1973

Ubiquitous Detailman: An Inquiry Into His Functions and Activities and the Laws Relating to Them

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A salesman of ethical pharmaceuticals is no ordinary salesman. True, he sometimes earns his commissions based on his sales, as do other salesmen, but there the similarity ends, for he is charged not only with selling his product, but also with unselling it. He is often called the detailman, defined as:

[One who] promotes [the] use of and sells ethical drugs and other pharmaceutical products to physicians, dentists, [and] hospitals . . . utilizing knowledge of medical practices, drugs, and medicines. [He] [i]nforms customer[s] of new drugs, explains characteristics and clinical studies conducted with drug[s]. [He] discusses dosage, use, and effect of new drugs and medical preparations.

Thus the pharmaceutical detailman is not the average cardboard box salesman whose misinformation to the customer might lead only to the damage of parcels packed in a carton which is not strong enough to bear the weight of its contents; his misinformation to the customer (i.e., the physician) regarding his products may result in physical injury, pain, suffering, even death, to the ultimate consumer (i.e., the patient).

The “ubiquitous detailman” is a phrase taken from a Washington state court decision. He is ubiquitous in the truest sense of the word. To the medical and health professions he is omnipresent. He

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1. Ethical pharmaceuticals are also known as prescription drugs. For a statutory definition see Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 353(b) (1970).

2. See Incollingo v. Ewing, 444 Pa. 263, 292, 282 A.2d 206, 222 (1971) in which the Supreme Court of Pennsylvania states: “. . . the trial court instructed the jury that if it found that Parke Davis was on notice that the drug was being used indiscriminately, and yet failed to restrict its use to proper situations, then the company could be found negligent.”


can be found in the practitioner's inner office, in the pharmacy, and in the hospital corridors speaking with interns, residents, and attending staff. He is at the nurse's station and outside the ICU and CCU. He is in the medical, dental, and nursing schools, at medical conventions, seminars and exhibits, and even in the hospital coffee shop enjoying a snack with a hospital physician, pharmacist, administrator, or formulary committee member. In short, he is found with anyone who may now or in the future have the occasion to use or encourage the use of his products. His purpose is not only to inform these members of the health team of the proper use of his company's products, but also to expand his market of potential prescribers, dispensers, and users.

The detailman is the most important liaison between the pharmaceutical company and the medical profession. While the Congress and the federal judiciary are keenly aware of the need to control the relationship of the drug industry and the medical profession, the most effective controls growing out of the Federal Food, Drug, and Cosmetic Act do not provide the federal government with any power to control the detailman or the quality of his product presentations. This is so because the Act and FDA regulations apply only to written statements coming from the manufacturer. Nor have the courts adequately considered the detailman's responsibilities. Scholars have made a few attempts to analyze his function, but these have been cursory. This is possibly because, as one writer quite correctly notes, "the only way to get a fair picture of [the detailman's] activi-

5. An excellent empirical study which analyzes the attitudes of physicians and detailmen in regard to the latter's function in the large teaching hospital setting is Burkholder, The Role of the Pharmaceutical Detailman in a Large Teaching Hospital, 20 Am. J. Hosp. Pharm. 275 (1969), in B. Keller and M. Smith, Pharmaceutical Marketing: An Anthology And Bibliography 280 (1969). Pharmaceutical Marketing is a comprehensive collection of articles relating to all phases of pharmaceutical marketing. Numerous selections therein deal with non-legal background material on detailing activities.

6. ICU and CCU are, respectively, the commonly used initials for the intensive care unit and the coronary care unit of the hospital wherein critically ill patients are kept under close surveillance largely through the use of electronic monitoring devices.

7. For a discussion of the significance of the formulary committee in choosing the drugs to be purchased by the hospital and prescribed by the hospital's physicians, see Burkholder, in B. Keller and M. Smith, supra note 5, at 280.

8. Statutory and regulatory provisions relevant to this study are cited and analyzed infra.

9. The federal government's lack of jurisdiction over the detailman's oral promotional statements is the central theme of Section II B of this article, infra, Federal Statutory and Regulatory Standards.

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ties is to 'live' them for a while." This author did just that for a period of 27 months. These experiences underly the analysis of the law relating to detailmen which follows. The analysis will include first a discussion of the importance of the detailman to the drug manufacturer in the sale of its products, and his role as the physician's principal source of drug information. Second, it will include a consideration of several issues arising out of this duality of functions and its legal consequences. This section will survey alternative theories which courts may use to impose liability on the manufacturer. In conclusion, a proposal will be offered which may help to alleviate the strain placed upon the detailman as a result of his conflicting duty to sell his employer's drugs on the one hand and his duty to warn the physician of product dangers on the other.

I. THE DETAILMAN'S DILEMMA: THE DUTY TO SELL V. THE DUTY TO WARN

In terms of agency law the detailman is the servant of the pharmaceutical manufacturer. As master, the manufacturer is vicariously liable for the acts of his servants which occur within the scope of employment. It is therefore in the employer's economic interest to prevent his detailmen from pursuing activities which may cause such liability to be imposed.

Because of the need to increase and protect the substantial profits which drug manufacturers realize from the sale of their products, several companies have gone to great expense to develop and

11. From June, 1969 to September, 1971 this author was employed as a Professional Representative for the New York regional office of Merck Sharp and Dohme, division of Merck & Co., Inc. [hereinafter MSD].
12. In order to distinguish between discussions and conclusions based on the author's personal experience as a detailman, and those which were derived from research and documentary sources, an effort has been made to separate the two through the appropriate use of footnotes.
13. There is an express employment agreement between the detailman and the drug manufacturer. Courts have found that the detailman is also the manufacturer's agent for purposes not contemplated by the employment agreement: Schering Corporation v. Cotlove, 94 Ariz. 365, 365 P.2d 294, 17 A.L.R.3d 617 (1965). For a comparison of servant and agent see F. Mecham, On Agency § 56 (2d ed. 1914) and Restatement (Second) of Agency, § 220 (1958).
administer training programs\textsuperscript{16} for their detailmen. This training serves a dual purpose. On the one hand the detailman is instructed to give only reliable, accurate and current information to physicians. On the other, he is taught sales techniques and managerial skills which seek to foster market expansion. Often these two training goals conflict with one another, leaving the detailman in a dilemma as to which should prevail.

A. The Duty to Sell

The need for training programs becomes evident when viewed in the context of the detailman's importance to the manufacturer.\textsuperscript{17}

Detailing . . . has received increased emphasis in the postwar period. Indeed, its importance to the marketing effort has increased . . . . The postwar period has seen increasing emphasis on research and development. Expenditures for research and development by member firms of the Pharmaceutical Manufacturing [sic] Association rose from $60 million [to] . . . $400 million for 1966. This is a 667 per cent increase during the sixteen-year period.

From these budgetary increases came new and sophisticated phar-

\textsuperscript{16} The preliminary training this author had at MSD extended over a period of nine months and consisted of three phases. Phase \#1 was an eight week period of intensive programmed learning in the general fields of medicine related to the company's products. Phase \#2 consisted of two weeks of lessons dealing with specific product information, detailing methods, and medical lectures by practicing physicians. A six month interval followed during which the detailman, under his manager's supervision, became acquainted with his territory, his physicians, and his pharmacy accounts. Phase \#3 followed this intervening practical experience and consisted of two weeks of additional product information and medical lectures. The major portion of this last preliminary phase, however, was managerial training wherein the class of detailmen used, as its standard texts, G. ODORNE, \textit{Management By Objectives: A System Of Managerial Leadership} (1965) and J. NIRENBERG, \textit{Getting Through To People} (1965), in addition to other training aids compiled by the company's training staff. All phases of training involved numerous written examinations, the passing grade of which were 90\%. Follow-up training in the form of week-long seminars and lectures every year or two, programmed correspondence courses, journal articles, and one- or two-day lecture sessions at necessary intervals are part and parcel of the detailman's job at MSD.

