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UNAVOIDABLY UNSAFE PRODUCTS: CLARIFYING THE MEANING AND POLICY BEHIND COMMENT K

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INTRODUCTION

It has been wisely said that words not placed in context are merely pretext. This sage advice provides illumination for understanding and clarifying both the policy that underlies, and the meaning of, comment k of *Restatement (Second) of Torts*, Section 402A—unavoidably unsafe products.[1] The context for the development of comment k was the formal birth of strict products liability tort law.[2] Strict products liability theory emerged in the early 1960's when the reporter of the *Restatement of Torts*, William Prosser, and his council of advisors were attempting to synthesize a group of cases that had permitted persons injured by products to recover damages without having to prove that the manufacturer failed to use reasonable care. A careful examination of the Appendix to Section 402A of the *Restatement*[3] and discussions by the eminent Professor John W. Wade,[4] who later became the reporter for the *Restatement* itself, show that all of the cases that were considered involved *mismanufactured* products—contaminated food products or products with construction defects. These were cases where products contained foreign objects, were missing important parts, or were not assembled in accordance with the manufacturer's own design plans.[5] Nevertheless, when the language of Section 402A of the *Restatement* was drafted, it did not use the phrase, "mismanufactured products." It simply spoke of products that were "in a defective condition unreasonably dangerous to the user or consumer. . . ."[6] Although the *Restatement* had addressed the issue of

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

2. *See* RESTATEMENT (SECOND) OF TORTS § 402A comment a (1965).

3. RESTATEMENT (SECOND) OF TORTS, Appendix, Vol. 3 at 1 (1966).

4. *See* Wade, *On the Nature of Strict Tort Liability for Products*, 44 MISS. L. J. 825, 830-31 (1973).

5. *See, e.g.*, Mazetti v. Armour & Co., 75 Wash. 622, 135 P. 633 (1913); Coca-Cola Bottling Works v. Lyons, 145 Miss. 876, 111 So. 305 (1927).

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

liability for the design of products in an earlier section,[7] specifically referred to warnings in comment j of Section 402A, and made clear in *both* cases that the liability basis was negligence, the generality in the language of 402A created in the mind of the reporter a need to show with some specificity what Section 402A did *not* cover. The American Law Institute's debates on Section 402A make this absolutely clear.[8] A description of the group of products which the reporter did not wish to place under the rule of Section 402A were set forth in comment k—so called "unavoidably unsafe products." It is appropriate to begin with the description of those products from the *Restatement* itself:

> 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 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 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 the 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 a qualification that they are properly prepared and marketed, and proper warning is given, when the situation calls for it, is not to be he 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.

Although learned scholars[9] have suggested that the words are obscure or even meaningless, a careful consideration of these words demonstrates that they have a definite meaning.

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7. RESTATEMENT (SECOND) OF TORTS § 398 (1965).

8. American Law Institute, *38th Annual Meetings,* A.L.I. PROC. 87-88 (1962).

9. *See* Twerski, *National Product Liability Legislation: In Search for the Best of all Possible Worlds,* 18 IDAHO L. REV. 411, 430 (1982); Page, *Generic Product Risks: The Case Against Comment k and For Strict Liability,* 5 N.Y.U.L. REV. 853 (1983).

More importantly the policy behind the words should be clear to both lawyer and non-lawyer alike—maybe even clearer to the non-lawyer. In that regard, unfortunately, an ingredient that sometimes creeps into the legal profession is an overly technical reading of a document—so overly technical that it misses the basic message. The basic message here is that, in general, ethical drugs and harms that arise out of their use should not subject their manufacturer, distributor or retailer to strict liability. Society wishes to encourage the manufacture of ethical drugs, and the research and development of new drugs. The imposition of strict liability would stifle these goals.

On the other hand, neither the letter of, nor policy underlying, the comment gives carte blanche to pharmaceutical companies to manufacture unreasonably unsafe products. If an ethical drug, in light of the state of human knowledge at the time of manufacture, can be made safe for its intended and ordinary use, the manufacturer is to meet that standard. If it is not possible to meet this goal, the product still must be "properly prepared"—mismanufactured products will not be tolerated, unless, in light of the current knowledge it is impossible to guarantee "purity of ingredients." Perhaps more importantly, all pharmaceutical products have to be accompanied by proper directions and warnings.[10] This article will expand upon this guideline later.

