No. 09-152

IN THE
# Supreme Court of the United States

RUSSELL BRUESEWITZ AND ROBALEE BRUESEWITZ,
PARENTS AND NATURAL GUARDIANS OF
HANNAH BRUESEWITZ, A MINOR CHILD,
AND IN THEIR OWN RIGHT,
*Petitioners*,
v.

WYETH, INC. F/K/A WYETH LABORATORIES,
WYETH-AYERST LABORATORIES, WYETH LEDERLE,
WYETH LEDERLE VACCINES, AND LEDERLE LABORATORIES,
*Respondent*.

**On Writ of Certiorari**
**to the United States Court of Appeals**
**for the Third Circuit**

## BRIEF OF MARK A. GEISTFELD AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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## INTEREST OF *AMICUS CURIAE*[1]

Mark A. Geistfeld is the Sheila Lubetsky Birnbaum Professor of Civil Litigation at New York University School of Law, where he has been a member of the fulltime faculty since 1991. His primary teaching areas are Insurance, Products Liability, and Torts. He has also taught Law and Economics.

Professor Geistfeld's research addresses the common-law rules governing the prevention of and compensation for physical harms. He has published dozens of articles on a broad range of products liability and tort doctrines. He is the author of two leading legal textbooks, TORT LAW: THE ESSENTIALS (Aspen Pub. 2008); PRINCIPLES OF PRODUCTS LIABILITY (Foundation Press 2006). Professor Geistfeld is also the author of a new casebook, PRODUCTS LIABILITY LAW (Aspen Pub. forthcoming 2011).

The instant case is of central interest to Professor Geistfeld insofar as it involves the interpretation of Restatement (Second) of Torts § 402A comment k (1965).

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[1] Pursuant to Supreme Court Rule 37.6, *amicus* represents that he authored this brief and that no person or entity other than *amicus* made a monetary contribution to the preparation or submission of the brief. *Amicus* represents that counsel for all parties have consented to the filing of this brief, and letters reflecting their blanket consent to the filing of *amicus* briefs have been filed with the Clerk.

## STATEMENT

In the case at issue, petitioners brought suit against respondent Wyeth, Inc., a manufacturer of a whole-cell diptheria-pertussis-tetanus (DPT) vaccine that allegedly caused petitioners' daughter to suffer seizures after receiving a dose of the vaccine. Respondent moved for summary judgment. The United States District Court for the Eastern District of Pennsylvania, Baylson, J., granted the motion. On appeal, the United States Court of Appeals, Third Circuit, Smith, J., affirmed, holding that the National Childhood Vaccine Injury Act of 1986 (the Vaccine Act) expressly preempts both strict liability and negligent design defect claims. *Bruesewitz v. Wyeth, Inc.*, 561 F.3d 233 (3d Cir. 2009)

In its preemption analysis, the Court of Appeals concluded "that the Vaccine Act reflected the *principle* of Restatement (Second) of Torts § 402A comment k, which states that sellers of certain products, including vaccines, should not be strictly liable for harm caused by their products when it is not possible to make these products entirely safe." *Id.* at 247-248 (footnotes omitted). The Court of Appeals then rejected the interpretation of comment *k* adopted by the Georgia Supreme Court in *American Home Products Corp. v. Ferrari*, 668 S.E.2d 236 (Ga. 2008), *petition for cert. pending*, No. 08-1120 (U.S. filed Mar. 5, 2009), because that interpretation "does not bar any design defect claims." 561 F.3d at 246. Reasoning that the Vaccine Act most plausibly bars at least *some* design defect claims, the Court of Appeals concluded that the Act must expressly preempt *all* such claims. *Id.* at 248.

## SUMMARY OF ARGUMENT

The Court of Appeals' preemption analysis rests on a mistaken evaluation of comment *k*. When interpreted by reference to the type of defect of concern to comment *k*, the Vaccine Act bars strict products liability claims only for certain types of manufacturing and design defects defined exclusively in terms of product malfunctions. Moreover, comment *k* does not insulate the seller of an unreasonably dangerous product from liability. Applied to the facts of this case, comment *k*—and the Vaccine Act—does not prevent petitioners from establishing liability for defective design by proving that a reasonable (and safer) alternative design to Wyeth's whole-cell DPT vaccine was available when Hannah Bruesewitz was inoculated.

The Restatement (Second) of Torts § 402A rule of strict products liability is based on case law involving defects that render a product unable to perform its manifestly intended function. The rule originated with contaminated food cases and was gradually extended to other products containing defects that caused the product to malfunction in a self-defeating manner, such as an exploding bottle of soda. Restatement (Second) of Torts § 402A cmt. b.

