay a blanket fee regardless of their liability exposure, they have an incentive to develop new products.

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318 See supra Part III.C.
319 See supra Part III.D.
320 See supra Part III.
321 See Danner, supra note 315, at 78.
322 See id.
323 See id. at 79.
324 Id.; see supra Part III.C.
325 The IDA would be able to impose an increase on a company that abused the equal payment structure of the tax fund; thus, companies would have an incentive to make sure that their products did not require excessive payouts from the fund.
to make a return on that fee. Thus, the IDA tribunal system of product liability will prevent distortions in the pharmaceutical market, decrease costs for both manufacturers and consumers, and encourage the development of new products.

VI. CONCLUSION

When the United States felt that its negligence standard for product liability was inefficient and unfair, it adopted a new strict liability standard. When the European Union felt individual Member States' determination of product liability standards was inefficient and caused trade problems, it adopted a more uniform system of strict liability modeled after the United States. When Japan felt that its product liability system was unresponsive to consumers, it too changed to a more uniform system of strict liability patterned after the United States and the European Union. Unfortunately, the problems of inefficiency and inequity continue. Despite, or perhaps because of the individual efforts of these three regimes, product liability in the pharmaceutical industry has not achieved the uniformity it needs to eliminate distortions in the market, decrease costs, and encourage the development of new products. Thus, the United States, the European Union, and Japan should continue to evolve their product liability systems. They should take the next step toward harmonization and, this time, create a truly international, uniform product liability system for the pharmaceutical industry. The IDA will provide that system. The IDA will help consumers without hurting pharmaceutical companies. It will eliminate uncertainty in product liability cases and cure the negative effects caused by that uncertainty. The United States, the European Union, and Japan must not shy away from international uniformity in product liability. It is time to let the pharmaceutical product liability system break away from domestic uncertainties and catch up with this international industry.

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326 Id.
327 See RESTATEMENT (SECOND), supra note 14.
328 See Directive, supra note 38.
329 See Liability Law, supra note 79.