Other drug manufacturers send their representatives to the Certified Medical Representative training program. Eli Lilly and Company, for example, may avoid similar training costs by hiring pharmacists as their detailmen. For a brief discussion of the training, duties, recruitment, and managerial functions of the detailmen see M. SMITH, \textit{Principles Of Pharmaceutical Marketing} 299-312 (1968). See further bibliographical references, \textit{id.} at 316.

\textsuperscript{17} D. KING, \textit{Marketing Prescription Drugs} 59 (1968).
maceutical products with which physicians had little familiarity. Ordinary journal advertising and mass mailing campaigns were not sufficient to persuade the medical profession to use these products, and more effective promotional techniques had to be used.

In 1960, there were about 15,000 detailmen employed by American drug manufacturers. While the ratio of detailmen to all other employees of selected pharmaceutical firms varies from 1:10 to 1:6, about 25% of all employees in the industry are absorbed in marketing functions. Fifty four percent of these are involved in detailing alone.

It is difficult to document precisely how much the pharmaceutical industry spends on detailing activities. In 1957, Eli Lilly and Company estimated that a direct mailing to a single doctor costs 7½¢ per piece and a journal advertisement 1¢ per physician, but one detailing visit costs $7.50 per doctor. Two years later, Smith Kline and French Laboratories estimated their detailing cost at between

18. For an interesting but cursory analysis of the effects of rapid pharmaceutical progress in the postwar period and legislative attempts to control the ensuing ramifications see Lasagna, The Pharmaceutical Revolution: Its Impact on Science and Society, 166 SCIENCE 1227 (Dec. 5, 1969).
19. A good summary of several empirical studies which show, among other things, the importance of the detailman in motivating physicians to prescribe particular pharmaceutical products appears in M. SMITH, supra note 16, at 62-77, 298. But see Burkholder in B. KELLER AND M. SMITH, supra note 5, at 281-82, wherein he states:

There are conflicting reports on the merits of the pharmaceutical detail man's role. Physicians often deny that detail men are of major importance in convincing them relative to the selection of drugs used in treating their patients. They even minimize the extent to which they rely on detail men as a source of information in such matters. There are, of course, studies which show the reverse. However, any results must always be seriously questioned when it is not clear what population is being analyzed or in what manner the sample members were selected. It is no less important to know for whom the study was done, who carried it out and who financed it.
20. D. KING, supra note 17, at 60:
The detailman invests promotion with the human approach, for which there is no substitute. The two-way communication possible in the face-to-face interview has always been the marketer's most forceful means of persuasion. The detailman is given an average of only eight to ten minutes of the physician's time per call. Yet in this brief time he can accomplish what other forms of promotion cannot do. He can answer directly and immediately the [physician's] unusual questions. Furthermore, he can detect the cause of the physician's doubts and address his sales presentation to their elimination by combining his scientific training and persuasive selling techniques into a well-thought-out presentation.
21. Id. at 65. See also Haggins, Due Care by Physicians, 14 CLEV.-MAR. L. REV. 506, 508 (1965) (brief treatment of the role of the detailman and the extent to and reason for which he is used in drug promotion).
$9 and $10 per physician call. A more recent source states that in 1966 approximately three quarters of a billion dollars [was] spent by some sixty drug companies in order to reach, persuade, cajole, pamper, outwit, and sell one of America's smallest markets—its 180,000 practicing physicians. ... A little over half of these promotional expenses (which represents approximately 25% of the receipts from sales of drugs) are for advertisements or samples and the other half for salaries of detailmen.

As part of his sales effort the detailman brings gifts and gimmicks to the physician. The purpose of these gifts is not only to woo the physician, but more important, to act as a constant reminder to the doctor to prescribe the detailman's products. The gifts usually re-

22. D. King, supra note 17, at 64. Some idea as to how much a manufacturer might spend on detailing, in comparison to other forms of promotion, in order to introduce a new product to physicians is given by Ben Gaffin & Associates in The FOND DU LAC STUDY: AN INTENSIVE STUDY OF THE MARKETING OF FIVE NEW ETHICAL PHARMACEUTICAL PRODUCTS IN A SINGLE MARKET, RESULTING IN SOME THEORY OF SCIENTIFIC MARKETING AND SERVICE PROGRAMS FOR ACTION (A BASIC MARKETING STUDY PREPARED FOR THE AMERICAN MEDICAL ASSOCIATION, 1956), reprinted in Hearings on Present Status of Competition in the Pharmaceutical Industry Before the Subcomm. on Monopoly of the Select Comm. on Small Business, U.S. Senate, 91st Cong., 1st Sess., pt. 14, App. XII, 5811 at 5856 (1969) [hereinafter FOND DU LAC STUDY].

Id. at 5889 and at 5884 the following figures are given for promotional expenditures by Ciba in 1954 in its effort to introduce its antihypertensive SERPASIL:

<table>
<thead>
<tr>
<th>Promotion Type</th>
<th>Expenditure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detailing</td>
<td>$900,000</td>
</tr>
<tr>
<td>Convention exhibits</td>
<td>150,000</td>
</tr>
<tr>
<td>Sampling</td>
<td>200,000</td>
</tr>
<tr>
<td>Journal advertisements</td>
<td>220,000</td>
</tr>
<tr>
<td>Direct mail</td>
<td>400,000</td>
</tr>
</tbody>
</table>

Id. at 5882 and at 5889 the following figures are given for promotional expenditures by Geigy from May, 1962 to the end of the year, in its effort to introduce its anti-inflammatory BUTAZOLIDIN:

<table>
<thead>
<tr>
<th>Promotion Type</th>
<th>Expenditure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detailing</td>
<td>$140,000</td>
</tr>
<tr>
<td>Direct mail</td>
<td>190,000</td>
</tr>
<tr>
<td>Convention exhibits</td>
<td>6,000</td>
</tr>
<tr>
<td>Sampling</td>
<td>40,000</td>
</tr>
<tr>
<td>Journal advertising</td>
<td>45,000</td>
</tr>
</tbody>
</table>

Id. at 5896 and at 5903 the following figures are given for Lederle's first year promotional expenditures in its effort to introduce its antibiotic ACHROMYXIN:

<table>
<thead>
<tr>
<th>Promotion Type</th>
<th>Expenditure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detailing</td>
<td>$1,026,000</td>
</tr>
<tr>
<td>(includes literature and samples for detailmen)</td>
<td></td>
</tr>
<tr>
<td>Direct mail</td>
<td>851,000</td>
</tr>
<tr>
<td>Journal advertising</td>
<td>470,000</td>
</tr>
<tr>
<td>Convention exhibits</td>
<td>100,000</td>
</tr>
</tbody>
</table>

main or easily come into the physician’s view when he writes a prescription for a patient. Of course, these gifts are inscribed with the name of the product being promoted. Thus, it is rare to find a doctor’s office without advertising pens, memo pads, paper weights, ash trays, desk blotters, apothecary jars, coffee mugs and other paraphernalia distributed by the drug companies through their detailing forces.