At this point, however, the policy underlying comment k should be clear: it balances basic tort law considerations of deterrence, incentives of safety, and compensation. The *Restatement* authors believed that classic negligence law was adequate and sufficient to provide incentives for safety for the *design* of ethical drugs and vaccines.[11] They also believed that it was inappropriate to impose tort law rules for compensation in this context. 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 and this assumption as a *practical matter* appears to be correct.[12] This article will discuss, briefly, some areas where comment k has created uncertainty at least in the mind of some courts and scholars. The article will utilize the basic policy goals that underlie comment k to resolve these purported ambiguities with the hope that this analysis will be of assistance to courts and others that must now and in the future address these problems. The article does not intend to treat comment k as revealed Gospel, but to indicate where and where not the author believes the choices made under comment k are appropriate.

The areas focused on will include:

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10. *See, e.g.*, Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1276 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974).

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

12. *See, e.g.*, Lindsay v. Ortho Pharmaceutical Corp., 637 F.2d 87 (2d Cir. 1980); Page, *supra* note 9, at 853.

(1) Does comment k include drugs that, over time, are shown not to be efficacious?

(2) How does comment k treat known risks?

(3) Does comment k include products that contain risks that are unknown at the time the product is manufactured, but manifest themselves later?

(4) How does comment k relate to the duty to warn about risks?

(5) Decision-making under comment k: Who should resolve the key questions?

1. Does Comment K Include Drugs that, Over Time, Are Shown Not to Be Efficacious?

As most people know, before drugs are placed in the marketplace, they must go through intensive testing by the Food and Drug Administration.[13] On the average, it takes at least seven to ten years for a drug to receive unconditional approval for marketing, with a physician's prescription, to the general public. A principal focus of the Food and Drug Administration, apart from safety, is efficacy. Since every drug includes some risks, the Food and Drug Administration regards efficacy as essential—if one is to take risks, he or she should obtain the desired result.

There has been a suggestion in at least one case that comment k should only apply to drugs that turn out to be efficacious.[14] Nevertheless, nothing in comment k states this, and, in fact, its underlying policy suggests the opposite. Comment k notes that its policy applies in particular "to 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 purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. . . ."[15] I am *not* referring here to situations in which the drug manufacturer withheld information from the Food and Drug Administration, engaged in fraud or negligent conduct. To the contrary, I am

13. Before new drugs may be sold, the Food and Drug Administration must approve a New Drug Application (NDA) which shows that the drug is safe and effective. 21 U.S.C. § 355 (1972). NDA safety tests are conducted under detailed regulations. 21 C.F.R. § 312 (1985). *See generally,* Virts and Weston, *Expectations and the Allocation of Research and Development Resources,* in DRUGS AND HEALTH (R. Helms ed. 1981); R.W. Hansen, *The Pharmaceutical Development Process: Estimates of Development Costs and Times and the Effects of Proposed Regulatory Changes,* in ISSUES IN PHARMACEUTICAL ECONOMICS (R. Chien ed.).

14. Ferrigno v. Eli Lilly & Co., 175 N.J. Super. 551, 556, 420 A.2d 1305, 1319 (Law Div. 1980), *vacated on authority of* Namm v. Charles E. Frosst & Co., 178 N.J. Super. 19, 427 A.2d 1121 (App. DN. 1981).

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

referring here to the situation in which there has been reasonable care on the part of the manufacturer, and presumably on the part of the Food and Drug Administration, and where, at the time of manufacture, it was believed that the drug would be efficacious. In that context, does the policy underlying comment k suggest that we should hold the manufacturer *strictly liable* for an adverse result? If the authors of the *Restatement* were willing to allow drugs in the marketplace where there could not be a guarantee of "purity of ingredients," one can reasonably conclude that they would permit the marketing, without strict tort liability, of drugs that *appeared* to be efficacious. If there is further doubt about this matter, one should focus on the closing words in comment k which exclude the application of strict liability to "an *apparently* useful and desirable product. . . ."[16] While the focus in this sentence, again, is on the "risk" attendant to some products, the execution would apply with equal fortitude to products that appeared from all scientific testing by both the manufacturer and the Food and Drug Administration to work and work well.

