

Design Defect Liability and Prescription Drugs: Who's in Charge?

DAVID S. TORBORG*

While the Restatement (Second) of Torts generally imposes strict liability upon manufacturers of defectively designed products, it provides an exemption from this general rule for unavoidably unsafe products, most notably including certain pharmaceutical products. Courts have split over the extent of this exemption. A majority of jurisdictions examine each particular pharmaceutical product to determine whether the policy behind the exemption applies to that pharmaceutical, while a minority of jurisdictions grant blanket exemption to any drug which has obtained FDA approval. The ALI is currently working on a proposed Restatement (Third) which closely follows, without expressly adopting, the latter approach. However, this proposal does not go far enough. National legislation regarding pharmaceutical design defect liability is long overdue. FDA experts are far more competent than juries or judges in determining whether the benefits of a particular pharmaceutical outweigh its risks. Furthermore, federal pre-emption of state law can create the desired consistency in application among states and keep litigation costs to a minimum.

I. INTRODUCTION

Among the innumerable products available to consumers, prescription drugs are unique.¹ While many consumer products seek to make life more convenient or enjoyable for the user, prescription drugs often make that life possible. The unique nature and utility of prescription drugs has led to a distinct niche in the products liability field. This niche finds its roots in the controversial comment k² to Section 402A of the Restatement (Second) of Torts³—perhaps

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¹ See, e.g., *Brown v. Superior Court (Abbott Lab.)*, 751 P.2d 470 (Cal. 1988).

But there is an important distinction between prescription drugs and other products such as construction machinery In the latter cases [not dealing with prescription drugs], the product is used to make work easier or to provide pleasure, while in the former [cases dealing with prescription drugs] it may be necessary to alleviate pain and suffering or to sustain life.

Id. at 478.

² RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

³ This section reads:

the most economically influential section of any Restatement. In Section 402A, commonly known as "strict liability," the American Law Institute (ALI) recognized a policy decision which several courts made towards demanding both enhanced product and consumer safety.⁴ Strict liability, besides expanding the scope of who can be sued, eliminates the plaintiff's burden of showing that a manufacturer was negligent or at fault when designing, manufacturing, or marketing a product. Briefly stated, the doctrine of strict liability was established to further three basic policy concerns. First, because the injuries caused by the product's defective design or malfunction are extremely unpredictable, it is thought that the industries manufacturing these products are better able to compensate for these incidents by (1) adjusting the price of the product, or (2) obtaining insurance for the possibility of product liability, i.e. "loss spreading."⁵ Second, the doctrine of strict liability is thought to provide incentives for the manufacturer to produce safer products.⁶ Finally, even if fault or negligence on the part of the manufacturer were present, it is too difficult, if not impossible, to prove these elements due to the technical complexities inherent in modern products.⁷ Therefore, the doctrine of strict liability is believed to be a necessary aid to the plaintiff's success on his or her claim.⁸

Comment k to Section 402A,⁹ providing an exemption from strict liability

(1) One who sells any product in a defective condition unreasonably dangerous to the user or the consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

- (a) the seller is engaged in the business of selling such a product, and
- (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

- (a) the seller has exercised all possible care in the preparation and sale of his product, and
- (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Id. § 402A.

⁴ See *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 441 (Cal. 1944) (Traynor, J., concurring).

⁵ W. PAGE KEETON ET AL., *PROSSOR AND KEETON ON THE LAW OF TORTS* § 98, at 692-93 (5th ed. 1984).

⁶ See *id.* at 693.

⁷ See *id.*

⁸ See *id.*

⁹ Comment k provides:

Unavoidably unsafe products. There are some products which, in the present state

for certain “unavoidably unsafe products,” reflects a different policy rationale—the affordability and availability of certain pharmaceutical products and vaccines.¹⁰ The comment seeks to insulate from the doctrine of strict liability those products that ought not be subject to such sweeping liability because their unique utility justifies their availability, even in the face of recognized dangers. Comment k recognizes the fear that imposing strict liability on pharmaceutical manufacturers may hinder the industry’s ability to adequately provide such uniquely beneficial products by making the production and marketing of pharmaceuticals too risky a business.

To illustrate the effect of comment k, consider the following. When a consumer successfully recovers on a strict product liability claim, the consumer has established, at least to the court or jury, that the product in question was “unreasonably dangerous.”¹¹ The purpose of comment k is to establish that

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 leads invariably 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 direction and warning, 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 cannot legally be sold except to physicians, or under the 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 for 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.

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

¹⁰ See, e.g., *Brown v. Superior Court (Abbott Lab.)*, 751 P.2d 470, 475 (Cal. 1988) (“[I]t would be ‘against the public interest’ to apply the doctrine [strict liability] to such products [prescription drugs] because of ‘the very serious tendency to stifle medical research and testing.’”) (quoting 38 A.L.I. PROC. 50, 90–92 (1961)); *Toner v. Lederle Lab., A Div. of Am. Cyanamid Co.*, 732 P.2d 297, 306 (Idaho 1987).

¹¹ RESTATEMENT (SECOND) OF TORTS § 402A (1965).

Unreasonably dangerous. The rule stated in this Section applies only where the defective condition of the product makes it unreasonably dangerous to the user or consumer. Many products cannot possibly be made entirely safe for all consumption, and any food or drug necessarily involves some risk of harm, if only from overconsumption. . . . The article sold must be dangerous to an extent beyond that which

“some products” are not “unreasonably dangerous” to the consumer, even if they are “quite incapable of being made safe for their intended and ordinary use.”¹² Hence, if a manufacturer can establish that its product falls within the range of products protected by comment k, the product will automatically fail the necessary “unreasonably dangerous” condition of strict liability, and the plaintiff will be forced to pursue the manufacturer on ordinary negligence grounds, which require a showing of fault by the manufacturer.

Because pharmaceutical products were specifically included in the definition of “unavoidably unsafe products,”¹³ pharmaceutical companies wasted little time in using the comment as a defense in prescription drug and vaccine tort liability cases.¹⁴ Most commonly, comment k has been invoked in design defect cases.¹⁵ Comment k, by its very language, seems to preclude its use in defending against failure-to-warn and manufacturing defect cases: “Such a product, *properly prepared, and accompanied by proper direction and*

would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics. Good whiskey is not unreasonably dangerous merely because it will make some people drunk, and is especially dangerous to alcoholics; but bad whiskey, containing a dangerous amount of fuel oil, is unreasonably dangerous. Good tobacco is not unreasonably dangerous merely because the effects of smoking may be harmful; but tobacco containing something like marijuana may be unreasonably dangerous. Good butter is not unreasonably dangerous merely because, if such be the case, it deposits cholesterol in the arteries and leads to heart attacks; but bad butter, contaminated with poisonous fish oil, is unreasonably dangerous.

Id. cmt. i.

¹² *Id.* cmt. k.

¹³ *Id.*

¹⁴ See, e.g., *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 425–26 (2d Cir. 1969) (noting that for products falling under the comment k umbrella, strict liability cannot be used unless the consumer establishes a breach of the manufacturer’s duty to warn); *Chambers v. G.D. Searle & Co.*, 441 F. Supp. 377, 380–81 (D. Md. 1975), *aff’d per curiam*, 567 F.2d 269 (4th Cir. 1977) (holding that manufacturer of oral contraceptives escapes liability, and noting that comment k transforms the strict liability claim to a negligence claim); *Gaston v. Hunter*, 588 P.2d 326, 338–41 (Ariz. Ct. App. 1978) (holding that manufacturer avoids design defect liability for experimental drug chymopapain, used for back pain, because of comment k).

¹⁵ Not only does comment k preclude its use by defendants in failure-to-warn and manufacturing defect cases, it provides further support for a plaintiff’s claim that strict liability should be used to hold defendants liable in failure-to-warn and manufacturing defect cases. The reasoning behind this assertion is that comment k provides an exception to its rule if the conditions of comment k are not satisfied because of improper warning or manufacture. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965). Strict liability will still apply under these circumstances. Therefore, while comment k can be used to protect against design defect claims, it is ineffectual in defending against failure-to-warn or manufacturing defect cases and, in fact, seems to promote such claims.

warning, is not defective, nor is it unreasonably dangerous.”¹⁶ Therefore, one should conclude that comment k is aimed at protecting some class of products from a claim that they are defectively designed. The controversy, as discussed below,¹⁷ centers around what is included in that class of products.

More recently, comment k protection has been extended to design defect cases involving medical devices, as courts have found that the policy reasons for protecting prescription drugs also apply to protecting medical devices.¹⁸ While on the surface this analogy makes sense, the inclination to treat prescription drugs and medical devices identically causes some concern. For example, the Supreme Court of Utah has relied on different policy grounds than those originally stated in comment k to justify its decision to provide comment k protection to all prescription drugs (“blanket immunity”).¹⁹ Because many of these policy rationales are unique to prescription drugs,²⁰ and may not apply to medical devices, the focus of this Comment will be on prescription drugs (including vaccines), rather than medical devices.

