

# THE IMPACT OF TECHNOLOGICAL ADVANCEMENT ON PHARMACEUTICAL COMPANY LIABILITY

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## INTRODUCTION

Technological advancement is generally regarded as beneficial to society. Increases in technology tend to positively impact both individuals and business entities. For individuals, technological advancement usually translates to a higher standard of living or quality of life. This can materialize in the form of a more comfortable lifestyle and a more satisfying personal and professional life. For business and industry, such advancements are usually considered opportunities for increasing efficiency and higher profits. However, businesses should be aware that, from a legal standpoint, technological advancements may also result in increased responsibilities and liabilities to customers, business partners, and society as a whole. The positive and negative implications of technological advancements are quite possibly most profound in the medical and pharmaceutical industries.

It is not uncommon for unsafe or defective drugs to reach pharmacies or other ultimate outlets for retail consumption, nor is it uncommon for there to be newly discovered drug interactions, adverse reactions, contraindications, or precautions, of which ultimate distributors and retailers need to be made aware. In such instances, pharmaceutical manufacturers are compelled to notify such pharmacies to recall or issue notifications regarding drugs that have been previously distributed to wholesalers and retail pharmacies. Such notifications often require distributors and salespersons to stop selling the drug at issue and require pharmacies to remove such drugs from their shelves or provide more adequate warnings regarding newly discovered information. However, there is often a significant delay after an announced recall or other need for notification before pharmacies across the country are notified. During this period of delay, distribution and sale of the drug often continues, allowing consumers additional exposure to the unsafe, defective, or deceptive product.

Although early notification systems are, and should be, utilized for recall and post-distribution notifications of all defects, situations requiring recall are the most serious. The focus of this Article is the legal implications associated with drug recall. However, they also apply to the need to notify retailers regarding newly discovered drug interactions, adverse reactions, contraindications or other needs for precautions.

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This Article will first provide a general overview of federal regulations governing drug recalls. It will then examine the potential liability of pharmaceutical manufacturers and distributors for any injury or damage to consumers resulting from use of a drug after discovery of a defect and subsequent recall or issuance of a warning regarding newly discovered information about a drug. Specifically, this Article discusses the increased potential for liability resulting from the development of innovative nationwide systems by which pharmacies can be notified of the need to remove drugs from their shelves or the need to take other appropriate precautions within hours of the issuance of a notice of a defect. This Article concludes that the failure to utilize an early notification system could expose pharmaceutical manufacturers and distributors to costly lawsuits by consumers harmed by defective products, and that employing a service technologically equipped to provide the earliest possible notification of drug recalls is a cost-effective method of avoiding potential liability.

### I. GENERAL OVERVIEW OF APPLICABLE FEDERAL REGULATIONS

A recall generally occurs because the drug in question is unsafe or problematic to the public, or violates Food and Drug Administration (FDA) regulations.<sup>1</sup> Manufacturers often recall drugs at the FDA's request, although the manufacturer itself may initiate a recall.<sup>2</sup> The FDA will request that a drug be recalled when it determines: "(1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception[;] (2) [t]hat the firm has not initiated a recall of the product[; and] (3) [t]hat an agency action is necessary to protect the public health and welfare."<sup>3</sup>

The applicable federal regulations do not set forth specific procedures that manufacturers must follow when recalling a drug. Instead, federal regulations require only that manufacturers employ a recall strategy suitable to the circumstances of a particular recall, taking into account the depth of the recall necessitated by the product's hazardous nature and extent of distribution, the necessity for public warning, and the utilization of procedures to verify the effectiveness of a recall.<sup>4</sup>

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1. The general policy governing drug recalls appears in the Code of Federal Regulations as follows:

Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration. Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective.

21 C.F.R. § 7.40(a) (1996).

2. *Id.* § 7.40(b).

3. *Id.* § 7.45(a).