This result is in accord with sound social policy. Again, remember that liability is not being barred where there has been fault. Rather, the concern here is with cases in which drugs have been manufactured in accordance with the highest standard of reasonable care. It is in society's interest to encourage the marketing of drugs that will help eliminate the dreaded scourges of mankind—cancer, liver and kidney ailments, heart disease. Do we want, by hindsight, to impose absolute or strict liability where, in spite of the best of intentions, learning and study, a drug did not fulfill the goal? It is hard to think of a more certain way to stifle and discourage attempts to cure.

2. How Does Comment K Treat Known Risks?

The first part of comment k, particularly the example of the Pasteur treatment of rabies, discusses the exclusion of strict liability for drugs where, at the time of marketing, it is crystal clear that the benefits of the drug outweigh the risks. There could be no clearer example of situations encompassed by the comment than where, in the words of comment k, "the disease itself invariably leads to a dreadful death . . . and ingestion of or vaccination with the pharmaceutical will prevent death. . . ."[17] It is clear that the comment applies where lifesaving drugs contain risks of harmful side effects. Many pharmaceuticals that have been in the marketplace for a long time, such as penicillin, aureomyecin, or even ordinary aspirin, involve a similarly easy to understand risk-benefit analysis with easy conclusions that the product should be marketed in spite of risks that it might entail.

There are those who might argue that this is where the protection of comment k should stop: in the case where it is crystal clear that the benefits

16. *Id.* (emphasis added).
17. *Id.*

of a drug outweigh its risks. But that is *not* where comment k does stop. Comment k also focuses on "many new or experimental drugs. . .where there can be no assurance of safety. . ."[18] and where a risk-benefit analysis shows that the product was "*apparently* useful and desirable. . . ."[19] Moreover, the comment includes products that are attended with a "known but apparently reasonable risk."[20]

As the majority of the case law reflects, risk-benefit analysis *must* be viewed at the time of marketing, not later. This is why in a case in which the drug Chloroquine resulted in the loss of sight, the court held for the defendant.[21] If comment k is confined to classic well-known drugs with clear risk-utility results and the word "apparently" is left out, we lose the basic public policy thrust that underlies comment k—to encourage the development of *new* drugs that have the potential for conquering disease.

3. Does Comment K Include Products that Contain Risks that are Unknown at the Time of Manufacture but Manifest Themselves Later?

It has been argued that comment k only covers risks that are known at the time the product is marketed.[22] Comment k states, in part, that it addresses products with a "known but apparently reasonable risk. . . ."[23] The comment was applied in a case involving the drug aralen, where the drug appeared to have some risks affecting eyesight, but later turned out to be much more serious and caused blindness.[24] What if there were no hint of the risk involved at the time the drug was marketed?

Almost all courts have said comment k still applies.[25] The overall context of the comment itself suggests that it should apply a fortiori. Again, comment k excludes strict liability for drugs where "there can be no assurance of safety. . . ."[26] One might assume, in plain English, that "no" means "no." While the *unknown* risk is something that we all dread, it is the very and most worrisome factor that the Food and Drug Administration and pharmaceutical manufacturers must guard against.

Applying comment k to drugs that contain risks that were unknown at the time of manufacture simply keeps these drugs within the ambit of negligence law. Under negligence law, the pharmaceutical company is held

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18. *Id.*

19. *Id.* (emphasis added).

20. *Id.*

21. Cochran v. Brooke, 243 Or. 89, 409 P.2d 904 (1966).

22. *See* Twerski, *supra* note 9, at 430-31 n.54.

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

24. *See* Cochran v. Brooke, 243 Or. 89, 409 P.2d 904 (1966).

25. *See, e.g.*, Ortho Pharmaceutical Corp. v. Chapman, 180 Ind. App. 33, 388 N.E.2d 541, 545 (Ind. Ct. App. 1979); Gaston v. Hunter, 121 Ariz. 33, 588 P.2d 326, 338 (Ariz. Ct. App. 1978); Chambers v. G.D. Searle & Co., 441 F. Supp. 377, 380 (D. Md. 1975), *aff'd*, 567 F.2d 269 (4th Cir. 1977).