Just as these gifts seek to remind the physician to prescribe the products which the detailman has promoted, they may also have a reverse effect. When a physician’s patient has adversely reacted to a drug which has been heavily promoted, and for which a gift has been distributed, the physician may well be reminded not to prescribe that drug. It is preposterous to assume that a physician will continue to use a bad product even though he has received a promotional gift from that company’s detailman.24


Question 2—Which of the following do you think most influences you to use a drug for the first time?

From these results it would appear that most doctors like to obtain information on new drugs from their colleagues (Table II). Continuing education programs dealing with pharmacology and therapeutics could supply at least some of this information.

TABLE II.—PREFERRED SOURCE OF INFORMATION ON NEW DRUGS

<table>
<thead>
<tr>
<th>Choice of answers</th>
<th>Distribution of answers</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer’s written advertising (direct mail, advertisements in journals, etc.) ..........</td>
<td>Specialists ............ 6</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>General practitioners 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All doctors ............ 4</td>
</tr>
<tr>
<td>Manufacturer’s spoken advertising (detailman, exhibits, etc.) ................................</td>
<td>Specialists ............ 18</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>General practitioners 31</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All doctors ............ 24</td>
</tr>
<tr>
<td>Colleague or consultant recommendation ........</td>
<td>Specialists ............ 57</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>General practitioners 54</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All doctors ............ 56</td>
</tr>
<tr>
<td>Patient request ......</td>
<td>Specialists ............ 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>General practitioners 11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All doctors ............ 15</td>
</tr>
<tr>
<td>Other ........................................</td>
<td>Specialists ............ 19</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>General practitioners 11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All doctors ............ 15</td>
</tr>
</tbody>
</table>

Note: Total number of doctors replying, 521.

It is the author’s opinion that both the physicians he serviced and MSD preferred...
One part of the detailman's sales responsibility is to coordinate drug promotion in his "territory." He is required to submit reports of how many physicians he has visited each day. These records are used to determine the detailman's effectiveness in terms of the relation of total sales to the number of completed physician calls. The assumption on the part of the detailman's manager is that more calls lead to higher sales. Thus, to his employer, the detailman is primarily a salesman whose continued employment and good standing depend largely on how successful he is in achieving and exceeding his sales quotas.26

B. The Duty to Warn

Nevertheless, the physician views the detailman as the single most important,28 worthwhile,27 and acceptable28 source of informa-

discontinuing the distribution of promotional materials which had no relevance to the doctors' practice. But see M. SMITH, supra note 16, at 311, wherein he states:

[F]alling under the heading of sales promotion are the many "giveaways" with which the detailman is usually supplied. These items may range from books of matches to elaborate desk sets—all appropriately inscribed with the drug name, of course. The use of these gimmicks has received strong criticism from industry critics, but anyone who has visited his physician recently will have to admit that the physician seems willing to make use of them.

25. See Whitehead, Drug Peddler, 67 New Statesman 906, June 12, 1964, for an interesting account of a British detailman's shortlived career, reprinted in B. KELLER AND M. SMITH, supra note 5, at 329.

26. FOND DU LAC STUDY, supra note 22, at 5830.

27. Id. at 5840.

28. Physicians' Reactions, supra note 24, at 5741:

Question 1—Which of the following drug promotion methods do you think usually is most informative and/or most acceptable? and Which of the following drug promotion methods do you think is least informative and/or least acceptable?

Analysis showed that 56% of the general practitioners replying to this question considered the drug detailmen most informative and/or acceptable and 76% indicated that direct mail advertising is least informative and/or acceptable. Not so many specialists (57%) appeared to find the drug detailmen most informative or acceptable, and not quite as many (59%) reacted adversely to direct mail.

Fig. 1 summarizes the reactions of all doctors replying and shows clearly that, taken separately, the method of drug promotion most informative and/or acceptable involves the drug detailmen, whereas the least informative and/or acceptable is direct mail advertising.

It is realized, of course, that some of the reactions expressed to this and several other questions may have been coloured by the impressions made on doctors by the drug detailmen and direct mail arriving in the office just before the questionnaire. But the answers given lead us to conclude that in many cases these opinions are held strongly and were not prompted by the questions themselves.
TABLE 1.—PERCENTAGE DISTRIBUTION OF ANSWERS FROM ALL DOCTORS

<table>
<thead>
<tr>
<th>Choice of answers</th>
<th>Most informative and/or most acceptable</th>
<th>Least informative and/or least acceptable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct mail advertising</td>
<td>6</td>
<td>67</td>
</tr>
<tr>
<td>Drug detailman</td>
<td>46</td>
<td>18</td>
</tr>
<tr>
<td>Exhibits at medical meetings, etc. [2]</td>
<td>20</td>
<td>8</td>
</tr>
<tr>
<td>Advertising in medical journals</td>
<td>19</td>
<td>12</td>
</tr>
<tr>
<td>Other</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>Total number of doctors replying</td>
<td>521</td>
<td>521</td>
</tr>
</tbody>
</table>

1. To the question on "Most acceptable" 16 doctors gave more than 1 answer but did not rank them; both answers are included in totals and percentage calculations. Similarly, for "Least acceptable," 39 doctors gave 2 unranked replies and these are included.

[2. Such exhibits are conducted by detailmen.]

Id. at 5743:

**Question 7. How would you grade most detailmen with regard to the following attributes?**

Table VII shows that the majority of doctors rated most detailmen favourably (i.e., "good" or "excellent") as to personality (86%), reliability (65%) and honesty (69%); not so favourably (i.e., "fair" or "poor") in the categories of general knowledge (67%), knowledge of drugs (63%) and usefulness (59%).

### TABLE VII.—ASSESSMENT OF DETAILMEN

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Poor (percent)</th>
<th>Fair (percent)</th>
<th>Good (percent)</th>
<th>Excellent (percent)</th>
<th>Total answers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personality</td>
<td></td>
<td>14</td>
<td>74</td>
<td>12</td>
<td>519</td>
</tr>
<tr>
<td>Reliability</td>
<td>5</td>
<td>30</td>
<td>56</td>
<td>9</td>
<td>504</td>
</tr>
<tr>
<td>Honesty</td>
<td>2</td>
<td>30</td>
<td>60</td>
<td>9</td>
<td>503</td>
</tr>
<tr>
<td>General knowledge</td>
<td>11</td>
<td>56</td>
<td>32</td>
<td>2</td>
<td>506</td>
</tr>
<tr>
<td>Knowledge of drugs</td>
<td>13</td>
<td>50</td>
<td>34</td>
<td>3</td>
<td>513</td>
</tr>
<tr>
<td>Usefulness</td>
<td>18</td>
<td>41</td>
<td>38</td>
<td>3</td>
<td>509</td>
</tr>
</tbody>
</table>

**Question 8—Have you ever reduced or stopped your use of a drug manufacturer's products because of what you believe to be misleading or objectionable advertising in any form (i.e. include impressions made by drug detailman)?**

In their answers to this question there was a marked divergence between specialists and general practitioners, but the reasons for this are not known (Table VIII). In any case, it is significant that almost one-half of all doctors replying stated that they had reacted in this way to misleading or objectionable advertising.

