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Comment k of the Restatement (Second) of Torts section 402A,\(^1\) has been one of the most widely cited and hotly debated comments of the

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1. Comment k, labeled Unavoidably Unsafe Products, states:

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. They are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which, not uncommonly, leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and 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 justifies the marketing and use of the drug notwithstanding 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 the unfortunate consequences attending their use, merely because he
entire Restatement. Comment k deals specifically with strict liability and unavoidably unsafe products, but it has grown to be the comment most generally associated with prescription drugs. Because of the exponential increase in both the number and variety of prescription products, as well as the harmful side effects that often accompany these new products, comment k has assumed a position of great importance in the evolving law of product liability.

Until recently, Nebraska, along with a relatively small number of other state jurisdictions, used comment k to provide blanket immunity to prescription drug manufacturers. For over twenty years in Nebraska, so long as the product had FDA approval and included the accepted warnings described in section 402A, drug manufacturers in Nebraska and elsewhere were above reproach for the products they designed and manufactured.

Abruptly, the days of blanket immunity have ceased with the decision of the Nebraska Supreme Court in Freeman v. Hoffman La-Roche, Inc. The plaintiff, Freeman, took a prescription drug called Accutane for two different one-month periods in an effort to treat her acne. Freeman alleged that as a result of taking Accutane, she developed several health problems, including colitis, inflammatory polyar-
thritis, nodular episcleritis OS, and optic nerve head drusen. She alleged several theories of recovery including negligence, misrepresentation, failure to warn, breach of implied and express warranty, fear of future product failure, and a strict liability claim that is the focus of this Note.

Although her claim failed in the trial court, Freeman perfected an appeal to the Nebraska Supreme Court. The court ruled in her favor on the design defect and fraudulent misrepresentation causes of action, and reversed and remanded the case for further hearings pursuant to its new position. In Freeman, the Nebraska Supreme Court overruled twenty-four years of precedent, co-opting most of the new standard from the state's general law of products liability. Furthermore, the court declined to adopt either section 6(c) or section 2(b) of the Restatement (Third) of Torts: Products Liability, instead employing the consumer expectations test and retaining comment k as a case-by-case affirmative defense.

By taking this position, the Nebraska Supreme Court created a body of law that is considerably more plaintiff-friendly, more likely to trigger adjustments in the practice of law, and more apt to bring about changes in the way drugs are designed, manufactured, tested, and approved. Despite this shift, Nebraska maintains a high burden of proof for any plaintiff attempting to prove strict product liability against a drug manufacturer. This burden, combined with the availability of the comment k affirmative defense, means that although changes will certainly occur throughout Nebraska's prescription drug law, the changes will be moderate and manageable.

This Note analyzes Nebraska's new prescription drug standards and requirements, as well as the nuances practitioners must become familiar with to effectively litigate under Freeman. It argues in favor of the scheme implemented by the Nebraska Supreme Court in Freeman and asserts that the blanket immunity standard, the risk utility balancing test (and its accompanying reasonable alternative design standard), and the proposed standards of both section 6(c) and section 2(b) of the Third Restatement are inappropriate and inferior to the standard adopted in Freeman.

Part I provides a technical analysis of the law necessary to examine and understand the Nebraska Supreme Court's decision in

5. See id. at 554, 618 N.W.2d at 832.
6. See, e.g., Haag v. Bongers, 256 Neb. 170, 184, 589 N.W.2d 318, 329 (1999) (noting that under this test, "unreasonably dangerous" means that a product has the propensity for causing physical harm beyond which would be contemplated by the ordinary user who purchases it, with ordinary knowledge common to a foreseeable class of users as to its characteristics.).
7. See Freeman, 260 Neb. at 568, 618 N.W.2d at 840.
8. See id. at 577, 618 N.W.2d at 845-46.
Freeman. This section examines the foundational tests of the new law and the criticisms of and alternatives to Nebraska's new scheme. Part I also supplies working definitions of all the relevant terminology and applicable standards discussed in this Note as well as in Freeman itself.

Part II ventures into the body of the Freeman decision to determine the prudence of such sweeping changes. It explores the process of sifting through all of the available standards to cobble together a rule that provides the most protection to all interested parties, while allowing for pragmatic implementation of the law handed down in Freeman. This section agrees with the approach of the Nebraska Supreme Court and it argues that, while the new standard is not flawless, the Freeman court made the best of a complex and continuously morphing body of law.

Part III examines possible rationales behind the court's decision in Freeman. The Author believes that three factors likely influenced the timing and result of this judgment: (1) the state of prescription drug law in other states; (2) the fact that Freeman involved a cosmetic, as opposed to a therapeutic, drug; and (3) the potential pitfalls of section 6(c). All three factors played a role in the outcome of Freeman, and the importance of these three factors becomes evident not only when reading the opinion itself, but also by examining the primary and secondary sources the Court used to formulate and defend its position.

Part IV explores the potential impact of this decision on both Nebraska's legal and social frontiers. From adjusted pleading and proof requirements for both plaintiffs and defendants, to safer testing mechanisms and more attentive doctors, a host of changes loom on the horizon. Part IV disagrees with critics' claims that increased strict liability for drug manufacturers will cause all of the costs associated with the production of prescription drugs to explode and the price to soar, making drugs less available to those who need them the most. Little evidence supports this claim and any new litigation that results from Freeman should have a lesser effect on drug prices than either market-share competition or availability of generic alternatives.

Part V looks to the future of practicing law under Freeman. Lawyers must realize that to maintain a successful practice, one must constantly adapt to meet new demands. This section explores the nuance of practicing law, and perhaps medicine, in Nebraska after Freeman, while offering suggestions to increase firm productivity and client service. Innovation and education are key to understanding Nebraska's new prescription drug law, and this Note aspires to begin part of that education process.
II. BACKGROUND

A. McDaniel v. McNeil Laboratories, Inc.

From 1976 to 2000, Nebraska provided all prescription drug manufacturers with what scholars and advocates have called "blanket immunity" from litigation for defective design. This blanket immunity was derived from comment k of section 402A of the Restatement (Second) of Torts and was applied to all claims of strict liability against the manufacturers of prescription drugs. The most widely recognized case in Nebraska's body of prescription drug law since the adoption of the Restatement (Second) is McDaniel v. McNeil Laboratories, Inc.\textsuperscript{9} In McDaniel, the Nebraska Supreme Court evaluated a lawsuit stemming from a defective prescription drug.

After being given between two or three doses of a prescription drug, Innovar, during surgery, Marjorie McDaniel was rendered permanently comatose. At the time of McDaniel's surgery, the FDA had approved the warnings and information contained in Innovar's package inserts.\textsuperscript{10} McDaniel contended that the defendant manufacturer, McNeil Laboratories, was negligent in failing to warn, strictly liable under section 402A of the Restatement (Second), and liable under a theory of express or implied warranty.\textsuperscript{11} The trial court submitted the issue of negligence to the jury but did not submit the claims based on strict liability or warranty to the jury. On appeal, the Nebraska Supreme Court upheld the judge's decision not to submit the strict liability claim to the jury, based in large part on the fact that Innovar had received FDA approval.\textsuperscript{12}

The Nebraska Supreme Court reasoned that since Innovar had received FDA approval, it could not be an unavoidably unsafe drug.\textsuperscript{13} The court went on to cite section 402A of the Restatement (Second) to determine that Innovar was properly prepared, compounded, packaged, distributed, and included the approved directions and warn-

\textsuperscript{9} 196 Neb. 190, 241 N.W.2d 822 (1976).
\textsuperscript{10} To receive FDA approval, prescription drugs are generally required to be distributed with printed package inserts. The inserts contain "pharmacological information, safety evaluations, recommended dosages and administration, and warnings as to adverse reactions and control measures to be taken in such event." Id. at 194-95, 241 N.W.2d at 825.
\textsuperscript{11} See id. at 202, 241 N.W.2d at 829.
\textsuperscript{12} See id. at 199-204, 241 N.W.2d at 828-30.
\textsuperscript{13} The court reasoned that:

While approval by the Food and Drug Administration is not necessarily conclusive, its determinations, based upon the opinions and judgment of its own experts, should not be subject to challenge in a product liability case simply because some other experts may differ in their opinions as to whether a particular drug is reasonably safe, unless there is some proof of fraud or nondisclosure of relevant information by the manufacturer at the time of obtaining or retaining such federal approval.