Additionally, the concern of this Comment is manufacturer liability for *design defects*. When a consumer alleges that he or she has been injured due to the effects of a prescription drug, there are many avenues for recovery. Most typically, the consumer alleges a failure-to-warn.²¹ Additional possibilities

¹⁶ *Id.* (emphasis added).

¹⁷ See *infra* Part II.

¹⁸ See, e.g., *Perfetti v. McGhan Medical*, 662 P.2d 646 (N.M. Ct. App. 1983) (applying comment k to breast implants); *Tansy v. Dacomed Corp.*, 890 P.2d 881 (Okla. 1994) (considering whether penile implants deserved comment k protection, eventually concluding they do); *McKee v. Moore*, 648 P.2d 21 (Okla. 1982) (applying comment k to intrauterine devices); *Hoyt v. Vitek, Inc.*, 894 P.2d 1225 (Or. Ct. App. 1995) (considering whether temporomandibular implants deserve comment k protection, eventually concluding that they do not, after weighing risks and benefits).

¹⁹ See *Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991). Specifically, the court in *Grundberg* cited the elaborate regulatory system overseen by the FDA, the cost-effectiveness of prescription drugs, and the difficulties of non-scientists in understanding “the numerous chemical properties of the product and their relationship to the vast physiologic idiosyncracies of each consumer for whom the drug is designed.” *Id.* at 95–96, 99.

²⁰ For example, the FDA approval process for medical devices is far less complex than it is for prescription drugs. See *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2246 (1996). The FDA separates medical devices into three classes (I, II, and III) depending on the risk that they pose to the public (Class I posing the least risk). Only Class III devices require pre-market approval, which requires testing averaging 1200 hours. *Id.* at 2247. Most Class III devices on the market today, however, escaped elaborate testing because of exceptions to the pre-market approval requirement (the most common being a grandfathering provision and a “substantially similar” to already existing products exception). *Id.* Therefore, the *Grundberg* court’s reliance on the elaborate FDA regulatory structure may not apply to medical devices.

²¹ Failure-to-warn claims easily constitute the overwhelming majority of prescription

include fraud²² and manufacturing defects.²³ Hence, while many of the legal approaches discussed in this Comment would preclude plaintiffs from succeeding on a design defect claim, an injured consumer is far from without a remedy.²⁴

This Comment explores the evolving nature, and possible future, of design defect liability regarding prescription drugs and vaccines. Part II of this Comment analyzes the differing approaches state courts have taken in interpreting comment k and the reasoning behind those decisions. Part III provides a thumbnail sketch of the ALI's proposed draft regarding liability for design defects in the pharmaceutical industry. Part IV discusses the role of the federal Food and Drug Administration (FDA) in regulating prescription drugs, focusing on the specific measures taken by the FDA regarding a combined diphtheria, tetanus, and pertussis vaccine (DPT), a vaccine that has been the subject of successful plaintiff recoveries on a design defect claim. Finally, Part V argues for federal legislation in this area so that a consistent products liability landscape can be established in the area of prescription drug design defect liability.

II. THE LACK OF UNIFORMITY IN APPLYING COMMENT K TO PRESCRIPTION DRUG DESIGN DEFECT LIABILITY CLAIMS

Courts disagree on the appropriate way to interpret and apply the basic premise of comment k. The difficulty centers around which pharmaceutical products should be classified as comment k products, and therefore immune

drug liability cases. See James A. Henderson, Jr. & Aaron D. Twerski, *A Proposed Revision of Section 402A of the Restatement (Second) of Torts*, 77 CORNELL L. REV. 1512, 1537 (1992).

²² One of the most notable examples of pharmaceutical litigation concerned fraud on the part of Merrell Dow Pharmaceuticals. In 1960, Merrell Dow's application to market MER/29, a drug designed to reduce the level of cholesterol in the bloodstream, was approved by the FDA. The drug was eventually found to result in numerous side effects, including cataracts, baldness, and severe dermatitis. An FDA inspection of Merrell Dow records subsequent to the drug's withdrawal from the market revealed that the FDA had received incorrect animal data from the company. It is estimated that Merrell Dow paid over \$200 million in damages. See Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 HASTINGS L.J. 301, 315 (1992) (quoting Gina B. Kolata, *How Safe Is Bendectin?*, 210 SCIENCE 518, 519 (1980)).

²³ See M. STUART MADDEN, PRODUCTS LIABILITY § 9.2, at 322 (2d ed. 1988) (distinguishing manufacturing defects from design defects).

²⁴ See generally *Grundberg*, 813 P.2d at 97 ("Plaintiffs may still recover under a strict liability claim by demonstrating that the product was unreasonably dangerous due to an inadequate warning, a manufacturing flaw, mismarketing, or misrepresenting information to the FDA.").

from strict liability claims of defective design (assuming proper warning and preparation). Most courts agree that at least some prescription drugs should be given protection from strict liability claims.²⁵ These courts, however, follow two distinct models in determining the scope of comment k protection: (1) comment k protection for prescription drugs must be determined on a case-by-case basis, so that some prescription drugs deserve protection from strict liability, while others do not; and (2) all prescription drugs that acquire FDA approval, absent fraud, should be protected from strict design defect liability. This second approach is commonly known as the "blanket immunity" approach. Essentially, the difference between the opposing views is that the case-by-case model posits that comment k was never intended to cover all prescription drugs, but only those drugs making a major contribution to public health, while those following the blanket immunity approach feel that all prescription drugs should be insulated from strict design defect liability as a matter of public policy and judicial fairness.

A. Case-by-Case Method

A majority of courts that have considered the application of comment k have adopted the case-by-case approach, concluding that prescription drugs are not automatically shielded from design defect liability.²⁶ These courts are

²⁵ Some courts, however, have rejected comment k entirely. In *Shanks v. Upjohn Co.*, 835 P.2d 1189 (Alaska 1992), the Alaska Supreme Court found it unnecessary to adopt a different liability standard for prescription drugs, noting that comment k added confusion to the already blurry distinction between strict liability and negligence. *See id.* at 1197. The court also questioned the policy rationale behind comment k, stating that "we find it speculative at best that restricting strict liability design defect claims against prescription drug manufacturers will serve the public interest by enhancing the availability and affordability of prescription drugs." *Id.* at 1195. While the Alaska Supreme Court rejected comment k, it has not rejected the policy underlying unavoidably unsafe products. *See id.* at 1198. Alaska instead treats each drug on a case-by-case basis, as it would any ordinary product, to determine if the product was unreasonably dangerous. *See id.* Therefore, Alaska's treatment of pharmaceutical design defects is, in substance, really no different than those states which apply comment k on a case-by-case basis, as discussed below. *See id.*; *infra* Part II.A. The Supreme Court of Wisconsin has reached a similar conclusion. *See Collins v. Eli Lilly Co.*, 342 N.W.2d 37 (Wis. 1984).

²⁶ *See, e.g.*, *Rohrbough v. Wyeth Lab., Inc.*, 719 F. Supp. 470, 476-77 (N.D. W. Va. 1989) (stating that design of vaccine is subject to ordinary risk-utility analysis), *aff'd*, 916 F.2d 970 (4th Cir. 1990); *Kociemba v. G.D. Searle & Co.*, 695 F. Supp. 432, 433 (D. Minn. 1988) (holding that a single balancing test for reasonableness determines liability for design defects); *West v. Searle & Co.*, 806 S.W.2d 608, 611-13 (Ark. 1991) (noting that a manufacturer may defend against design defect claim by demonstrating through risk-utility analysis that product was unavoidably unsafe); *Adams v. G.D. Searle & Co.*, 576 So. 2d 728,

faithful to the precise language of comment k itself, asserting that comment k will only shield the manufacturer from design defect liability if the court finds that the drug's benefits outweigh the drug's risks.²⁷ While this determination is usually made by the trial judge, at least one court has concluded that the risk-benefit balancing is a question of fact for the jury if "reasonable minds can differ on the question."²⁸ One of the earliest cases utilizing the case-by-case approach was *Kearl v. Lederle Laboratories*.²⁹ In *Kearl*, a patient who received an oral polio vaccine brought a products liability action against the manufacturer of the vaccine after the patient began to develop paralysis. The court was asked to decide whether comment k applied to the polio vaccine at issue. In making that determination, the court set out the following three-part test: (1) Was the product intended to provide an "exceptionally important benefit that made its availability highly desirable?"; (2) Was the risk posed by the product "substantial" and "unavoidable" when distributed?; and (3) Did "the interest in availability . . . outweigh[] the interest in promoting enhanced accountability?"³⁰

The basic purpose of comment k, according to courts adhering to the case-by-case approach, is to protect from liability a product that is especially beneficial to society. These courts reason that comment k was never intended to apply to all prescription drugs.³¹ They hold that a distinction must be drawn

732-33 (Fla. Dist. Ct. App. 1991) (stating that protection from design defect liability extends only to products that pass risk-utility balancing test for reasonable design, not to all drugs and medical devices per se); *Toner v. Lederle Lab., A Div. of Am. Cyanamid Co.*, 732 P.2d 297, 308-09 (Idaho 1987) (stating in dictum that protection from design defect claims will be given only on a case-by-case basis; that applicability of "unavoidably unsafe" exemption depends on whether the product's benefits outweigh the risks; and that comment k by its terms does not give "blanket immunity" to all drugs); *White v. Wyeth Lab., Inc.*, 533 N.E.2d 748, 752 (Ohio 1988) (holding prescription drugs do not, per se, fall within comment k, but will be considered on a case-by-case basis); *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 781 (R.I. 1988) (holding that exemption from strict liability based on design defect will be available only if drug's apparent benefits outweigh apparent risks).