### TABLE VIII.—INFLUENCE ON PRESCRIBING PRACTICES OF OBJECTIONABLE ADVERTISING

<table>
<thead>
<tr>
<th>Choice of answers</th>
<th>Yes (percent)</th>
<th>No (percent)</th>
<th>Total answers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialists</td>
<td>39</td>
<td>61</td>
<td>263</td>
</tr>
<tr>
<td>General practitioners</td>
<td>59</td>
<td>41</td>
<td>248</td>
</tr>
<tr>
<td>All doctors</td>
<td>49</td>
<td>51</td>
<td>518</td>
</tr>
</tbody>
</table>
tion on new drugs. The question inevitably arises: Is he qualified to assume that responsibility? The lay press has answered "no" with generalized accusations portraying detailmen as "unethical," misleading, and dangerous 29 "drug peddlers" 30 who in their relations with the medical profession follow the maxim: "if you can't convince them, confuse them." 31 Academic investigators have reached contrary conclusions, stating that "85% of general practitioners [give the detailman] a strong vote of confidence because his new drug information is valuable to them." 32 These researchers show that the detailman is second in importance only to experience with products in affecting the physician's opinion of a specific drug company. 33 Other investigators have found that except for the opinions of physician's colleagues, the most preferred source of information relating to drugs is the detailman. 34

Whereas the lay press has exposed the vices of the detailman and academic researchers have applauded his virtues, the law has been derelict in recognizing his existence. Courts have focused precious little attention on him. More disturbing, the Federal Food, Drug, and Cosmetic Act, 35 its comprehensive 1962 Drug Amendments, 36 and the rules of the Food and Drug Administration 37 are not applicable to the detailman's activities.

II. THEORIES OF LIABILITY

A. Common Law and State Imposed Standards

1. Negligence and Strict Liability

The common law imposes upon the manufacturer the duty to warn 38 of dangers involved in the use of his product of which he
knows, should know, or has reason to know.39 If he does not, the manufacturer is negligent.40 This duty extends beyond the time of sale and attaches as soon as the manufacturer discovers that his product is dangerous or defective.41 The manufacturer, however, is not obliged to warn of dangers which are known or obvious to the user or are so generally well known that one can reasonably assume that the user is aware of them.42 It is doubtful, however that this excep-


39. To be sure these terms have been diversely construed by various courts. See MacPherson v. Buick Motor Co., 217 N.Y. 382, 389, 111 N.E. 1050, 1053 (1916) ("There must be knowledge of danger, not merely possible, but probable") (emphasis added). But see O'Hare v. Merck & Co., 381 F.2d 286, 291 (8th Cir. 1967):

The [drug] manufacturer's duty to warn users of potential dangers inherent in its product is *commensurate with its actual knowledge of risk involved to those users or knowledge constructively imparted to it by available scientific or other medical data* (emphasis added).

Sterling Drug Inc. v. Cornish, 370 F.2d 82, 84 (8th Cir. 1966) (knew or should have known). Braun v. Roux Dist. Co., Inc., 312 S.W.2d 758, 763 (Mo. 1958) (Manufacturer must keep abreast of scientific advances concerning his products and is held to an *expert's standard of care in his field*) (emphasis added). Farley v. Edward E. Tower & Co., 271 Mass. 230, 237, 171 N.E. 639, 642 (1930) (Manufacturer is *presumed to have knowledge of the nature and quality of his product*) (emphasis added).

RESTATEMENT (SECOND) OF TORTS § 12 seeks to clarify the distinction between these terms:

§ 12. Reason to Know; Should Know

(1) The words "reason to know" are used throughout the Restatement... to denote the fact that the actor has information from which a person of reasonable intelligence or of the superior intelligence of the actor would infer that the fact in question exists, or that such person would govern his conduct upon the assumption that such fact exists.

(2) The words "should know" are used throughout the Restatement... to denote the fact that a person of reasonable prudence and intelligence or of the superior intelligence of the actor would ascertain the fact in question in the performance of his duty to another, or would govern his conduct upon the assumption that such fact exists.

The manufacturer's liability for allergic reactions to his products is a well explored field, but beyond the scope of this Comment. See Noel, *The Duty to Warn Allergic Users of Products*, 12 Va. L. Rev. 331 (1950); Whitmore, *Allergies and Other Reactions Due to Drugs and Cosmetics*, 19 Sw. L.J. 76 (1965); Wright v. Carter Products, Inc., 244 F.2d 53 (2nd Cir. 1967); Braun v. Roux Dist. Co., supra. See also Keeton, *Some Observations About Strict Liability of the Maker of Prescription Drugs: The Aftermath of MER/29*, 56 Cal. L. Rev. 149, 154 (1968).


42. See, e.g., 1 Fruzer & Friedman §§ 7.02, 8.04; Prosser 4th at 649; Singleton v. Olin-Matheson Chemical Corp., 191 So. 2d 329, 334 (3d Cir. Ct. App. La. 1961) ("Where consequences of improper usage are such that they will be readily cognizable there is
tion applies to the pharmaceutical manufacturer since dangers are involved in the use of his products which are not open and obvious. Indeed, adverse effects often accompany the therapeutic benefit to be derived.

A pharmaceutical manufacturer can be negligent in manufacturing a drug or in marketing it. Unless the product is contaminated, impure, defective, or adulterated at the time of manufacture, negligence in manufacturing is virtually impossible to show. Although pure drugs, by their very nature, are dangerous, such dangers are both reasonable and permissible in light of society's health needs. Indeed, standards for acceptable hazards are set by the FDA thus limiting the grounds for recovery.

Negligence in marketing can attach when the manufacturer begins to promote the sale or use of his product and often provides an easier way for an aggrieved plaintiff to recover. When the phar-maceutical manufacturer can be negligent in manufacturing a drug or in marketing it.

43. See Tampa Drug Co. v. Wait, 105 So. 2d 603, 607 (Fla. 1958); Bean v. Ross Manufacturing Co., 344 S.W.2d 18 (Mo. 1961) RESTATEMENT (SECOND) OF TORTS § 397 Comment b (1965).

44. For a discussion of the hazards accompanying the use of ethical pharmaceuticals see E. MARTIN, HAZARDS OF MEDICATION: A MANUAL ON DRUG INTERACTIONS, INCOMPATI-BILITIES, CONTRAINDICATIONS, AND ADVERSE EFFECTS (1971). See also PHYSICIAN'S DESK REFERENCE [hereinafter FDR]. FDR is a voluminous listing of the most commonly prescribed ethical drugs. A verbatim copy of each drug's direction circular, giving all the known features of each product is printed therein and is readily available for the doctor's reference. It is published by Medical Economics, Inc., a subsidiary of Litton Publications, division of Litton Industries, Inc. and is supplemented and revised wiser of necessity. The volume, supplements, and revisions are sent to each physician gratis; the costs entailed are covered by the drug manufacturers who publish their products' direction circulars in the PDR.

45. See Tinnerholm v. Parke Davis & Co., 285 F. Supp. 432 (S.D.N.Y. 1968). See also 1 FRUMER & FRIEDMAN § 8.01. For the purposes of this study, negligence in marketing is synonymous with the manufacturer's failure to convey adequate warning as to dangers attendant to the use of his products.

46. See 1 FRUMER & FRIEDMAN § 8.01 at 145 where it is stated: "... more often as not, proof of negligence as to [defect] ... presents more difficulties than proof of negligence in failing to warn." See also id. §§ 11.01, 12.02; Freedman, Defect in the Product: The Necessary Basis for Products Liability in Tort and in Warranty, in S. SCHREIBER AND P. RHEINGOLD, PRODUCTS LIABILITY: LAW, PRACTICE, SCIENCE at 11:5 (1967); Connolly, Evidentiary Problems in Product Cases, id. at 11:41.