4. *Id.* § 7.42. This section requires that the recall strategy employed by the manufacturer provide for the following factors:

(i) Results of health hazard evaluation.

Title 21, section 7.49 of the Code of Federal Regulations governs the actual manner by which drug manufacturers communicate recalls. This regulation provides discretionary guidelines for manufacturers regarding the manner in which they communicate the recall of a product to distributors and retail pharmacies. Section 7.49 states, in relevant part, that “[a] recalling firm is responsible for promptly notifying each of its affected direct accounts about the recall. The format, content, and extent of a recall communication should be commensurate with the hazard of the product being recalled and the strategy developed for that recall.”<sup>5</sup> Manufacturers may notify distributors and retail pharmacies by telegram, mailgrams, or first-class letters.<sup>6</sup> Notification may also be accomplished by telephone, although the regulation states that telephonic notification should be followed by written notice.<sup>7</sup>

The overall import of the federal regulations governing drug recalls is clear: manufacturers are given broad discretion so that they may utilize the method that most promptly and effectively communicates the recall of a product to the affected distributors and pharmacies. The granting of such discretion should prompt manufacturers to utilize the most technologically advanced communication method available, because they will have difficulty raising the defense of strict regulatory compliance in the event of a lawsuit by someone injured by a recalled product that was not removed from the shelves in the most prompt and effective manner.<sup>8</sup>

## II. THE ADVENT OF EARLY NOTIFICATION SYSTEMS

Recent technological advancements have led to the development of innovative

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- (ii) Ease in identifying the product.
  - (iii) Degree to which the product's deficiency is obvious to the consumer or user.
  - (iv) Degree to which the product remains unused in the market-place.
  - (v) Continued availability of essential products.

*Id.* § 7.42(a)(1). This regulation also requires the FDA to review the adequacy of a manufacturer's proposed recall strategy and recommend any appropriate changes thereto. *Id.* § 7.42(a)(2). When the FDA requests a drug's recall, the FDA develops the recall strategy, taking into account the same considerations outlined above. *Id.* § 7.42(a)(1).

5. *Id.* § 7.49(a).

6. *Id.* § 7.49(b).

7. *Id.*

8. Whether notification of a recall is sufficient and timely depends in part on the type of recall that is ordered. Recalls are categorized based upon the seriousness of the health risk presented by the product. Class III recalls are implemented when the defect or hazard is less serious and does not significantly alter the therapeutic effect of the prescribed drug. Class II recalls occur when the defect or hazard may alter the therapeutic effect of the prescribed drug, and the potential long-term effects may be life-threatening. Class I are considered emergency, and occur when the defect or hazard is immediate and life threatening to users. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., RECALL PROCEEDINGS, REG. PROC. MANUAL pt. 5, ch. 5, at 21-22 (1988). Logically, the potential exposure to liability for a delay in notifying pharmacies of a Class I recall is greater than it would be for a delay in notifying pharmacies of a Class III recall.

state-of-the-art systems by which manufacturers can notify distributors and pharmacies across the nation about drug recalls or other newly discovered risks or effects of particular drugs within hours of their issuance. The most comprehensive systems rely upon a combination of two primary notification methods.

First, technology is now available which allows manufacturers to notify by telephone virtually every pharmacy in the United States of drug recalls or other emergencies within two to four hours after the availability of the pertinent information. Notice by telephone involves a voice message system that is interactive with the recipient pharmacist or distributor to ensure receipt. Second, advances in technology have been developed to permit the printing, processing, and overnight delivery of a letter to virtually every pharmacy in the United States. Previously, no overnight carrier had the capacity to prepare and deliver up to 67,000 letters nationwide within a few hours notice.

A comprehensive state-of-the-art notification system would utilize both telephone voice messaging and an overnight delivery system in order to fully comply with the FDA recommendation that telephone notification of drug recalls be followed up with written notice.<sup>9</sup> Due to their reliance on technological advancements, comprehensive services such as those described can be performed relatively inexpensively. In fact, the legal fees alone for defending a pharmaceutical manufacturer against a lawsuit brought by a party injured due to untimely notification of a drug recall would likely far exceed the cost of implementation and use of the above-described system.

