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# The "Misuse" Defense in Drug Products Liability Cases

Jonathan E. Grant†

## I. Introduction

It is quite common for a prescription drug to have serious adverse side effects for the user-patient. Often, however, the prescription drug manufacturer warns about these effects by publishing a Food and Drug Administration approved warning in the Physician's Desk Reference<sup>1</sup> or by enclosing a package insert. Regrettably, some physicians, when prescribing a medication, will ignore or fail to read the issued warnings, resulting in injury or death to the patient. Consequently, both the physician and the drug company are sued. This Article will explore the legal defenses of the drug company in such situations.

## II. Background

### A. Federal Statutes and Regulations

The 1906 Food and Drug Act was the first comprehensive federal law regulating drugs.<sup>2</sup> It was silent, however, on the manner in which drugs should be dispensed.<sup>3</sup> When the 1938 Federal Food, Drug, and Cosmetic Act<sup>4</sup> was enacted, it too was silent with respect to the dispensing status of drugs. However, it took only six months from the date of passage of the 1938 Act for the Food and Drug Administration (FDA) to issue administrative pronouncements which initiated the distinction between over-the-counter and prescription drugs.

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1. See *infra* note 24.

2. Kaplan, *Over-the-Counter and Prescription Drugs: The Legal Distinction under Federal Law*, 37 FOOD DRUG COSM. LAW J. 441 (1982) [hereinafter Kaplan].

3. *Id.*

4. Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938).

This distinction began in August 1938 when the FDA issued its first "trade correspondence" announcing that sulfanilamide-containing drugs were dangerous unless their dosage was properly adjusted and their use "intelligently and expertly directed."<sup>5</sup> Within a few months of the first trade correspondence, the FDA issued a general announcement requiring a warning label on all drugs that might be considered dangerous to health unless used under appropriate supervision.<sup>6</sup>

In December 1938, only a few months after the Food, Drug, and Cosmetic Act was enacted, the FDA officially designated drugs requiring "appropriate supervision" as "prescription

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5. Trade Correspondence One (TC-1), Aug. 26, 1938, *reprinted in* V. KLEINFELD & C.W. DUNN, *FEDERAL FOOD, DRUG, AND COSMETIC ACT, JUDICIAL AND ADMINISTRATIVE RECORD 1938-1949*, 561 (1949) [hereinafter *KLEINFELD*]. The agency wrote that the indiscriminate use of such drugs would be considered violative of that section of the Food, Drug, and Cosmetic Act that deems a drug to be "misbranded" if it is "dangerous to health when used in the dosage or manner or with the frequency or duration prescribed, recommended, or suggested in [its] labeling."

The FDA stated that sulfanilamide drugs should be labeled with a warning cautioning against their unsupervised use by the public. TC-4 *cited in* *KLEINFELD* at 562.

6. *Id.* at TC-4 which states:

You are familiar with the trade notices issued by this Administration on August 26 and September 8, 1938, relating to the distribution of preparations containing aminopyrine, cinchophen, neocinchophen, sulfanilamide, and related products. In brief, these notices announced the Administration's opinion that such drugs, if distributed so that they would be used by the general public without appropriate medical supervision, would be regarded as misbranded in violation of Section 502(j) of the Food, Drug, and Cosmetic Act [redesignated as Section 352(f)].

Following the issuance of those announcements, manufacturers generally placed upon their labels such warnings as "To be used under the direction of a physician only," with or without a statement to the effect that the drug has been reported to have caused untoward reactions in some individuals.

That these warnings are not adequate to prevent the indiscriminate distribution and use of such drugs is obvious from the fact that, notwithstanding such labelings, they are reaching the general public in considerable quantities.

The purpose of this letter is to inform you that to the effect the obvious purpose of the law is the protection of the public health, preparations of the character referred to above will be regarded as misbranded if they are not labeled with a warning so conspicuous as to certainly arrest attention, and in such informative terms as will not fail to apprise the user of the danger of irreparable injury if the article is consumed without adequate and continuous medical supervision.

It should be understood that this principle applies not only to the specific drugs which were dealt with in the trade announcements referred to above, but is applicable to all drugs which may be dangerous to health unless used under appropriate supervision.

Please acknowledge receipt of this letter.

*Id.*

drugs.”<sup>7</sup> Under the FDA regulation, drugs were exempt from the statutory requirement that labeling include adequate directions for use,<sup>8</sup> if the label of a drug carried the statement “Caution: To be used only by or on the prescription of a physician.”<sup>9</sup> One of the other conditions for obtaining the exemption was that the labeling for the drug could not bear any information on conditions of use for the product that were “likely to be understood by the ordinary individual.”<sup>10</sup>

In the next thirteen years, the FDA continued to refine the distinction it had established between “prescription” and “non-prescription” drugs. In 1941, the adequate directions for use exemption was amended to prohibit any labeling representation concerning conditions of use for a drug that carried the “Caution” legend.<sup>11</sup>

In 1944, the FDA, through additional regulation, limited the availability of the exemption from adequate direction for use to any drug product which “because of its toxicity or other potentiality for harmful effect or the method of its use or the collateral measures necessary to its use, is not generally recognized among experts . . . as safe and efficacious for use except . . . under the use of a physician.”<sup>12</sup> In 1951, the Humphrey-Durham Amendment was enacted, which statutorily formalized the differences between over-the-counter and prescription drugs.<sup>13</sup>

The current Federal Food, Drug, and Cosmetic Act,<sup>14</sup> for the purposes of regulating the labeling of drug products, continues to distinguish between over-the-counter drugs and prescription drugs. Nonprescription drugs are deemed misbranded<sup>15</sup> if

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7. 3 Fed. Reg. 3167-68 (1938).

8. Kaplan, *supra* note 2, at 442 (citing 3 Fed. Reg. 3167-68 (1938)).

9. *Id.* (citing 3 Fed. Reg. 3168 (1938)).

10. *Id.*

11. 6 Fed. Reg. 1920 (1941).

12. Kaplan, *supra* note 2, at 442 (citing 9 Fed. Reg. 12,255 (1944)).

13. Federal Food, Drug, and Cosmetic Act, ch. 578, 65 Stat. 648 (1951) (codified as amended at 21 U.S.C. § 353 (1982)).

14. Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-392 (1982)).

15. 21 U.S.C. § 352(f) (1982). The statute provides:

A drug or device shall be deemed to be misbranded—(f)Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosages or methods or duration of administration or ap-

the labeling does not bear "adequate directions for use,"<sup>16</sup> because the directions are intended for the user. Prescription drugs,<sup>17</sup> however, need not bear "adequate directions for use" on the label going to the user.<sup>18</sup> Instead, the label for the user is a simplified statement, which must bear the words "Caution: Federal law prohibits dispensing without prescription."<sup>19</sup>

plication, in such manner and form, as are necessary for the protection of users: *Provided*, That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

*Id.*

16. *Id.*

17. *Id.* § 353. A prescription drug is defined as:

- (b)(1) A drug intended for use by man which;  
 (A) is a habit-forming drug to which § 352(d) of this title applies; or  
 (B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or  
 (C) is limited by an approved application under Section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug; shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

*Id.*

18. *Id.* Exemptions in case of drugs and devices.

(b) Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marijuana laws

. . . .

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of Section 352 of this title, except subsections (a), (i)(2) and (3), (k), and (l) of said section, and the packaging requirements of subsections (g), (h), and (p) of said section, if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the direction for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

*Id.*

19. *Id.* § 353 (b)(4). This code section states:

A drug which is subject to paragraph (1) of this subsection shall be deemed to be

The directions and warnings for use of a new prescription drug, which is sold by virtue of an approved New Drug Application,<sup>20</sup> are provided to the physician in the form of prescribing

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misbranded if at any time prior to dispensing its label fails to bear the statement: "Caution: Federal law prohibits dispensing without prescription." A drug to which paragraph (1) of this subsection does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.

*Id.*

20. New Drugs are defined as those drugs which have the following characteristics:

1. Classification as a drug;
2. Absence of general recognition of safety and effectiveness for the drug, a recognition of those attributes among qualified scientists rather than among the public or all practitioners, or absence of such general recognition as to any particular use for which it is proposed to be used and prescribed; and
3. Absence of a record of pre-1938 uses for that drug which match identically the uses for which the drug is now represented to be useful.

J. O'REILLY, FOOD AND DRUG ADMINISTRATION vol. 1, 13-18 (1987) [hereinafter O'REILLY]. The 1962 Drug Amendments, Pub. L. No. 87-781, 76 Stat. 780 (1962), expanded the *new drug* definition to include "efficacy." 87th Cong. 2d Sess. *Id.* at 13-18 n.5.

After 1962, new drugs, as well as new uses for drugs already in use, became subject to the new drug application (NDA) process whereby they must be approved as safe and effective for use under the conditions specified on their labels. *Id.* at 13-19 (citing 21 U.S.C. § 355 (1982)). 21 U.S.C. § 355 states in part:

(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.

(b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

21 U.S.C. § 355 (1982).

There are four main stages in the drug approval procedure. The first stage involves discovery of a new compound or experimentation with a known one; testing of the compounds in laboratory screening tests and animal studies; and the filing of an Investigational New Drug (IND) application, giving the FDA an opportunity to examine the proposal for human experimentation with the drug at least 30 days before commencement of the experimentation. O'REILLY, at 13-58.

The second stage is in preparation of the filing of the New Drug Application (NDA) and involves meetings between the FDA and the drug firm to examine the IND evidence to determine if there are any special problems or any additional testing to be done. *Id.* at 13-59.

The third stage of the approval process consists of clinical studies in which the evi-

information, or package inserts,<sup>21</sup> and are phrased in terms only intelligible to a physician. The physician must exercise his judgment in determining whether the indications for use exist in the particular person on the basis of his present condition, his medical history, and the illness or symptoms to be treated. Only the physician can decide whether the conditions observed call for the prescription of the drug. Since, by definition, the prescription drug can only be used under the direction of the doctor, such drugs are exempt from the requirement of adequate direction for use to the layman.<sup>22</sup> The prescribing information, supplied to the physician in the form of package inserts<sup>23</sup> or in the

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dence most critical to approval is developed. Meetings between the FDA and the drug firm continue throughout this stage for the purpose of reviewing findings. *Id.* at 13-60.

During the fourth stage, several component groups of the National Center for Drugs & Biology review the studies and produce recommendations. Questions are raised at FDA meetings and the drug firm is asked to respond to them. An FDA committee may suggest additional work that needs to be done. This fourth stage is the final one before formal acceptance of the NDA. *Id.*

21. "A package insert is a communication from a [drug] manufacturer to the medical profession, based on information usually generated or accumulated by the manufacturer and reviewed by the Food and Drug Administration (FDA). It is regulated, . . . comprehensively and meticulously controlled, by the FDA." Cooper, *Drug Labeling and Products Liability: The Role of the Food and Drug Administration*, 41 *FOOD DRUG COSM. L.J.* 233 (1986).