47. Reasonable and permissible dangers are those warnings, precautions, adverse reactions and contraindications which appear in the manufacturer's direction circular, and which, in the judgment of FDA, do not outweigh the beneficial aspects to be derived from the drug's use. See generally Simmons, FDA Looks at the Package Insert, 27 FOOD DRUG COSM. L.J. 117 (1972); Putnam, The Package Insert, id. at 109; Package Inserts as Legal Documents, in E. MARTIN supra note 44, at 98; An Exchange of Views on the Package Insert in W. CURRAN AND E. SHAPIRO, LAW, MEDICINE, AND FORENSIC SCIENCE 728-38 (2d ed. 1970).

48. This is also true in strict liability. See RESTATEMENT (SECOND) OF TORTS § 402A Comment k.

49. See generally, PROSSER 4TH at 646-7; Comment, 52 IOWA L. REV. 1213 (1967).
maceutical manufacturer markets his products, he must exercise his duty to warn of the dangerous propensities of his drugs. The purpose of such warning is to reduce the likelihood that a patient will be injured by those unavoidable product risks which are created during the manufacturing process. The detailman is the most significant means of conveying these warnings to the prescribing physician.\textsuperscript{60}

It is now generally accepted that a manufacturer must warn the ultimate consumer of product dangers. Where the product is a prescription drug however, the rule is not so clear. It has been argued\textsuperscript{61} that the aggrieved patient has no cause of action against a drug house for negligence in marketing because the duty to warn runs to the physician, not to the patient. The argument continues that an ethical drug is not intended for sale to or use by consumers without a doctor's prescription. Therefore the patient-consumer is disqualified from using the manufacturer's failure to warn the physician as the basis of a negligence action. There is precedent for this argument.\textsuperscript{62}

In 1964 this absolute bar was modified by Love \emph{v. Wolf}\textsuperscript{53} in which a California appellate court held that:

\begin{quote}
\ldots If adequate warning of the potential dangers of a drug has been given to doctors, there is no duty by the drug manufacturer to insure that the warning reaches the doctor's patient for whom the drug is prescribed.\textsuperscript{54}

\ldots But if the [detailman's] over-promotion can reasonably be said to have induced the doctor to disregard the warnings previously given, the warning given is thereby withdrawn or cancelled and if \ldots [a] jury could [find] that [a] doctor \ldots actually prescribed the drug to cure an infection for which the company's advertising or its detailmen actually recommended its use, then the pharmaceutical company's negligence remains as an inducing cause coinciding with the negligence of the doctor to produce the results.\textsuperscript{55}
\end{quote}

Since it is the patient who will make the actual purchase of the drug, he is the ultimate target of the detailman's promotional ac-

\begin{itemize}
\item \textsuperscript{50} See Sterling Drug, Inc. \emph{v. Yarrow}, 408 F.2d 978 (8th Cir. 1969) discussed infra.
\item \textsuperscript{51} Freedman, \textit{Prescription or Ethical Drugs: Fallacies as to Warranties, Failure to Warn, and Strict Liability in Tort}, 21 Food Drug Cosm. L.J. 599 (1960).
\item \textsuperscript{53} 226 Cal. App. 2d 378, 36 Cal. Rptr. 183 (3d D. Ct. App. 1964).
\item \textsuperscript{54} Id. at 395, 38 Cal. Rptr. at 193.
\item \textsuperscript{55} Id. at 400, 38 Cal. Rptr. at 195.
\end{itemize}
tivities. Therefore, the detailman's failure to discharge his employer's duty to warn the physician is negligence in marketing upon which a plaintiff's cause of action can be sustained. This is so because the warning is given to prevent harm to a foreseeable plaintiff—the patient.

In 1968, the question of to whom the pharmaceutical manufacturer owes the duty to warn was considered by the Ninth Circuit. In *Davis v. Wyeth Laboratories, Inc.*, the court reasoned that it is the manner in which a drug is distributed that determines to whom the manufacturer must state his warnings. The drug accused of causing irreparable injury to the plaintiff was the Sabin Type III polio vaccine. The court stated that:

Ordinarily in the case of prescription drugs warning to the prescribing physician is sufficient. In such cases the choice involved is essentially a medical one involving an assessment of medical risks in the light of the physician's knowledge of his patient's needs and susceptibilities. Further, it is difficult under such circumstances for the manufacturer, by label or direct communication, to reach the consumer with a warning. A warning to the medical profession is, in such cases, the only effective means by which a warning could help the patient.

Here, however, although the drug was denominated a prescription drug, it was not dispensed as such. It was dispensed to all comers at mass clinics without an individualized balancing by a physician of the risks involved. In such cases (as in the case of over-the-counter sales of non-prescription drugs) warning by the manufacturer to its immediate purchaser will not suffice. The decision (that on balance and in the public interest the personal risks to the individual was worth taking) may well have been that of the medical society and not that of [the manufacturer]. But just as the responsibility for choice is not one that the manufacturer can assume for all comers, neither is it one that he can allow his immediate purchaser to assume. In such cases then, it is the responsibility of the manu-

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56. See generally Prosser & Keeton at 642: "It is now generally recognized that a manufacturer or even a dealer has a responsibility to the ultimate consumer, based upon nothing more than the sufficient fact that... [their products] are likely to come into the hands of another, and to do harm if they are defective." But see Freedman, supra note 51, at 604, who maintains that a patient does not purchase a prescription drug since the filing of a physician's prescription is a service.

57. 399 F.2d 121 (9th Cir. 1968).

58. Id. at 130.
facturer to see that warning reach the consumer either by giv-
ing warning itself or by obligating the purchaser to give
warning.

The Davis ruling was revolutionary. This was the first time that
a prescription drug, statutorily defined in 21 U.S.C. § 353, was, by
operation of law, equated with a non-prescription drug where the
warning is stated directly to the consumer. The implication of such
reasoning is astounding. Although it is the responsibility of the phy-
sician to choose whether or not to prescribe a drug, under certain
circumstances the patient must be included in this decision making
process. It is the duty of the drug company to provide the patient
with sufficient information so that he can be an informed and in-
telligent participant in whatever choice is made.69

Although the court did not address itself to negligence in mar-
keting, but rather to strict liability,60 the resulting liability is indistin-
guishable from liability for negligence.61 This is so because failure
to warn constitutes negligence in marketing. In terms of strict liabil-
ity, a manufacturer is liable for injury resulting from a defective or
unreasonably dangerous product. Thus the negligence of the drug
manufacturer in not warning the proper party of dangers attendant
to the use of its product ipso facto renders that product defective or
unreasonably dangerous, at which point strict liability attaches. To
quote the Davis court:

[W]e reject [the manufacturer's] contention that the rule [of
strict liability] applies only where unreasonable danger results
because of an ascertained "defect" or "impurity" in the prod-
uct, and since this . . . [polio vaccine] was precisely what it was

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69. To be sure Davis, id., has opened a Pandora's Box. For a similar example, see
21 C.F.R. § 130.45 (1972) wherein the FDA requires that manufacturers of oral con-
traceptives give consumers a diluted warning of side effects and dangers. Although
fascinating, examination of the Box and its contents is beyond the scope of this Com-
ment.