As § 402A recognizes, liability for this type of unavoidable defect could create problems for products having a primary purpose of health or safety, such as drugs or vaccines posing inherent risks of side effects. The manifest purpose of these products is to promote the consumer's health, and so in the event that an unavoidable side effect causes injury to the consumer, the drug or vaccine has performed in a self-defeating manner that typically would trigger the rule of strict liability for product malfunctions.

Comment *k* recognizes that subjecting these products to strict liability could be socially problematic because the imposition of strict liability would not promote product safety for an "unavoidably unsafe" product. Consequently, it exempts "unavoidably unsafe" products from the § 402A rule of strict products liability. *Id.* cmt. k.

The comment *k* exemption only applies to the § 402A rule of strict products liability and does not otherwise exempt product sellers from negligence liability. The principle of comment *k* bars the application of strict liability only when doing so would undermine the public interest in product safety, whereas negligence liability promotes safety by incentivizing producers to eliminate unreasonably dangerous products from the marketplace. To be sure, negligence liability can threaten the financial viability of producers—a distinct possibility implicit in comment *k*'s retention of liability for inadequate warnings—but this is a consequence inherent in tort law's goal of promoting product safety.

In light of the historical foundation of comment *k*, the corresponding exemption of liability in the Vaccine Act clearly does not bar petitioners' claim for defective design. Petitioners allege that the DPT vaccine is not "unavoidably unsafe" because a reasonable alternative design would reduce the risk of side effects. This tort claim furthers the safety objective of products liability and therefore is not barred by comment *k*.

## ARGUMENT

### I. The Vaccine Act Incorporates Comment *k* into Its Substantive Provisions

Section 300aa-22 of the Vaccine Act, entitled "Standards of Responsibility," provides:

> (a) General rule
>
> Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death.
>
> (b) Unavoidable adverse side effects; warnings
>
> (1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

42 U.S.C. § 300aa-22.

The language of subsection 22(b)(1) mirrors comment *k* of the Restatement (Second) of Torts § 402A, which exempts "unavoidably unsafe products" from the § 402A rule of strict products liability:

> 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 direction and warning, is not defective, nor is it *unreasonably* dangerous. The same is true in particular 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 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.

A comparison shows that subsection 22(b)(1) of the Vaccine Act incorporates comment *k*. That subsection provides an exemption from liability for "side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings," a provision substantively

identical to comment *k*'s exemption for vaccines involving an "unavoidable high degree of risk" if the vaccine is "properly prepared, and accompanied by proper directions and warning." *Compare* 42 U.S.C. § 300aa-22 *with* Restatement (Second) of Torts § 402A cmt. k.

This conclusion is fully supported by the legislative history of the Vaccine Act. The House Committee on Energy and Commerce "had jurisdiction over the Vaccine Act and guided the legislation through passage." *Bruesewitz*, 561 F.3d at 247 (citing H.R. Rep. No. 99-908, pt. 1 (1986)). The Committee Report expressly acknowledges that comment *k* is the substantive basis for subsection 22(b)(1) of the Vaccine Act:

> Subsection (b)—Unavoidable Adverse Side Effects; Direct Warnings.—This provision sets forth the principle contained in Comment k of Section 402A of the Restatement of Torts (Second) that a vaccine manufacturer should not be liable for injuries or deaths resulting from unavoidable side effects even through the vaccine was properly prepared and accompanied by proper directions and warnings.
>
> *The Committee has set forth Comment K in this bill because it intends that the principle in Comment K regarding "unavoidably unsafe" products, i.e., those products which in the present state of human skill and knowledge cannot be made safe, apply to the vaccines covered in the bill and that such products not be the subject of liability in the tort system.* The vaccines addressed in this legislation certainly present the hardest case for the application of Comment K. In such a case, the plaintiff is almost invariably a young child, often badly

> injured or killed, and free from wrongdoing. And, even if the defendant manufacturer may have made as safe a vaccine as anyone reasonably could expect, a court or jury undoubtedly will find it difficult to rule in favor of the "innocent" manufacturer if the equally "innocent" child has to bear the risk of loss with no other possibility of recompense.

H.R. Rep. No. 99-908, pt. 1, at 25-26 (emphasis added). In sum, then, the express language of the Vaccine Act and its legislative history both support the conclusion that subsection 22(b)(1) of the Vaccine Act incorporates comment *k*.