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

to the very *highest* of standards.[27] The pharmaceutical company must act as a reasonable person would have acted in the same or similar circumstances. The circumstances in which pharmaceutical manufacturers must deal directly involve severe risks to human life. Thus, their standard of care is not the "reasonableness" of a person who repairs a television set or drives a car[28]—it is the most serious and intense obligation that one can find in the entire body of negligence law. To go beyond this, and require manufacturers to be responsible for the unknown (that is, to impose absolute or strict liability), flies in the face of the overall policy underlying the section. The Supreme Court of New Jersey, not known for comforting product manufacturer defendants, appears to have recognized this fact. In addressing the case in which a risk of harm was alleged to have been *unknown* at the time of manufacture, the New Jersey Supreme Court indicated that it would not impose liability for either the design, the drug, or the failure to warn about the unknown risk.[29] Even in one of the few decisions that appeared to reject comment k, *Collins v. Eli Lilly Co.*,[30] the Supreme Court of Wisconsin acknowledged that it: "[R]ecognized that in some exigent circumstances it may be necessary to place a drug on the market before adequate testing can be done. . . ."[31]

The issue at hand, however, is not whether comment k applies to drugs containing risks that could have been known at the time of manufacture. Rather, we are focusing here on situations in which the very best experience and knowledge existing when the product was made indicated that the drug was safe.

Finally, as a practical matter, there is little difference in the terms of actual harm between a risk that was "apparently reasonable" and turned out not to be (for example, risk of slight impairment of vision was known but *blindness* resulted) and a totally unknowable risk. To differentiate between the known risk that turns out to be more serious and a totally new risk, which may indeed be a minor risk, does not square with the policy underlying comment k or for that matter with common sense. The only reasonable conclusion is that comment k includes products which contain risks that were not knowable at the time of manufacture.

4. How Does Comment K Relate to the Duty to Warn About Risks?

It is surprising that something that is clear from the text of the *Restatement* has not always been regarded as such by courts or commentators:

27. *See* 21 U.S.C. § 355 (1972); 21 C.F.R. § 312 (1985).

28. *See* W. PROSSER, J. WADE, V. SCHWARTZ, CASES AND MATERIALS ON TORTS at 203 (7th Ed. 1982).

29. Feldman v. Lederle Laboratories, 97 N.J. 429, 479 A.2d 374 (1984).

30. Collins v. Eli Lilly Co., 116 Wis.2d 166, 342 N.W.2d 37, 52, *cert. denied,* 105 S. Ct. 107 (1984).

31. *Id.* at____, 342 N.W.2d at 52.

comment k deals with liability for *design* of, and not the warning about, products. With one possible exception, dealing with a situation in which it is virtually impossible to have "purity of ingredients," which could be called a construction defect (and the focus probably was on blood transfusion cases where, at the time, hepatitis virus could not be detected), it is *design* liability that comment k speaks to.

When we are talking about drugs that are apparently useful and desirable at the time of marketing, the policy underlying comment k would strongly suggest that it would be inappropriate, at a later date, to impute knowledge to the manufacturer and ask "whether a person having that knowledge would have marketed the product."[32] Nevertheless, the "black letter" of comment k gives us only a rather non-descriptive word about what should be done about warning. Comment k of Section 402A speaks to products "accompanied by proper directions and warning. . . ."[33] But what is proper?

The *Restatement* itself, for all products, answers this question in comment j to Section 402A. This, too, has been recognized by the Supreme Court of New Jersey.[34] The manufacturer must warn about risks of which he has knowledge or, by the application of reasonable, developed human skill and foresight, he should have knowledge—the presence of the ingredient and the danger.[35]

Note that comment j talks about "human skill" not skill beyond what prudent and reasonable human beings can achieve. In today's product liability context, it is important to note that the word used is "foresight" not hindsight. Obviously, it would have been clearer if comment k referred to comment j, but the *Restatement* authors did not do this. They did the next best thing, they put one comment next to the other.

As the Supreme Court of New Jersey has recognized: "[A]s to warnings, generally, conduct should be measured by knowledge at the time the manufacturer distributed the product."[36] Did the defendant know, or should he have known, of the danger, given the scientific, technological and other information available when the product was distributed? Or, in other words, did he have actual or constructive knowledge of the danger?