60. 399 F.2d 121 at 125: "Appellant stated claims found on (1) negligent manufac-
ture, (2) failure to warn of known dangers, (3) strict liability in tort and (4) breach of
implied warranty of fitness." The court relied on Restatement (Second) of Torts
§ 402A Comments j and k as the basis of imposing liability on the manufacturer, id.
at 127, n.10.

occasional cases, such as [Davis], the liability has been put on the basis of implied
warranty, or strict liability in tort, on the ground that a product sold without adequate
warning is unsafe or 'defective.' But since the question is one of reasonable warning,
the liability is not distinguishable from negligence." But see Keeton, PRODUCTS LIABIL-

Although distinctions between various theories of liability may at times be ob-
scured, the affirmative defenses appropriate to each serve to remind us of the impor-
tant differences between the theories.
intended to be, there was no such defect. The true test in a
case of this kind is whether the product was unreasonably
dangerous.62

We conclude that the facts of this case imposed on the
manufacturer a duty to warn the consumer (or make ade-
quate provision for his being warned) as to risks involved, and
that failure to meet this duty rendered the drug unfit in the
sense that it was thereby rendered unreasonably dangerous.
Strict liability, then, attached to its sale in the absence of
warning.63

While in 1968 the Davis court addressed itself to the question of
to whom the manufacturer must direct its warning, in 1969 the
Eighth Circuit, in Sterling Drug, Inc., v. Yarrow,64 directed its atten-
tion to the problem of how this warning must be conveyed. The
court held that the manufacturer must deliver the warning to the
proper party in the “most effective” method.65 The trial court had
found that the “most significant and efficient means”66 of conveying
this warning is neither through revisions of advertising material, nor
through PDR supplementation, nor via a first class letter personally
addressed to the physician on which is boldly printed: IMPORTANT DRUG PRECAUTION, but instead, through the detail-
man. The trial court declared that since67

. . . the doctor is inundated with the literature and product
cards of various manufacturers . . . a change in the literature
or an additional letter intended to present new information
on drugs to the doctor is insufficient [although this is all the
FDA requires]. The most effective method employed by the
drug company in the promotion of new drugs is . . . [the] de-
tail man; thus, . . . this would also present the most effective
method of warning the doctor about recent developments in
drugs already employed by the doctor, at no great additional
expense. The detail men visit the doctors at frequent intervals

62. Davis v. Wyeth Laboratories, Inc., 399 F.2d 121, 128 (9th Cir. 1968).
63. Id. at 130.
64. 408 F.2d 978 (8th Cir. 1969).
65. Id. at 993. Accord, Incollingo v. Ewing, 444 Pa. 265, 289, 282 A.2d 206, 220
(1971).
F.2d 978 (8th Cir. 1969), But cf. Nolan v. Dillon, 261 Md. 516, 523, 276 A.2d 36, 40
(1971) (duty of drug manufacturer is to give reasonable warning, not the best one).
67. 263 F. Supp. 159 at 163. See also the appellate court's response to appellant's
argument that this finding is erroneous, 408 F.2d 978 at 993.
and could make an effective oral warning, . . . that would affirmatively notify the doctor of side effects . . .

On appeal, the force of this finding was somewhat attenuated in that the court only held that: 68

[W]here a drug is manufactured without negligence, but is unreasonably dangerous if a reasonable warning of a side effect is not given, the manufacturer may be held liable for the injury resulting from the failure to give a warning reasonable under the circumstances.

The appellate court was not as emphatic as the trial court that the detailman is the “most effective method” of conveying the warning to the physician. In an effort that appears to skirt this question the higher court adopted Restatement (Second) of Torts § 295A. 69 Applying the custom of the industry standard to drug manufacturers, this custom must be considered as a factor in whether or not the defendant manufacturer acted reasonably in not using its detailing force. Since the custom was to warn through the detailman 70 and because Sterling did not even inform its detailmen about the newly discovered side effect, it had acted unreasonably. It was therefore both strictly liable in tort and negligent in marketing as well.

The negligence and strict liability actions have been the most widely exploited causes of action against the drug manufacturer who fails to warn of dangers attendant to the use of his products. Questions as to whom the warning must go and how it should be conveyed have been progressively given answers which signal a departure from older more settled precedent.

2. Deceit

The conflict between the duty to sell and the duty to warn is clearly visible in the detailman’s statements to physicians. Where the detailman de-emphasizes or omits product risks in his discussions with the doctor in order to induce him to prescribe, the drug manu-

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68. 408 F.2d 978 at 993. See also Comment 55 Minn. L. Rev. 148 (1970).
69. § 295A Custom:
In determining whether conduct is negligent, the customs of the community, or others under like circumstances, are factors to be taken into account, but are not controlling where a reasonable man would not follow them.
70. Compare with Incollingo v. Ewing, 444 Pa. 263, 289, 282 A.2d 206, 220 (1971) in which the court states that whether the detailman is an effective means of selling a product and explaining its nature is a determination for the jury. If so, whether he is also an effective medium of conveying warning is a question for the jury too.
facturer may be held liable for deceit. While this ancient intentional tort action has not been used as frequently against the drug manufacturer as negligence and strict liability have been, several holdings indicate that the plaintiff's major obstacles to recovery for deceit have been largely removed.

To recover damages for deceit the patient who is injured by the detailman's failure to warn the physician must establish the following elements to sustain his cause of action:

a. that the detailman made a material representation of fact;
b. that this representation was false;
c. that the detailman "knew" of the falsity of the representation;
d. that the detailman intended the plaintiff to rely upon the representation and that the plaintiff justifiably relied on this statement; and

e. that the misrepresentation was the proximate cause of the plaintiff’s injury.

a. Materiality of the factual representation: While it is unlikely today that the detailman would promote a drug for a disease entity for which it is not indicated he need not go that far in order to make a material misrepresentation of fact. Where a detailman intentionally fails to disclose dangerous or fatal propensities of his product he has thereby made the requisite material misrepresentation. It is now generally accepted that where one begins to speak “he must disclose enough to prevent his words from being misleading.” Although the extent of the detailman’s non-disclosure may help to define whether or not his statement is “material” such a determination can only be made by looking also at the experience and knowledge of the prescribing physician to whom the detailman

71. See e.g. F. MECEM, ON AGENCY § 1995 et seq. (2d ed. 1914); 2 FRUMER & FRIEDMAN § 17.
72. PROSSER 4th at 685.
73. See an excellent and frequently cited article by Rheingold, Products Liability—The Ethical Drug Manufacturer’s Liability, 18 RUTGERS L. REV. 947, 980 (1964). See also Comment, Products Liability—The Expansion of Fraud, Negligence, and Strict Liability in Tort, 64 MICH. L. REV. 1350, 1351 (1966).
74. These, of course, are the elements of a misrepresentation action. See generally 2 FRUMER & FRIEDMAN § 17. See also 3 FRUMER & FRIEDMAN § 33.03 discussing and citing several deceit cases against drug manufacturers.
75. The issue of causation has long been a source of debate. Space limitations would render a distinct injustice to this lively topic if it were treated herein. It has therefore been omitted.
76. This is a conclusion drawn from personal experience.
78. PROSSER 4th at 696.
spoke. Non-disclosure is probably more "material" when the detail-
man addresses a physician who has had little experience prescribing
the drug being promoted than when an experienced prescriber of
that product is involved.

A more reliable barometer of materiality of representations is
found in the physician-detailman relationship. This relationship
may be characterized as fiduciary in nature. Because of this special
relationship of trust and reliance a high degree of disclosure is neces-
sary.

The classic problem of whether a salesman's statements are his
own opinion or a form of "puffing" or whether they are factual is
of little importance to the detailman. The detailman is, of course, the
representative of the drug company to the physician. Since a phar-
maceutical manufacturer is held to an expert's standard of care, the
detailman's statements are by implication based on superior
knowledge. Thus the court in Toole v. Richardson-Merrell stated:

Where the party making the representations has superior
knowledge regarding the subject matter of his representations
and the other party is so situated that he may reasonably rely
on such supposed superior knowledge or special information
the representations may be construed as fact and not opinion.

b. The "falsity" of the representation: There are three types of
statements which may render the detailman's representation false.