Finally, early notification may also be accomplished by the use of facsimile machines and computers. Both methods are fast and accurate. However, because these methods require pharmacies to be equipped with either facsimile machines or computers with compatible software, they are less comprehensive than a system which utilizes telephone and mail delivery. The more comprehensive method of utilizing telephone and mail delivery for notification best fulfills the conditions necessary to protect manufacturers from delay-based liability; recall information is communicated accurately and reaches virtually all affected parties almost immediately.

### III. THEORIES OF LIABILITY

A party injured by a recalled drug that was not removed from pharmacy shelves in the most timely manner available could bring legal action against pharmaceutical manufacturers based on general principles of negligence, as well as under the rubric of a manufacturer's post-sale duty to warn consumers of a defective product.

#### A. *Negligence: General Principles*

In order to understand the potential liability that drug manufacturers face, it is necessary to understand the general tort principles of negligence. Negligence is "conduct which falls below the standard established by law for the protection

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9. See *supra* note 7 and accompanying text.

of others against unreasonable risk of harm.”<sup>10</sup> Generally, the standard of conduct to which this refers is “that of a reasonable man under like circumstances.”<sup>11</sup> The reasonable person standard may be established in one of four ways: (1) by legislative enactment or administrative regulation providing a standard of reasonable conduct; (2) by judicial interpretation of a legislative enactment or administrative regulation as the standard of reasonable conduct; (3) by judicial decision; or (4) by determination of a trial judge or jury, when there is no applicable legislative enactment, administrative regulation, or judicial decision.<sup>12</sup>

The conduct at issue may consist of either an act<sup>13</sup> or a failure to act when a duty to act exists.<sup>14</sup> The omission of an act is negligent when the actor has a duty to do something that is necessary for the protection or assistance of another person, and the actor fails to do so.<sup>15</sup>

It is the omission of an act that is relevant in the context of a manufacturer’s failure to provide prompt notice of a drug recall. Specifically, the applicable federal regulations clearly place a duty on manufacturers to recall products that either the manufacturers or the FDA determine to be violative of the law, deceptive, or otherwise hazardous to consumers.<sup>16</sup> Although the applicable regulations do not require that manufacturers notify distributors and pharmacies

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10. RESTATEMENT (SECOND) OF TORTS § 282 (1965).

11. *Id.* § 283. Comment b to this section defines the qualities of a “reasonable man” as follows:

The words “reasonable man” denote a person exercising those qualities of attention, knowledge, intelligence, and judgment which society requires of its members for the protection of their own interests and the interests of others. It enables those who are to determine whether the actor’s conduct is such as to subject him to liability for harm caused thereby, to express their judgment in terms of the conduct of a human being. The fact that this judgment is personified in a “man” calls attention to the necessity of taking into account the fallibility of human beings.

*Id.* cmt. b. This standard, which is based on individual judgment, must be distinguished from the negligence standard, which is based on the level of standard demanded by the community for protection of its members against unreasonable risk of harm. The negligence standard is that:

Negligence is a departure from a standard of conduct demanded by the community for the protection of others against unreasonable risk. The standard which the community demands must be an objective and external one, rather than that of the individual judgment, good or bad, of the particular individual. It must be the same for all persons, since the law can have no favorites; and yet allowance must be made for some of the differences between individuals, the risk apparent to the actor, his capacity to meet it, and the circumstances under which he must act.

*Id.* cmt. c.

12. *Id.* § 285.

13. *Id.* § 2. This section defines an act as “an external manifestation of the actor’s will and does not include any of its results, even the most direct, immediate, and intended.”

14. *Id.* § 282 cmt. a.