The package insert is regulated in great detail by the FDA. The fundamental requirements are that the inserts: "contain a summary of the essential scientific information needed for the safe and effective use of the drug," 21 C.F.R. § 201.56(a) (1987); "be informative and accurate and neither promotional in tone nor false or misleading in any particular," *id.* § 201.56(b); "be based whenever possible on data derived from human experience," *id.* § 201.56(c); and not contain any "implied claims . . . if there is inadequate evidence of safety or lack of substantial evidence of effectiveness." *Id.* The insert must include basic information regarding the drug, including its description, clinical pharmacology, indications and use, warnings, precautions, adverse reactions, abuse and dependence, overdosage, dosage and administration, and available dosage forms. *Id.* § 201.56(d)(1). Where appropriate, the insert may include information regarding animal pharmacology, animal toxicology, and clinical studies as well. *Id.* § 201.57(l), (m).

22. See 21 U.S.C. § 353(b)(2) (1982).

23. INSTITUTE OF CONTINUING EDUCATION, *DRUG LIABILITY LITIGATION* 26 (1967). Package inserts containing the language approved as part of the NDA give "a comprehensive discussion of the drug, its usefulness, and of the precautions to be observed in its use. This brochure contains the approved claims and needed warnings, and serves as the basis for all allowable advertising and other promotional claims. It is the basic document that the physician needs to understand the use and the limitations on the administration of the prescription drug. . . . It is what the manufacturer is authorized to claim about the effectiveness of the drug and it contains the warning information that he is required to present." *Id.* at 43-44.

Physician's Desk Reference (PDR),<sup>24</sup> contains specific language which has had the prior approval of the FDA.<sup>25</sup>

*B. Physician as Learned Intermediary Between the Patient and Pharmaceutical Manufacturer*

A drug manufacturer has a duty to provide to the prescribing physician, and, at times to the treating physician, an adequate warning of the side effects of the drug and any adverse reactions the drug may produce which are known to the manufacturer or should be known, given the level of scientific knowledge at the time the prescription drug is developed.<sup>26</sup>

With most products, to avoid liability under a warning defect theory, the warning must be communicated to the ultimate user of the product.<sup>27</sup> The supplier is responsible for seeing to it

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24. The Physicians' Desk Reference (PDR) is published once a year by Medical Economics Inc. and contains verbatim reproductions of the FDA approved labeling for more than 2,000 drug products. PHYSICIANS' DESK REFERENCE ii (42d ed. 1988). Thus, the PDR is a significant source of information regarding the "indications, effects, dosages, routes, methods, and frequency and duration of administration and any relevant warnings, hazards, contraindications, side effects, and precautions" of drugs. *Id.* The information is provided to the PDR by the drug manufacturers. *Id.* To guarantee that the information be complete, the PDR requires that the manufacturer submit to it the most recent FDA approved labeling. Yacura, *Inside the PDR*, TRIAL, June 1984, at 64. During the course of the year, the PDR publishes supplements making available new or revised information. PHYSICIANS' DESK REFERENCE ii. The PDR does not list every drug, only those submitted to it for listing by the manufacturers. Yacura, *supra*, at 64.

25. See *supra* note 21.

26. Brushwood & Simonsmeier, *Drug Information for Patients*, 7 JOURNAL OF LEGAL MEDICINE 279, 283 n.12 (1986) [hereinafter Brushwood]. What constitutes an adequate warning has been described as follows:

(1) the warning must adequately indicate the scope of the danger; (2) the warning must reasonably communicate the extent or seriousness of the harm that could result from misuse of the drug; (3) the physical aspects of the warning must be adequate to alert a reasonably prudent person to the danger; (4) a simple directive warning may be inadequate when it fails to indicate the consequences that might result from failure to follow it; and, (5) the means to convey the warning must be adequate.

*Id.* (citing *Richards v. Upjohn Co.*, 95 N.M. 675, 625 P.2d 1192 (1980); *Feldman v. Lederle Laboratories*, 97 N.J. 429, 479 A.2d 374 (1985); *Mahr v. G.D. Searle and Co.*, 72 Ill. App. 3d 540, 390 N.E.2d 1214 (1979)).

27. *Id.* at 284 n.17 (citing RESTATEMENT (SECOND) OF TORTS § 388 (1965)). The Restatement provides:

One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical



that this warning does reach, directly or indirectly, persons known by the supplier to use the product.<sup>28</sup> Although suppliers can usually rely on intermediaries to transmit warnings to users, when a highly dangerous product is involved and the supplier can, without difficulty, warn the user directly, failure to provide this direct warning may not be justifiable.<sup>29</sup>

Drugs differ from most other products for two main reasons. First, prescription drugs are frequently recognized as unavoidably unsafe products. Generally speaking, many drugs which are necessary for survival or well-being cannot be made any safer given the present state of human knowledge. Under the Restatement of Torts,<sup>30</sup> the manufacturers of these drugs will not be

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harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier

(a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and

(b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and

(c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

RESTATEMENT (SECOND) OF TORTS § 388 (1965).

28. Brushwood, *supra* note 26, at 284-85.

29. *Id.*

30. RESTATEMENT (SECOND) OF TORTS § 402A comment k (1965). This section on unavoidably unsafe products provides:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper 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 as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

held strictly liable for unfortunate consequences attending their use if the drugs are properly prepared and marketed, and proper warnings are given.<sup>31</sup>

Second, it is almost universally recognized that, while the duty to warn normally extends to the ultimate users of a product or to those persons the manufacturer has reason to believe will be placed at risk by the product, and while patients are the ones who are the ultimate users of, or put at risk by, prescription drugs, the warning regarding these drugs must be given to the prescribing physician.<sup>32</sup> It is the prescribing physician, not the patient, who is best able to measure the benefits of a drug against the risks involved in its use.<sup>33</sup> Thus, a warning to the medical profession is the most effective method of protecting a patient against the harmful results of a drug.<sup>34</sup>

Courts have, quite properly, characterized the physician as a "learned intermediary" who is charged with the responsibility of knowing his patient, being apprised of the effects of the drug use, and exercising his medical judgment accordingly.<sup>35</sup> The very

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31. *Id.*

32. Lawrence, *Drug Manufacturer's Recommendations and the Common Knowledge Rule to Establish Medical Malpractice*, 63 NEB. L. REV. 859, 862 (1984).

33. *Id.*

34. *Id.* In *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 95 Cal. Rptr. 381 (1971), a products liability action was brought on behalf of a woman who suffered pulmonary embolisms and thrombophlebitis allegedly caused by the drug Enovid, used in treating endometriosis. The court affirmed a jury verdict in favor of Searle and stated:

It is the general rule that the duty of adequate warning by the manufacturer of an ethical drug is discharged by its warning of hazards to doctors who may in the exercise of their medical judgments decide to use the drug as part of their chemotherapy. . . . [A]bsent special circumstances, known or foreseeable in the exercise of due care by the manufacturer, there is no duty to warn the patient.

*Id.* at 989, 95 Cal. Rptr. at 400 (citation omitted).

The rationale of the foregoing rule is: (1) The doctor is intended to be an intervening party in the full sense of the word. Medical ethics as well as medical practice dictate independent judgment, unaffected by the manufacturer's control, on the part of the doctor. (2) Were the patient to be given the complete and highly technical information on the adverse possibility associated with the use of the drug, he would have no way to evaluate it, and in his limited understanding he might actually object to the drug, thereby jeopardizing his life. (3) It would be virtually impossible for a manufacturer to comply with the duty of direct warning, as there is no sure way to reach the patient.

*Id.* at 989, 95 Cal. Rptr. at 400-01 (quoting Rheingold, *Products Liability — The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947, 987 (1964)).

35. *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966). In *Cornish*, the court stated:

rationale for warnings, the prevention of injury, dictates the rule that the manufacturer has only the duty to warn the physician and it is only by warning the physician that injury can be prevented.<sup>36</sup> The patient simply does not have the knowledge or training to exercise the medical judgment necessary to choose a prescription drug.

In *Terhune v. A. H. Robins Co.*,<sup>37</sup> the Supreme Court of Washington held that the "manufacturer of [an intrauterine contraceptive device] obtainable only through the services of a physician, fulfills its duty if it warns the physician of the dangers attendant upon its use . . . ."<sup>38</sup> In *Terhune*, the plaintiff brought a products liability action against A. H. Robins for damages allegedly sustained as a result of the use of a Dalkon Shield, an intrauterine contraceptive device.<sup>39</sup> Specifically, after the birth of her second child, the plaintiff was informed by her physician of the advantages and disadvantages of a variety of birth control methods.<sup>40</sup> The plaintiff selected the Dalkon Shield, supplied by Robins to physicians only, and not directly to patients, because of the medical expertise and equipment required for insertion of the Shield.<sup>41</sup> Robins instructed the physician on the procedure to be followed in inserting the Shield and warned the physician of the risks attendant to its use, including the possibility of perforation of the uterus if insertion procedures were not adequately followed.<sup>42</sup> Brochures written for patients describing

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[I]n this case we are dealing with a prescription drug rather than a normal consumer item. In such a case the purchaser's doctor is a learned intermediary between the purchaser and the manufacturer. If the doctor is properly warned of the possibility of a side effect in some patients, and is advised of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can be avoided.

*Id.* at 85.

36. *Id.* The court found that the drug manufacturer should have warned plaintiff's doctor of potentially dangerous side effects of Aralen, a drug used in the treatment of arthritis; *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143, 146 (Mo. 1967) (the court noted that it is only through a proper warning to the physician that the chance of injury to the user can be avoided).

37. 90 Wash. 2d 9, 577 P.2d 975 (1978).

38. *Id.* at 17, 577 P.2d at 979.

39. *Id.* at 9-10, 577 P.2d at 975.

40. *Id.* at 10, 577 P.2d at 976.

41. *Id.*

42. *Id.*

the Shield and highlighting its advantages were supplied to the physician; the transmission of these brochures to the patient was left to the physician's discretion.<sup>43</sup> The *Terhune* court held that there was no need to warn the patient as well.<sup>44</sup> The court noted that "where a product is available only on prescription or through the services of a physician, the physician acts as a 'learned intermediary' between the manufacturer or seller and the patient,"<sup>45</sup> and that the physician has a "duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product."<sup>46</sup> The patient is expected to rely on that judgment. The physician decides what facts the patient should be told.<sup>47</sup>

In *Chambers v. G. D. Searle & Co.*,<sup>48</sup> the court recognized the federal statutory basis of the case law rule that the drug manufacturer's duty was only to warn the physician, the learned intermediary, of possible side effects of the drug. The case concerned a prescription drug regulated by federal law which could only be used under the professional supervision of a doctor licensed to administer the drug.<sup>49</sup> Recognizing the technical nature of drug warnings, the court held that it is quite clear that

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43. *Id.*

44. *Id.* at 18, 577 P.2d at 979.