First, there is blatant misrepresentation, the falsity of which can
be easily ascertained by an inspection of a product's direction circu-
lar. Thus a detailman seeking to persuade a physician that his com-
pany's brand of chloramphenicol may be used to treat minor sore
throats and colds has blatantly misrepresented the true purpose for
which this drug should be used.

Second, the extent of the detailman's non-disclosure may deter-
mine whether or not his statement is false. Thus, for example, if a

79. See Section I B of text supra.
80. See 14 AM. & ENG. ENCY. OF LAW 123, as cited in Edward Barron Estate Co. v.
    Woodruff Co., 163 Cal. 561, 576, 126 P. 551, 357 (1912) ("When one of the parties . . .
    places a known trust and confidence in the other, any misrepresentation by the party
    confided in with respect to a material fact and constituting an inducement to the
    other party . . . is regarded as a fraud. The same is true where the circumstances are
    such that one of the parties must necessarily trust in the representations of the other.")
81. PROSSER 4th at 653, 721. See also 46 AM. JUR., Sales § 326.
84. Id. at 706, 60 Cal. Rptr. at 411.
85. PDR, 1971 at 996 (Parke Davis' CHLOROMYCETIN); 882 (McKesson's AMPHICOL);
            1066 (Rachelle's MYCEL).
detailman honestly informs a physician that his brand of indomethacin is effective in reducing fever, but omits that it is indicated only in certain types of arthritic conditions, then that physician may conceivably prescribe this drug for an infant running a high fever, a condition for which it is specifically contraindicated. The sensitive question which a jury must answer in such cases is: At what point does a detailman’s non-disclosure of dangers attendant to the use of a drug necessarily render his statement false? For the drug manufacturer to raise his product’s direction circular as a defense to intentional non-disclosure begs the question. Most physicians do not have time to read numerous and complicated direction circulars prior to deciding which drug is appropriate for each patient. For this reason he must rely on the detailman’s encapsulated statement of warnings and proper usage. Furthermore, even if proper warning is given in the direction circular the detailman’s over-promotion may nullify the printed warning.

Third, ambiguities in the detailman’s statements may render them false. Thus a detailman may tell a physician that his brand of phenylbutazone is indicated for patients with gout. The physician may reasonably understand this statement, albeit true, to mean that this product is effective in alleviating the etiology of gout, i.e., increased uric acid levels. This impression is substantially false: phenylbutazone has only a mild effect on the etiology of gout; in fact, when used to treat this chronic disease, its toxicity precludes its use in long term therapy. The late Dean Prosser is instructive on this point:

Ambiguous statements which are reasonably capable of both a true and a false meaning will amount to misrepresentation if the false meaning is accepted. Likewise, misrepresentation may be found in statements which are literally true, but which create a false impression in the mind of the hearer.

c. “Knowledge” of the falsity of the representation: The requirement that the detailman “know” that his statement is false does not

86. PDR, 1971 at 947 (MSD’s INDOMIN).
87. See the Yarrow court’s reasoning on this point supra note 67 and accompanying text.
89. PDR, 1971 at 722 (Geigy’s BUTAZOLIDIN).
90. PROSSER 4th at 695. See also Keeton, Fraud: Concealment and Non-Disclosure, 15 TEXAS L. REV. 1 (1936); Int'l Products Co. v. Erie R.R. Co., 244 N.Y. 931, 938, 155 N.E. 662, 664 (1927).
place a serious burden on a plaintiff since courts have interpreted "knowledge" liberally. Difficulty may arise however in imputing this knowledge to the defendant drug manufacturer in a deceit action. The thrust of authority recognizes that in view of the doctrine of *respondeat superior* and general principles of agency law this problem is academic.

d. **Intent and reliance:** The intent of the defendant manufacturer that the physician rely on the detailman’s statements presents no obstacle to recovery since this is the very purpose for which detailmen are employed. The detailman however does not make any representations to the patient who has sustained a drug-induced injury. The detailman does not intend that the patient rely on any statement nor can the patient justifiably rely on any representation not made to him. How then can the injured plaintiff sustain this burden?

The court in *Wechsler v. Hoffman-La Roche* stated that:

Reliance upon fraudulent representations by persons who are not the direct addressees thereof but who may be intended or expected to learn of and act upon such representations will found an action in fraud and deceit. Defendant here claims, however, that its representations were made to physicians and not to the intestate... and would thus avoid liability in fraud even if the allegations in the complaint are true. But in my view one who misrepresents for his gain and benefit, at the expense of human life, should be answerable in fraud for all reasonable and foreseeable consequences of his deception. If a more direct nexus between the fraudulent misrepresentation and the intestate is essential, it may be supplied by the circumstance that the physician who prescribed the drug was acting on behalf of the intestate and the fraud committed on the doctor was, therefore, a fraud upon the intestate.

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91. Even where one makes a statement without knowledge of its truth or falsity, and this statement is in fact false, the lack of such knowledge is sufficient to supply the intent required in a deceit action. See, e.g., Jos. Greenspon’s Son Pipe Corp. v. Hyman Michaels Co., 133 S.W.2d 426, 428 (St. Louis Ct. App. Mo., 1939); Prosser 4th at 701. See also Comment, 64 Mich. L. Rev. *supra* note 76, at 1352.


93. See *Restatement (Second) Agency*, §§ 251, 257, 261, 265-7. See also Ira S. Bushey & Sons, Inc. v. United States, 398 F.2d 167 (2d Cir. 1968) (If the servant's intentional torts were committed within the "activities of the enterprise" the master will be charged with liability as a cost of the enterprise).

94. See Section I B of text *supra*.


96. Id. at 541-542, 99 N.Y.S.2d at 590.
In Marcus v. Specific Pharmaceuticals, the court found that the defendant was not negligent for failure to give adequate information regarding its prescription product, but had the plaintiff brought an action for misrepresentation, recovery might have been granted. In dicta the court stated:

... it is difficult to see on what basis this defendant can be liable to plaintiff. It made no representation to plaintiff. . . . To physicians it did make representations. And should any of these be false it might be claimed with propriety that they were made for the benefit of the ultimate consumer. But there is no such claim. The sole claim is not misrepresentation or even concealment, but a negligent failure to give adequate warning . . .

In Toole v. Richardson-Merrell, where the manufacturer withheld clinical investigation reports on its product, MER/29, in order to secure FDA approval for marketing, the court characterized the physician who received the fraudulent statements as the agent of the injured patient:

Appellant . . . says there is no evidence to show that respondent relied upon any of its representations. But there was evidence from which the jury could readily infer reliance on the representations. Respondent’s doctor, his agent, relied upon them. The doctor . . . relied upon the literature supplied by appellant and . . . he talked to appellant’s [detailman] on many occasions about the drug. The [fraudulent] statements concerning safety of the drug and its lack of side effects were included in the literature, and the salesman had been instructed to stress such factors when talking to doctors. The jury could infer that appellant’s representations were read and heard by respondent’s doctor and that he relied upon them in prescribing the drug for respondent’s use.