²⁷ See *supra* note 26.

²⁸ *Castrignano*, 546 A.2d at 781-82.

²⁹ 218 Cal. Rptr. 453 (Cal. Ct. App. 1985), *overruled by* *Brown v. Superior Court (Abbott Lab.)*, 751 P.2d 470, 481-83 (Cal. 1988).

³⁰ *Id.* at 464 (emphasis added).

³¹ See, e.g., *Toner*, 732 P.2d at 308.

Obviously, the comment [k] does not apply to *all* drugs. Rather, the comment applies "when the situation calls for it," which is when the product is unavoidably unsafe, but is "an apparently useful and desirable product, attended with a known but apparently reasonable risk," or with an unknown risk which is not yet reasonably discoverable at the time of marketing.

between drugs which have an enormously profound impact on society's health and drugs which merely make life more convenient.³²

B. *Blanket Immunity Approach*

A minority of jurisdictions have applied comment k's protection from design defect liability to all prescription drugs.³³ The landmark case introducing the blanket immunity approach was *Brown v. Superior Court (Abbott Laboratories)*.³⁴ In *Brown*, the California Supreme Court overruled the initial risk-benefit analysis enunciated in *Kearl v. Lederle Laboratories*,³⁵ reasoning that the policy underlying comment k (increased availability of affordably priced drugs and vaccines) is frustrated by the case-by-case risk-benefit balancing approach:

Under the "mini-trial" directed by *Kearl*, a drug manufacturer has no assurance that a product he places on the market will be measured by the liability standard of comment k because the trial judge could decide that the benefit of the drug was not "exceptionally important" so as to make its availability "highly desirable," or that the interest in its availability did not outweigh the public's interest in subjecting the producer to strict liability. . . . A manufacturer's incentive to develop what it might consider a superior product would be diminished if it might be held strictly liable for harmful side effects because a trial court could decide, perhaps many years later, that in fact another product which was available would have accomplished the same result.³⁶

The court in *Brown* also expressed concern that the case-by-case approach would lead to inconsistent results and increased litigation costs.³⁷ Hence, the

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

³² *See id.* at 306 ("This weighing process should consider the value of the benefit, the seriousness of the risk, and the likelihood of both.").

³³ *See, e.g., In re Eli Lilly & Co., Prozac Prods. Liab. Litig.*, 789 F. Supp. 1448 (S.D. Ind. 1992); *Brown v. Superior Court (Abbott Lab.)*, 751 P.2d 470 (Cal. 1988); *Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991); *Young v. Key Pharm., Inc.*, 922 P.2d 59 (Wash. 1996).

³⁴ 751 P.2d 470 (Cal. 1988).

³⁵ 218 Cal. Rptr. 453 (Cal. Ct. App. 1985), *overruled by* *Brown v. Superior Court (Abbott Lab.)*, 751 P.2d 470, 481-83 (Cal. 1988).

³⁶ *Brown*, 751 P.2d at 481-82.

³⁷ *See id.* Subsequent decisions from other jurisdictions have criticized and rejected *Brown's* policy determinations. *See, e.g., West v. Searle & Co.*, 806 S.W.2d 608, 612 (Ark. 1991) ("We adopt this second view [case-by-case approach] because of the wording of the comment itself and because it is the better public policy."); *Castrignano v. E.R. Squibb &*

state that first articulated the case-by-case approach was also the first to abandon it—in favor of blanket immunity. Most other states, however, have failed to follow a similar path.

A more recent, and expansive, decision granting blanket immunity from design defect liability to prescription drugs was offered by the Utah Supreme Court in *Grundberg v. Upjohn Co.*³⁸ In *Grundberg*, the plaintiff shot her mother allegedly as a result of taking a 0.5 milligram dose (the manufacturer's recommended dose) of Halcion, an insomnia drug. She filed suit, claiming not only that Upjohn failed to warn of the drug's dangers, but also that Halcion was defectively designed. The Utah Supreme Court would not allow recovery on the design defect claim, invoking comment k. The court refused an attempt to reconcile the language of comment k with the blanket immunity approach; instead, it flatly admitted that the blanket immunity approach runs counter to the express language of the Restatement.³⁹ The *Grundberg* court, like the court in *Brown*, felt that comment k's policy rationale is better served by the blanket immunity approach.⁴⁰

The strength of the *Grundberg* decision is the increased attention the court paid to the underlying justifications for limiting design defect liability for prescription drugs. First, the court noted the "unique nature and value" of prescription drugs, namely that "[b]ecause prescription drugs are chemical compounds designed to interact with the chemical and physiological processes of the human body, they will almost always pose some risk of side effects in certain individuals."⁴¹ Second, and most importantly, the court outlined the extensive influence of the FDA regulatory scheme,⁴² a factor given a mere footnote of attention in *Brown*.⁴³ The cornerstone of the *Grundberg* opinion is the court's conclusion that the *proper forum* for making the determination of whether or not a drug's benefits outweigh its risks rests within the FDA, not with the individual judges and juries.⁴⁴

Sons, Inc., 546 A.2d 775, 781 (R.I. 1988) ("Although both approaches have merit, we believe the societal interest in ensuring the development and marketing of prescription drugs will be adequately served by extending comment-k protection to prescription drugs on a case-by-case basis.").

³⁸ 813 P.2d 89 (Utah 1991).

³⁹ See *id.* at 95 ("[W]e need not be bound by the specific language of comment k and may adopt and apply its fundamental policy without restricting ourselves to what we perceive to be its literal interpretation.").

⁴⁰ See *id.*

⁴¹ *Id.*

⁴² See *id.* at 96–98.

⁴³ See *Brown v. Superior Court (Abbott Lab.)*, 751 P.2d 470, 483 n.12 (Cal. 1988).

⁴⁴ See *Grundberg*, 813 P.2d at 99. The court stated:

C. *Advantages and Disadvantages of the Two Approaches*

It is readily apparent that both the case-by-case and blanket immunity approaches each have advantages over the other. Each can be persuasively argued. The case-by-case approach is truer to the original rationale behind comment k—only those pharmaceutical products that have a significantly positive effect on public health should be protected from strict liability, not all prescription drugs per se. The case-by-case approach also allows an additional avenue of attack for the suffering patient, so that the cost of recovery may be borne by the manufacturer who can more easily spread the loss. The blanket immunity approach, on the other hand, allows for more consistent results, less litigation, and arguably better serves the policies of comment k. Because the courts disagree on which approach to adopt, pharmaceutical manufacturers currently face different design defect liability standards depending on in which state the plaintiff files his or her claim. This inconsistency has led the ALI to reevaluate comment k. As a result, the ALI has proposed an entirely separate section in the Restatement (Third) of Torts devoted specifically to pharmaceutical liability, entitled “Liability of Seller or Other Distributor for Harm Caused by Defective Prescription Drugs and Medical Devices.”⁴⁵

To determine whether a drug’s benefit outweighs its risk is inherently complex because of the manufacturer’s conscious design choices regarding the numerous chemical properties of the product and their relationship to the vast physiologic idiosyncracies of each consumer for whom the drug is designed. Society has recognized this complexity and in response has reposed regulatory authority in the FDA. Relying on the FDA’s screening and surveillance standards enables courts to find liability under circumstances of inadequate warning, mismanufacture, improper marketing, or misinforming the FDA—avenues for which the courts are better suited. Although this approach denies plaintiffs one potential theory on which to rely in a drug products liability action, the benefits to society in promoting the development, availability, and reasonable prices of drugs justifies this conclusion.

Id. Furthermore, the court was swayed by the technical expertise of the FDA:

Although the FDA may have internal differences of opinion regarding whether a particular new drug application should be approved, the individuals making the ultimate judgment will have the benefit of years of experience in reviewing such products, scientific expertise in the area, and access to the volumes of data they can compel the manufacturer to produce. Nor is the FDA subject to the inherent limitations of the trial process, such as the rules of evidence, restrictions on expert testimony, and scheduling demands.

Id. at 98.

⁴⁵ RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (Proposed Final Draft

III. THE ALI'S NEW PROPOSAL

A. *A Rule Closely Resembling Blanket Immunity*

The split in the states over pharmaceutical design defect liability has prompted the ALI to include a separate section in the proposed Restatement (Third) of Torts specifically governing the liability faced by sellers and distributors of prescription drugs and medical devices.⁴⁶ The ALI⁴⁷ has taken a “clean slate” approach to the problem of pharmaceutical design defect liability. The design defect liability section of the proposed Restatement, however, is not a “restatement” of the current law practiced in most jurisdictions.⁴⁸

The relevant language of the proposed Restatement (dealing with design defect liability) provides:

(a) A manufacturer of a prescription drug or medical device who sells or otherwise distributes a defective drug or medical device is subject to liability for harm to persons caused by the defect. A prescription drug or medical device is one that may be legally sold or otherwise distributed only pursuant to a health care provider's prescription.