45. *Id.* at 14, 577 P.2d at 978.

46. *Id.*

47. *Id.* See, e.g., *Johnson v. Upjohn Co.*, 442 S.W.2d 93 (Mo. App. 1969); *Oppenheimer v. Sterling Drug, Inc.*, 7 Ohio App. 2d 103, 219 N.E.2d 54 (1964); *Parke-Davis & Co. v. Mayes*, 124 Ga. App. 224, 183 S.E.2d 410 (1971); *Leibowitz v. Ortho Pharmaceutical Corp.*, 224 Pa. Super. 418, 307 A.2d 449 (1973); *Carlsen v. Javurek*, 526 F.2d 202 (8th Cir. 1975); *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974); *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132 (3d Cir. 1973); *Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919 (8th Cir. 1970); and *Basko v. Sterling Drug, Inc.*, 416 F.2d 417 (2d Cir. 1968). All of these cases recognized the general rule that in the case of prescription drugs, the manufacturer can fulfill its duty to warn by warning the medical profession.

48. 441 F. Supp. 377 (D. Md. 1975), *aff'd*, 567 F.2d 269 (4th Cir. 1977). The plaintiff sought recovery for injuries sustained as a result of a stroke which was allegedly caused by taking oral contraceptives manufactured by the defendant Searle. The court applied the doctrine of RESTATEMENT (SECOND) OF TORTS § 402A comment k (1965). *Id.* at 380. The court held that the warning given to the physician was adequate and granted defendant's motion for a directed verdict. *Id.* at 384-85.

49. *Chambers*, 441 F. Supp. at 381.

the warning which must be examined is that given to the physician and not that given to the "user"<sup>50</sup> and that "the purchaser's doctor is [the] learned intermediary between the purchaser and manufacturer."<sup>51</sup>

As these and other cases amply hold, the drug manufacturer's duty is to warn the physician, who is a learned intermediary between the manufacturer and the patient-consumer.<sup>52</sup> Based on his knowledge of the drug from information garnered from the PDR, package inserts, advertisements, and from per-

50. *Id.* (quoting *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966)). The court cited to *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 95 Cal. Rptr. 381 (1971), which noted that the doctor is "an intervening party who is required to exercise his own independent judgment on the basis of the technical information furnished." *Chambers*, 441 F. Supp. at 381.

51. *Chambers*, 441 F. Supp. at 381.

52. See *supra* note 35 and accompanying text. There are two main exceptions to the rule that drug manufacturers do not have to directly warn the consumer-patient. A few recent cases in a select number of jurisdictions have held that a manufacturer of birth control pills has a common law duty to warn not only the physician, but also the ultimate user, of risks inherent in the use of this particular medication. See *Odgers v. Ortho Pharmaceutical Corp.*, 609 F. Supp. 867 (E.D. Mich. 1985) (court recognized a common law duty on part of drug manufacturers to warn user directly of the dangers of the use of the contraceptive, Ortho-Novum); *Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379 (E.D. Mich. 1985) (manufacturer of Ovulen 21, birth control pills, had a duty to warn patient directly of risk of side effects); *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 475 N.E.2d 65, *cert. denied*, 474 U.S. 920 (1985) (manufacturer had a duty to warn user of the potential risk of a stroke when taking Ortho-Novum, an oral contraceptive). *But cf. In re Certified Questions*, 419 Mich. 686, 358 N.W.2d 873 (1984) (in absence of action by legislature, there is no rule of law relating to a manufacturer's duty to warn patients directly of the dangers of use of the contraceptive, Ortho-Novum).

The distinction between oral contraceptives and other prescription drugs is based on three points: (1) for oral contraceptives, patient choice plays a much more prominent role than in the case of drugs prescribed for the treatment of illness or injury; (2) as the result of manufacturer generated publicity, patients eager to take the pill have specifically requested it as the most effective means of preventing unwanted pregnancies; and (3) physicians usually do not supervise the use of oral contraceptives, as they do the use of other drugs.

*Brushwood*, *supra* note 14, at 291-92 (citing the dissent in *In re Certified Questions*).

In two polio vaccine cases, *Davis v. Wyeth Laboratories*, 399 F.2d 121 (9th Cir. 1968) where the plaintiff was given polio vaccine in a mass immunization clinic, and *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974), where the plaintiff received polio vaccines at a county health clinic, the courts ruled that when a manufacturer of a prescription drug knows or has reason to know that the drug will be dispensed or administered without a physician present to weigh the risk versus the benefit of a particular patient using the drug, the manufacturer must provide the consumer with adequate information to do his or her own balancing of the risks and benefits of using that drug.

sonal knowledge, and based on his knowledge of his patient, the physician decides whether to prescribe the drug in question.

Regrettably, the use of some drugs results in an adverse reaction in some patients, and as a result, some of these patients bring lawsuits against the drug manufacturer. In many of these actions, the drug in question qualifies as a Comment k product<sup>53</sup> in which the manufacturer has issued complete and adequate warnings,<sup>54</sup> but the prescribing physician misused the drug.

### III. Misuse of Prescription Drugs by the Physician

A proper warning by a drug manufacturer is useless unless the physician reads and follows it.<sup>55</sup> The Restatement (Second) of Torts states that "[w]here warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in a defective condition, nor is it unreasonably dangerous."<sup>56</sup>

Under products liability law, failure to follow adequate instructions is considered misuse which bars a plaintiff's recovery.<sup>57</sup> Physicians have the duty to read the drug manufacturers' warnings, and with those exceptions necessitated by the individual patient's needs, adhere to them. When a patient suffers injury or death because the physician has ignored the drug's labeling, then the physician's misuse of the product serves as the intervening cause of any injury which may result to the patient. Misuse of a drug by a physician occurs either when the physician prescribes the medication without reading the directions or when he reads the directions but ignores them.

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53. See *supra* note 48.

54. See *supra* note 37 and accompanying text.

55. Lawrence, *Drug Manufacturer's Recommendation and the Common Knowledge Rule to Establish Medical Malpractice*, 63 NEB. L. REV. 859, 864 (1984).

56. RESTATEMENT (SECOND) OF TORTS § 402A comment j (1965).

57. *Pinto v. Clairol, Inc.*, 324 F.2d 608, 610 (6th Cir. 1963) (plaintiff who failed to take a patch test before dyeing her hair as package instructed was barred from recovery); *Proctor & Gamble Mfg. Co. v. Langley*, 422 S.W.2d 773 (Tex. Civ. App. 1967) (plaintiff's "violation of the plain instructions and warnings was a misuse of [the product] and constitutes a defense to the cause of action").

### A. *Failure to Follow Directions*

In *Magee v. Wyeth Laboratories*,<sup>58</sup> the court affirmed a jury verdict<sup>59</sup> in favor of a pharmaceutical company in a suit for the wrongful death of Tarance Magee due to the administration of the prescription drug Sparine. Mr. Magee, who was suffering from emotional depression, entered Las Encinas Sanitarium on October 7, 1958. Between that date and November 17, 1958, when he died, he was administered Sparine.<sup>60</sup> During that period, Mr. Magee contracted a blood disorder—agranulocytosis—which depletes white corpuscles and hinders the body's ability to fight infection.<sup>61</sup> The court addressed the issue of proximate cause insofar as the drug manufacturer's warnings and actions were concerned. During the trial, one of the physician defendants testified that he read the direction sheet and literature left by Wyeth Laboratories and that he knew, prior to Mr. Magee's death, that rare individuals might be sensitive to the drug in question and that death might result in such individuals.<sup>62</sup> The evidence warranted an inference of negligence on the part of the prescribing physician who failed to follow directions (emanating from the manufacturer) although all of them were known to him. Neither the physician nor the plaintiffs questioned the adequacy of the warning.

The court held that a “[f]ailure to follow an unchallenged method of use prescribed by the manufacturer constitutes a break in causation which exonerates the manufacturer from any

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58. 214 Cal. App. 2d 340, 29 Cal. Rptr. 322 (1963). A wrongful death action was brought by a widow and her children against Wyeth Laboratories for the wrongful death of her husband caused by the administration of Sparine, a drug used to treat depression. *Id.* at 344, 29 Cal. Rptr. at 324. Mrs. Magee and her children sued on the theories of negligence and implied warranty. *Id.* at 347, 29 Cal. Rptr. at 326.

59. *Id.* at 359, 29 Cal. Rptr. at 333. The plaintiff named Las Encinas Sanitarium, Wyeth Laboratories, Inc., seven doctors, and nine nurses as defendants. Before trial, however, all defendants except Wyeth Laboratories settled. *Id.* at 344, 29 Cal. Rptr. at 324.

60. *Id.* at 344-45, 29 Cal. Rptr. at 324.

61. *Id.* at 345, 29 Cal. Rptr. at 324.

62. *Id.* at 345, 29 Cal. Rptr. at 325. The doctor was also familiar with the portion of the document which stated, “Agranulocytosis has occurred in 18 instances from some 3 ½ million patients who have received the drug. Patients should be observed frequently and asked to report immediately any sudden appearance of any signs of infection . . . .” *Id.* at 346, 29 Cal. Rptr. at 325.

liability.”<sup>63</sup> Furthermore, “[t]he intervention of such negligence of the doctor is not a foreseeable consequence of the sale of the drug within the narrow field in and for which it was distributed.”<sup>64</sup> The court went on to note that the warranty does not run to a person who cannot reasonably be expected to use the drug; similarly, one who fails to follow adequate manufacturer’s warnings is not within the warranty.<sup>65</sup> Thus, by providing adequate warnings to reasonably foreseeable users, the manufacturer protects itself from liability under the warranty.<sup>66</sup>

In *Mulder v. Parke-Davis & Co.*,<sup>67</sup> the court cited *Magee* to support affirmance of a lower court’s decision to grant Parke-Davis’ motion for a directed verdict.<sup>68</sup> In *Mulder*, the plaintiff brought a wrongful death action claiming Parke-Davis was negligent in failing to give adequate warnings<sup>69</sup> to the medical profes-

63. *Id.* at 351-52, 29 Cal. Rptr. at 328.

64. *Id.* at 349, 29 Cal. Rptr. at 327.

65. *Id.* at 350, 29 Cal. Rptr. at 327-28.