15. *Id.* § 284(b).

16. 21 C.F.R. §§ 7.40, 7.45 (1996); see *supra* note 3 and accompanying text.

of a drug recall in a certain manner, the applicable regulation does require prompt notification, "commensurate with the hazard of the product being recalled."<sup>17</sup> Historically, such notification has been via regular mail, leading to a significant lapse of time between the recall order and removal of the product on the retail level. This industry custom creates a window of negligence liability for manufacturers that could be easily avoided by implementing an early notification system.

The question of whether following an industry custom that lags behind technology meets the standard of reasonable care, thus avoiding negligence liability, was addressed in 1932.<sup>18</sup> In a case dealing with the advanced receiver technology that had become available for tracking barges at sea, the Second Circuit determined that tugs were negligent in failing to equip themselves with functional receivers that would have picked up weather transmissions warning them of the storm in which they lost two barges belonging to the Northern Barge Company. In that case, the owners of the cargo on the barges sued Northern Barge Company under their carrier contracts; and in turn, Northern Barge Company sued the tugs on their towing contracts, seeking damages for the loss of the barges as well as the loss of the cargo by the barges. The court held that the tugs were liable for their loss of the barges and the barges' cargo.<sup>19</sup>

The crux of the court's decision was the fact that radio receivers were technologically available. The court noted that although it was not the general custom of sea carriers to equip their tugs with receivers, an adequate receiver was available at that time at a small cost and should have been utilized.<sup>20</sup> Specifically, the court stated:

Is it then a final answer that the business had not yet generally adopted receiving sets? There are, no doubt, cases where courts seem to make the general practice of the calling the standard of proper diligence; we have indeed given some currency to the notion ourselves. Indeed in most cases reasonable prudence is in fact common prudence; but strictly it is never its measure; a whole calling may have unduly lagged in the adoption of

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17. *Id.* § 7.49(a); see *supra* note 5 and accompanying text.

18. *The T.J. Hooper*, 60 F.2d 737 (2d Cir. 1932).

19. *Id.* at 739-40.

20. In this regard, Judge Hand stated,

It is not fair that there was a general custom among coastwise carriers so to equip their tugs. One line alone did it; as for the rest, they relied upon their crews, so far as they can be said to have relied at all. An adequate receiving set suitable for a coastwise tug can now be got at a small cost and is reasonably reliable if kept up; obviously it is a source of great protection to their tows. . . . Whatever may be said as to other vessels, tugs towing heavy coal laden barges, strung out for a half a mile, have little power to maneuver, and do not, as this case proves, expose themselves to weather which would not turn back stauncher craft. They can have at hand protection against dangers of which they can learn in no other way.

new and available devices. It never may set its own tests, however persuasive be its usages. Courts in the end must say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission.<sup>21</sup>

Accordingly, the court concluded that the losses were a direct consequence of the tugs' failure to utilize the reasonably available equipment.<sup>22</sup>

This general principle has been universally adopted by the courts and incorporated into modern negligence theory and applied to advancements in other industries.<sup>23</sup> Section 295A of the Restatement (Second) of Torts provides: "In determining whether conduct is negligent, the customs of the community, or of others under like circumstances, are factors to be taken into account, but are not controlling where a reasonable man would not follow them."<sup>24</sup> Comment c to this section further describes the circumstances under which industry or trade custom would not be controlling:

Any such custom is, however, not necessarily conclusive as to whether the actor, by conforming to it, has exercised the care of a reasonable man under the circumstances, or by departing from it has failed to exercise such care. . . . No group of individuals and no industry or trade can be permitted, by adopting careless and slipshod methods to save time, effort, or money, to set its own uncontrolled standard at the expense of the rest of the community. If the only test is to be what has always been done, no one will ever have any great incentive to make any progress in the direction of safety. It follows, therefore, that whenever the particular circumstances, the risk, or other elements in the case are such that a reasonable man would not conform to the custom, the actor may be found negligent in conforming to it; and whenever a reasonable man would depart from the custom, the actor may be found not to be negligent in so

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21. *Id.* at 740.