## II. The Principle of Comment *k*

When the American Law Institute promulgated Restatement (Second) of Torts § 402A in the mid-1960s, it announced a liability rule that was based on cases involving defects defined by a self-defeating product malfunction, such as the exploding bottle of soda at issue in the case that ushered in the era of strict products liability, *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 461 (Cal. 1944) (Traynor, J., concurring). As Professor Michael Green has explained:

> The strict liability proposed by section 402A was not limited to manufacturing defects. Indeed, that section, influenced by its warranty heritage—the then-existing source of strict liability in the law—employed a conceptual framework independent of specific types of defect. Rather than the familiar three-defect world in which we find ourselves today, section 402A contemplated a performance-based idea for defect. If a product performed in a way that revealed a defect—regardless of its source—

> then it was defective. Thus, if a gun went off when being held by its owner without the owner engaging its trigger, the gun was defective and we need not trace the source of that defect.

Michael D. Green, *The Unappreciated Congruity of the Second and Third Tort Restatements on Design Defects*, 74 Brooklyn L. Rev. 807, 812 (2009) (footnote omitted); *see also* Restatement (Second) of Torts § 402A cmt. b (discussing how rule of strict products liability evolved from cases involving the sale of contaminated or "corrupt" food and drink).

Performance-based defects ordinarily stem from construction or manufacturing flaws, but a product malfunction can also be attributable to defective design. *See McCabe v. L.K. Liggett Drug Co.*, 112 N.E.2d 254 (Mass. 1953) (finding that the defendant breached the implied warranty by selling a coffeepot with a design that caused it to explode during normal use); Restatement (Third) of Torts: Products Liability § 3 cmt. b (1998) ("[O]ccasionally a product design causes the product to malfunction in a manner identical to that which would ordinarily be caused by a manufacturing defect.").

Because § 402A was formulated by reference to performance-based defects or product malfunctions, comment *k* addresses the problems that this rule of strict liability could pose for products that have an intended purpose of promoting health or safety. If a drug or vaccine has an unavoidable side effect that injures the user, for example, then in this instance it has functioned in a self-defeating manner that typically would trigger the rule of strict products liability. *Cf. id.* § 3 cmt. b (explaining rule that enables plaintiff to recover without proof of a specific defect

for "situations in which a product fails to perform its manifestly intended function"). The vaccine or drug was supposed to promote the health of the user, but instead it caused injury. Whether such a "malfunction" ought to be governed by the rule of strict liability is the issue addressed by comment *k*. *Cf.* James A. Henderson, Jr. & Aaron D. Twerski, *A Proposed Revision to Section 402A of the Restatement (Second) of Torts*, 77 Cornell L. Rev. 1512, 1541 (1992) (providing "strong evidence" that Dean Prosser, "who was the Reporter for the Second Restatement and who dominated the development of section 402A," developed comment *k* out of concern "that manufacturers of even well-designed drugs of unquestioned social utility would be subject to liability for idiosyncratic drug reactions whose dangers were known and warned against").

When comment *k* is interpreted by reference to defects defined by a product malfunction, its principle becomes readily apparent. As *amicus* has explained at length elsewhere:

> To understand comment *k*, we can consider [its invocation of] the "outstanding example" of an "unavoidably unsafe" product—the Pasteur rabies vaccine. Even when the manufacturer has "properly prepared" the vaccine, it can be contaminated with brain tissue, creating dangerous side effects for the user. [Rogers v. Miles Lab., 802 P.2d 1346, 1350-51 (Wash. 1991).] Consequently, the rabies vaccine can have "no assurance … of purity of ingredients," because these "products … in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." Impurities, like those in contami-

nated food, are a common form of construction or manufacturing defect subject to strict liability, but the seller of "properly prepared" rabies vaccine accompanied by a "proper warning" is not subject to liability for injuries caused by contaminated vaccine. The vaccine treats a disease that "invariably leads to a dreadful death," so the seller should not incur liability for supplying "the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk" [as per comment *k*].

… The express rationale for doing so, however, would seem to apply to numerous other products. The "present state of human knowledge" does not make it possible to have perfect quality-control measures in the construction of automobiles. These products are "useful and desirable" while being "attended with a known and apparently reasonable risk." Automobiles would appear to satisfy all of the express requirements for an "unavoidably unsafe" product under comment *k*, but the limitation of strict liability no longer seems so sensible.