The court then went on to cite comment j.[37] All of this is in full accord with the policy underlying comment k. But then, to adhere with what appeared to be an obeisance to verbal semantics, the Supreme Court of New Jersey has suggested that approaching things in this way would not be true

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32. *See* Phillips v. Kimwood Machine Co., 269 Or. 485, 525 P.2d 1033, 1036-38 (1974); Hayes v. Ariens Co., 391 Mass. 407, 462 N.E.2d 273, 277 (1984); *see also* WADE, *supra* note 4, at 834-37.

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

34. Feldman v. Lederle Laboratories, 97 N.J. 429, 479 A.2d 374, 386 (1984).

35. *Id.* at____, 479 A.2d at 386.

36. *Id.*

37. *Id.*

"strict liability."[38] So, to adhere to a label, the court put the burden of proof on the defendant to show why it did not know of the risk.[39] Unfortunately, this approach invites the trier of fact to do the very thing the *Restatement* has cautioned to against: apply hindsight rather than foresight. Also, as all persons who have argued cases in court know, it is extradordinarily difficult to prove a negative—that you did not know of a risk. The myriad of cases where plaintiff's counsel has been able, by the preponderance of evidence, to prove that manufacturers knew or should have known of a risk are ample pragmatic evidence that the burden of proof should remain on the plaintiff—discovery works. There is nothing in comment k or j that suggests reversing the burden of proof and, hopefully, the Supreme Court of New Jersey, as it ultimately did in *Beshada v. Johns-Manville Products Corp.*[40], will retreat from this untenable position and join the overwhelming majority of courts and the *Restatement:* the burden of proof shall be on the plaintiff.

Comment k and j as they apply to warnings can potentially give too much protection to drug manufacturers because a black letter reading of the two comments can suggest that obligations regarding liability are frozen in time. After a drug has been manufactured, new knowledge can, under and through the operation of reasonable prudence, come to the attention of a drug manufacturer. New data and information about the pharmaceutical continue to develop and come to light. The public policy of encouraging the production of new and hopefully efficacious drugs is not compromised by imposing a reasonable standard on manufacturers to be responsible for new developments and risks in drugs they have marketed. Again, this is not found in the black letter text of comment k, but it is in accord with tort law and its policy of balancing compensation and incentives for safety. The Uniform Product Liability Act[41] contains such an obligation as does recent legislation proposed in the United States Congress.[42]

5. Decision-Making Under Comment K: Who Should Resolve the Key Questions?

One ambiguity that has risen under comment k is much more procedural than substantive—who should decide the key questions that underlie comment k, the judge or jury? As this article has empirically demonstrated, the basic issues underlying comment k are not questions of what occurred at a particular time or of who did what to whom. To the contrary, they are questions of law and policy. Does comment k include drugs that, over time,

38. *Id.*

39. *Id.* at____, 479 A.2d at 388.

40. 90 N.J. 191, 447 A.2d 539 (1982).

41. Model Uniform Product Liability Act § 104(B)(6), 44 Fed. Reg. 62721 (Oct. 31, 1979).

42. *See* S. 100, 99th Cong., 1st Sess., 131 CONG. REC. S218 (daily ed., Jan. 3, 1985) (Product Liability Act).

are shown not be efficacious? How does comment k treat known risks? Does comment k include products that contain risks that are unknown at the time the product is manufactured but manifest themselves later? How does comment k relate to the duty to warn about risks? All of these questions are matters of interpretation of law and the application of policy. They are particularly suited for discussion, analysis and resolution by a court.

In that regard, a court can consider both hearsay and non-hearsay evidence. The court can take judicial notice of the debates by the American Law Institute, practices of the Food and Drug Administration, law review articles and other scholarship. With due respect for the powers of a jury to go back in time and understand and draw opinions about events that have occurred in the past, the jury is not in a position to resolve the questions that stream around comment k. It is the responsibility of the judicial branch and, hopefully, it will be carried out wisely.

CONCLUSION

While some scholars and courts recently have suggested that comment k is obscure or even inappropriate, it has served the law well over the past 20 years. While no legal document is free from ambiguity, and this is certainly the case with comment k, many of the problems in this area are more apparent than real. As this article has pointed out, many of the so-called ambiguities can be answered in the language of the comment itself. When doubt enters into the picture, the underlying policy of comment k can provide the answer. The policy of encouraging innovation in the drug field would seem to be one that should not wither with time but should be encouraged now and in the future. This was seen even in the time of initial exploration and perhaps overfondness for strict product liability—by the authors of the *Restatement* themselves.