Id. at 199-201, 241 N.W.2d at 828.
ings. Additionally, the court classified Innovar as *unavoidably* unsafe and, therefore, used comment k to provide blanket immunity to McNeil Laboratories and to all non-fraudulent prescription drug manufacturers since. The court concluded, as a matter of law, that a drug could not be defective or unreasonably dangerous without proof of inaccurate, incomplete, misleading, or fraudulent information furnished by the manufacturer in connection with the FDA approval process or later revisions thereof.

Nebraska, along with a minority of other jurisdictions, held that although FDA approval was not considered conclusive in determining whether a drug was or was not unreasonably unsafe, FDA experts should not be subject to second guessing by the courts if the following two requirements are met: (1) the drug was approved by the FDA; and (2) it followed the warning guidelines from comment k. Innovar was approved by the FDA and provided the requisite warnings and labeling. Consequently, it was not unreasonably unsafe and McNeil Laboratories was immune from liability for defective design. In defense of this position, courts and scholars suggest that it is in the public's best interest to allow prescription products which are unavoidably, unreasonably unsafe to be marketed if the benefits of the product justify the risks.

The strict liability holding of McDaniel remained virtually unchallenged for almost twenty-five years. Consequently, Nebraska's body of strict liability case law since McDaniel remained consistent until the dramatic changes implemented in the Freeman decision.

B. General Product Liability in Nebraska—the Transition to Freeman

Although Nebraska did not recognize strict liability for manufacturers of prescription drugs until Freeman, since 1987 Nebraska has enforced strict tort liability for products other than prescription drugs. In Rahmig v. Mosley Machinery Co., the Nebraska Supreme Court recognized three problems or defects that would justify holding a manufacturer strictly liable: a manufacturing defect; a design defect; and a

14. See id.
15. See id.
16. See supra note 3 for other states which have adopted the blanket immunity standard.
17. See McDaniel, 196 Neb. at 201, 241 N.W.2d at 828.
18. See supra note 3.
19. After McDaniel, Nebraska had seen no significant state case law until Freeman. However, there had been a limited number of federal cases originating in Nebraska. See, e.g., U.S. v. Articles of Drug, 825 F.2d 1238 (8th Cir. 1987); Groth v. Sandoz, Inc., 601 F. Supp. 453 (D. Neb. 1984).
failure to warn. Additionally, Rahmig established the standard that Nebraska uses in general strict product litigation and later transposed to prescription drug litigation. The standard was taken from section 402A, comment i of the Restatement (Second) and is commonly called the consumer expectations test.

In Rahmig, Nebraska applied the consumer expectations test to general strict product liability but it did not extend that standard to prescription drugs and drug manufacturers. Consequently, under Rahmig, general product liability in Nebraska took a positive step forward, while patients injured taking prescription drugs were left with little recourse.

III. ANALYSIS

By overruling McDaniel, and declining to adopt the Restatement (Third) of Torts: Products Liability section 6(c) or section 2(b), the Nebraska Supreme Court's ruling in Freeman balanced the twin goals of providing redress for consumers harmed by defective drugs and ensuring the continued production and distribution of quality pharmaceuticals. The result is a standard that encourages and protects manufacturer innovation yet offers patients and consumers notably more just results.

A. Technical Analysis of the Freeman Decision

In Freeman, the Nebraska Supreme Court adopted a more universal standard for analyzing the strict liability of prescription drug manufacturers. The court began this landmark decision by overruling McDaniel and ended by declining to adopt section 6(c) or section 2(b) of the Restatement (Third) of Torts: Products Liability. Both prongs

21. See id. at 437-38, 412 N.W.2d at 67 (quoting Nerud v. Haybuster Mfg., 215 Neb. 604, 610-11, 340 N.W.2d 369, 373-74 (1983) ("[T]he notion of a defective product embraces two separate concepts. The first, commonly labeled a manufacturing defect, is one in which the product differs from the specifications and plan of the manufacturer . . . . The second concept . . . is one in which the product meets the specifications of the manufacturer but the product nonetheless poses an unreasonable risk of danger. This condition is generally characterized as a design defect.").

22. Comment i of the Restatement (Second) of Torts states that the rule in section 402A "applies only where the defective condition of the product makes it unreasonably dangerous to the user or consumer . . . [and is] dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics."

23. See supra note 6.


25. See supra note 2 for a list of cases adopting the majority position.

26. See Freeman, 260 Neb. at 562-63, 618 N.W.2d at 837.

27. See id. at 567-68, 618 N.W.2d at 840.
of the court's decision are accurate interpretations of existing law and precedent and both shall receive equal attention in this Note.

1. New Nebraska Law: Section 402A, Comment k, and the Learned Intermediary Doctrine

Since its inception, comment k has been interpreted in a variety of ways and much disagreement remains regarding its application.\(^2\) However, despite the contention surrounding its application, it is quite unlikely that the American Law Institute intended it to provide blanket immunity to all prescription drug manufacturers based solely on FDA approval. That the majority of jurisdictions currently using comment k apply it on a case-by-case basis only strengthens this claim.\(^2\) These jurisdictions believe that the societal interests in ensuring the marketing and development of prescription drugs can be served adequately without providing blanket immunity to manufacturers.\(^3\)

However, as Nebraska moved away from the blanket immunity of McDaniel, it added its own twist to the handling of strict liability for design defect. Rather than adopting a risk-utility balancing test\(^3\) to determine liability, Nebraska borrowed from its Rahmig line of cases\(^3\) and adopted the consumer expectations test\(^3\) to determine strict liability for design defects.


29. See supra note 2 for a list of cases.


31. "A method of imposing product liability on a manufacturer if the evidence shows that a reasonable person would conclude that the benefits of a product's particular design versus the feasibility of an alternative safer design did not outweigh the dangers inherent in the original design." BLACK'S LAW DICTIONARY 1329 (7th ed. 1999).


33. See Freeman, 260 Neb. at 568, 618 N.W.2d at 840 (discussing the requirement that the plaintiff plead the consumer expectations test in prescription drug cases).
a. Working Definitions of Both Tests

Under a consumer expectations test, an "unreasonably dangerous" product is one that causes harm beyond that which a reasonable consumer (in the expected class of users) would foresee.34 Under a risk-utility balancing test, the fact finder evaluates whether the benefits provided by the drug outweigh the foreseeable risks associated with that particular drug.35 The benefit or "utility" of the drug may be small and the risk large, but under the risk-utility balancing test, the judgment of a health-care provider is often deferred to, and the risk is deemed acceptable as long as the proper warnings are given to the doctor or the patient. Based on the functional definitions established in this section, both tests can now be compared and evaluated.

b. Differences Between the Standards

One main difference between the tests is the placement and nature of the burden of proof. In jurisdictions that apply the consumer expectations test, the burden of proof on the plaintiff is much more manageable.36 A plaintiff is not forced to plead a reasonable alternative design, but only that the drug in question was unreasonably dangerous.37 Once that burden is met, the burden of proving that the drug should be exempted from strict product liability then shifts to the defendant, and a fact finder must determine if comment k will apply as an affirmative defense.38

Conversely, in most jurisdictions that apply the risk-utility test, a plaintiff must first plead that the drug has no benefit or utility that compares to the risk of harm, and then prove that a reasonable alternative design is available.39 Because of the added pleading and proof requirements, the burden on the plaintiff is much greater under the risk-utility test than under the consumer expectations test.