22. *Id.*

23. *See, e.g.,* *Rodi Yachts, Inc. v. National Marine, Inc.*, 984 F.2d 880, 888 (7th Cir. 1993) ("One of the best-known principles of tort law . . . is that compliance with custom is no defense to a tort claim."); *Tug Ocean Prince, Inc. v. United States*, 584 F.2d 1151, 1156 (2d Cir. 1978) ("Methods employed in any trade, business, or profession, however long continued, cannot avail to establish as safe in law that which is dangerous in fact."); *Advincula v. United Blood Servs.*, 654 N.E.2d 644, 649 (Ill. App. Ct. 1995) (local custom did not conclusively determine proper standards of practice in any profession); *Clark v. St. Dominic-Jackson Mem'l Hosp.*, 660 So. 2d 970, 973 (Miss. 1995) (conformity with established medical custom was not conclusive of compliance with physicians' duty of care); *Brooks v. Beech Aircraft Co.*, 902 P.2d 54, 64 (N.M. 1995) (custom of airline industry did not provide conclusive evidence that airline manufacturer met the standard of due care); *Attocknie v. Carpenter Mfg., Inc.*, 901 P.2d 221, 228 (Okla. Ct. App. 1995) (compliance with federal safety standards did not necessarily relieve automobile manufacturer from potential liability for a design defect).

24. RESTATEMENT (SECOND) OF TORTS § 295A (1965).

departing.<sup>25</sup>

As a result of this principle of tort law, businesses and industries must constantly strive to remain abreast of technological advancements that could potentially affect their exposure to negligence liability.

### B. *Manufacturers' Post-Sale Duty to Warn*

Manufacturers may have a post-sale duty to warn under both negligence and strict products liability theories. The common law duty of a manufacturer to warn under negligence theory is controlled by the reasonable or prudent person standard as discussed above.<sup>26</sup> Liability under a strict products liability theory is often determined pursuant to statute.

1. *Negligent Failure to Warn.*—The negligence principles outlined often above have not yet been applied by our courts specifically to a pharmaceutical manufacturer's duty to provide timely notification of newly discovered risks and defects or drug recalls. However, potentially applicable cases that frequently arise in courts around the nation may be grouped in the category of negligent failure to warn cases.

General negligence principles require manufacturers to act with reasonable care upon learning of defects or risks associated with products already distributed into the stream of commerce.<sup>27</sup> Reasonable care under these circumstances has been interpreted as a duty to warn consumers of the risk involved in use of the product.<sup>28</sup> Moreover, in order to satisfy its duty to warn, a manufacturer must give an *effective* warning of that risk.<sup>29</sup>

Whether a warning is effective is a question for the trier of fact and is determined, in part, by the apparent dangers of the product as well as by the time at which those dangers became apparent.<sup>30</sup> Factors a jury might consider in determining whether a warning was adequate include: (1) the hazard presented by the product; (2) how the product is used; (3) the form and magnitude of the warning; and (4) the foreseeability that the warning will be communicated to

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25. *Id.* cmt. c.

26. *See supra* note 11 and accompanying text.

27. *See, e.g.*, *Richter v. Limax Int'l, Inc.*, 45 F.3d 1464, 1467 & n.3 (10th Cir. 1995); *Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919, 922 (8th Cir. 1970); *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 426. (2d Cir. 1969); *Reed v. Ford Motor Co.*, 679 F. Supp. 873, 879 (S.D. Ind. 1988) (interpreting IND. CODE § 33-1-1.5-2.5 (1988)); *Comstock v. General Motors Corp.*, 99 N.W.2d 627, 634 (Mich. 1959); *Cover v. Cohen*, 461 N.E.2d 864, 871 (N.Y. 1984). *See also* Janet Fairchild, Annotation, *Liability of Manufacturer or Seller for Injury or Death Allegedly Caused by Failure to Warn Regarding Danger in Use of Vaccine or Prescription Drug*, 94 A.L.R. 3d 748 (1979).