The courts have not exempted automobile sellers from strict liability. "While comment *k* could be read to apply to other products, it does not really give us any examples or suggest other areas where the policy balancing is precisely the same. For this reason, the courts and most commentators have assumed that comment *k* relates to pharmaceuticals …." [Victor E. Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy*

> *Behind Comment k*, 42 Wash. & Lee L. Rev. 1139, 1141 (1985).] The practical effect of this interpretation has been enormous. A "great majority" of courts have relied upon comment *k* to exempt from strict liability the manufacturers of pharmaceutical products. [David G. Owen et al., 2 MADDEN & OWEN ON PRODUCTS LIABILITY § 22:3, at 558 (3d ed. 2000).]
>
> This interpretation of comment *k* is problematic. Comment *k* uses pharmaceutical products to illustrate the relevant characteristics of an "unavoidably unsafe" product; it does not define an "unavoidably unsafe" product as a pharmaceutical product. Perhaps the relevant characteristics of an "unavoidably unsafe" product effectively limit comment *k* to pharmaceutical products. That conclusion, though, should be based upon analysis rather than being assumed. To interpret comment *k*, we need to identify the reasons why some products like the rabies vaccine ought to be exempt from strict liability.

Mark A. Geistfeld, PRINCIPLES OF PRODUCTS LIABILITY 75-76 (2006).

The rationale for comment *k* is most easily illustrated by cases involving blood contaminated by a virus, such as hepatitis, that was not detectable at the time of sale. According to Justice Roger Traynor of the California Supreme Court, blood is a "classic example" of an "unavoidably unsafe product" under comment *k*. Roger Traynor, *The Ways and Meanings of Defective Products and Strict Liability*, 32 Tenn. L. Rev. 363, 367 (1965). "[L]ike contaminated blood, Pasteur Vaccine [discussed in comment *k*] is impure, and its use may have adverse consequences which

cannot be predicted or avoided." *Belle Bonfils Mem'l Blood Bank v. Hansen*, 665 P.2d 118, 124 (Col. 1983).

Consider a case involving the defendant blood bank's sale of blood contaminated by a virus that was unknown at the time of sale. The presence of such a virus in the blood constitutes a construction or manufacturing defect because it is a departure from the "design" or specification for the blood. *Cf.* Restatement (Third) of Torts: Products Liability § 2 cmt. c ("[A] manufacturing defect is a departure from a product unit's design specifications."). As in a case of contaminated food, the seller of contaminated blood can be subject to strict liability regardless of whether the virus could have been discovered by the exercise of reasonable care. *See*, *e.g.*, *Cunningham v. MacNeal Mem'l Hosp.*, 266 N.E.2d 897, 903 (Ill. 1970) ("[W]e believe that whether or not defendant can, even theoretically, ascertain the existence of serum hepatitis virus in whole blood employed by it for transfusion purposes is of absolutely no moment. Any other ruling would be entirely inconsistent with the concept of strict tort liability."), *overruled by statute*, 745 Ill. Comp. Stat. Ann. 4012, enacted in 1971; *see also* Jay M. Zitter, *Liability of blood supplier for injury or death resulting from blood transfusion*, 24 A.L.R.4th 508, § 2[a] (1983) ("[I]n several blood transfusion cases wherein injury or death resulted from blood which was contaminated with serum hepatitis, a theory was asserted that since the blood was impure and unfit for its intended uses, the blood bank in the sale of the blood had breached an implied warranty under a sales act or the Uniform Commercial Code, or should be held liable under strict liability in tort for the sale of an unreasonably dangerous product.").

The application of strict liability in these cases would result in blood suppliers facing liability, even though the blood was sold in a state that was safe as possible at that time. The effect of liability in such cases would not have made the blood supply more safe, but rather would have disrupted the provision of blood and caused a substantial loss of social value.

In one case, for example,

> the experts for both sides all agreed that in December 1966 (when the blood was transfused) there was no known scientific or medical test for determining whether blood drawn from a donor contained serum hepatitis virus. Further, Dr. Robert Goodman, a pathologist and medical director of County Blood Bank, testified that as of that date the overall incidence of transfusion hepatitis was "about 1.3 in a hundred cases transfused" and that "the carrier rate, the people who remain with residual virus after infection, is five percent."

*Brody v. Overlook Hosp.*, 317 A.2d 392, 395 (N.J. App. Div. 1974), *aff'd*, 332 A.2d 596 (N.J. 1975). Based on these facts, a blood supplier ordinarily would incur strict liability for hepatitis injuries for every one consumer out of a 100, an amount that vastly exceeds the liabilities typically generated by construction or manufacturing defects (such as the occasional bottle of soda that explodes).