While it may be beneficial and is permitted, pleading and proving a reasonable alternative design in a jurisdiction that applies a consumer expectations test is usually unnecessary. Under a consumer expectations test, the only determinative question is as follows: What would a reasonable customer in the position of the injured patient have rea-

34. See Haag, 256 Neb. at 184, 589 N.W.2d at 329. See also supra note 22 (quoting the Restatement's formulation of the consumer expectations test).
35. See supra note 31.
36. In jurisdictions that apply the consumer expectations test, such as Nebraska, the plaintiff is not forced to plead or prove a reasonable alternative design. See generally Rahmig v. Mosly Mach. Co., 226 Neb. 423, 412 N.W.2d 56 (1987). See also Freeman v. Hoffman La-Roche, 260 Neb. 552, 618 N.W.2d 827 (2000).
37. See supra note 22.
38. See Freeman, 260 Neb. at 568, 618 N.W.2d at 840 (explaining the use of comment k in Nebraska).
reasonably expected from the drug? Therefore, adopting the consumer expectations test to evaluate strict prescription drug liability is a better choice for Nebraska because manufacturers are only exempt if they can prove that the drug they manufactured is unavoidsably, unreasonably dangerous. Plaintiffs still have to prove that the actions of the manufacturer fell below the applicable standards, but, in Nebraska, that is now a more manageable burden.

2. Application of Section 6(c) and Section 2(b) to Prescription Drugs

The following is a technical exploration of the applicability of section 6(c) and section 2(b) of the Restatement (Third) to strict liability for prescription drugs.

a. Section 6(c)

Much criticism has been generated regarding section 6(c) of the Restatement (Third) of Torts: Products Liability.\footnote{40} Section 6, entitled Liability of Commercial Seller or Distributor for Harm Caused by Defective Prescription Drugs and Medical Devices, states as follows in subsection (c):

\begin{quote}
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 reason-able health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.\footnote{41}
\end{quote}

Section 6(c) suggests a net-benefit test for prescription drug strict liability.\footnote{42} Comment b explains that although the Reporters do not believe that drug manufacturers should have carte blanche when it comes to drugs with FDA approval, section 6(c) does propose that manufacturers should be given a large amount of discretion in marketing pharmaceuticals.\footnote{43} Judging by the standard proposed in section 6(c) and the comments that follow, the Reporters appeared to believe that abrogating a strict standard and giving manufacturers in-

\begin{enumerate}
\item \textit{See George W. Conk, Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?}, 109 \textit{Yale L.J.} 1087, 1101 (2000); \textit{see also Restatement (Third) of Torts: Products Liability § 6(c) cmt. f} (1998) (describing the test proposed in section 6(c) in terms of a net-benefit test).
\item “At the same time, manufacturers must have ample discretion to develop useful drugs and devices without subjecting their design decisions to the ordinary test applicable to products generally under § 2(b).” \textit{Restatement (Third) of Torts: Products Liability § 6(c) cmt. b} (1998).
\end{enumerate}
creased discretion would allow drug manufacturers greater freedom to develop and market new drugs. Although this is a powerful theory, the validity of the argument is severely limited when applied to practical situations.

For example, comment f generally called the "reasonable physician" standard, has no practical application because it is overly complicated, rigid, and scarcely offers any relief or protection to patients. Under this standard, the issue in a design defect claim is whether, objectively viewed, a reasonable physician knowing the foreseeable risks and benefits of a particular drug would prescribe it for any class of patients. Liability is imposed only in the unusual situation such that no reasonable physician would prescribe the drug for any reason to any class of patients.

Later in the Note, the criticisms of section 6(c) will be discussed at length. For now, knowing that from a purely technical standpoint section 6(c) proposes a net-benefit test and incorporates the 'reasonable physician' standard is enough.

b. Section 2(b)

Section 2, Categories of Product Defect, states the following rule regarding strict liability for design defect:

A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. A product:

(b) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe.

Section 2(b) was specifically intended to deal with general product liability and was not designed to deal with prescription drugs. However, because section 2(b) is discussed briefly in Freeman and has been proposed as an alternative to both section 402A and section

44. See id.
45. "However when a drug or device provides net benefits to no class of patients, when reasonable, informed health-care providers would not prescribe it to any class of patients, then the design of the product is defective and the manufacturer should be subject to liability for the harm caused." Id. at comment f.
46. See id.
47. See infra text accompanying notes 70-83.
49. In fact, the Reporters discuss the differences between section 2(b) and section 6(c) in comment b of section 6 and note that the standard in section 2(b) was not intended for, and is too broad to address, the particular features of prescription drug litigation.
50. See Freeman, 260 Neb. at 567-569, 618 N.W.2d at 840-841.
6(c), it warrants a short technical explanation in this section, with a more detailed analysis to follow.

Section 2(b) is the section of the *Third Restatement* that deals with general strict product liability. Similar to the net-benefit test in section 6(c), it proposes a risk-utility balancing test for determining liability. Section 2(b), however, does not include the reasonable physician standard contained in section 6(c), but instead proposes a more universal standard for determining liability, that of "reasonable alternative design."

In several regards, the approach of section 2(b) resembles the way a majority of jurisdictions currently implement section 402A of the *Second Restatement*. Section 2(b) is distinguishable from Nebraska's method for handling prescription drug strict liability by the absence of the comment k affirmative defense. In section 2(b), the burden of proving a reasonable alternative design is placed on the plaintiff, essentially serving the same purpose as the comment k affirmative defense portion of Nebraska's scheme. If there is no safer alternative available, then the drug is unavoidably unreasonably unsafe and there is no liability. However, section 2(b) places the burden of proof on the plaintiff rather than on the defendant and, therefore, creates an unnecessarily arduous process for plaintiffs.

**B. Freeman Was an Insightful Decision**

The Nebraska court made a wise decision to break with *McDaniel* for two reasons: (1) the blanket immunity *McDaniel* created was ineffective in protecting patients and created patently unjust results; and (2) the new standard promotes increased protection of patients, the manufacture of safer products, and continued innovation by drug companies, all without forcing manufacturing and litigation costs to skyrocket.

Demonstrating a willingness to re-evaluate long-standing law, the Nebraska Supreme Court crafted a standard and application that incorporated the needs and rights of all affected parties. Consequently,

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51. See, e.g., Conk, *supra* note 42.
52. See *supra* text accompanying notes 83-90.
53. See *generally* *RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY* § 2(b) cmt. a (1998) (explaining section's applicability).
54. Id. at § 2(b).
55. See Conk, *supra* note 42, at 1094-98 (explaining that the majority of jurisdictions apply section 402A using a risk-utility balancing test accompanied by pleading a reasonable alternative design by the plaintiff to determine strict products liability for prescription drugs).
56. See *generally* Cupp, *supra* note 40, 96-97 (criticizing the results that would accompany the adoption of section 6(c) as the standard as well as its inflexible nature).
57. See id.
the design defect portion of the *Freeman* holding is not only an accurate statement of the applicable law and a positive step in the protection of consumers and patients, but a decision which encourages the manufacture and distribution of experimental drugs.

1. **McDaniel to Freeman—Righting a Wrong**

The law, as established in *McDaniel*, was both an inaccurate application of comment k and incapable of providing legitimate protection to patients. Under *McDaniel*, drug companies had nearly complete immunity from strict liability, in tort, for design defects.58 As long as a drug was approved by the FDA, prepared properly, and accompanied by the required directions and warnings, the drug was neither defective nor unreasonably dangerous as a matter of law.59

This use of comment k left patients like Marjorie McDaniel with limited legal recourse when they were injured by a prescription drug. To prove liability, McDaniel had to prove that the manufacturer of the drug fraudulently mislead the FDA.60 In jurisdictions like Nebraska, plaintiffs lost time and time again on any strict liability claim against drug manufacturers,61 and had little hope of proving strict liability in prescription drug cases (until, of course, *Freeman*).