(b) For purposes of liability under Subsection (a), a prescription drug or medical device is defective if at the time of sale or other distribution the drug or medical device: . . .

(2) is not reasonably safe due to defective design as defined in Subsection (c)

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

1997).

⁴⁶ *See id.*

⁴⁷ The drafters of the section on prescription drug and medical device product liability in the proposed Restatement are James A. Henderson and Aaron D. Twerski, who two years earlier co-authored an article proposing a revision to comment k. *See Henderson & Twerski, supra* note 21.

⁴⁸ The drafters specifically stated:

[T]his is not an area in which we can satisfy ourselves with a restatement of the case law. Case law that is unintelligible cannot be intelligibly restated. There is a need in this area to clarify the issues and to provide direction to the courts as to how this very special genre of cases can be sensibly approached.

Id. at 1545.

*class of patients.*⁴⁹

Two general observations about this Proposed Final Draft become immediately apparent. First, this proposal combines the claims of strict liability and negligence. The drafters intended that the proposal apply to any suit alleging a prescription drug or medical device was defectively designed, whether involving a strict liability or negligence claim.⁵⁰ The reason for this change is the general belief that comment k's balancing of risks and benefits is similar to the "reasonableness" test involved in a negligence claim.⁵¹

⁴⁹ RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (Proposed Final Draft 1997) (emphasis added). Subsections (d) and (e), respectively concerning failure-to-warn and manufacturing defect liability, are of little concern to this discussion and are therefore omitted.

⁵⁰ The elimination of the negligence claim has drawn much criticism. See, e.g., Richard L. Cupp, Jr., *Rethinking Conscious Design Liability for Prescription Drugs: The Restatement (Third) Standard Versus a Negligence Approach*, 63 GEO. WASH. L. REV. 76, 76 (1994) (arguing that, contrary to the beliefs of the Proposed Final Draft composers, there are practical differences between negligence and strict liability standards in conscious design cases due to the different psychological impact of labeling an action as one in strict liability or negligence, the role of comparative negligence, and the availability of multiple defendants in strict liability design claims); Angela C. Rushton, Comment, *Design Defects Under the Restatement (Third) of Torts: A Reassessment of Strict Liability and the Goals of a Functional Approach*, 45 EMORY L.J. 389, 428-30 (1996) (arguing that the courts have invariably noted that when comment k is applied to preclude recovery under strict liability, the plaintiff may still bring a case in negligence) (citing *Stone v. Smith, Kline & French Lab.*, 447 So. 2d 1301, 1303 (Ala. 1984); *Brown v. Superior Court (Abbott Lab.)*, 751 P.2d 470, 483 (Cal. 1988); *Kearl v. Lederle Lab.*, 218 Cal. Rptr. 453, 454 (Cal. Ct. App. 1985), *overruled by Brown*; *Johnson v. American Cyanamid Co.*, 718 P.2d 1318, 1323-24 (Kan. 1986); *Feldman v. Lederle Lab.*, 479 A.2d 374, 381 (N.J. 1984)).

⁵¹ See *Brown*, 751 P.2d at 475 ("Comment k has been analyzed and criticized by numerous commentators. While there is some disagreement as to its scope and meaning, there is a general consensus that, although it purports to explain the strict liability doctrine, in fact the principle it states is based on negligence."); *Toner v. Lederle Lab.*, A Div. of Am. Cyanamid Co., 732 P.2d 297, 310 (Idaho 1987) ("As the Restatement notes, for an act to be unreasonable and thus a breach of duty under negligence analysis, the risk must be 'of such magnitude as to outweigh what the law regards as the utility of the act or of the particular manner in which it is done.'") (quoting RESTATEMENT (SECOND) OF TORTS § 291 (1965)); *Brizendine v. Nampa Meridian Irrigation Dist.*, 548 P.2d 80, 86 (Idaho 1976) ("[I]n negligence cases, the duty is always the same, to conform to the legal standard of reasonable conduct in the light of apparent risk."); see also *Henderson & Twerski*, *supra* note 21, at 1544.

To discover whether a comment k exemption from strict liability is appropriate, [courts] undertake risk-utility balancing, insisting that this balancing process be performed as of the time when the drug was distributed. This is nothing other than a negligence test. If a

Second, while at first glance the proposal may seem to mirror the case-by-case approach followed in a majority of jurisdictions, a closer analysis reveals that the drafters swayed widely from that approach. Under the proposal, design defect liability will be precluded unless “[t]he foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its therapeutic benefits that reasonable healthcare providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for *any class of patients*.”⁵² Therefore, as long as the drug passes a reasonable medical provider’s risk-benefit test for any class of patients, no one can successfully sue on a design defect claim. This test differs significantly from the case-by-case approach discussed above. The proposed Restatement apparently abandons an overall analysis of whether the drug’s risks outweigh its benefits in relation to *all potential patients* in favor of a test that focuses on a narrower class of patients. Under the ALI proposal, if the drug has therapeutic benefits that outweigh the dangers for *any class* of patients, the risk-benefit test is passed. Effectively, this precludes liability on a design defect claim, as it would be nearly impossible to find a drug approved by the FDA which cannot pass the risk-benefit test for at least one potential class of patients.⁵³

While the proposed Restatement does not actually embrace the minority blanket immunity approach, the drafters seem persuaded by many of the same policy factors that impressed the *Brown* and *Grundberg* courts:⁵⁴

Courts have also recognized that the regulatory system governing prescription drugs is a legitimate mechanism for setting the standards for drug design.⁵⁵ In

court finds that the product meets the threshold test for strict liability exemption, it has perforce made a finding that the defendant was not negligent. How then can the courts declare that the exemption is only for strict liability?

Id.

⁵² RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c) (Proposed Final Draft 1997) (emphasis added).

⁵³ This change was not lost on the drafters. The drafters flatly admit: “Given this very demanding objective standard, liability is likely to be imposed only under unusual circumstances.” RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 cmt. f (Proposed Final Draft 1997); see also Teresa Moran Schwartz, *Prescription Products and the Proposed Restatement (Third)*, 61 TENN. L. REV. 1357, 1383–84 (1994).

⁵⁴ See *supra* Part II.B (discussing the blanket immunity approach taken by *Brown v. Superior Court (Abbott Laboratories)*, 751 P.2d 470 (Cal. 1988) and *Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991)).

⁵⁵ Note the similarity of this rationale to that of the decision in *Grundberg*, 813 P.2d at 97 (“We find this extensive regulatory scheme capable of and appropriate for making the preliminary determination regarding whether a prescription drug’s benefits outweigh its risks.”).

part, this deference reflects concerns over the possible negative effects of judicially imposed liability on the cost and availability of valuable medical technology. This deference also rests on two further assumptions: first, that prescribing health care providers, when adequately informed by drug manufacturers, are able to assure that the right drugs and medical devices reach the right patients; and second, that governmental regulatory agencies adequately review new prescription drugs and devices, keeping unreasonably dangerous designs off the market.⁵⁶

The Reporters' notes accompanying the proposed Restatement further explain the reasoning behind Section 6:

The proposed rule in Section 6(c) [concerning design defect liability] best advances the policies and values explicated in Comment *b*. It shows appropriate deference to the regulated market, where the FDA and learned intermediaries select which drugs should be available to the public generally and which drugs should be given to individual patients, respectively. It does not, on the other hand, wholly exempt defendants from liability simply because other institutions have taken steps to improve product safety.⁵⁷

⁵⁶ RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 cmt. b (Proposed Final Draft 1997). The drafters obviously have overstated their position here. While they recognize that a growing number of courts have determined that unqualified deference to these regulatory mechanisms is unjustified, their comments do not recognize that this view is in fact the majority approach.

⁵⁷ *Id.* § 6 cmt. f (Reporters' Note). The drafters included this last sentence in an attempt to differentiate their approach from the blanket immunity approach best reflected by *Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991). The *Grundberg* court held that all prescription drugs approved by the FDA are protected against strict liability design defect claims. *See id.* at 90. The drafters included a hypothetical problem of a prescription drug which still could be the subject of a successful design defect claim:

ABC Pharmaceuticals manufactures and distributes D, a prescription drug intended to prolong pregnancy and thus to reduce the risks associated with premature birth. Patricia, six months pregnant with a history of irregular heart beats, was given D during a hospital stay. As a result, she suffered heart failure and required open heart surgery. In Patricia's action against ABC, her expert testified that, notwithstanding FDA approval of D, the drug did not prolong pregnancy for any class of patients and posed serious risks of heart failure in patients with a history of irregular heart beats. Notwithstanding a finding by the trier of fact that ABC gave adequate warnings to the prescribing physician, the trier of fact can find that reasonably informed healthcare providers would not prescribe D for any class of patients, thus rendering ABC subject to liability.

RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 cmt. f, illus. 1 (Proposed Final Draft 1997).