66. *Id.* at 350, 29 Cal. Rptr. at 327-28 (citing *Nishida v. E.I. Du Pont De Nemours & Co.*, 245 F.2d 768, 774 (5th Cir. 1957), *cert. denied*, 355 U.S. 915 (1958)). The court stated:

The manufacturer is at least entitled to assume that his product will be put to a normal use; and he is not subject to liability where it would ordinarily be safe, but injury results because it is mishandled, or is used in some unusual or unforeseeable way . . . . In the ordinary case the maker may also assume a normal user; and he is not liable where the injury is due to some allergy or other personal idiosyncrasy of the consumer, found only in an insignificant percentage of the population. But if the allergy is one common to any substantial number of possible users, the seller may be required at least to give warning of the danger.

*Id.* at 352, 29 Cal. Rptr. at 329 (citation omitted).

67. 288 Minn. 332, 181 N.W.2d 882 (1970). Plaintiff’s widower brought a wrongful death action against Parke-Davis, the manufacturer of the antibiotic Chloromycetin and the prescribing physician, Frank E. Mork. *Id.* at 333, 181 N.W.2d at 884.

68. *Id.* The supreme court affirmed the directed verdict as to the manufacturer, but ordered a new trial as to the physician, holding that evidence that the manufacturer’s instructions were not followed and that failure to do so resulted in patient’s death was sufficient to make out a prima facie case of liability. *Id.* at 339, 181 N.W.2d at 887.

69. *Id.* at 334, 181 N.W.2d at 884. The warning which Parke-Davis gave is as follows:

Serious and even fatal blood dyscrasias (aplastic anemia, hypoplastic anemia, thrombocytopenia, granulocytopenia) are known to occur after the administration of chloramphenicol. Blood dyscrasias have occurred after both short-term and prolonged therapy with this drug. Bearing in mind the possibility that such reactions may occur, chloramphenicol should be used only for serious infections caused by organisms which are susceptible to its antibacterial effects. Chloramphenicol should not be used when other less potentially dangerous agents will be effective, or in the treatment of trivial infections such as colds, influenza, or viral



sion about the dangers of Chloromycetin, an antibiotic manufactured and marketed by Parke-Davis. Specifically, on June 24, 1965, the decedent, the plaintiff's wife, had consulted defendant Dr. Frank E. Mork for an infection in her left ear.<sup>70</sup> She was treated with penicillin but her condition did not improve and she returned to the doctor four days later when her condition was diagnosed as purulent otitis media.<sup>71</sup> Dr. Mork took a culture, tested it with fifteen antibiotics and found the most effective to be Chloromycetin.<sup>72</sup> He then prescribed one 250-milligram capsule four times daily for four days.<sup>73</sup> Since Mrs. Mulder's condition improved, the prescription was renewed.<sup>74</sup> However, on September 22, examination by a different doctor revealed a worsening of Mrs. Mulder's otitis, and the Chloromycetin prescription was renewed again.<sup>75</sup> The same treatment was prescribed by Dr. Mork three days later, following a hemoglobin test, and was renewed, once more, a week later.<sup>76</sup> On January 10, 1966, Dr. Mork discovered that Mrs. Mulder had been hemorrhaging in her arms, legs, and breast.<sup>77</sup> She died on January 29, 1966, from gastrointestinal hemorrhage due to aplastic anemia or bone marrow depression.<sup>78</sup> In addition to allegations that the defendant drug company's warning was inadequate, the plaintiffs also claimed that the warning did not come to the doctor's attention.<sup>79</sup>

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infections of the throat, or as a prophylactic agent.

Precautions: It is essential that adequate blood studies be made during treatment with the drug. While blood studies may detect early peripheral blood changes such as leukopenia or granulocytopenia, before they become irreversible, such studies cannot be relied on to detect bone marrow depression prior to development of aplastic anemia.

*Id.* at 334-35, 181 N.W.2d at 884-85.

Plaintiffs asserted that Parke-Davis' "so-called detail men who called on doctors, failed to mention dosage[s], length of therapy, level of concentration of the drug in the blood, or side effects of the drug." *Id.* at 334, 181 N.W. 2d at 884.

70. *Id.* at 333, 181 N.W.2d at 884.

71. *Id.*

72. *Id.*

73. *Id.*

74. *Id.*

75. *Id.*

76. *Id.* at 333-34, 181 N.W.2d at 884.

77. *Id.*

78. *Id.*

79. *Id.*

In its affirmation of the directed verdict, the Minnesota Supreme Court noted that the doctor had testified that he was aware of the side effects and possible complications in the use of Chloromycetin, one of which was the dyscrasia, an imbalance of components in the blood, experienced by Mrs. Mulder.<sup>80</sup> Citing to *Magee*, the Minnesota Supreme Court held that where the only issue is failure to communicate a warning, the manufacturer is not liable if the doctor was fully aware of the facts which were the subject of the warning.<sup>81</sup> Again the court held that “[f]ailure [of the doctor] to follow an unchallenged method of use prescribed by the manufacturer constitutes a break in the chain of causation. . . .”<sup>82</sup>

In *Love v. Wolf*,<sup>83</sup> an earlier Chloromycetin case in another jurisdiction, the California Court of Appeals reversed a judgment for the plaintiffs due to the lawyer’s trial misconduct,<sup>84</sup> but refused to grant Parke-Davis’ motion for a directed verdict.<sup>85</sup> The court in *Wolf* acknowledged the doctrine stated in *Magee* that a drug company has no duty to insure that the warning reaches the doctor’s patient for whom the drug is prescribed.<sup>86</sup> The court also noted that Parke-Davis<sup>87</sup> warned about the side

80. *Id.* at 335, 181 N.W.2d at 885.

81. *Id.* (citing *Magee v. Wyeth Laboratories, Inc.*, 214 Cal. App. 2d 340, 351, 29 Cal. Rptr. 322, 328 (1963)).

82. *Id.* at 336, 181 N.W.2d at 885 (citing *Magee v. Wyeth Laboratories, Inc.*, 214 Cal. App. 2d 340, 351, 29 Cal. Rptr. 322, 328 (1963)).

83. 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964). The plaintiff recovered \$334,046 in damages for severe anemia which plaintiff suffered after taking the antibiotic, Chloromycetin, prescribed for her by Dr. Wolf and manufactured by Parke-Davis and Company. *Id.* at 382, 38 Cal. Rptr. at 184.

84. *Id.* at 385, 38 Cal. Rptr. at 186.

Misconduct by the plaintiff’s attorney, Mr. Boccardo, permeated the proceedings. Counsel selected as his principle target Parke-Davis. Typical is the assertion in the opening statement that after Parke-Davis “started to use this stuff *all over the country came reports of people dying from it*, people suffering from aplastic anemia and dying.” Later in the trial, counsel referred to Chloromycetin as a “death-dealing drug.” He also stated: “[T]here isn’t a bigger *con outfit* in the world than Parke-Davis, and I will prove it before I get through with this case.” *Id.* Finally, in closing arguments, Mr. Boccardo compared Parke-Davis and Dr. Wolf to Fagin and Oliver Twist and later to a “gangster and his gunman.” *Id.* at 386, 38 Cal. Rptr. at 187.

85. *Id.* at 382, 38 Cal. Rptr. at 184.

86. *Id.* at 402-03, 38 Cal. Rptr. at 198.

87. In 1952, following an investigation by the FDA, a cautionary warning for circulars, packages, and labels was prescribed. The following warning was to appear at the top

effects of Chloromycetin and that Dr. Wolf knew of the dangers attendant with the use of Chloromycetin.<sup>88</sup> However, in its decision not to order a nonsuit, the court recognized the plaintiff's legal contention that a "proper warning . . . given [to] Dr. Wolf and the rest of the medical profession . . . [is] cancelled out if overpromotion through a vigorous sales program persuaded doctors to disregard the warnings given."<sup>89</sup>

The court took note of the large sales figures for Chloromycetin<sup>90</sup> and the fact that the use of the drug had not been limited to the treatment of typhus, typhoid, Rocky Mountain fever, and other infections to which the plaintiff's experts asserted

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of the circular:

"Certain blood dyscrasias (aplastic anemia, thrombocytopenic purpura, granulocytopenia and pancytopenia) have been associated with the administration of Chloromycetin. It is essential that adequate blood studies be made when prolonged or intermittent administration of this drug is required. Chloromycetin should not be used indiscriminately or for minor infections." *Id.* at 383, 38 Cal. Rptr. at 185. The FDA also prescribed the following warning which was to be included on the label: "WARNING: Blood dyscrasias may be associated with intermittent or prolonged use and it is essential that adequate blood studies be made." *Id.*

These directives were immediately complied with by Parke-Davis. *Id.*, 38 Cal. Rptr. at 185. Also, on July 7, 1952, Parke-Davis sent letters to 200,000 physicians advising them of the association between Chloromycetin and aplastic anemia and stating that while the number of cases was unknown, "many have terminated fatally." *Id.* In particular, Parke-Davis called attention to the danger resulting from intermittent or indiscriminate treatment. *Id.* at 383-84, 38 Cal. Rptr. at 185. These letters were supplemented by full page announcements in the American Medical Association Journal. *Id.* at 384, 38 Cal. Rptr. at 185.

88. *Id.* at 395-96, 38 Cal. Rptr. at 193. The court stated that "Dr. Wolf knew of the potential danger: (1) from the warnings from labels and packages received by him and from the advertising literature and letters received from Parke-Davis; (2) also from studies made in medical school and in special research during his internship, and (3) from articles in professional magazines." *Id.*

89. *Id.* at 396, 38 Cal. Rptr. at 193. The court took the position that Parke-Davis "played down" the dangers of Chloromycetin. *Id.* at 398, 38 Cal. Rptr. at 195. It pointed to advertisements which included such statements as "[m]ore than 11,000,000 patients have been treated with this important antibiotic" and "[t]ruly one of the world's outstanding therapeutic agents." *Id.* The advertisements also stated, "[a] review of the literature points up the fact that the great majority of investigators who study this drug clinically report no evidence of untoward reactions. Side effects occur infrequently with Chloromycetin and, when encountered, are generally . . . mild for this type of therapy." *Id.* Another advertisement quoted from an unnamed article which stated, "[i]n no case have we seen any evidence of depression of the hemopoietic system resulting in aplastic anemia or agranulocytosis. We are now certain that Chloromycetin is effective with very minimal untoward side effects." *Id.*

90. *Id.* In 1961, \$68,000,000 of Parke-Davis' total gross sales of \$190,000,000 came from the sale of Chloromycetin. *Id.*

its use to be limited.<sup>91</sup>

There are troubling aspects to the court's position that facts indicative of "overpromotion" prevent a directed verdict. As the court itself noted, Dr. Wolf was fully cognizant of the dangers inherent in the use of Chloromycetin.<sup>92</sup> Since he knew of the dangers of the drug he was prescribing, the court's reliance on Parke-Davis' "overpromotion" of Chloromycetin to deny a non-suit was unfounded.<sup>93</sup>

*Love v. Wolf* is just one example of a court's failure to recognize the misuse defense in drug liability cases.<sup>94</sup> If a physician was fully aware of the dangers and warnings of a drug, then the alleged "overpromotion" of that drug is irrelevant.