The intended and appropriate application of comment k is, and has been for some time, hotly contested by scholars.62 Although comment k seeks to encourage innovation by providing protection for manufacturers of products like prescription drugs, nowhere is it expressly stated that all prescription drug manufacturers should be given blanket immunity from strict liability. Rather, a common sense interpretation leads a reader to the same conclusions that the Nebraska Supreme Court made in *Freeman* when it decided to adopt comment k as a case-by-case affirmative defense.63

Jurisdictions that adopt comment k as a case-by-case affirmative defense do not drastically reduce the protection they offer to manufacturers. They simply shift the burden of proof to defendants and re-

58. See text accompanying notes 9-18.
59. See id.
60. See id.
61. See, e.g., Brown v. Superior Court, 751 P.2d 470 (Cal. 1988). Both *Brown* and the extensive line of cases in California to follow it, are examples of what happens to plaintiffs under a system like *McDaniel*.
62. In fact, comment k is generally the most consistently debated comment to section 402A. See, e.g., Ian Birkett, *Arkansas Adopts Comment k as an Affirmative Defense in Prescription Drug Actions*, 14 U. ARK. LITTLE ROCK L. REV. 199 (1991) (dissecting the adoption of comment k in Arkansas); Thomas M. Moore and Scott L. Hengesbach, *Comment k: A Prescription for the Over-the-Counter Drug Industry*, 22 PAC. L.J. 43 (1990) (arguing that all over-the-counter drugs should be exempted from strict liability).
63. See supra text accompanying notes 9-18.
quire them to prove that the product is unavoidably, unreasonably unsafe to avert liability. The protection of comment k remains available to all prescription drug manufacturers. The difference between McDaniel and Freeman is the shift from blanket immunity sans fraud by the manufacturer, to earned immunity when deserved and justified. By re-interpreting comment k and subsequently shifting the burden of proof to defendants, the Nebraska Supreme Court created a more useful system predicated on a more accurate reading of the law.

2. Freeman: A More Precise and Protective Standard

Nebraska's adoption of a new standard for strict prescription drug liability adequately and accurately achieves the goals of prescription drug law. Because drug manufacturing is a profit driven business, the possibility of increased strict liability encourages exploration of new and better methods for testing and design of products.64 It is no longer safe for manufacturers to feel content that the benefit of a drug they manufacture is comparable to the risks it creates and therefore exempts them from strict liability.65 Instead, drug companies now have to be convinced that there is no reasonable, safer, alternative design before marketing a drug, which can only lead to safer, healthier patients.

Critics of strict liability for prescription drugs have cited increased costs associated with verdicts, litigation costs, settlements, and more expensive testing programs as reasons to avoid enforcing strict liability against drug manufacturers. While increased costs could serve as a deterrent to the adoption of a tougher standard, the cost of new tests or judgements against drug manufacturers can be spread out over each prescription making the cost increase negligible when compared with the results.66 Not only will patients get better drugs under Nebraska's new standard, but the drugs will be safer since drug companies should be persuaded to take more time and greater precautions in the development process to avoid potential liability.

Additionally, drug companies will continue to search for new cures and medicines. If the drug is new, it is likely that there are few known risks, only known benefits. As long as the manufacturer warns the doctor or patient of any known foreseeable risks, the chances of manu-

64. See Conk, supra note 42, at 1131 (allying critic's fears of increased cost and decreased experimentation by detailing the potential for increased safety through strict liability litigation).
65. See Restatement (Third) of Torts: Products Liability § 6(c) cmt. k (1998) (discussing Pasteur's rabies vaccination as an example of a medicine that has foreseeable risks but is still quite useful).
facturers being held strictly liable for new innovations is not likely, given the availability of the comment k affirmative defense. Since manufacturers are not facing any consequential rise in exposure for new drugs, innovation will continue under *Freeman*.

Accompanying these benefits is the realization that the new standard will give back to the courts some of the discretion they lost under *McDaniel*. Although the FDA might be the regulatory body most able to test the design and nature of a drug, their process is not flawless. All regulatory agencies make mistakes or receive errant test results. It is important to realize that there is a second buffer zone between prescription drugs and the public. Because of the Nebraska Supreme Court's holding in *Freeman*, the courts can now be such a zone for Nebraska. In fact, one could argue that litigation regarding prescription drugs is, and should be, part of the process and must be allowed to further ensure the safety of patients.

For those still wary of strict liability for prescription drug manufacturers, it bears noting that even though it took several substantial steps, the *Freeman* court's ruling does not guarantee the success of all strict liability claims against drug manufacturers. In Nebraska, plaintiffs must still overcome a demanding burden of proof, because the comment k affirmative defense will ferret out bogus claims. *Freeman* merely returns to the courts some of the discretion absent for the twenty-five years since *McDaniel* and it should lead to more just results for both parties.

Whether attributable to *McDaniel*'s shortcomings, the realization that the FDA cannot be the sole protector of patients, or the belief that Nebraska's prescription drug law was outdated and lacking, the Nebraska Supreme Court saw fit to make a change. *Freeman* is not only legally accurate, but is focused on ensuring just results for both patients and manufacturers. These substantial benefits make it clear that the court was correct to overrule the blanket immunity of *McDaniel*.

3. Not Too Much, Not Too Little, but Just Right

The court was able to make *Freeman* sufficiently narrow by: (1) declining to adopt section 6(c); and (2) not stretching the doctrine of section 2(b) beyond its intended use. Although no other state court had faced this question at the time *Freeman* was decided, the court steered Nebraska's tort law in a positive direction without creating an

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67. *See generally* Cupp, *supra* note 40, at 81-88 (criticizing the loss of some of the courts' discretion in jurisdictions that apply comment k blanket immunity).
68. *See id.* at 104-05 (advocating and discussing the benefits of litigation as a secondary precaution to an overworked, underfunded FDA).
69. *See id.*
70. *See Freeman*, 260 Neb. at 565, 618 N.W.2d at 838.
overly broad, untenable position. Declining to adopt section 6(c) and section 2(b) was central to this decision. Further examination of the problems with section 6(c) and section 2(b) demonstrate why the Nebraska Supreme Court was correct not to adopt either as law.

Adopting section 6(c) has several obvious drawbacks. The following discussion of the four general limitations of the proposed law will detail why the Nebraska Supreme Court was correct in declining to adopt section 6(c).

a. Section 6(c) Does Not Accurately Restate the Law

Section 6(c) does not restate the law as it is, but instead attempts to make new law. First, section 6(c) proposes an inflexible, overly complicated standard for evaluating design defects. The “reasonable physician” standard allows strict liability for prescription drugs only when no reasonable physician would prescribe the product because it is not useful to any class of persons. The majority of jurisdictions do not advocate and have not adopted this as the standard and, consequently, it does not serve as a restatement or clarification of the law. Rather, most jurisdictions apply some version of risk-utility balancing to determine strict liability for design defect in prescription drugs. These jurisdictions use a variety of factors to determine liability and often require the plaintiff to plead and prove a reasonable alternative design. Section 6(c) merely offers a hypothetical solution that fails

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72. This discussion is by no means all-encompassing, but rather focus on the glaring defects of section 6(c). For a more exhaustive examination, see Conk, supra note 42.


[T]here is no support in the case law for the application of a reasonable physician standard . . . . Rather, . . . the majority of courts apply some form of risk-utility balancing that focuses on a variety of factors . . . . The few cases that the Third Restatement cites to as support for the reasonable physician test also apply a risk-utility test. Thus, section 6(c) does not restate the law and instead seeks to formulate new law with no precedential support.

74. Even jurisdictions that may not conform to the majority do not apply the “reasonable physician” standard. Instead, they apply either a test like McDaniel, Freeman, or a risk-utility balancing test with the reasonable alternative design standard.

75. See Freeman, 260 Neb. at 562, 618 N.W.2d at 837 (discussing the method of application and factors used in other jurisdictions' risk-utility test, and explaining why Nebraska rejects that test).
to clarify strict product liability for design defect regarding prescription drugs, in effect muddling the issues as opposed to helping courts manage the changing legal landscape of prescription drug litigation.