B. *A Useless Loophole?*

After reading the proposed Restatement provisions, one must ask: If no reasonable and informed medical provider would prescribe the drug to *any class* of patients at some point in time, how was the drug approved by the FDA in the first place? By refusing to recognize the grand improbability of such a scenario, the drafters in effect created an escape hatch designed to appease those opposing full deference to the FDA. This escape hatch seems only to defeat the original purpose of the proposal—to provide consistency among the courts and to reduce litigation costs. Plaintiffs will still find it plausible to introduce the testimony of expert witnesses claiming that no reasonable, informed doctor would prescribe the drug, while defendants will be forced to introduce experts to counter such evidence. In essence, we are back to where we started. Once again, the plaintiff will provide his or her experts, claiming that no “reasonable” physician would have prescribed this drug to any patient—no “reasonable” physician would have prescribed the product because its risks are simply too high. Once again, the judge or jury is asked to perform a risk-balancing test, albeit more limited in scope. The jury (or the judge on a motion for summary judgment) will listen to both sides and decide if, in fact, a reasonable medical doctor would prescribe the drug. While the proposed Restatement favors manufacturers in that the drug must only pass the risk-benefit test for one class of patients, rather than the general public at large, it also provides a useless loophole that would rarely, if ever, succeed. It simply increases litigation (most probably initiated to procure settlement) and generally defeats the manifest purpose of the proposal.

C. *Expanding the Blanket Immunity Approach*

It seems apparent that the ALI’s position closely follows the blanket immunity approach taken by a minority of courts.⁵⁸ The drafters flatly state that the approach taken by the Restatement (Third) of Torts would make successful claims of design defects rare.⁵⁹ This position stands in stark contrast to the case-by-case approach used by a majority of courts,⁶⁰ which stresses the value of the tort system in reviewing design defects even in the area of pharmaceuticals.⁶¹

⁵⁸ See *supra* Part II.B (discussing the blanket immunity against design defect claims granted to pharmaceutical manufacturers by some courts).

⁵⁹ See *supra* note 53.

⁶⁰ See *supra* Part II.A (discussing the case-by-case approach).

⁶¹ See, e.g., *Toner v. Lederle Lab., A Div. of Am. Cyanamid Co.*, 732 P.2d 297, 313 (Idaho 1987) (Huntley, J., concurring) (“I fear the day when any supreme court can be convinced that an agency such as the FDA, no matter how well-intentioned, can supplant the

Furthermore, the drafters' rationale for limiting the liability for design defects of pharmaceuticals almost mirrors the rationale of the *Brown* and *Grundberg* courts, which adopted a blanket immunity approach.⁶² In fact, the ALI approach seems more pro-manufacturer in numerous ways than even the blanket immunity approach.

One predominant difference between the ALI proposal and the blanket immunity approach is the inclusion of medical devices under what, while not "blanket immunity," still seems a very pro-manufacturer test for design defect liability. All of the cases utilizing the blanket immunity approach have done so while considering prescription drugs or vaccines, not medical devices.⁶³ This is an important distinction, in that one important underlying rationale for adopting the blanket immunity approach is that the FDA is the proper forum for making the determination that a prescription drug's benefits outweigh its risks. Inherent in that assertion is the courts' reliance on the extensive regulatory screening and post-approval process required by the FDA.⁶⁴ As noted earlier, this extensiveness, in a large measure, does not apply to medical devices.⁶⁵ Furthermore, the courts have often noted that the chemical complexity involved in prescription drug design defect cases makes it difficult, if not impossible, for a jury to competently make a determination as to the true benefits and risks posed by the drug.⁶⁶ This factor, again, is not necessarily applicable to medical devices as the jury may have an easier time understanding the risks and benefits posed by these products because they are more mechanical, rather than chemical, in nature. Therefore, the persuasiveness of the ALI approach must be analyzed separately for prescription drugs and medical devices because the persuasiveness of the blanket immunity approach depends on which category is being considered. While I believe the ALI approach to prescription drug design

American judicial system."); *Allison v. Merck & Co.*, 878 P.2d 948, 954 (Nev. 1994) ("It is not easy to divine just why the framers of the comment [k] thought that a drug manufacturer should be excused in cases in which it manufactured a drug that was 'known' to be dangerous. The whole idea behind strict tort liability is that the manufacturer, not the consumer, should bear the responsibility for injuries . . ."); see also *Cupp*, *supra* note 50, at 76, 105-10.

⁶² See *supra* Part II.B; *supra* text accompanying note 54.

⁶³ See *In re Eli Lilly & Co., Prozac Prods. Liab. Litig.*, 789 F. Supp. 1448 (S.D. Ind. 1992) (involving prescription drug Prozac, an anti-depressant drug); *Brown v. Superior Court (Abbott Lab.)*, 751 P.2d 470 (Cal. 1988) (considering prescription drug diethylstilbestrol, used to prevent miscarriages); *Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991) (involving prescription drug Halcion, used to treat insomnia); *Young v. Key Pharm., Inc.*, 922 P.2d 59 (Wash. 1996) (considering prescription drug theophylline, used to treat asthma).

⁶⁴ See, e.g., *supra* note 44.

⁶⁵ See *supra* notes 18-20 and accompanying text.

⁶⁶ See *supra* note 44.

defect liability deserves support, I find the almost-blanket immunity approach for medical devices seriously lacking in rationale and case support.⁶⁷

Even if the Proposed Final Draft of the Restatement is adopted, two opposing models will likely continue to govern the issue of prescription drug design defect liability. One school of thought, represented by, *inter alia*, the *Brown* and *Grundberg* courts and the proposed Restatement (Third) of Torts, posits that the court system is not the appropriate forum to review the benefits and risks of prescription drugs because that responsibility has already been delegated and is being performed (while not perfectly, but relatively) effectively by the FDA. A second approach, advocated by a majority of this nation's courts as well as numerous commentators, concludes that not all prescription drugs should be given protection from design defect liability, essentially due to the value of the tort system in indirectly regulating the pharmaceutical industry and the inability of the FDA to adequately protect consumers.

IV. THE FDA REGULATORY SCHEME

Those advocating the blanket immunity approach to prescription drug design defect liability (or approaches substantially identical, such as the proposed Restatement), find compelling support for this approach in the fact that the FDA already makes the determination of whether or not a drug's benefits justify its risks. This is not to say that the FDA is perfect,⁶⁸ but rather, compared to judges and juries, the FDA is comprised of individuals with significant expertise having access to the best available knowledge about the particular drug in question. Therefore, the FDA necessarily makes a more informed determination on whether a prescription drug is defectively designed. To properly assess the persuasiveness of the blanket immunity approach, some familiarity with the FDA regulatory scheme, both its pre-approval and post-approval processes, is necessary.⁶⁹

⁶⁷ As noted above, it is impossible to do justice to the topic of design defects by analyzing prescription drugs and medical devices simultaneously. The policy rationales simply do not co-exist. *See supra* notes 18–20 and accompanying text.

⁶⁸ Such an argument would be foolish. A laundry list of FDA miscues can be readily introduced. *See, e.g.*, *Singer v. Sterling Drug, Inc.*, 461 F.2d 288, 290–91 (7th Cir. 1972) (noting that FDA approved drug Aralen proven to cause blindness); *Feldman v. Lederle Lab.*, 479 A.2d 374, 385 (N.J. 1984) (stating that studies showed tetracycline stained teeth well in advance of FDA action to require warnings); *Cudmore v. Richardson-Merrell, Inc.*, 398 S.W.2d 640, 644 (Tex. Civ. App. 1965) (noting that FDA certified drug MER-29 proven to cause cataracts). For an excellent discussion of the limitations of the FDA, see Schwartz, *supra* note 53, at 1385–90 (discussing fiscal and legal limitations, how politics influence safety, and manpower shortages).

⁶⁹ On November 11, 1997 President Clinton signed the Food and Drug

A. The General FDA Regulatory Scheme

A pharmaceutical company seeking to receive FDA approval for a prescription drug it desires to market must first file an investigational new drug application with the agency. This application requires the pharmaceutical company to provide information on the drug's chemistry, pharmacology, and toxicology, as well as the results of any animal and laboratory testing.⁷⁰ This application must be filed, and approved by the FDA, before human trials on the drug can commence.⁷¹

The human clinical trial process consists of three phases. Phase I involves testing on only a small number of healthy adults and is designed to provide information concerning "the metabolism and pharmacologic actions of the drug in humans, [and] the side effects associated with increasing doses."⁷² Upon the successful completion of Phase I, Phase II commences. This phase is broader in scope and usually involves trials with two hundred to three hundred people afflicted with the disease or illness the drug is designed to treat. The purpose of Phase II is "to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study," and any resulting side effects.⁷³ Successful Phase II completion leads to Phase III testing, which involves a much larger sample of one thousand to three thousand patients afflicted with the disease or illness.⁷⁴ As Phase III testing reaches its

Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296. While some consumer groups have claimed that the Act will adversely affect consumers, see *Green Light for Streamlined Drug Approvals*, CHEMICAL MARKET REP., Oct. 13, 1997, at 7, 18, the Act will have little effect on the FDA regulatory approval process discussed in this Comment. The legislation does more to "speed-up" rather than "streamline" the approval process for ordinary prescription drugs. The Act accomplishes this by authorizing the employment of 600 new reviewers by the FDA—reviewers paid for by pharmaceutical companies. The Pharmaceutical Research and Manufacturers of America has estimated that the \$327 million collected from the pharmaceutical industry since 1992 has cut the average review time for the FDA nearly in half. See *Thoroughly Modern*, Med Ad News, Jan. 1, 1998, available in 1998 WL 10478901. The Act will, however, allow certain drugs to obtain approval through the use of an independent testing firm rather than the FDA. Nonetheless, the FDA will continue to be responsible for the approval of drugs thought to be closer determinations. The Act also allows the FDA to grant conditional approval to certain drugs used to treat life-threatening or serious conditions.