The Michigan Court of Appeals in *Formella v. Ciba-Geigy Corp.*<sup>95</sup> took a different position from the court in *Wolf* when it held that the negligence of the physician was the intervening, independent, sole proximate cause of a patient's injuries when she developed aplastic anemia as a direct result of taking the drug, even if the manufacturer had been negligent in over-promoting use of the drug. In *Formella*, the plaintiff, who had complained of lower back pain, was diagnosed as having osteoarthritis and was prescribed Tandearil by Dr. Murguz.<sup>96</sup> She returned to Dr. Murguz' office two weeks later, at which time he continued the drug treatment.<sup>97</sup> Dr. Murguz did not perform any blood tests at any time during her treatment.<sup>98</sup> Several weeks

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91. *Id.* at 398-99, 38 Cal. Rptr. at 195.

92. *See supra* note 88.

93. 226 Cal. App. at 402, 38 Cal. Rptr. at 197. The concept of overpromotion is itself a dubious one. A pharmaceutical company is a "for profit company"; it is in business to make money. A doctor who chooses to misuse the drug should not blame the drug manufacturer's successful marketing of the drug for that misuse.

94. *See, e.g.,* Richards v. Upjohn, 95 N.M. 675, 625 P.2d 1192 (1980) (holding that the treating physician's failure to consult the PDR, which contained the manufacturer's warnings, and the resulting misuse of the product were foreseeable, thereby precluding a summary judgment). *See also infra* note 101 and accompanying text.

95. 100 Mich. App. 649, 300 N.W.2d 356 (1980). Helen Formella and her husband brought an action against the prescribing physician, Dr. Murguz, and the Ciba-Geigy Corporation. They alleged that as a result of taking Tandearil for lower back pain caused by osteoarthritis, Mrs. Formella suffered aplastic anemia. *Id.* at 651-52, 300 N.W.2d at 357. The Formellas alleged that Ciba-Geigy failed to adequately warn physicians of the dangers of Tandearil and overpromoted its use. *Id.* at 652, 300 N.W.2d at 357.

96. *Id.* at 652, 300 N.W.2d at 357.

97. *Id.*

98. *Id.*

later, Mrs. Formella complained to Dr. Murguz of multiple bruises and tiredness.<sup>99</sup> Dr. Murguz stated that he suspected that Tandearil had caused Mrs. Formella to develop aplastic anemia. Hospital tests confirmed Dr. Murguz' suspicions.<sup>100</sup>

The court in *Formella* quite properly recognized that over-promotion is a side issue and irrelevant when the prescribing physician knows of the dangerous side effects of a drug.<sup>101</sup> The physician, being the skilled, learned intermediary, has the responsibility to read and follow the warnings when prescribing a medication and not to rely on sales promotions.

It is the very hazards of prescription medicines that require a doctor's authorization for a patient to purchase and receive them. Otherwise, there would be no need for prescription medications and salesmen could promote these medicines directly to the public. To blame the malfeasance of a physician who failed to follow directions when prescribing the medications on "over-promotion" by the drug manufacturers violates the very spirit of the FDA regulations.

Other cases have continued to hold that a physician's failure to follow a drug manufacturer's directions for use serves as the intervening, independent and sole proximate cause of a patient's injuries. In *Dyer v. Best Pharmacal*,<sup>102</sup> the plaintiff, Betty Dyer, was given an intramuscular injection of NOL-LA, an anorexiant drug, as a treatment for weight control.<sup>103</sup> She was hospitalized the following day with a diagnosis of subarachnoid hemorrhage.<sup>104</sup> She was comatose for several weeks and developed cardiovascular complications.<sup>105</sup>

The drug, NOL-LA, was sent directly to the physician, Dr.

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99. *Id.*

100. *Id.*

101. *Id.* at 653, 300 N.W.2d at 357-58. The court in *Formella* stated that there was no evidence that the drug was overpromoted. *Id.* at 654, 300 N.W.2d at 358. Dr. Murguz stated that he was told by detail men that the drug was good "with a safety margin." *Id.* The court noted "although some of the early literature tends to play down the possible side effects of the drug and recommends its use for extended periods of time, all of the literature submitted to this court includes a warning that blood tests should be frequently conducted on the patient." *Id.*

102. 118 Ariz. 465, 577 P.2d 1084 (1978).

103. *Id.* at 466, 577 P.2d at 1085.

104. *Id.*

105. *Id.*

Augustus Stewart, from Best Pharmacal and was accompanied by a package insert. The package insert recommended the drug as an anorexiant for weight control, but also listed hypertension and cardiovascular disease as contraindications of the drug's use.<sup>106</sup>

The court declined to find Best Pharmacal guilty of negligence per se for failing to file a New Drug Application.<sup>107</sup> Instead, the court examined the legal theories of successive and concurrent causes of an event<sup>108</sup> and found that the successive act of the physician in prescribing the drug NOL-LA, an anorexiant, to Mrs. Dyer served as the proximate cause of her injuries.<sup>109</sup> The court found that the drug manufacturer could not be "required legally to foresee that a licensed physician [would] disregard express warnings regarding a drug's use."<sup>110</sup>

The importance of *Dyer* lies not merely in the reiteration of *Magee* and its legal progeny, but also in the court's recognition of the fact that the drug manufacturer cannot insure against the prescribing physician disregarding the drug manufacturer's

106. *Id.*

107. *Id.* at 467, 577 P.2d at 1086. The court stated:

It is true that a person who violates a statute enacted for the protection and safety of the public is guilty of negligence per se. Even assuming for the purposes of review that Mrs. Dyer is one of the class that can raise the effect of non-compliance with the FDCA, appellants still have failed to explain exactly how the appellee's alleged violation of the FDCA by their failure to file a New Drug Application resulted in Mrs. Dyer's injuries . . . .

*Id.*

108. *Id.* The court in *Dyer* held that "when two forces combine to produce an injury, they are labeled either concurrent or successive causes. If the forces are concurrent, both or either may be the proximate cause of the injury. If the two forces are successive, only the most immediate is the proximate cause of the injury." *Id.* Citing to *Lyric Amusement Co. v. Jeffries*, 58 Ariz. 381, 388, 120 P.2d 417, 420 (1941), the *Dyer* court stated:

The difference between concurrent and successive causes may be stated as follows: If two distinct causes are operating at the same time to produce a given result which might be produced by either alone they are concurrent, but if they are successive and unrelated in their operation, they cannot be concurrent, and one must be the proximate and one the remote cause. In such a case the proximate is the responsible cause and the law disregards the remote one.

*Id.*

109. *Id.* at 468, 577 P.2d at 1087. The court noted there were cases when the rule governing concurrent forces applies to successive causes of an injury. In those cases, the defendant's negligent course of conduct has ended and only the risk of harm created by the negligent conduct is present at the time of the injury. *Id.* at 468, 577 P.2d at 1087.

110. *Id.* at 469, 577 P.2d at 1088.

warnings. To require the drug manufacturer to be liable for a physician's possible failings would force the manufacturer into becoming, in effect, a health care insurer, an untenable legal and financial position for the company.

In *Beyette v. Ortho Pharmaceutical Corp.*,<sup>111</sup> the plaintiff Rene Beyette alleged that Ortho Pharmaceutical Corp. (Ortho) had failed to warn her about the increased risk of infection associated with the use of its intrauterine birth control device (IUD) known as the Lippes Loop.<sup>112</sup> Mrs. Beyette also claimed that Ortho had breached the express warranties of product safety contained in its product information sheet.<sup>113</sup>

The physician, Dr. Kaufman, had originally inserted the IUD in 1972.<sup>114</sup> But prior to inserting the IUD, he had consulted the accompanying product information sheet.<sup>115</sup> Under the "side effects" heading, the product information sheet explained that twenty-three out of 1,673 patients fitted with the Lippes Loop were tentatively diagnosed as having a history of pelvic inflammatory disease.<sup>116</sup>

After the plaintiff had the IUD removed and replaced twice, Dr. Kaufman inserted a third Lippes Loop in 1975. In 1977, following a directive from the FDA, Ortho changed its warning to include a reference to the reported increased risk of pelvic infec-

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111. 823 F.2d 990 (6th Cir. 1987).

112. *Id.* at 992. Defendant-appellant, Ortho Pharmaceutical Corporation (Ortho), appealed from a judgment for plaintiffs-appellees, Rene Beyette and her husband Ronald Beyette, entered pursuant to a jury verdict in a diversity action for personal injuries. *Id.* at 990.

113. *Id.* at 992.

114. *Id.* at 991.

115. *Id.*

116. *Id.* at 991 n.2. The product information sheet stated:

Lippes reported 23 patients with tentative diagnoses or histories of pelvic inflammatory disease among 1,673 patients fitted with LIPPES LOOP Intrauterine Double-S. Of these 23, the tentative diagnosis was unsupported by laboratory corroboration in 8; 3 were found to have urinary tract infections; 1 had appendicitis; 1 had regional ileitis [sic]; and 1 had postoperative wound infection with septicemia following a posterior colporrhaphy.

The remaining 9 cases recovered promptly; in half of these cases, the device was not removed.

The base line rate of pelvic inflammatory disease in the population studied is not available. It is estimated that the rate reported with LIPPES LOOP Intrauterine Double-S in place is essentially that which would have occurred without it.

*Id.*

tion.<sup>117</sup> In a letter dated November 7, 1977, Ortho advised Dr. Kaufman of the revised product literature.<sup>118</sup> The revised warning stated that "[u]se of an IUD in those patients with cervicitis should be postponed until treatment has cured the infection."<sup>119</sup>

On July 24, 1978, Dr. Kaufman discovered that Mrs. Beyette had a severe cervical infection.<sup>120</sup> The IUD was not removed until a year later, at which time Mrs. Beyette, in critical condition, required a total abdominal hysterectomy.<sup>121</sup>

Dr. Kaufman testified that by December 1977, he realized that there had been a change in the package insert accompanying the Loop.<sup>122</sup> He conceded, however, that he had not notified Mrs. Beyette of the changes.<sup>123</sup> Mrs. Beyette testified at trial that had she been advised of the revised warning, she would have requested the removal of the IUD.<sup>124</sup>

The court of appeals overturned the jury verdict,<sup>125</sup> holding that there was insufficient evidence to support a verdict on Mrs. Beyette's cause of action charging a failure to warn of the potential hazards associated with use of the Lippes Loop.<sup>126</sup> The court reiterated the following legal doctrine:

A manufacturer has a continuing duty to warn the medical profession, not the patient, of any risks inherent in the use of the product which the manufacturer knows or should know to exist. A manufacturer has a continuing duty to inspect and test its product during the course of manufacture and to warn the medical profession of any side effects associated with the product's use.<sup>127</sup>

The court concluded, however, that Ortho's failure to warn

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117. *Id.* at 991.