Instead of representing the current state of prescription drug liability, or restating the law as it is, section 6(c) proposes sweeping changes with no basis in law. Not surprisingly, the Reporters themselves did not believe that the standard proposed in section 6(c) would be widely accepted for that very reason. Rather, the Reporters intended to create a new standard, which they quite notably accomplished. Unfortunately, the section as drafted does little to simplify or articulate the law of strict liability for prescription drugs and, consequently, is of little practical use.

b. The Reasonable Physician—an Unreasonable Standard

Another criticism of section 6(c) is the nature and proposed application of the reasonable physician standard. The reasonable physician standard is a demanding objective standard, less concerned with the actions of individual doctors or the safety of actual patients, and more concerned with what a "reasonable physician" would do. In fact, comment f of section 6 goes so far as to assert that while evidence regarding the conduct of the actual health-care provider is relevant and admissible, it is not controlling. According to the Reporter's notes, the issue before a fact finder is whether a reasonable provider, aware of the foreseeable risks and benefits of a drug, would prescribe it for any class of patients. Consequently, as one commentator noted, there is no need for fact finders with any critical thinking skills. Rather, fact finders will be required to evaluate expert testimony and decide based solely on the opinion of those experts. It matters not what a jury or judge believes is reasonable, or even what a given community believes is reasonable; it only matters what an expert says a "reasonable physician" would do, no matter how absurd.

76. Reporter James Henderson acknowledged that, although the new Restatement will "bring clarity," it is quite possible that courts will not accept it in whole or part. In 1993 he stated: "I believe the Restatement will have normative force. The prestige of the American Law Institute will give it weight. However, I doubt that every court will adopt it. I do not think it will meet the reception of the Restatement (Second) of Torts section 402A, which was an idea whose time had come." James Henderson, Revising Section 402A: The Limits of Torts as Social Insurance, 10 TOURO. L. REV. 107, 108 (1993).

77. See supra note 45 and accompanying text (discussing reasonable physician standard).


79. See id.

Consequently, the Nebraska Supreme Court was justified in rejecting section 6(c) as its standard for prescription drug liability because the "reasonable physician" standard is impractical, allows little, if any, discretion on the part of fact finders, and does nothing to improve the plight of patients. The Nebraska court made the best of a complex body of law in deciding to evaluate each claim on a case-by-case basis, ensuring more just results.

c. Cosmetic vs. Therapeutic

Another difficulty facing jurisdictions choosing to adopt section 6(c) is that the test in section 6(c) treats all drugs, no matter what their utility, similarly. Nowhere are the problems with this proposition more evident than in a case like Freeman. Accutane, the drug Freeman alleged was defectively designed, is an oral medication designed to treat acne. While clear skin may be important to a large percentage of people, very few people would equate a medication that cures acne with the types of chemotherapy designed to fight cancer. While not ideal, side effects from a drug that can save lives may be tolerable if there is no safer alternative. Conversely, serious side effects from a cosmetic drug such as Accutane are unacceptable. Under section 6(c), both the drugs used in chemotherapy and the cosmetic drug would be exempted from liability because both drugs could benefit a certain class of people and would, therefore, pass the "reasonable physician" test.

In contrast, under the new Nebraska standard, if the drug is more dangerous than a reasonable consumer with ordinary knowledge would reasonably expect, enforcing strict liability against the manufacturer is possible. Since plaintiffs have a more effective remedy available, there will be more pressure on manufacturers to comply with the new standard, and patient safety should continue to increase.

Although Freeman increases patient remedies, Nebraska's new standard still promotes the development of new drugs. Generally, when a prescription drug is new, no alternatives exist, let alone safer alternatives. Consequently, a manufacturer would rarely, if ever, be held liable, absent fraud or deception, for a new or experimental drug, especially if it is a potentially life-saving drug. Only if the drug is avoidably, unreasonably unsafe and the manufacturer's actions fall below acceptable standards will courts in Nebraska be able to impose strict liability. Accordingly, because section 6(c) does not make any allowance for the differing usefulness of prescription drugs, and because the Freeman court was able to craft a simpler and more flexible

81 In a March 28, 1998 edition of the Lancet, there was a discussion of the FDA's reaction to Hoffman La-Roche's questionable advertising in light of Acutane's known side effects. THE LANCET, Mar. 28, 1998.
standard, the Nebraska Supreme Court acted in the best interests of fairness when it declined to adopt section 6(c).

d. Ease of Claim Dismissal

Strict liability under section 6(c) is virtually impossible to adequately prove, and plaintiffs would find getting beyond summary judgment, let alone succeeding at trial, an inherently unattainable goal. The relative ease with which a consumer's claim could be defeated is perhaps the most obvious reason that Nebraska decided to reject section 6(c).82

For example, if the standard in section 6(c) were applied to a strict liability claim like Freeman's, Freeman would have lost. To prevail, Hoffman La-Roche (the manufacturer of Accutane) would only have needed to produce evidence of the countless known prescriptions still being written for Accutane. Since doctors all across the country still prescribe Accutane daily, despite the foreseeable and known risks, the reasonable physician test is passed, and Freeman would have no remedy in strict liability. Patients would have no real solution and drug companies would have no incentive to change, defeating the original goals of strict product liability.83

Furthermore, on the rare occasion that a claim for strict prescription drug liability gets beyond the summary judgement stage, under section 6(c) the fact finder is not allowed to give any weight to the availability of other, less harmful drugs which may be just as effective. Judges or juries are not allowed to decide what an "ordinary consumer" should have expected as reasonable side effects to the drug taken. Rather, they must rely solely on the word of an expert testifying to what a reasonable physician would do. This is a sinister design because the fate of the plaintiff rests solely in the hands of an expert, often a professional witness. Reaching a just decision is made more difficult and arriving at a clearly refined and articulated body of law is nearly impossible.

Based on the enumerated flaws in section 6(c), the Nebraska Supreme Court crafted a thoughtful opinion and was able to balance the interests of all involved when it chose to reject section 6(c). Section 6(c) does not accurately restate the law, the reasonable physician test is artificial and unreasonable, the usefulness of the drug is not balanced against its utility, and plaintiffs will very infrequently stand a chance of meeting such a high burden. Consequently, section 6(c) did not become a component of prescription drug law in Nebraska.

82. Commentators have noted several additional problems with section 6(c). See generally Cupp, supra note 40, at 88; Conk, supra note 42, at 1088-90.
83. See generally Epstein, supra note 66, at 728-47.
4. 2(b) or Not 2(b)

After explaining its reasons for declining to adopt section 6(c), the Nebraska Supreme Court briefly discussed the relevance of section 2(b) to prescription drug law. The court quickly dismissed the applicability of section 2(b) because it was crafted for general products liability and the parties in the case did not address it as an alternative to McDaniel, section 402A, or section 6(c). This segment of the Note will more thoroughly examine the application of section 2(b) to determine its place in prescription drug litigation.

Despite the suggestion of at least one author that section 2(b) can be used as an alternative to section 6(c), Nebraska chose not to adopt section 2(b) to serve as its guide to prescription drugs. In response to any claim that section 2(b) should be applied to prescription drugs, one must start with the Third Restatement itself. Comment b of section 6 states that section 2(b) does not apply to prescription drugs and medical devices because the standard in section 2(b) is a less rigorous standard than section 6(c). Although proposing a less rigorous standard than section 6(c) is not necessarily a negative, credence must be given to the fact that the Reporters themselves did not believe section 2(b) was capable of evaluating prescription drugs.

More important to Nebraska’s courts and attorneys than the Reporter’s view of section 2(b) is the standard and burden of proof proposed. Similar to the net-benefit test in section 6(c), section 2(b) proposes a risk-utility balancing test for determining strict liability. One distinct difference between section 2(b) and section 6(c) is that in place of the reasonable physician standard, section 2(b) proposes a more universal standard for determining liability: that of reasonable alternative design. Thus, the approach of section 2(b) is quite similar to that of the majority of jurisdictions currently implementing section 402A of the Second Restatement. In Freeman, Nebraska rejected both the risk-utility balancing test and the reasonable alternative design standard, and consequently, maintained consistency by in rejecting the adoption of section 2(b) as Nebraska’s prescription drug model for the same reasons.