⁷⁰ See 21 C.F.R. § 312 (1997).

⁷¹ See generally David A. Kessler, *The Regulation of Investigational Drugs*, 320 NEW ENG. J. MED. 281 (1989) (reviewing FDA regulation of investigational drugs).

⁷² 21 C.F.R. § 312.21(a) (1997).

⁷³ *Id.* § 312.21(b).

⁷⁴ See *id.* § 312.21(c).

conclusion, the pharmaceutical company often submits to the FDA a New Drug Application (NDA) for the drug. This NDA is a compilation of all available data on the drug's efficacy and safety.⁷⁵

The FDA review process of a new drug often takes years⁷⁶ after the FDA receives the NDA.⁷⁷ Furthermore, the FDA review process is expensive: a 1987 estimate placed the cost of the NDA review process at \$231 million.⁷⁸ The ultimate approval by the FDA reflects a risk-benefit judgment that the product will enhance public health.⁷⁹

The FDA's involvement with a drug does not end once approval is granted. The drug's manufacturer is required to share all subsequently observed risk information with the FDA.⁸⁰ A comprehensive, post-marketing system of reporting and record-keeping requires that the manufacturer report adverse side effects discovered in clinical, epidemiological, or surveillance studies, through review of the medical literature, or otherwise.⁸¹

⁷⁵ See *id.* § 314.50 (describing the specific requirements of a New Drug Application). A New Drug Application must include:

- (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether the drug is effective in use;
- (B) a full list of the articles used as components of such drug;
- (C) a full statement of the composition of such drug;
- (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;
- (E) such samples of such drug and the articles used as components thereof as the Secretary may require; and,
- (F) specimens of the labeling proposed to be used for such drug.

21 U.S.C. § 355(b)(1) (1994).

⁷⁶ The process typically takes five to seven years. See Mary T. Griffin, *AIDS Drugs & the Pharmaceutical Industry: A Need for Reform*, 17 AM. J.L. & MED. 363, 378 n.90 (1991) (citing Gordon, *The Drug Development and Approval Process*, in PHARMACEUTICAL MFRS. ASS'N, NEW MEDICINES IN REVIEW 5 (1990)).

⁷⁷ See W. Kip Viscusi et al., *Detering Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1444 (1994); see also Kessler, *supra* note 71, at 283 ("A study of 637 NDAs received since 1981 found that the FDA returned two thirds to the sponsor with requests for more information.").

⁷⁸ See Viscusi et al., *supra* note 77, at 1444 n.30.

⁷⁹ See Richard A. Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 10 (1973); Viscusi et al., *supra* note 77, at 1444 (quoting Bruce N. Kuhlik & Richard F. Kingham, *The Adverse Effects of Standardless Punitive Damage Awards on Pharmaceutical Developments and Availability*, 45 FOOD DRUG COSM. L.J. 693, 695 (1990)).

⁸⁰ See 21 C.F.R. § 314.80 (1997).

⁸¹ See *id.* §§ 310.303(a), 314.80(c); see also Viscusi et al., *supra* note 77, at 1447 n.46.

B. The FDA Scheme in Action

Tetramune, a childhood vaccine developed and marketed by Lederle Laboratories which protects against diphtheria, tetanus, pertussis, and *Haemophilus b*, provides an illustration of how the FDA scheme really works. Tetramune is a good case study for two reasons. First, the vaccine was approved in 1992, so the regulatory action taken with respect to the vaccine is indicative of contemporary regulation in this area. Second, while Lederle Laboratories has not yet been subject to product liability over Tetramune, a main component of the Tetramune vaccine is Tri-Immunol⁸² (the diphtheria, tetanus, and pertussis—DPT—portion of the combined vaccine), a vaccine that has spawned much litigation.⁸³

When the FDA approves a drug or vaccine, the agency prepares a

⁸² Tri-Immunol was the only combined diphtheria, tetanus, and pertussis (“DPT”) vaccine on the United States market for nearly two decades. Tri-Immunol is a so-called whole cell vaccine because it contains whole killed pertussis organisms. During the 1950s Eli Lilly Company developed a fractionated version of the pertussis vaccine called Tri-Solgen that was developed in the hope that it would reduce the adverse effects of the whole cell version. Eli Lilly exited the vaccine market, however, and the FDA never relicensed the fractionated version, the rights of which were sold to Wyeth Laboratories. In early 1997, however, Lederle Laboratories received FDA approval for its version of the fractionated vaccine. See *Toner v. Lederle Lab., A Div. of Am. Cyanamid Co.*, 732 P.2d 297, 300–01 (Idaho 1987). The moral of the story is that at the time Tri-Immunol was used by the claimants in litigation involving the vaccine, it was the only DPT vaccine approved by the FDA.

⁸³ See, e.g., *Abbot v. American Cyanamid Co.*, 844 F.2d 1108 (4th Cir. 1988); *Pease v. American Cyanamid Co.*, 795 F. Supp. 755 (D. Md. 1992); *Jones v. Lederle Lab., A Div. of Am. Cyanamid Co.*, 785 F. Supp. 1123 (E.D.N.Y.), *aff’d per curiam*, 982 F.2d 63 (2d Cir. 1992); *Toner v. Lederle Lab., A Div. of Am. Cyanamid Co.*, 732 P.2d 297 (Idaho 1987). Another compelling reason for focusing on the DPT vaccine is that it illustrates one of the case-by-case approach’s greatest downfalls—inconsistency. In *Toner*, the Idaho Supreme Court was asked to decide whether or not Tri-Immunol should be afforded comment k protection from a design defect claim. The jury had awarded the plaintiff \$1,131,200. The Idaho Supreme Court refused to make the determination that Tri-Immunol was precluded from a design defect claim. Instead, it deferred to the trial court’s determination that the vaccine’s risks outweighed its benefits. See *Toner*, 732 P.2d at 299, 308–09. In *Pease*, by contrast, the district court judge refused to allow the plaintiff to recover on a design defect claim:

Briefly put, how can Tri-Immunol be said to be “*unreasonably dangerous*” if there is a strong consensus among the majority of physicians and scientists who have studied the issue that whole cell DPT vaccine has not been shown to cause permanent neurological damage and that it is at least as efficacious as any other available vaccine?

Pease, 795 F. Supp. at 758.

“Summary Basis of Approval,” which outlines, among other things, the studies that have been made of the product and a discussion of the product’s benefits.⁸⁴ A cursory look at the Summary Basis of Approval for Tetramune provides insights into the degree of testing the FDA requires of a drug or vaccine manufacturer. The safety of Tetramune was tested in a study involving 6497 infants in California who received three injections at approximately two, four, and six months of age.⁸⁵ The test examined 1347 of the 6497 infants to determine if there were differences in systemic reactions between those infants receiving Tetramune and those receiving separate shots of Tri-Immunol and HbOC (HibTITER) (separate *Haemophilus b* vaccine).⁸⁶ A second study of Tetramune’s safety analyzed a randomized enrollment of 378 infants at five clinical centers who received the Tetramune vaccine to see if any systemic and acute local adverse effects occurred within seventy-two hours of injection.⁸⁷ A similar study was conducted on toddlers who were given Tetramune.⁸⁸ In addition to these studies, Lederle Laboratories has agreed to conduct post-approval studies to help insure that any suspect discrepancies between infants receiving Tetramune and Tri-Immunol were mere chance.⁸⁹

The Summary Basis of Approval for Tetramune also discusses the benefits that the original DPT vaccines, including Tri-Immunol, have had on public health. It noted that in 1921, before the general use of a diphtheria vaccine, over 200,000 cases of diphtheria were reported. Only fifteen cases of the disease were reported between 1980 and 1983.⁹⁰ Similarly, the “incidence of tetanus in the United States has dropped dramatically with the routine use of tetanus toxoid.”⁹¹ Finally, the danger of pertussis, a highly communicable disease with an attack rate in unimmunized households of over ninety percent, has diminished dramatically. In 1950, pertussis accounted for 120,000 cases and 1100 deaths. In recent years, an average of 3500 cases appear annually, claiming approximately ten lives each year.⁹² Due to this marked improvement, it is not difficult to understand how the FDA made the determination that the vaccine’s benefits to public health outweighed its risks. It is, however, difficult

⁸⁴ These documents are available from the FDA via the Freedom of Information Act. See 5 U.S.C. § 552 (1994).

⁸⁵ See DEPARTMENT OF HEALTH AND HUMAN SERVS., REF. NO. 92-0003, SUMMARY BASIS OF APPROVAL—TETRAMUNE 7 (1992).