118. *Id.*

119. *Id.*

120. *Id.* at 992.

121. *Id.* at 991.

122. *Id.*

123. *Id.*

124. *Id.* at 991-92.

125. *Id.* at 992. The jury "returned a verdict of \$500,000 in favor of Beyette and \$63,000 in favor of her husband." *Id.*

126. *Id.*

127. *Id.* (citing *Smith v. E.R. Squibb & Sons, Inc.*, 405 Mich. 79, 88, 273 N.W.2d 476, 479 (1979); *Muilenberg v. Upjohn Co.*, 115 Mich. App. 316, 331, 320 N.W.2d 358, 366 (1982); *Taylor v. Wyeth Laboratories, Inc.*, 139 Mich. App. 389, 395, 362 N.W.2d 293, 296 (1984)).



of the increased risk of infection associated with the Lippes Loop prior to the insertion of Mrs. Beyette's third Loop in 1975 was not the proximate cause of her injuries.<sup>128</sup> The product literature issued by Ortho in 1977 included a warning that there was a significant risk of pelvic inflammatory disease (PID) associated with the use of IUDs.<sup>129</sup> Based on Dr. Kaufman's knowledge by December 1977 that the product literature had been modified to include warnings of the increased risk of PID and his failure both to inform Mrs. Beyette of the increased risks and to remove the Loop under a diagnosis of "severe cervicitis," the court concluded that Ortho's failure to issue adequate warnings prior to the insertion of Mrs. Beyette's third Lippes Loop was not the proximate cause of her injuries.<sup>130</sup>

The court in *Beyette* accepted the plaintiff's argument that the pre-1977 product literature for the Lippes Loop was inadequate.<sup>131</sup> The court, however, recognized that once the physician has knowledge of the new warnings in the package insert, it becomes his responsibility to follow those instructions.<sup>132</sup> The logic behind this ruling is inarguable. A pharmaceutical manufacturer abides by the FDA laws and regulations. Upon orders of the FDA, the manufacturer changes its warnings in the package inserts and in the PDR. Once the physician has notice of these changes, it is his responsibility to prescribe the medication or product accordingly. The pharmaceutical manufacturer cannot stand over the physician every time he prescribes a drug. The position of the drug manufacturer can be analogized to that of the automobile manufacturer who is not responsible for an accident caused by an individual who buys a car and then runs a red light.

### B. *A Physician's Failure to Read a Drug Manufacturer's Warnings*

When a physician reads a manufacturer's warning and fails to heed it, the plaintiff and a co-defendant physician may raise

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128. *Id.* at 993.

129. *Id.*

130. *Id.*

131. *Id.*

132. *Id.*

the issue of the *adequacy*<sup>133</sup> of the warning. Often, the drug company can overcome this issue by introducing into evidence a physician's affidavit,<sup>134</sup> or by merely illustrating the forcefulness of the warning.<sup>135</sup> Sometimes, however, the drug manufacturer is absolved of liability because the physician failed to consult the PDR, the package insert, or any other warning or instruction before prescribing the drug.

In *Douglas v. Bussabarger*,<sup>136</sup> an action in damages for personal injuries brought against a physician and Sterling Drug, the plaintiff questioned whether Sterling was negligent in not placing a warning label on an anesthetic drug container.<sup>137</sup> After stomach surgery, the plaintiff suffered an impairment of the functioning of her right foot, bowels and bladder.<sup>138</sup> Sterling Drug had supplied some of the anesthetic used in the surgery.<sup>139</sup> The jury returned a verdict in favor of both Sterling and the physician, Dr. Bussabarger, and the plaintiff appealed.<sup>140</sup>

The court found that certain trial errors entitled plaintiff to a new trial as to Dr. Bussabarger. However, the court found that the correctness or purity of the anesthetic had not been brought into question.<sup>141</sup> Furthermore, Dr. Bussabarger had testified that he had not read the labeling on the anesthetic container but had relied on his own knowledge of anesthetics. The court concluded that if Sterling Drug was negligent in not placing a warning on the anesthetic container, the plaintiff's injury was not proximately caused by this negligence.<sup>142</sup>

By ruling in favor of Sterling Drug, the court in *Bussabarger* implicitly recognized that no warning is of any use when the physician fails to read it. The adequacy of the warning simply becomes irrelevant to the issue of the proximate cause. If a drug manufacturer's warning is insufficient, the prescribing

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133. See *supra* note 26.

134. See, e.g., *Wooten v. Johnson & Johnson Prods., Inc.*, 635 F. Supp. 799 (N.D. Ill. 1986); *Goodson v. Searle Laboratories*, 471 F. Supp. 546 (D. Conn. 1978).

135. See *supra* note 26.

136. 73 Wash. 2d 476, 438 P.2d 829 (1968).

137. *Id.* at 478, 438 P.2d at 831.

138. *Id.*

139. *Id.*

140. *Id.*

141. *Id.*

142. *Id.*

doctor's knowledge of the drug's character can be a sufficient intervening act to absolve the manufacturer of any liability for failure to render an adequate warning.<sup>143</sup>

In *Oppenheimer v. Sterling Drug, Inc.*,<sup>144</sup> the court, in its discussion of the possible negligence of the drug manufacturer in failing to give adequate warnings, noted that there was nothing to indicate that the treating physician relied upon any information furnished by Sterling Drug in prescribing the medication for his patient.<sup>145</sup> The court subsequently upheld a directed verdict for the drug manufacturer. In rendering its decision, the court noted that the "[p]laintiff's doctor failed to observe the warnings set out in the Physicians' Desk Reference, *if he ever saw them.*"<sup>146</sup>

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143. See also, *Wolfgruber v. Upjohn*, 72 A.D.2d 59, 423 N.Y.S.2d 95 (4th Dep't 1979), *aff'd*, 52 N.Y.2d 768, 417 N.E.2d 1002, 436 N.Y.S.2d 614 (1980) (physician who treated himself with antibiotic in disregard of manufacturer's adequate warning of dangers, had no basis for suit against manufacturer).

144. 7 Ohio App. 2d 103, 219 N.E.2d 54 (1964). The plaintiff consulted Dr. James McCreary concerning a skin disorder. After receiving a lab report, the doctor prescribed chloroquine. Although the legend on the prescription indicated that the prescription was refillable for six months from the date of the original prescription, the prescription was refilled over a period of more than two years. *Id.* at 104, 219 N.E.2d at 55-56. Subsequently, the plaintiff visited Dr. William Havener, an ophthalmologist, and revealed to the doctor the nature of her skin disorder, lupus discoid erythematosus, and the fact that she had been treated for the disorder with cortisol steroids and chloroquine. *Id.* at 104, 219 N.E.2d at 56. Dr. Havener found the plaintiff to have a marked loss in her field of vision, and diagnosed the cause as chloroquine retinopathy. *Id.* at 104-05, 219 N.E.2d at 56.

The plaintiff alleged that Aralen, or chloroquine phosphate, was a harmful product, although distributed as an effective, safe treatment for chronic discoid lupus erythematosus, and its use caused the damage to and loss of vision in her eyes. *Id.* at 105, 219 N.E.2d at 56. She alleged that defendant was negligent in selling the harmful product, in failing to discover the defects in the preparation, and in failing to warn the plaintiff of its harmful effects. She further claimed that such negligence [was] the cause of her loss of vision and permanent damage to her eyes. In addition to the negligence claim, plaintiff also alleged that the defendant breached its express warranty and an implied warranty of fitness for use which ran with the product. *Id.*

145. The court stated:

In the record before us, there is nothing to indicate that the doctor relied upon any information furnished by the defendant in prescribing Aralen for his patient, the plaintiff herein, even though he did say that he relied upon [the] Physicians' Desk Reference and drug company literature. The doctor later specifically said — "I don't recall specifically reading the precautions" — when referring to plaintiff's exhibit No. 3. He said, further, that he did not know it, Aralen, to be a prescription drug, and that in the use of it he relied upon his own experience . . . . *Id.* at 108, 219 N.E.2d at 59.

146. *Id.* at 109, 219 N.E.2d at 59 (emphasis added). The court stated:

As part of her argument, the plaintiff in *Oppenheimer* alleged that the defendant had breached an express warranty and that an implied warranty of fitness for use ran with the product.<sup>147</sup> The court disposed of these arguments by noting that even if the defendant had failed in its duty to the plaintiff by reason of any erroneous publication, the record was completely silent as to any reliance on those warranties on the part of the plaintiff's doctor.<sup>148</sup>

Not all courts accept the doctrine that a treating physician's misuse of a drug due to a failure to consult a drug manufacturer's warnings constitutes an intervening act. In *Richards v. Upjohn*,<sup>149</sup> an action was brought to recover for deafness allegedly resulting from medical treatment with the drug neomycin sulfate. It was held that the treating physician's failure to consult the PDR, which contained the manufacturer's warnings, and the resulting misuse of the drug were foreseeable, thereby pre-

[The doctor's] recollection was not clear as to the readings in [the] Physicians' Desk Reference and defendant's literature circulated to physicians and druggists. It can hardly be said that he relied upon anything produced by the defendant or found in the general literature.

*Id.*

147. *Id.* at 105, 219 N.E.2d at 56.

148. *Id.* at 110, 219 N.E.2d at 59. Since the record failed to disclose any reliance by the plaintiff upon anything published or said by defendant, there cannot be a successful claim for breach of warranty, either express or implied, as to that plaintiff. *Id.*

149. 95 N.M. 675, 625 P.2d 1192 (1980). The plaintiff brought an action against a drug manufacturer for deafness which allegedly resulted from application of the antibiotic neomycin sulfate to a leg wound over a three day period.

Upjohn had published warnings in the Physicians' Desk Reference (PDR) and in the package inserts of the neomycin sulfate it sold that the drug was ototoxic (toxic to the nerve controlling hearing) and nephrotoxic (toxic to the kidneys), and could cause deafness. The 1971 PDR indicated that the drug could be used topically and stated that "[n]eomycin sulfate . . . may be used effectively as wet dressings, packs, or irrigations in secondarily infected wounds . . . ." The warning stated that "[i]n patients with impaired kidney function or with prerenal azotemia, systemic use of neomycin sulfate may result in irreversible deafness . . . ." *Id.* During and after 1971, Upjohn withdrew its recommendation for any uses other than intramuscular, apparently after the National Academy of Scientists — National Research Council and the Food and Drug Administration had determined the drug was probably not effective for topical use and/or as an irrigation solution for open wounds. The 1972 and 1973 PDRs indicated the drug was for intramuscular use only. Neomycin sulfate had been on the market and used topically for many years prior to 1971.