28. *See infra* note 35 and accompanying text.

29. *Basko*, 416 F.2d at 426 (emphasis added) (citing *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978 (8th Cir. 1969)).

30. *Id.*

product users.<sup>31</sup> Inherent in the factor concerning the form and magnitude of the warning is the speed in which notice thereof reaches its intended recipients, as well as the accuracy of that notice.

The ready availability of technological advances in the systems available for notification of risks and defects, as well as drug recalls, increases the risks of negligence liability for those companies that do not avail themselves of such technology.

2. *Strict Products Liability.*—In *Basko v. Sterling Drug, Inc.*, the court addressed circumstances in which manufacturers of drugs containing chloroquine failed to warn physicians and consumers of the risk that use of the drug would cause idiosyncratic retinal damage. The court stated:

Our case presents special problems because when chloroquine was first developed and tested, there was no known or foreseeable risk of idiosyncratic retinal damage. Thus, defendant could not initially be expected to warn of unknown dangers. When the risk became apparent, however, a duty to warn attached.<sup>32</sup>

In *Basko*, the court based its analysis in terms of Section 402A of the Restatement (Second) of Torts (addressing strict products liability). Section 402A provides:

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

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

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

- (a) the seller has exercised all possible care in the preparation and sale of his product, and
- (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.<sup>33</sup>

However, language in comment k to Section 402A makes an exception to strict liability for sellers of unavoidably unsafe products, such as drugs:

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. . . . The seller of such

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31. *Dougherty v. Hooker Chem. Corp.*, 540 F.2d 174, 179 (3d Cir. 1976) (citing *Thomas v. Arvon Prod. Co.*, 227 A.2d 897 (Pa. 1967)); *Weekes v. Michigan Chrome & Chem. Co.*, 352 F.2d 603 (6th Cir. 1965); *Tampa Drug Co. v. Wait*, 103 So. 2d 603 (Fla. 1958); *West v. Broderick & Bascom Rope Co.*, 197 N.W.2d 202 (Iowa 1972); *Younger v. Dow Corning Corp.*, 451 P.2d 177 (Kan. 1969); *Seibel v. Symons Corp.*, 221 N.W.2d 50 (N.D. 1974).

32. *Basko*, 416 F.2d at 426.

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

products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.<sup>34</sup>

The *Basko* court concluded that, in the drug context, comment k simply adopted the

ordinary negligence concept of duty to warn. If proper warning is given "where the situation calls for it," the manufacturer is "not to be held to strict liability for the unfortunate consequences . . . merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk."<sup>35</sup>

The court of appeals thus analyzed all of the plaintiff's claims in terms of a negligent failure to warn of discovered defects.

The duty to warn in the context of dangerous or defective drugs normally extends only from manufacturers to physicians, based on the "learned intermediary" doctrine.<sup>36</sup> Under this doctrine, the manufacturer has no duty to warn the patient, but need only warn the patient's doctor:

To recover for a failure to warn under this doctrine, a plaintiff must show: (1) that the defendant failed to warn the physician of a risk associated with the use of the product, not otherwise known to the physician, and (2) that the failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury. Because the defective aspect of the product must cause the injury, the plaintiff must show that a proper warning would have changed the decision of the treating physician, i.e. that but for the inadequate warning, the treating physician would not have used or prescribed the product.<sup>37</sup>

The practical application of the learned intermediary doctrine insulates manufacturers from failure to warn claims if the manufacturer has provided reasonable notification of the potential hazard to the physician.

Although in drug cases, the learned intermediary doctrine has generally been

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34. *Id.* cmt. k.