84. See Freeman, 260 Neb. at 568, 618 N.W.2d at 840.
85. See generally Conk, supra note 42 (proposing section 2(b) as a better standard for prescription drugs than section 6(c)).
86. See Restatement (Third) of Torts: Products Liability § 6(c) cmt. b (1998).
87. See id. at § 2(b).
88. See id.
89. See generally Conk, supra note 42, 1094-96 (examining how the majority of jurisdiction apply section 402A and comment k to claims of prescription drug strict liability).
90. See Freeman, 206 Neb. at 568, 618 N.W.2d at 840.
Based on the shifted and increased burden of pleading and proof on the plaintiff, the loss of comment k as an affirmative defense, and the fact that the drafters never intended section 2(b) for use on prescription drugs, the Nebraska Supreme Court was justified in declining to adopt section 2(b) as the test for prescription drug strict liability. The resulting law is more reasonable, allows courts more discretion, and more aggressively protects the rights of patients while not impeding innovation. Additionally, if strict liability is to continue evolving, the law must strike a balance between no liability for manufacturers and no justice for patients. With its ruling in Freeman, the Nebraska Supreme Court determined the course of prescription drug liability in Nebraska and articulated such a balance.

C. Possible Reasons for the Court’s Decision

Several possible reasons exist for the Nebraska Supreme Court’s decision to overrule McDaniel and not adopt section 6(c) or section 2(b) of the Third Restatement: (1) the state of the law in other jurisdictions;91 (2) the fact that Freeman involved a cosmetic drug that was avoidably, unreasonably dangerous; and (3) the fact that section 6(c) has so many potential pitfalls.92 One such reason alone may not have been enough to overrule twenty-four years of precedent, but the combination of all three pieces made the Nebraska Supreme Court’s decision landmark, and dramatically transformed Nebraska’s position on strict liability for prescription drugs.

Although all three elements were substantial conditions, two of the three elements cannot be underestimated. The type of drug involved in Freeman combined with the nature of strict liability for prescription drugs in most other jurisdictions, presumably swayed the Nebraska court as much, or more, than any other element of this decision. No doubt, the court felt pressure to conform its laws with that of the majority of jurisdictions, especially since patients and plaintiffs were being treated unjustly under McDaniel. Even if Nebraska was not planning to adopt the same prescription drug standards as other jurisdictions, Nebraska’s body of prescription drug law was in desperate need of updating.

The awareness that Nebraska prescription drug law needed an overhaul to better protect patients combined with the chance to shape new law without wrestling with the complications presented by a less cosmetic, more therapeutic drug, provided the ideal setting for a such a decisive break with McDaniel. These two significant factors, combined with the sub-standard nature of section 6(c), led the court to

91. See generally, Cupp, supra note 40 (organizing jurisdictions into three general categories by how each handles prescription drug strict liability).
92. See supra text accompanying notes 70-83.
break with old law and introduce a more universally recognized and considerably more just standard for prescription drug liability.

D. Projections of the Future Social and Legal Impact of Freeman

Because the Nebraska court adopted the consumer expectations test and the doctrine of the learned intermediary,93 several social and legal changes are foreseeable. Among the projected changes are the way pleadings are constructed, the way the elements are presented, the pretrial and out-of-court duties of attorneys, and the several social ramifications of this landmark decision.

1. Legal

By adopting a new standard for prescription drug strict liability cases in Freeman and overruling the blanket immunity for drug manufacturers provided by McDaniel, Nebraska potentially opened its courts up to a flood of litigation. Some critics point to the missing requirement of the reasonable alternative design “buffer” against increased litigation as a serious flaw in Nebraska’s scheme. These critics argue that by not forcing the plaintiff to plead a reasonable alternative design, liability is determined solely by what a reasonable consumer should have expected, not by what is actually possible. The result these critics fear, is a situation in which every cause of action could reach the trial phase. Consequently, critics caution, the cost of litigation could skyrocket because of the extra time and resources spent defending frivolous claims under the consumer expectations standard.

A closer examination of the Freeman decision exposes the weaknesses of these criticisms. By allowing comment k to function as an affirmative defense for manufacturers, there may be a small increase in the numbers of claims that reach trial, but there should be no discernable elevation in litigation costs.94 Even if more claims progress beyond the summary judgment phase, the actual number of cases in which liability is imposed would not increase greatly, because the buffer critics have clamored for is directly under their collective noses, albeit in a slightly different configuration.

The use of comment k as an affirmative defense allows the question of the availability of a reasonable alternative to be presented to a fact finder. However, it places the burden of pleading and proof on the

93. See Restatement (Third) of Torts: Products Liability § 6(d) (1998) (outlining what triggers the learned intermediary doctrine and describing its role in the Third Restatement).

94. See Conk, supra note 42 (providing statistics that support a claim that litigation costs will not greatly increase with the shift Nebraska made).
defendant and forces a manufacturer, intending to avoid strict liability, to explain to a jury why the drug is unavoidably, unreasonably unsafe. No portion of the risk-utility balancing test or the reasonable alternative design test is lost under the consumer expectations test. Rather, under recent Nebraska law, the burden of proving that a drug is unavoidably, unreasonably unsafe is shifted to the defendant, which is the most logical place for this particular burden. After all, manufacturers are in the best position to know of the availability of a reasonable alternative,95 and defendants are in the most effective position to prevent the harm caused to the patients.

Moreover, in *Freeman*, Nebraska returned to the roots of strict liability: corrective justice.96 The goal of corrective justice is to place the loss incurred on the party who created the condition, as opposed to placing an undue burden on the party who suffered from that condition.97 The defendant’s drug “caused”98 the harm and the manufacturers are the experts on the drug that caused the harm. Therefore, to escape liability, the defendant should be the party forced to prove that no safer alternative was available at the time of the manufacturing of the drug.

Furthermore, by forcing the manufacturer to plead and prove that comment k should apply to its particular product, litigation costs may decrease because manufacturers will have more incentive to design, manufacture, and market safer drugs. If a manufacturer knows that there is a reasonable alternative available, it essentially is faced with two alternatives: (1) either switch production to mirror that of the safer alternative before distribution;99 or (2) continue to manufacture products in the same ‘dangerous’ manner, knowing that liability is probable.100 In either scenario, no discernable upsurge in money or time spent litigating cases will occur, while the potential for increased patient safety and just results increases greatly. Considering these reasons, it seems clear that the Nebraska court was correct in adopt-

95. Based on the expertise from the design and manufacture of a drug, and the intimate knowledge that accompanies this process, manufacturers know more than patients, plaintiffs, and possibly some doctors.
96. See Epstein, *supra* note 66, at 746 (explaining the concept of corrective justice and the role it plays in strict liability).
97. See id. at 746-47.
98. Throughout this paragraph, “caused” is to be interpreted in the loosest sense, as in led to or contributed, but not as in fault.
99. If a manufacturer switches design to meet the safer possibility before hand, then it will likely not become a defendant because there will be no litigation related to that drug.
100. If there is no change in the design of the drug when a claim arises, defendant manufacturers will probably settle early, knowing that they would likely lose at trial because a safer alternative is available.
ing comment k as a buffer to liability under a consumer expectations test.\textsuperscript{101}

2. Social

Coupled with the possible legal ramifications of the \textit{Freeman} decision, several social changes may spring from the new Nebraska law. The \textit{Freeman} decision may lead to: (1) better warnings and testing by drug companies; (2) more awareness on the part of doctors regarding a drug’s side-effects and the availability of alternative drugs; and (3) fewer patient injuries. Though not inevitable, if even one of the discussed social changes occurs, it would be another feather in the cap of the \textit{Freeman} court.

\textbf{a. Better Warnings and Testing}

When operating a business, the bottom line is the bottom line. Investment in pharmaceutical companies is generally a very secure venture.\textsuperscript{102} The preceding statement is not intended to suggest that a healthy bottom line should be held against drug companies, or any other companies for that matter. In fact, many scholars have argued that capitalistic competition for market-share often drives businesses to make better, cheaper, and safer products.\textsuperscript{103}

However, just as automobile and general product litigation have forced manufacturers to provide safer products and better warnings, so too, can prescription drug litigation force manufacturers to be more precise. Hitting a company in its pocketbook is one of the most effective ways to institute change, and even a few million-dollar settlements could cause a company to alter its business practices.\textsuperscript{104} Higher litigation costs coupled with increased market-share competition will likely trigger positive changes in testing measures employed by prescription drug manufacturers.