*Id.* at 677, 625 P.2d at 1194.

cluding summary judgment for the manufacturer.<sup>150</sup> The court found that when the doctor's act was reasonably foreseeable,<sup>151</sup> it could not constitute an independent intervening cause as a matter of law.<sup>152</sup>

The issue as framed by the court was whether the physician's use of the antibiotic neomycin sulfate in an irrigation solution was reasonably foreseeable by Upjohn.<sup>153</sup> Upjohn argued that the negligence of the physician in failing to consult the most recent PDRs concerning neomycin sulfate insulated Upjohn from liability.<sup>154</sup>

The court disagreed and noted that the plaintiffs had presented evidence that the physician's use of neomycin sulfate in an irrigation solution was reasonably foreseeable, since the 1971 PDR indicated that the drug could be used topically in irrigating wounds.<sup>155</sup> The court rejected the holdings of *Oppenheimer* and *Bussabarger* which held that the inadequacy of a drug company's warnings cannot be the proximate cause of the patient's injury when the physician fails to consult the literature or observe the warnings concerning the drug he used.<sup>156</sup> Instead, the court held that when a drug company's warnings are inade-

150. *Id.* at 680, 625 P.2d at 1198.

151. *Id.* at 679, 625 P.2d at 1196. The court cited the definition of an independent intervening cause set out in *Thompson v. Anderman*, 59 N.M. 400, 411-12, 285 P.2d 507, 514 (1955), where the New Mexico Supreme Court wrote:

The independent intervening cause that will prevent a recovery of the act or omission of a wrongdoer must be a cause which interrupts the natural sequence of events, turns aside their cause, prevents the natural and probable results of the original act or omission, and produces a different result, that could not have been reasonably foreseen.

*Id.* (emphasis omitted).

152. *Id.* (citing *Stevens v. Parke-Davis & Co.*, 9 Cal. 3d 51, 507 P.2d 653, 107 Cal. Rptr. 45 (1973)).

153. *Richards*, 95 N.M. at 679, 625 P.2d at 1196.

154. *Id.* at 680, 625 P.2d at 1197.

155. The court stated that "[w]hile the recommendation for topical use was withdrawn in two of the 1971 PDR supplements, there is no doubt that, at one time not too distant from the incident in this suit, Upjohn recommended its product to physicians as being effective for the very use to which [the doctor] put it." *Id.*

156. *Id.* The court also noted *Mulder* was not apposite because in that case "the physician testified he was aware of the dangers of the drug and of the dosage recommended by the drug company, but simply chose not to be governed by that information." *Id.* at 680-81, 625 P.2d at 1197-98. In *Richards*, both physicians had testified that they were not aware of the dangers associated with the use of neomycin sulfate nor were they aware that such usage was no longer recommended. *Id.* at 681, 625 P.2d at 1198.

quate, and it was foreseeable that doctors might not consult the PDR or package inserts before using the drug, the actual failure of a doctor to consult the inadequate warnings does not constitute an independent intervening cause relieving a drug company, whose warnings were inadequate, from liability.<sup>157</sup>

The very facts of *Richards* belie the court's decision. The administration of the drug and the resulting deafness of the plaintiff occurred in 1973, over two years after the drug's topical use recommendation had been withdrawn.<sup>158</sup> The court relied on Dr. Weaver's testimony to show that it was foreseeable that Dr. Weaver would not reread the PDR before administering the drug.<sup>159</sup> The warning found in the PDR and the package inserts had been altered over two years before the physician prescribed the drug for the plaintiff.<sup>160</sup> During that two year period, trade advertisements<sup>161</sup> may have appeared and "Dear Doctor" letters<sup>162</sup> may have been sent to prescribing physicians. Although it may be foreseeable that a physician would not know of a PDR warning more than two years after it has been changed, it is not necessarily "reasonable." It is certainly unreasonable and impossible to require a drug manufacturer to personally call each treating physician or to stand next to the doctor every time he prescribes the medication,<sup>163</sup> which is the only absolute way to

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157. *Id.* at 680, 625 P.2d at 1197. In support of its position, the court cited to the RESTATEMENT (SECOND) OF TORTS § 449, which reads: "If the likelihood that a third person may act in a particular manner is the hazard or one of the hazards which makes the actor negligent, such an act whether innocent, negligent, intentionally tortious, or criminal does not prevent the actor from being liable for harm caused thereby." *Id.*

158. *Id.* at 677, 625 P.2d at 1194.

159. *Id.* at 680, 625 P.2d at 1197. Dr. Weaver testified that it is not standard practice for a physician to reread the PDR every time a drug is given, especially when the drug has been on the market for a long time. *Id.* In addition, evidence was presented to show that neomycin sulfate had been used by physicians for over ten years. *Id.*

160. *Id.* at 677, 625 P.2d at 1194.

161. When a prescription drug is advertised by a drug manufacturer in the *New England Journal of Medicine*, the *Journal of the American Medical Association*, or any other physician's magazine, it is FDA policy that warnings of adverse reactions are printed in the advertisement.

162. Often, when the directions or warnings for a prescription drug are altered, the drug manufacturer is required to send doctors (who prescribe the medication) letters informing them of the changes.

163. See *Swayze v. McNeil Laboratories, Inc.*, 807 F.2d 464 (5th Cir. 1987). In *Swayze*, "[t]he plaintiff's son, Michael, died three years after surgery from . . . an overdose of the narcotic anesthetic fentanyl, a prescription drug produced and marketed by

insure that directions are read and followed. The court in *Richards* set a standard for reasonable foreseeability which a drug manufacturer could rarely overcome.

The court in *Formella v. Ciba-Geigy Corp.*<sup>164</sup> did not directly address the issue of "reasonable foreseeability" but instead recognized the doctrine that when a physician fails to read the warnings, there can be no negligence on the part of the drug manufacturer for the insufficiency of the warnings.<sup>165</sup> While noting that "[t]he adequacy of the warning is a question of fact, properly left to the jury,"<sup>166</sup> the court recognized that the physician's failure to read the directions effectively removed the determination of the warning's adequacy from the jury's province.<sup>167</sup>

Similarly, in *Peterson v. Parke-Davis & Co.*,<sup>168</sup> the defendant drug company denied it had breached its duty to warn in regard to the use of its product.<sup>169</sup> The plaintiff Peterson suffered from a severe overdose of the prescription drug Dilantin,

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the defendant. During the operation, the drug was administered to Michael without proper supervision from an anesthesiologist or the supervising surgeon. The plaintiff argued that the defendant should be charged with knowledge that the administering of anesthetic drugs without prescription is a violation of Mississippi law. *Id.* at 465. The court noted that it was "impractical and unrealistic to expect drug manufacturers to police individual operating rooms to determine which doctors adequately supervise their surgical teams." *Id.* at 471. The defendant could not be expected to control the individual practices of the individual members of the medical community. *Id.* at 472.

164. 100 Mich. App. 649, 300 N.W.2d 356 (1981). See *supra* note 66.

165. *Id.* at 656, 300 N.W.2d at 359. The PDR and other publications stated that blood tests should be given weekly to older people taking the drug and it was also recommended that they not take it longer than one week. The drug was also contraindicated for drug allergies, such as Mrs. Formella's allergy to penicillin. *Id.*

166. *Id.* (citing *Gutowski v. M. & R. Plastic & Coating, Inc.*, 60 Mich. App. 499, 506-08, 231 N.W.2d 456, 460-61 (1975)). See also *Smith v. E.R. Squibb & Sons, Inc.*, 405 Mich. 75, 90, 273 N.W.2d 476, 480 (1979) (holding that when liability turns on the adequacy of the warning, the issue is one of reasonable care).

167. Plaintiff's expert Dr. Lerman stated that he felt the PDR warning and package inserts were inadequate in view of their length and the presence of inconsistencies. As an example of an inconsistency, Dr. Lerman noted that the warnings stated both that the drug should not be given to individuals who were senile as well as warnings that the drug should not be used for over a week in persons over age 60. Dr. Lerman also testified that he did not prescribe the drug to people over age 60 because of the warnings against such use. He concluded that if the warnings were read, they were adequate. *Formella*, 100 Mich. App. at 654, 300 N.W.2d at 358.

168. 705 P.2d 1001 (Colo. Ct. App. 1985).

169. *Id.* at 1003.

an anticonvulsant medication<sup>170</sup> which had been prescribed to control an apparent epileptic seizure.<sup>171</sup> When he began to act in a confused manner he was admitted first to a general hospital and then to a psychiatric center for observation. At the psychiatric center he came under the care of Dr. Mardock<sup>172</sup> who continued the administration of the drug without checking the package insert or the PDR. Peterson's condition deteriorated and he developed difficulties with walking, speaking, balance, coordination, and mental alertness. He also experienced dizziness and unsteadiness.<sup>173</sup> Blood serum tests found a toxic level of the drug, and Peterson was taken off Dilantin, but only after brain damage had occurred.<sup>174</sup>

At trial, it was alleged that the warnings which accompanied Dilantin did not adequately warn of the possibility of permanent neurological damage from Dilantin toxicity which could arise when the dosage was too high.<sup>175</sup> Parke-Davis asserted that the warnings were adequate and that it was the physician's misuse of the drug which caused Peterson's injuries.<sup>176</sup> The psychiatrist, Dr. Mardock, testified that he had not read the package insert nor had he consulted the PDR pertaining to Dilantin since 1966.<sup>177</sup> Furthermore, Dr. Mardock did not have blood serum tests done on Peterson, even when Peterson showed signs of Dilantin toxicity.<sup>178</sup>

Noting the warnings in the package insert,<sup>179</sup> the court upheld the verdict and judgment for Parke-Davis. The court found no merit in the plaintiff's contention that the court erred in refusing to instruct the jury that Parke-Davis had a duty to warn the entire medical community, and not just the attending physician.<sup>180</sup> More importantly, the court found that when an attend-

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170. *Id.*

171. *Id.*

172. *Id.* at 1002-03.

173. *Id.* at 1003.