The potential scope of strict liability for blood suppliers was then substantially increased by the AIDS epidemic. The first AIDS diagnosis occurred in 1981, and so any tests or warnings regarding the virus were not feasible for all blood products sold prior to then. "By this time, however, a large number of he-

mophiliacs had become infected. The plaintiffs have presented evidence that 2,000 hemophiliacs have died of AIDS and that half or more of the remaining U.S. hemophiliac population of 20,000 may be HIV-positive." *In re Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293, 1296 (7th Cir. 1995). Liability for these injuries would "hurl the industry into bankruptcy." *Id.* at 1300.

The problem of contaminated blood accordingly reveals the underlying principle of comment *k*. Holding suppliers liable for contaminated blood, even though it was impossible to make the blood more safe, might have led to the pernicious effect of decreasing the supply of blood with no concomitant gains in safety.

> A higher risk of injury, coupled with a social concern for bankruptcy rooted in the requirements of public health and safety, differentiates blood and other pharmaceutical products from the vast majority of other products. These characteristics justify the exemption of a product from strict liability under comment *k* of the *Restatement (Second)*, much like a highly risky activity with significant social value is exempted from the *Restatement (Second)* rule of strict liability for abnormally dangerous activities. [Restatement (Second) of Torts § 520(f)].

Geistfeld, *supra*, at 78-79.

Recognizing the problem, virtually all state legislatures have responded by adopting statutes that immunize blood suppliers from strict liability. *See* Restatement (Third) of Torts: Products Liability § 19 cmt. c ("Absent a special rule dealing with human blood and tissue, such contamination presumably

would be subject to the rule[ of strict liability for a construction defect]…. However, legislation in almost all jurisdictions limits the liability of sellers of human blood and human tissue to the failure to exercise reasonable care, often by providing that human blood and human tissue are not 'products' or that their provision is a 'service' [and therefore not subject to strict *products* liability]."). In justifying the exemption, courts and legislatures have often expressed concern about the way in which strict liability could have a potentially disruptive effect on the supply of blood. *See*, *e.g.*, *Zichichi v. Middlesex Mem'l Hosp.*, 528 A.2d 805, 810 (Conn. 1987).

In cases not governed by these statutes, courts have reached the same outcome by applying comment *k* to the sale of blood products containing an undetectable virus at the time of sale that would otherwise constitute a defect subject to strict liability. *See*, *e.g.*, *Rogers v. Miles Labs., Inc.*, 802 P.2d 1346, 1352 (Wash. 1991) ("Numerous other jurisdictions are in accord with our decision not to apply the theory of strict liability to suppliers of blood and manufacturers of blood products") (citations omitted); *Miles Labs., Inc. v. Doe*, 556 A.2d 1107, 1121 (Md. 1989); *Belle Bonfils Mem'l Blood Bank*, 665 P.2d at 121; Restatement (Third) of Torts: Products Liability § 19 cmt. c ("Where legislation has not addressed the problem, courts have concluded that strict liability is inappropriate for harm caused by such product contamination."). *But see Cunningham*, 266 N.E.2d at 903 (applying strict liability to sale of blood contaminated by a virus that was not reasonably detectable at the time of sale).

Thus, comment *k* is based on a safety principle that exempts a performance-based defect from strict lia-

bility when the product furthers the public interest in health and safety and is "unavoidably unsafe." The imposition of strict liability would not make the product safer—it is "unavoidably unsafe"—and could result in a socially problematic safety outcome by disrupting the supply of a product that furthers the public interest in health and safety. In cases of this type, application of strict liability would be contrary to the safety rationale for strict products liability, justifying the limitation of strict liability embodied in comment *k*. *See*, *e.g.*, *Belle Bonfils Mem'l Blood Bank*, 665 P.2d at 124 ("[T]he *raison d'etre* of strict liability is to force some hazardous products out of the market. The same rationale does not apply to blood or *vaccines* which are life-saving and *which have no known substitutes*.") (emphasis added); *Miles Labs.*, 556 A.2d at 1121 ("[T]he fundamental purpose underlying the theory of strict tort liability is to force hazardous products from the market.").