⁸⁶ See *id.*

⁸⁷ See *id.* at 11.

⁸⁸ See *id.* at 13.

⁸⁹ See *id.* at 10.

⁹⁰ See *id.* at 5.

⁹¹ *Id.* at 6.

⁹² See *id.*

to imagine how a court could hold Lederle responsible under a strict liability theory claiming that Tri-Immunol was an unreasonably dangerous product when it was the only vaccine for these diseases on the market at that time.⁹³

The inconsistent results of DPT litigation⁹⁴ highlight the concerns voiced by adherents to the "blanket immunity" approach. An analysis of jury verdicts in DPT cases illustrates the contention asserted by the *Grundberg* court that juries are not the appropriate forum to make design defect determinations.⁹⁵ Consider the following inconsistencies from cases all considering the same issue—whether a pharmaceutical manufacturer should be held liable for defectively designing the same DPT vaccine and the damages (if any) imposed upon the manufacturer: (1) a jury in Kansas returned a \$15 million verdict in favor of a plaintiff who suffered permanent brain damage;⁹⁶ (2) a jury in Ohio returned a \$2.1 million verdict in favor of a plaintiff who suffered permanent brain damage;⁹⁷ (3) juries returned defense verdicts (no award) in Louisiana,⁹⁸ California,⁹⁹ and Florida.¹⁰⁰

V. THE NEED FOR LEGISLATIVE INVOLVEMENT

A. A Plea for National Guidance

Whether all prescription drugs should be insulated from design defect liability is, undeniably, a policy question.¹⁰¹ Some claim that the FDA cannot

⁹³ See *Toner v. Lederle Lab., A Div. of Am. Cyanamid Co.*, 732 P.2d 297, 312–13 (Idaho 1987).

⁹⁴ See *supra* note 83.

⁹⁵ See *supra* note 44 and accompanying text.

⁹⁶ See *Graham v. Wyeth Lab., Inc.*, No. 85-1481P (D. Kan. 1987) (LEXIS, Verdict Library, Allver File).

⁹⁷ See *White v. Wyatt Lab., Inc.*, No. 712-20 (Ohio Ct. C.P. 1986) (LEXIS, Verdict Library, Allver File).

⁹⁸ See *Caruso v. Lawrence*, No. 77913 A, 1992 WL 677859 (La. Dist. Ct. St. Tammany County 1992) (plaintiff suffered severe mental deficiency).

⁹⁹ See *Bovey v. Parke, Davis & Co.*, No. 84993 (Cal. Super. Ct. Solano County 1988) (LEXIS, Verdict Library, Allver File) (plaintiff suffered severe brain damage); *Coppo v. Connaught Lab.*, No. V08479 (Cal. Super. Ct. Contra Costa County 1987) (LEXIS, Verdict Library, Allver File) (plaintiff suffered brain damage).

¹⁰⁰ See *Knudsen v. Connaught Lab.*, No. 85-703-Civ-J-16 (M.D. Fla. 1987) (LEXIS, Verdict Library, Allver File) (plaintiff died); *Zofay v. Lederle Lab., A Div. of Am. Cyanamid Co.*, No. 85-3021 CA (L) I (Fla. Palm Beach County Ct. 1988) (LEXIS, Verdict Library, Allver File) (plaintiff rendered incompetent).

¹⁰¹ The Supreme Court recently decided that, absent clear congressional language to the contrary, compliance with national food and drug laws will not pre-empt state tort law

adequately determine if the risks of a prescription drug outweigh its benefits, therefore, and since it is impossible to determine how safe a product really is, the risk of the drug's dangers should rest with the manufacturer, who stands to benefit financially from the prescription drug's sale.¹⁰² These critics advocate that a strong tort system is needed to help insure the safety of prescription drugs, primarily because the current regulatory system is under-staffed and under-funded.

On the other hand, advocates for design defect immunity counter with competing policy considerations. The cost of pharmaceuticals is already too high in the United States,¹⁰³ in large part because of the litigation¹⁰⁴ and liability costs drug manufacturers must bear.¹⁰⁵ Furthermore, they argue, the availability of drugs may be severely curtailed if drug companies are subject to design defect liability. Moreover, design defect liability in this field forces the court or jury to make determinations about a drug's risks and benefits that it is simply ill-equipped to make. That determination is already made by the FDA, a more appropriate and informed forum for such balancing. Finally, fundamental fairness dictates that a pharmaceutical company should not be sued on the design of its drug when the FDA has already approved it.

Criticism of courts advocating a case-by-case approach cannot rest in finding fault with the way in which they have "interpreted" the law. There is,

remedies. *See Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2250 (1996).

¹⁰² *See, e.g., Schwartz, supra* note 53, at 1386-95. The pharmaceutical industry enjoys the "highest return on sales, the highest return on assets, and the highest return on stockholder equity of any industrial group in the Fortune 500." *Do We Pay Too Much for Prescriptions?*, 58 CONSUMER REP. 668, 669 (1993).

¹⁰³ Consumers in the United States pay 62% more for prescription drugs than Canadians and 54% more than Europeans. *See Schwartz, supra* note 53, at 1400 n.279 (citing STAFF OF SENATE SPECIAL COMM. ON AGING, 102D CONG., 1ST SESS., THE DRUG MANUFACTURING INDUSTRY: A PRESCRIPTION FOR PROFITS 7 (Comm. Print 1991)).

¹⁰⁴ Some commentators have noted that total litigation costs have exceeded total plaintiff recoveries in the area of prescription drug design liability. *See Viscusi et al., supra* note 77, at 1461.

¹⁰⁵ The effect of litigation and liability costs on pharmaceutical companies has been difficult to measure, mostly because of the difficulties in acquiring such information from pharmaceutical manufacturers. For an excellent discussion on this point, see Schwartz, *supra* note 53, at 1398-405 (citing OFFICE OF TECHNOLOGY ASSESSMENT, PHARMACEUTICAL R&D: COSTS, RISK, AND REWARDS 170 (1993) (concluding that the cost implications caused by product liability law in the pharmaceutical industry are difficult to discern due to the lack of information released by the industry); STEVEN GARBER, PRODUCT LIABILITY AND THE ECONOMICS OF PHARMACEUTICALS AND MEDICAL DEVICES xxv (1993) (concluding that critical information concerning research and development activities provided to regulators has not been made available to the public)).

in fact, little law on the subject, except for judge-made common law.¹⁰⁶ National legislation on the issue of pharmaceutical design defect liability is long overdue. Congress has the authority to regulate in this field and can pre-empt state tort law under its broad Commerce Clause powers. For example, Congress continues to consider bills that would cap punitive damages in all product liability actions in state and federal courts to two times the sum of plaintiff's economic and noneconomic losses, or \$250,000, whichever is greater.¹⁰⁷ The field of drugs is already regulated nationally. In fact, while the federal food and drug laws do not purport to pre-empt state law remedies, they clearly establish that no state can force drug manufacturers to meet additional requirements before their products can be sold in a particular state.¹⁰⁸ While state legislative determinations on design defect liability might be an improvement over the current situation, in that the policy question is answered democratically, it seems counterproductive and fundamentally unfair for claimants to be treated differently depending on the state in which they happen to get injured. It makes little theoretical sense to allow a claimant to collect on a design defect claim involving the drug Halcion in Ohio, but not in Utah. This is not to say that states should not take the responsibility to protect the health of their citizens. Rather, it is time to recognize that prescription drugs and vaccines are a field for which the federal government has been given that responsibility.

¹⁰⁶ Courts which have considered the issue of design defect liability have relied on comment k, a policy instituted by unelected legal leaders without the force of law. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

¹⁰⁷ See S. 648, 105th Cong. § 108 (1997); S. 5, 105th Cong. § 108 (1997). Many states have precluded punitive damages in drug design defect cases when FDA approval was given for the drug and no fraud was involved. See ARIZ. REV. STAT. ANN. § 12-701 (West 1992); N.J. STAT. ANN. § 2A:58C-5(c) (West 1987 & Supp. 1997); OHIO REV. CODE ANN. § 2307.80(c) (Anderson 1995); OR. REV. STAT. § 30.927 (1992); UTAH CODE ANN. § 78-18-2 (1992).

¹⁰⁸ See 21 U.S.C. § 360k(a) (1994).

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device

Id. Pharmaceutical manufacturers have claimed that common-law tort actions create an additional "requirement" which violates this provision. This argument was finally put to rest by the Supreme Court in *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2258–59 (1996).

B. National Legislation Proposals

If national legislation were pursued, what would it look like? A number of possibilities are plausibly available. First, Congress could pass a statute establishing a rebuttal presumption that any prescription drug or vaccine which has received FDA approval, absent fraud, is not defectively designed. This presumption could be rebutted only by clear and convincing evidence that the drug's risks should have been known to far outweigh the drug's benefits. This strategy appropriately recognizes the work done by the FDA, while not totally precluding design defect review. A situation may arise in which the drug's approval was a close call within the FDA and that determination later leads to disastrous results. In such a case, policy considerations may tilt the balance toward allowing the injured party to sue. The main disadvantage of this approach is the uncertainty of its application. Would a rebuttable presumption really make much of a difference? Would an injured person still bring suit hoping to convince a sympathetic jury of her case?