174. *Id.*

175. *Id.*

176. *Id.*

177. *Id.*

178. *Id.*

179. *Id.* Parke-Davis' warnings on the use of Dilantin stated that if toxic effects occurred, the drug dosage should be reduced or discontinued. *Id.*

180. *Id.* at 1003-04. Here, as in other cases, the concern was with the warning given



ing physician prescribes the use of a drug but disregards the manufacturer's warnings and instructions, the physician's conduct is what renders the product unreasonably dangerous, and thus defective. The adequacy or inadequacy of the warnings and instructions are not relevant.<sup>181</sup>

The court in *Rhoto v. Ribando*,<sup>182</sup> also found that warnings supplied by the drug manufacturers adequately informed the patient through her doctor of known risks associated with the normal use of their products, and thus the manufacturers could not be held liable for injuries resulting from the misuse of their products.<sup>183</sup> The plaintiff had claimed that the warnings for the individual drugs were inadequate in that they did not have timely warnings about the misuse of their products in weight control programs, a practice plaintiff claimed the drug's manufacturers knew or should have known was taking place.<sup>184</sup>

The court noted that Dr. Ribando's prescription of the combination of drugs was a gross misuse of the products,<sup>185</sup> and that a manufacturer is required only to provide an adequate warning

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to the attending physician. Whether others were warned is irrelevant. *Id.* at 1004.

181. *Id.* at 1003. See *Uptain v. Huntington Laboratories, Inc.*, 685 P.2d 218 (Colo. Ct. App. 1984), cert. granted, July 16, 1984 (in a products liability action against the manufacturers of a cleaning compound, the court found the misuse defense was available where the manufacturer could reasonably assume that the warning would be read and heeded); *Hamilton v. Hardy*, 37 Colo. App. 375, 549 P.2d 1099 (1976). The *Peterson* court stated: "Misuse of a product is all possible types of use, or conduct affecting use, by the plaintiff or a third party which is improper in light of the qualities and characteristics of the product itself." *Id.* at 1003 (citing *Uptain*, 685 P.2d at 218).

The *Peterson* court also stated: "'Misuse . . . which cannot reasonably be anticipated by the manufacturer can be utilized as a defense in a products liability case by showing that the conduct of the user [here the attending physician], and not the alleged defect in the product, actually caused the [injury].'" *Id.* at 1003 (quoting *Jackson v. Harsco Corp.*, 673 P.2d 363 (Colo. 1983)).

182. 504 So. 2d 1119 (La. Ct. App. 1987). Mrs. Judy Rhoto was examined by Dr. R.T. Ribando, who claimed to be a weight reduction specialist. Although he had not received specialized training in bariatric medicine, he prescribed a regimen of prescription medications and a conservative diet plan, which allegedly produced significant weight loss. Mrs. Rhoto took Ortho Novum, a birth control pill; Thyrolar 5, a thyroid medication; Renese, a diuretic; human chorionic gonadotropin, a fertility hormone; and Eskatrol, an amphetamine. After two weeks Mrs. Rhoto suffered a massive stroke. *Id.*

183. *Id.*

184. *Id.* at 1124.

185. *Id.* Both the expert called by plaintiffs and the expert called by defendants agreed that the combination of drugs used by Dr. Ribando was a gross misuse of the products. They also testified that they would never have prescribed such a diet plan.

of any danger arising from the *normal use* of its product when such danger is not within the knowledge of, or obvious to, the ordinary user.<sup>186</sup>

Finally, there are those situations in which the adequacy of the warning cannot be the proximate cause of the plaintiff's injuries because the prescribing physician had prior knowledge of the risks inherent in the use of the drug.

In *Stanback v. Parke-Davis & Co.*,<sup>187</sup> the court held that when a physician prescribes a drug with full knowledge of the risks associated with the use of that drug, the drug manufacturer is insulated from any liability resulting from its failure to warn.<sup>188</sup> In *Stanback*, the plaintiff, after receiving a flu vaccine, was diagnosed as having Guillain-Barre Syndrome (GBS), a neurological disorder.<sup>189</sup> The manufacturer of the flu vaccine, Parke-Davis, did not warn of the risk of GBS associated with the vaccine in its 1976 package insert.<sup>190</sup> Dr. Edmunds testified that he had not read the package insert accompanying the vaccine but he was aware of the risk of GBS associated with the use of the drug.<sup>191</sup> The court distinguished between a case in which the physician might have responded to an adequate warning and a case in which it is clearly established that the physician would not have so responded. In the first case, evidence of causation may be established; in the latter case it cannot be.<sup>192</sup> In *Stan-*

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186. *Id.* at 1123 (quoting *Halphen v. Johns-Manville Sales Corp.*, 484 So. 2d 110, 114-15 (La. 1986)). Upon reading PDR warnings, the court found that most of the prescribed drugs either warned against the use of the drug for the treatment of obesity, did not indicate a use in weight control programs, or warned against the use while smoking. See *id.* at 1124-26.

187. 657 F.2d 642 (4th Cir. 1981). The plaintiff suffered an attack of influenza with bronchitis during the spring of 1976. Because of that illness, she resolved to get a flu shot the following fall. She returned to her doctor's office on September 23, 1976, at which time she received a half-dose of Fluogen, a Parke-Davis flu vaccine. She subsequently received a second half-dose of the flu vaccination on October 27, 1976, and soon began to experience neurological symptoms. She was eventually diagnosed as having Guillain-Barre Syndrome. *Id.*

188. *Id.*

189. *Id.* at 644.

190. *Id.* Mrs. Stanback was unaware of any such risk when she received the vaccinations. *Id.*

191. *Id.*

192. *Id.* at 645-46. The court referred to the following cases: *Chambers v. G.D. Searle & Co.*, 441 F. Supp. 377 (D. Md. 1975), *aff'd*, 567 F.2d 269 (4th Cir. 1977) (plaintiff failed to establish causation when evidence showed that warnings of risks associated

back, no evidence was presented indicating that Parke-Davis' failure to warn the patient's physician was a factor in producing her injury, since Dr. Edmunds' decisions and actions would not have been affected in the least by the communication of an adequate warning.<sup>193</sup>

Similarly, the Michigan Court of Appeals in *Mowery v. Crittenton Hospital*<sup>194</sup> held that the defendant drug company's failure to adequately warn the physician due to inadequate testing is not the proximate cause of the plaintiff's injuries where the physician was aware of the drug's risks from other sources of information.<sup>195</sup> The court noted that even if the physician had been given additional warnings by the drug company of the risks

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with the use of a drug would not have made a difference in physician's treatment of plaintiff); *Vaughn v. G.D. Searle & Co.*, 272 Or. 367, 536 P.2d 1247 (1975), *cert. denied*, 423 U.S. 1054 (1976) (no evidence was presented that had a physician been properly warned he would have treated plaintiff differently so there was no proof of causation); *but cf. McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 375, 528 P.2d 522 (1974) (substantial evidence was presented that had adequate warnings been given to physicians, they would have recommended that plaintiff cease using the drug before her injuries became irreversible and therefore, there was sufficient proof of causation). *Id.* at 646.

193. *Id.* In an affidavit, Dr. Edmunds stated: "It is not my practice, and I do not deem it necessary, to advise patients about the package insert 'warning' which accompanies flu vaccines. This was true before the Guillain-Barre Syndrome [sic] warning in 1976 and it is true today." *Id.* at 644.

194. 155 Mich. App. 711, 400 N.W.2d 633 (1987). A patient suffered a retinal detachment after her physician prescribed phospholine iodide to prevent the dislocation of the patient's artificial intraocular lens. The physician explained the risks of retinal detachment and possible complications arising from the use of general anesthesia to the plaintiff. *Id.* at 713-14, 400 N.W.2d at 634-35.

Despite the risks of retinal detachment with the use of Phospholine Iodide, Dr. Malach prescribed this eye medication because it could prevent dislocation of the intraocular lens. Such dislocation could damage the cornea's endothelium (the outer covering of the eye), which would require a corneal transplant.

Because plaintiff's intraocular implant lens was again dislocated . . . , Dr. Malach discontinued the Phospholine Iodide. After several unsuccessful attempts to medically reposition the lens, Dr. Malach successfully surgically repositioned it. Phospholine Iodide was again used during the procedure.

*Id.* at 714, 400 N.W.2d at 635. Shortly thereafter, the plaintiff complained of a change of vision in her right eye and sought treatment from another doctor who diagnosed retinal detachment. *Id.*

195. *Id.* at 721, 400 N.W.2d at 638. Dr. Malach testified that she was aware of the risk of retinal detachment resulting from the use of phospholine iodide from reading ophthalmologic literature, a source other than the defendant. Despite this knowledge Dr. Malach prescribed the drug for the plaintiff, stating that it was worth the risks involved. *Id.*

of the drug, she probably still would have prescribed it.<sup>196</sup>

#### IV. Conclusion

A prescription drug's package inserts, PDR drug references, and other printed matter all exist to educate the physician concerning the benefits and dangers of the prescription drug. Most physicians are cautious and read the PDR, the package inserts, "Dear Doctor" letters, and any other information available before they prescribe a medication.

Some physicians, however, for inexplicable reasons, either read the drug's warnings and ignore them, or fail to read them at all. Such negligence on the part of these physicians can lead to tragic results. The manufacturer of the prescription drug cannot be held responsible for this intervening proximate cause, nor can the manufacturer be an absolute insurer of its products. Virtually all prescription drug products have adverse side effects and the drug manufacturers have the responsibility to provide adequate warnings. Once these warnings are provided, it is up to the physician to read them and abide by them.

It is important for the courts to recognize and apply the misuse defense because of the economic resources expended by the drug manufacturers and their insurers in the defense of these actions. As defense and liability costs mount, manufacturers of beneficial prescription drugs with potentially dangerous side effects will undoubtedly raise the price of their products<sup>197</sup> or stop manufacturing the "risky" but highly beneficial drugs.<sup>198</sup>

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196. *Id.*

197. Costly court judgments have forced up insurance costs to vaccine makers, fueling a dramatic price rise. The cost of Lederle's DPT (diphtheria-pertussis-tetanus) vaccine to physicians, for example, shot up to \$11.40 in 1986 from 50 cents in 1982, with \$8.00 of that amount earmarked for liability insurance. *New York Times* May 15, 1988, § 3, at 15. During this period several of Lederle's DPT insurers did not renew coverage, and Lederle eventually had to provide its own coverage by setting up a liability reserve fund. *Id.*

198. See Hoenig, *Products Liability: Recent Developments*, N.Y.L.J., Apr. 28, 1988, at 1, col. 1:

Thus, the "broader public in the availability of drugs at an affordable price must be considered in deciding the appropriate standard of liability . . ." Reluctance of drug manufacturers to undertake research programs to develop beneficial pharmaceuticals or to market others that are available might result from the "fear of large adverse money judgments." Similarly, the "additional expense of insuring against liability — assuming insurance would be available — and of research

Such a result will invariably have an adverse effect on consumer-patients because it will ultimately deprive them of the very product which could alleviate their suffering.

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programs to reveal possible dangers not detectable by available scientific methods could place the cost of medication beyond the reach of those who need it most.” *Id.* at 2, cols. 4-5 (quoting *Brown v. Superior Court*, 88 Daily J. D.A.R. 4211, 4213 (Calif. Sup. Ct. Mar. 31, 1988)).