35. *Basko*, 416 F.2d at 426 (quoting RESTATEMENT (SECOND) TORTS § 402A cmt. k) (omission in original).

36. See *Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1098 (5th Cir. 1991) (citing *Anderson v. McNeilab, Inc.*, 831 F.2d 92, 93 (5th Cir. 1987)); *Rhoto v. Ribando*, 504 So. 2d 1119, 1123 (La. Ct. App. 1987)). For additional cases citing the learned intermediary doctrine, see *Violette v. Smith & Nephew Dyoics, Inc.*, 62 F.3d 8, 13 (1st Cir. 1995); *Toole v. McClintock*, 999 F.2d 1430, 1433 (11th Cir. 1993); *Crisostomo v. Stanley*, 857 F.2d 1146, 1152 n.16 (7th Cir. 1988); *Nichols v. McNeilab, Inc.*, 850 F. Supp. 562, 564 (E.D. Mich. 1993).

37. *Willett*, 929 F.2d at 1098-99.

applied where physicians were the intermediaries, this doctrine could arguably be applied to insulate manufacturers from liability to consumers where pharmacies are the learned intermediaries, in the specific context of a drug recall.<sup>38</sup> Specifically, if a pharmaceutical manufacturer provided reasonable notice to pharmacies that a product was subject to recall and should not be dispensed, the manufacturer would not be liable to the ultimate consumer for damage caused by the product after notice was provided. Once again, the manufacturer's potential liability would turn upon whether it was negligent in its duty to warn pharmacies; that is, whether it gave reasonable notice to pharmacies of the drug's recall. Whether notice was reasonable would depend upon the principles of negligence discussed above.<sup>39</sup> Again, whether manufacturers would be considered negligent in warning of a product's danger would likely depend largely upon whether they utilized the most efficient means of notification technologically available.<sup>40</sup>

In addition to liability for damages under negligence theory, manufacturers who are aware that a product is defective, but fail to provide prompt notice of that defect to the necessary intermediaries or consumers, or fail to recall it as recommended by the FDA, may be subject to a claim for punitive damages.<sup>41</sup> Such potential for damage awards could be largely avoided by utilizing the most effective, technologically advanced notification system available to drug manufacturers.

#### CONCLUSION

Technological advances not only benefit society, but have the potential secondary effect of imposing higher standards of conduct on those in a position to prevent harm to others. In few fields are technological advances more prevalent than in medicine. This Article has demonstrated the potential liability for drug manufacturers who fail to employ the most efficient drug recall and notification systems technologically available. Liability in failure to warn cases may be founded in strict products liability or in general principles of negligence.

As technology advances, pharmaceutical manufacturers ought to take the steps necessary to ensure that they are utilizing the most accurate and timely notification

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38. The *Willett* court did not limit the learned intermediary doctrine to physicians. Instead, the court described the doctrine as generally applying to "the one to whom the warning is directed [by the manufacturer], and is the one who makes the decision whether to use the product." *Id.* at 1098 n.16 (citing *Halphen v. Johns-Mannsville Sales Corp.*, 484 So. 2d 110, 115 (La. 1988)). The court went on to interpret the duty to warn in the learned intermediary context as requiring an "adequate warning of inherent dangers not within the knowledge of or obvious to the average learned intermediate." *Id.*

39. See *supra* notes 26-31 and accompanying text.

40. *The T.J. Hooper*, 60 F.2d 737, 740 (2d Cir. 1932).

41. See *Lewy v. Remington Arms Co.*, 836 F.2d 1104, 1106-07 (8th Cir. 1988); *O'Gilvie v. International Playtex, Inc.*, 821 F.2d 1438, 1446 (10th Cir. 1987); *Gillham v. Admiral Corp.*, 523 F.2d 102, 107 (6th Cir. 1975). See also *Reed v. Ford Motor Co.*, 679 F. Supp. 873, 879-80 (S.D. Ind. 1988).