Second, Congress could set up a separate body within the FDA to adjudicate claims involving design defects. If the agency determines that the plaintiff should have recourse against the manufacturer, a separate fund could be established.¹⁰⁹ This approach has the advantage of consistency and, more importantly, the risk-benefit determination is made by more qualified individuals.¹¹⁰ Such a scheme, however, may not pass constitutional muster. A plaintiff who wants to sue a pharmaceutical company has a right to a jury trial

¹⁰⁹ Congress pursued a similar strategy with the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (amended 1987, 1989, 1990, and 1991). This Act created an administrative "no-fault" program to compensate children injured by vaccines as an alternative to state tort remedies. Congress was able to avoid abrogating plaintiffs' Seventh Amendment right to a jury trial by providing that a plaintiff has the choice of bringing her action as usual through the courts or bringing it in front of a special master under the statute. See 42 U.S.C. § 300aa-16(c) (1994). The payments made under the statute are financed by a federal excise tax on vaccine sales. Plaintiffs pursuing a design defect claim regarding DPT now almost universally bring their action under the statute, even though damages are limited to \$250,000 plus economic damages. Use of the statute effectively has foreclosed the entire argument of whether or not comment k should apply to DPT. See generally *Abbot v. American Cyanamid Co.*, 844 F.2d 1108 (4th Cir. 1988).

¹¹⁰ In England, the Legal Aid Board has proposed a medical tribunal with a legal chairman to investigate drug injury claims. The proposal followed mass litigation, costing £35 million of legal fees, involving tranquilizers and sleeping pills whereby not a single claimant recovered. So far, no product liability claim against a drug company has succeeded in English courts. See Clare Dyer, *Plea to Simplify Drug Injury Cases*, THE GUARDIAN (U.K.), June 14, 1994, at 4. Almost all European countries recognize a policy similar to comment k. They refer to it as the "development risk defense." See David McIntosh, *Dangers in the Toy Box*, FINANCIAL TIMES (U.K.), Jan. 24, 1995, at 14.

that may be difficult to overcome.¹¹¹ The proposed suggestion may be able to survive constitutional attack, however, since prescription drugs are such a heavily regulated industry.¹¹²

Third, Congress could explicitly pre-empt state tort law design defect claims involving prescription drugs and vaccines that were given FDA approval, absent fraud. This approach has the advantage of clarity and best accomplishes the policy goal of drug availability and affordability.¹¹³ It also best accomplishes the goal of reducing frivolous litigation costs.

This third option, federal pre-emption of state law prescription drug design defect claims, is the wisest choice. It has the advantage of consistency in application and defers the risk-benefit determination to the FDA, a body better equipped to assess such a determination. Also, the elimination of the design defect claim does not leave the plaintiff without a remedy. The claimant can still sue on a failure-to-warn or a manufacturing defect claim, or on a fraud theory. Furthermore, if a mass tort involving a prescription drug does occur, injured

¹¹¹ See generally KENNETH CULP DAVIS & RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE § 2.8, at 90-102 (3d ed. 1994) (outlining Supreme Court jurisprudence concerning agency adjudication of "private rights").

¹¹² It could be argued that the proposed scheme is really no different than workers' compensation and OSHA adjudications, categories of disputes courts have held can be constitutionally adjudicated outside of an Article III court. See, e.g., *Atlas Roofing Co. v. Occupational Safety & Health Review Comm'n*, 430 U.S. 442, 449-61 (1977) (holding that the Seventh Amendment does not bar Congress from assigning OSHA adjudications to an administrative agency); *Crowell v. Benson*, 285 U.S. 22 (1932) (workers' compensation). Federal courts acquiesce in the congressional transfer of these disputes (among others) from their dockets to specialized administrative tribunals because courts are institutionally unable to effectively resolve them. In *Commodity Futures Trading Commission v. Schor*, 478 U.S. 833 (1986), the Court pronounced a pragmatic approach to determining whether an administrative agency may constitutionally resolve a class of disputes. The following passage indicates the pragmatism of that approach:

[W]ere we to hold that the Legislative Branch may not permit such limited cognizance of common law counterclaims at the election of the parties, it is clear that we would "defeat the obvious purpose of the Legislation to furnish a prompt, continuous, expert and inexpensive method for dealing with a class of questions of fact which are peculiarly suited to examination and determination by an administrative agency specially assigned to that task."

Id. at 856 (quoting *Crowell v. Benson*, 285 U.S. at 46). One could argue that in the complex area of prescription drugs, an administrative agency such as the FDA is the only governmental body with the expertise to effectively adjudicate prescription drug design defect disputes.

¹¹³ Such heavy reliance on the FDA may conflict with a desire to streamline the FDA approval process.

consumers are not automatically without remedy. A national fund could be established or pharmaceutical manufacturers may be forced to provide consumers relief, not because the law requires them to, but because sound marketing policy encourages it.

VI. CONCLUSION

The ALI's efforts in the pharmaceutical product liability field should be commended. Perhaps the most encouraging aspect of the ALI's efforts is the recognition that prescription products require separate treatment, as evidenced by the devotion of an entire section in the proposed Restatement (Third) of Torts concerning the liability of pharmaceutical manufacturers.

The most intriguing aspect of the protection accorded to prescription drug manufacturers is the shift in rationale for this separate treatment. In the 1960s, when comment k was introduced, the protection it provided to at least some prescription drugs and vaccines represented a policy decision made by courts to encourage and maintain drug development. The policy decision weighed the availability and affordability of prescription drugs and vaccines against the consumer's ability to redress injuries allegedly caused by a dangerous product. While the original policy rationale for according pharmaceutical products protection from product liability, and design defect liability in particular, certainly still exists, it has in large part been supplanted by concerns of fundamental fairness and propriety. Many courts, best represented by the Utah Supreme Court, now justify their decision to preclude plaintiff recovery by asserting that the legal system, through judges or juries, is not the appropriate forum in which to ponder the relative risks and benefits of prescription drugs. Unlike most other products, that decision is already specifically mandated to a federal governmental body. The reason for this shift in focus is two-fold. First, more attention has been focused on the inappropriateness of asking lay juries to decide complex scientific questions, especially if those questions are already answered by a body more equipped to do so.¹¹⁴ Second, the lack of empirical

¹¹⁴ See generally Joe S. Cecil et al., *Citizenship Comprehension of Difficult Issues: Lessons for Civil Jury Trials*, 40 AM. U. L. REV. 727 (1991); Steven I. Friedland, *The Competency and Responsibility of Jurors in Deciding Cases*, 85 NW. U. L. REV. 190 (1990); Michael S. Jacobs, *Testing the Assumptions Underlying the Debate About Scientific Evidence: A Closer Look at Juror "Incompetence" and Scientific "Objectivity"*, 25 CONN. L. REV. 1083 (1993); Jody Weisberg Menon, *Adversarial Medical and Scientific Testimony and Lay Jurors: A Proposal for Medical Malpractice Reform*, 21 AM. J.L. & MED. 281 (1995); Joseph Sanders, *Jury Deliberation in a Complex Case: Havner & Merrel Dow Pharmaceuticals*, JUST. SYS. J., 1993, at 45; William W. Schwarzer, *Reforming Jury Trials*, 132 F.R.D. 575 (1991); Rita Sutton, *A More Rational Approach to Complex Civil Litigation in the Federal Courts: The Special Jury*, 1990 U. CHI. LEGAL F. 575; Jay Tidmarsh, *Unattainable Justice:*

data supporting the original policy decision protecting pharmaceutical manufacturers, concerning the effect of product liability litigation on the affordability and development of new drugs, has required courts desiring to keep the protection to develop additional rationales for their decisions.

This shift in focus should eventually result in national legislation preempting all state tort law prescription drug design defect claims. While the 1960s policy rationale for protecting prescription drug and vaccine manufacturers from design defect claims continues to provide support, that support is insufficient in itself. The lack of empirical support for its assertions weakens its persuasiveness, especially in a day and age when decisionmakers place a premium on empirical data. Moreover, when courts claim policy reasons support their claim that pharmaceutical companies should be protected from design defect liability, they are necessarily confronted by opposing policy considerations asserting that the public is not "better off" with such a policy. These opposing arguments are strong. These considerations have shifted the focus of the inquiry, from which approach promotes public policy, to which approach is fundamentally fair. A drug design defect claim requires a detailed analysis of the drug's risks and benefits. That inquiry should be made by the individuals best equipped to make that decision. Since that decision is made at the national level, national legislation should be initiated to recognize this fact.

The Form of Complex Litigation and the Limits of Judicial Power, 60 GEO. WASH. L. REV. 1683 (1992); Joseph C. Wilkinson, Jr. et al., *A Bicentennial Transition: Modern Alternatives to Seventh Amendment Jury Trial in Complex Cases*, 37 U. KAN. L. REV. 61 (1988); Keith Broyles, Note, *Taking the Courtroom into the Classroom: A Proposal for Educating the Lay Juror in Complex Litigation Cases*, 64 GEO. WASH. L. REV. 714 (1996).