## III. Comment *k* Does Not Bar Design Defect Claims Based on a Reasonable Alternative Design of the Vaccine That Reduces Risk of Side Effects

Properly interpreted, comment *k* bars certain claims of strict products liability in which the defect is defined solely in terms of product performance. For example, the Sabin oral polio vaccine uses an attenuated or weakened form of the viral agent to immunize the recipient, which in turn can cause vaccine-associated paralytic polio in either recipients or close contacts. In these cases, the design or formulation of the vaccine causes it to perform in a self-defeating manner, the paradigmatic example of a product malfunction that typically subjects the product seller to strict liability. *See*, *e.g.*, *Grinnell v.*

*Charles Pfizer & Co.*, 274 Cal. App. 2d 424, 433 (Cal. App. 1969) ("it is clearly the law in California that the theory of strict liability in tort is available in cases where the vaccinated individual contracts the disease the vaccine was designed to protect against"); *see also*, *e.g.*, *Allison v. Merck & Co.*, 878 P.2d 948, 952 (Nev. 1994) (holding that a measles, mumps and rubella vaccine "malfunctioned" and was subject to strict liability because an unavoidable side effect allegedly caused plaintiffs' son to suffer blindness, deafness and mental retardation). Such a claim of strict liability is barred by comment *k* when the vaccine is "prepared properly" in conformance with state of the art quality control and is accompanied by a proper warning. *See*, *e.g.*, *Johnson v. American Cyanamid Co.*, 718 P.2d 1318, 1323-24 (Kan. 1986) (applying comment *k* to a Sabin-type vaccine and concluding as a matter of law that an unavoidable side effect of the vaccine is not "a manufacturing or design defect").

When a vaccine is "unavoidably unsafe" under comment *k*, strict liability would not lead to a safer vaccine but instead could create the unsafe outcome in which liability reduces the supply and use of the vaccine within society. Comment *k* thus applies only when there is no safety rationale for liability. Consequently, it does not bar negligence liability, which necessarily targets unreasonably dangerous products in order to promote tort law's safety objective. *Compare* Restatement (Second) of Torts § 402A cmt. a ("The rule [of strict liability] stated here is not exclusive, and does not preclude liability based upon the alternative ground of negligence of the seller, where such negligence can be proved.") *with id.* § 395 cmt. f (adopting rule of negligence liability for product

design without any reference to drugs, vaccines or comment *k*).

To be sure, negligence liability could threaten the financial viability of a drug or vaccine manufacturer. Comment *k*, however, does not insulate the seller of an unreasonably dangerous product from the threat of bankruptcy. Comment *k* expressly contemplates liability for inadequate or defective warnings, and negligence liability for such warnings can be extensive, as illustrated by the asbestos cases. *See*, *e.g.*, *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076 (5th Cir. 1973) (applying Texas law) (upholding jury verdict finding that defendants failure to warn of asbestos hazards was subject to both negligence and strict products liability).

For these reasons, comment *k* does not prevent plaintiffs from establishing liability for defective design by proving that a vaccine or drug has a reasonable alternative design.

> The proof of defect shows that risk was avoidable, establishing that the product was not "unavoidably unsafe." The exemption from liability afforded by comment *k* turns out to be no different than the exemption afforded by the requirement of defect—an "unavoidably unsafe" product must not be capable of being reasonably redesigned and is not subject to liability for that reason alone. In these cases, comment *k* does not expressly provide for an independent limitation of liability justifying the special treatment of pharmaceutical products.

Geistfeld, *supra*, at 124; *see also* Henderson & Twerski, 77 Cornell L. Rev. at 1540 (arguing that the history of comment *k* shows that it "is simply unten-

able" to conclude that "comment *k* sought to establish sophisticated rules governing judicial review of conscious *drug* design choices").

This interpretation of comment *k* was not considered by the Court of Appeals in the present suit. The court assumed that a case-by-case application of comment *k* regarding defective design would eliminate any preclusive effect whatsoever: "If we interpret the Vaccine Act to allow case-by-case analysis of whether particular vaccine side effects are avoidable, every design defect claim is subject to evaluation by a court." *Bruesewitz*, 561 F.3d at 246. Because the Vaccine Act most plausibly provides at least some limitation of liability for defective design, the Court of Appeals concluded that the Act must preempt all claims of defective design. *Id.*

Properly interpreted, comment *k* only bars design and manufacturing defect claims based on product malfunctions involving unavoidable side effects, a limitation of liability permitting design claims alleging that the vaccine is not "unavoidably unsafe" because there is a reasonable alternative design that would reduce the risk in question. Based on comment *k,* the Vaccine Act does not preclude claims of the type brought by petitioners in the present case.

## CONCLUSION

The judgment of the Court of Appeals should be reversed.

Respectfully submitted.

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