Opponents of increased liability for drug manufacturers cling to the idea that forcing more safety testing and allowing more litigation will lead to astronomical increases in the cost of prescription drugs. These critics express concern that few citizens will be able to afford

\textsuperscript{101} Other potential legal changes may occur when the court is faced with a cause of action involving a less cosmetic, more therapeutic drug. The \textit{Freeman} standard appears to be solid, but the court may be forced to re-evaluate its position when such a claim arises.

\textsuperscript{102} Even during a time of recession lasting over a year, the biotech and drug industry is still the number one rated stock, per return on investment, on several websites.

\textsuperscript{103} This is a strong point, and generally easy to accept as true. However, realizing that prescription drug companies are profit driven and attempt to capture large portions of the market share only bolsters the argument that the only way to get them to take notice is to make them pay.

\textsuperscript{104} This Note is certainly not advocating obscene damage awards, and neither does that seem to be the goal of the Nebraska Supreme Court in \textit{Freeman}.
the newer, safer, more expensive drugs. However, such concerns are both unreasonable and unfounded. By examining the results of strict liability in the automobile industry, one can see that a balance between consumer wants and needs versus product price and safety is possible.

When discussing safety versus affordability and utility, cars have had the most analogous development pattern to that of prescription drugs. In automobiles, there are two extremes possible in the frame and body of a car. At one end of the spectrum is a car with a plastic frame and an open, fiberglass body. Such a vehicle would be remarkably inexpensive, very convenient, notably efficient in fuel consumption, but extremely dangerous to passengers and drivers. On the other end of the safety continuum is a vehicle with a steel cage and roll-bars for a frame, and thick, steel, unibody panels. This distinctive, tank-like car would be almost impenetrable during normal driving use, but it would guzzle gas and be prohibitively expensive to purchase.

One alternative that meets the needs and demands of both consumers and manufacturers is a car with a steel frame and thin composite aluminum and steel panels. Cars like this are lighter, more convenient, and less expensive than the tank, but substantially safer than the plastic and fiberglass option. Add airbags and shoulder harness seatbelts and the safety increases even more with very little added cost. This analogy proves that balancing safety with efficiency and cost effectiveness is quite possible.

Yet another example of this type of balance becomes clear upon examination of John Winger's plight. John has terrible allergies, but substandard insurance and average means. His choice spectrum includes the options of taking no medication and suffering greatly, but saving seventy-five dollars a month, or taking the drug that alleviates his allergy symptoms completely with no notable side-effects, but foregoing other essentials, like food, to afford it. Neither is a viable solution for John, so he must find a balance.

Enter the fifteen dollar per month alternative drug. Although not quite as effective as the seventy-five dollar a month medication, it is considerably more effective than taking nothing. John gets a safe drug that controls his allergies without having to sacrifice the rent payment to be allergy free. A balance such as Winger's is not only possible, but probable under Freeman, given the negative alternatives of patient injury or increased litigation costs that would result from no sustainable equilibrium. Based on the history of strict product liability in Nebraska, it is conceivable that consumer demands, combined

105. Based on a true story. Names have been changed to protect the innocent.
with regulation of new prices and increased marketplace competition, will lead to safer, yet affordable, drugs.

b. More Aware and Attentive Doctors

Patients and consumers should be hopeful that the pressure on drug companies will lead health-care workers to be more aware of the provided warnings and side-effects of the drugs they prescribe. Because of this potential liability, physicians will likely become more deliberate when they prescribe medication and, therefore, make better advocates for their patients.

The threat of potential liability may also help reverse the ongoing trend of doctors spending less and less time with individual patients. With the adoption of the learned intermediary doctrine, it will be in a doctor's best interest to know as much as possible about each patient, since a miscalculation from lack of familiarity can end a doctor's practice and a patient's life. Doctors who are potentially strictly liable for failure to warn patients will perhaps be more attentive to drug literature and available, alternative treatments.

Likewise, doctors will receive more warnings and information detailing side-effects from drug manufacturers before they begin prescribing a drug. By completely and accurately informing a physician of the potential dangers and side effects of a drug, manufacturers can be exempted from liability for failure to warn the patient under the learned intermediary doctrine. Doctors should be able to make more informed decisions based on increased information, resulting in fewer instances of careless prescriptions.

This increase in pressure should force drug manufacturers to create safer products. After all, if a drug is unsafe, large numbers of doctors will not prescribe it. Fewer prescriptions mean less money and, as discussed earlier, affecting the profit margin of any company or the livelihood of health-care professionals is the way to initiate change. These adjustments in procedure and policy will help curb the

106. See, e.g., Schenebeck v. Sterling Drug, Inc., 423 F.2d 919, 923 (8th Cir. 1970) (stating that a manufacturer's failure to warn the medical community of the risks involved with a drug vicariously breached the manufacturer's legal duty to the patient); Presto v. Sandoz Pharm. Corp., 487 S.E.2d 70, 73 (Ga. App. 1998) (holding that manufacturer of prescription anti-psychotic drug had no duty to directly warn the patient of risks of discontinuing use of the drug); Doe v. Alpha Therapeutic Corp., 3 S.W.3d 404, 419 (Mo. Ct. App. 1999) (affirming that the learned intermediary defense protected the manufacturer of blood products which were contaminated with HIV from failure to warn claims); McEwen v. Ortho Pharm. Corp., 528 P.2d 522, 529 (Or. 1974) (stating that the manufacturer is directly liable to the patient for a breach of its duty to warn the patient).

107. One can only assume that doctors choosing between two equally effective drugs will usually choose the safer of the two to prescribe for a patient.
senseless injuries and deaths that result from avoidably, unreasonably dangerous drugs and inadequate warnings.

E. Life After Freeman—What Lawyers Should Expect

Freeman will have a marked effect on Nebraska's attorneys. Lawyers on both sides will have several new responsibilities and opportunities in offering proper representation to their clients.

1. Plaintiffs' Attorneys

   a. Pleading and Proof

   The Nebraska Supreme Court established a new procedure for pleading a maintainable cause of action for strict liability based on design defect of a prescription drug. A plaintiff must now plead that the drug was unreasonably dangerous under a consumer expectations test. Additionally, any pleading alleging a warning defect must satisfy the requirements of the learned intermediary doctrine. This departure from pleading under McDaniel requires attorneys to be aware of the subtle and not so subtle differences that the Nebraska Supreme Court adopted in Freeman.

   Likewise, the burden of proof in Freeman is lower for plaintiffs than it was in McDaniel, and liability becomes more that just theoretically possible. By adopting comment k as a case-by-case affirmative defense, the court created a standard that is more plaintiff-friendly than the previous blanket immunity of McDaniel. If pled correctly, a claim now has a considerably better chance of surviving summary judgment and patients enjoy more likelihood of recovering for harm caused by defective, prescription drugs.

   b. The Effect of the Learned Intermediary

   In addition to the pleading requirements for making a claim against the manufacturer, plaintiffs' attorneys must also be aware of the requirements and consequences of the doctrine of the learned intermediary. If the manufacturer adequately warned the healthcare provider, then a cause of action for strict liability against a manu-

108. Although not discussed in this Note, the Freeman court discussed and articulated new law regarding causes of action alleging manufacturing defects as well. See Freeman, 260 Neb. at 569, 618 N.W.2d at 841.

109. See id. at 568, 618 N.W.2d at 840 (discussing the incorporation of the consumer-expectations text into Nebraska's body of law on strict liability for manufacturers of prescription drugs).

110. "We also adopt the learned intermediary doctrine as reflected in section 6(d) of the Third Restatement as the test to be applied when considering whether a warning defect exists in a prescription drug." Id. at 577, 618 N.W.2d at 845-846.

facturer will not survive a defense motion for summary judgment. Not only should plaintiffs' lawyers know whether or not the doctor was adequately warned by the manufacturer before suing on failure to warn, but plaintiffs' attorneys should consider suing doctors who fail to warn their patients adequately. Doctors are presumed to be more knowledgeable about a drug than their patients and are expected to be advocates of their patients' best interests. By holding doctors accountable for the drugs they prescribe, courts can protect patients while increasing the potential for better warnings and inserts accompanying all prescription drugs.

c. The Focus of the Litigation

Patients no longer have to prove fraud by the drug manufacturer to enforce strict liability. From expert and witness testimony to opening and closing statements to depositions and interrogatories, the focus for plaintiffs' attorneys must change. An attorney's time and energy should be directed primarily at proving that the drug in question was avoidably, unreasonably unsafe, based on the expectations of an ordinary consumer with ordinary knowledge.

Although proving the availability of a reasonable alternative design can bolster the claim that a product was unreasonably dangerous, it is not necessary and might cloud the minds of the jury. Instead of straying from the new burden of proof established in Freeman, plaintiffs' attorneys should let manufacturers spend time and money attempting to convince the jury that the drug is unavoidably, unreasonably dangerous. By concentrating on the pleading requirements of Freeman, plaintiffs' attorneys will not only conserve resources, but will not make any part of defendants' cases for them.

2. Defense Attorneys

The key to surviving the changes implemented by the Nebraska court in Freeman is proactive client management. Instead of waiting until litigation arises and then trying to defend against it, defense attorneys should seek out potential problems and defuse them before they explode. Education can be a huge time and money saver for both clients and attorneys.

a. Lawyers Representing Manufacturers

Whether it means hiring new lawyers with the requisite education and medical background, or contracting with other similar specialists, a firm must be able to adapt to the new demands Freeman has created. Meeting with clients to explain the law and the ways to avoid liability before a problem arises may be the best possible solution for

112. See supra text accompanying notes 25-39.
defense lawyers and their clients. By educating clients, defense attorneys are working to avoid the need to litigate prescription drug cases. Given the more plaintiff-friendly nature of the pleading and proof requirements set forth in *Freeman*, avoiding litigation would be ideal for defense attorneys and manufacturers alike.113

Defense lawyers and their clients can benefit from an “education first” approach to the *Freeman* decision in three main ways. First, by potentially saving the client millions of settlement dollars as well as the negative press that accompanies such cases, a defense attorney provides an invaluable service, thereby ensuring grateful clients. Although litigation costs per client may increase slightly as the new standard is implemented, a potential decrease in litigation and settlement costs is foreseeable for a manufacturer who is educated in the law. By focusing on the client’s long-term goals and bottom line, defense attorneys can provide the best possible service for their clients as well as saving the client money in the long run.

Second, as other non-client manufacturers get wind of firms with new “proactive” and “cost-effective” methods and policies, the possibility of increasing the firm’s client base soars. Non-client manufacturers, concerned with both public image and operating costs, will jump at the opportunity to save money and produce better products. A firm with a thorough understanding of the law handed down in *Freeman* and a program in place to convey that knowledge to a manufacturer, positions itself to benefit immensely from this change in Nebraska law.

Finally, billable hours per client should not change dramatically because clients can be billed for the time it takes to explain the new law and discuss preventative measures. This reality makes education even more of an incentive. Additionally, clients will save money on large litigation or settlements, even if budgeted per year litigation expenses do not immediately decrease. Therefore, firms that demonstrate an ability to adapt to the changes in prescription drug law will not only benefit as a firm, but can work wonders for their clients.

In addition to the chance to save patient lives and prevent serious injury, educating clients can have nothing but a positive effect on the bar and the prescription drug industry. Clients will be more satisfied with a firm’s performance, manufacturers can save money on avoided litigation and settlements, a firm’s client base can grow exponentially, and the firm’s income should not decrease dramatically and may actually grow—all thanks to the development and institution of an educa-

113. Although the court in *Freeman* eliminated blanket immunity for manufacturers and shifted the burden of proving the availability, or lack thereof, on the defendant, litigation by no means will be a “slam dunk” for plaintiffs. The availability of comment k as an affirmative defense affords defendants a legitimate chance to avoid liability.
tion program in response to the Nebraska Supreme Court's holding in *Freeman*.

b. *The Workload: Not More, Just Shifted*

After learning about some of the new challenges that will be facing defense attorneys, it may seem as if the workload has increased greatly; however, that is not the case. Rather, the attorney workload has shifted, requiring more hands-on work with the client to prevent litigation, and more time spent explaining to clients the need to:

1. Provide accurate warnings, both on products and directly to doctors. Such warnings can insulate the manufacturer from liability for failure to adequately warn.

2. Test all products thoroughly before marketing and document the method used and results of the tests. Drug companies can no longer assume that FDA approval is a "get out of jail free" card. Since comment k applies only on a case by case basis, the need for testing and re-testing of drugs before marketing is more important than ever.

3. Bring possible "dangerous" or "questionable" drugs and side-effects to the attention of an attorney to determine the potential liability of marketing the drug as is.

Likewise, for firms or lawyers that represent doctors and health care professionals, the job description has been altered. By meeting with clients individually or collectively and explaining what the new law is, what it means to them, and how to avoid liability and protect patients while still turning a profit, clients save money and heartache, and the earning potential of smart, forward-thinking firms and attorneys will increase.

A defense attorney must meet with the doctors and explain the need for them to do the following:

1. They must be selective in the types of drugs they prescribe. A health-care professional should not rely on the FDA or drug company's literature exclusively. Rather, they should know everything from the side effects, to interaction warnings, to what other doctors say about all drugs prescribed to any particular patient. This knowledge can not only alert doctors to potential health hazards for their patients, but help prevent potential career-ending liability.

2. They must read the warnings provided and explain what these warnings mean to patients. By reading and accurately conveying the meaning of all associated warnings, doctors not only help insulate

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114. However, for those looking forward to more work or more litigation, it is still quite possible. Several scholars have argued that one reason to avoid the approach Nebraska has taken is an increase of litigation costs. *See generally* Conk, *supra* note 42. No matter which side one is on, it is easy to see that, possibly with established education program, and probably without one, there will be more litigation resulting from *Freeman*. 
themselves from liability, but they protect patients from injury and the manufacturer from liability for failure to warn.

3. They must have a nurse or other appropriate employee present when explaining warnings and potential side effects. Although it will likely not be determinative in the mind of a jury, if litigation arises, having another witness to testify on behalf of the client is definitely an asset.

4. They must have patients sign a sheet, prepared by the firm, that confirms that the doctor explained the side effects and potential risks to the patient. This paper is not necessarily intended to absolve the doctor of fault, or to even be legally binding, but it is a way to make sure a patient is listening, and could have value as circumstantial evidence at trial. Not all patients will agree to sign it, which is why it is of increased importance to have a nurse or other appropriate employee present during the warning process.

3. Innovation—The Linchpin of a Successful Practice

Although Freeman dramatically changed the playing field, the Nebraska Supreme Court created a detailed blueprint that adequately serves both plaintiffs and defendants. To astute entrepreneurs, the new law creates a chance to distinguish themselves through innovative litigation techniques and client management. Plaintiffs have a realistic chance of proving strict liability against drug manufacturers, but their attorneys must be well-versed in the new law. Conversely, defense attorneys have an excellent opportunity to carve out a bigger, more successful piece of the proverbial pie by taking a proactive approach to the changes adopted in Freeman. Opportunity is knocking—who is going to answer?

IV. CONCLUSION

Although the Nebraska Supreme Court had to wade though twenty-four years of history and an immense assemblage of different standards, it was able to create a system that offered the best combination of results for all those affected by prescription drug litigation. The Freeman court was justified in overruling McDaniel and declining to adopt section 6(c) or section 2(b) of the Third Restatement. In Freeman the goals of the law of design defect for prescription drugs, both current and proposed, were balanced with the reality and demands of a product-driven society. Although the result is more of a beacon than a definitive, all-encompassing answer, the result is a standard and an application that encourages innovation, yet protects patients, consumers, and drug companies.

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