Whether we call the physician who receives the detailman’s statements the agent of the patient, or the “learned intermediary” between the drug manufacturer and the patient is not important. Deceit may be as appropriate a remedy for the injured plaintiff as negligence and strict liability, but this too does not address itself to

98. Id. at 287, 77 N.Y.S.2d at 509.
100. Id. at 707, 60 Cal. Rptr. at 411.
our main concern. The threat of tort liability hangs over the drug company, but the detailman usually does not appreciate it. Tort liability provides only remedial action against a master whose servant has erred; it does not offer solutions that would force a detailman to consider warning more important than selling.

3. Breach of Warranty

Unlike the negligence, strict liability, and deceit actions, a breach of warranty action is contractual in nature, hence governed by Article 2 of the Uniform Commercial Code. While roadblocks to recovery such as privity, necessity for a sale, and notification of breach have largely been removed by the courts in drug

102. This action is rooted in tort law and has developed along these lines. In view of the fact that a warranty also has commercial or contractual qualities, this section will analyze how the injured patient can use the warranties provided for in the Uniform Commercial Code as his basis of legal recourse. See generally, Spangenberg, Aspects of Warranties Relating to Defective Prescription Drugs, 37 U. of Colo. L. Rev. 194 (1965); Comment, The Contractual Aspects of Consumer Protection: Recent Developments in the Law of Sales Warranties, 64 Mich. L. Rev. 1430 (1966); Comment, Commercial Transactions: Defenses in Drug Product Liability Cases, 17 Okla. L. Rev. 318 (1964).


For a discussion of “vertical privity” see Uniform Commercial Code § 2-318, Comment 3.


106. See, e.g., Bennett v. Richardson-Merrell, Inc., 231 F. Supp. 150, 153 (E.D. Ill. 1964). See also PROSSER 4th at 655 where he states: “In order to circumvent the statute, the courts were forced to resort to rather transparent devices, holding that a long delay is ‘reasonable’ or that the provision was not intended to apply to personal injuries.” (footnotes omitted); Uniform Commercial Code § 2-607 Comment 4 regarding notification of breach in consumer and commercial cases; Phillips, Notice of Breach
liability cases, the central issue as to whether the detailman's oral promotional statements create warranties has received little attention. In regard to these statements, we are concerned only with those warranties created in the marketing of the drug, that is, express warranty and implied warranty of fitness for a particular purpose.

One recent case has alluded to the creation of express warranties as a result of the detailman's promotional statements. In Toole v. Richardson-Merrell the court found that an express warranty exists when factual statements regarding a drug's effectiveness and safety are "widely made to the medical profession generally, [are] orally made by detailmen in soliciting use of the drug by the profession, and [are] made by means of advertisement in medical journals and periodicals."108

A detailman's oral promotional statements of fact or promise can well create an express warranty under UCC § 2-313 provided that these affirmations are neither his opinion of the product nor a common sales talk.109 The plaintiff's major problem with the warranty action has been the requirement that he rely on the warranty statement in order for him to sustain the cause of action.110 To

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107. Id. at 706, 60 Cal. Rptr. at 411. In Tinnerholm v. Parke Davis & Co., 285 F. Supp. 432 (S.D.N.Y. 1968), the court thought it unnecessary to reach a decision as to whether oral promotional statements "can be properly characterized as express warranties" because of its finding that the manufacturer had breached an implied warranty of merchantability in releasing onto the market what the court felt was a "defective product." The court's reasoning as to the nature of the defect is at 436-440.

108. UNIFORM COMMERCIAL CODE § 2-313 provides:

(1) Express warranties by the seller are created as follows:

(a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.

(b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.

(c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

(2) It is not necessary to the creation of an express warranty that the seller use formal words such as "warrant" or "guarantee" or that he have a specific intention to make a warranty, but an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty.

Query as to whether product samples which the detailman gives the physician for his patients' use, create an express warranty under Uniform Commercial Code § 2-313 (1)(c).

109. See Rheingold, supra note 73, at 977; Bordicks, Unwanted Pregnancy and the Pill—The Question of Liability of the Manufacturer, 41 U. of Cin. L. Rev. 335, 341.
require this is to perpetuate the antiquities of an old common law tort action. Warranty in tort is a vestige which serves no useful function in a dynamic economic system. In order to deal with the legal complexities of our free enterprise system, the UCC was enacted into law. To ignore its existence is to defeat the purpose for which legislatures have enacted it.

UCC § 2-313 requires no reliance in order to create or prove the breach of an express warranty. The requirement which must be satisfied, however, is that the promise or affirmation of fact be "part of the basis of the bargain." The detailman's statement relating to the product may come either before or after the actual purchase of the drug by the patient. So long as the promise or affirmation of fact is part of the basis of an extended transaction between the manufacturer and the purchasing patient the warranty is created.

While there is no case law which holds that a detailman's statements create an implied warranty of fitness for particular purpose, a reasonable interpretation of UCC § 2-315 leads to this conclu-

(1972). The confusion as to whether or not a plaintiff must rely on an express warranty in order to prove its breach is exemplified by two articles by the same author. Compare Freedman, supra note 51, at 603 (reliance is required) with Freedman, Products Liability Under the Uniform Commercial Code, 10 PRAC. LAW. 49, 51 (April, 1964) (no reliance is required).

111. Admittedly, vestiges of tort law have been incorporated into UNIFORM COMMERCIAL CODE § 2-715:

(2) Consequential damage resulting from the seller's breach include
(b) injury to person or property proximately caused from any breach of warranty.

Regarding the proximate cause requirement see § 2-314 Comment 13; § 2-715 Comment 5.

112. See UNIFORM COMMERCIAL CODE § 2-313, Comment 3: "... no particular reliance on such statements need be shown in order to weave them into the fabric of the agreement." But see id. Comment 2: "... the warranty sections of this Article are not designed in any way to disturb those lines of case law growth which have recognized that warranties need not be confined either to sales contracts or to the direct parties to such a contract."

113. R. Nordstrom, SALES, 1970, §§ 67, 68; U.C.C. § 2-313 Comment 7:
The precise time when words of description or affirmation are made or samples shown is not material. The sole question is whether the language or samples or models are fairly to be regarded as part of the contract. If language is used after the closing of the deal ... the warranty becomes a modification, and need not be supported by consideration if it is otherwise reasonable and in order (Section 2-209).

114. UNIFORM COMMERCIAL CODE § 2-315, Implied Warranty: Fitness for Particular Purpose—

Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is, unless excluded or modified ... an implied warranty that the goods shall be fit for such purpose.
sion. Since the physician often relies on the detailman's skill or judgment in selecting a suitable product for particular disease entities, knowledge on the part of the detailman that the doctor is so relying may be sufficient to create the implied warranty under § 2-315.

Physicians do occasionally review a patient's medical chart with a detailman and ask for specific suggestions as to what course of therapy should be followed. Indeed, the detailman does not promote drugs in a vacuum. In his product discussions he often requests the physician to try his product samples on particular patients. In cases such as these a warranty action under UCC § 2-315 seems perfectly appropriate. Unlike other UCC warranties, this is the only one that requires that the physician, who receives the warranty statement for the benefit of the patient, actually rely on the detailman's statements.

B. Federal Statutory and Regulatory Standards

Governmental control of the pharmaceutical industry today stems from the Federal Food, Drug, and Cosmetic Act. An analysis of the statute reveals that no provision therein relates to the detailman nor to any oral statements that he makes in the promotion of drugs. One commentator has argued that "the detailer's oral presentation is subject to Section 502(f)(1) [of the Act] inasmuch as his mention of uses not covered by the approved new drug application or established as safe and effective for that drug would be actionable." There is no evidence to support this statement. Section 502(f)(1) provides that "A drug . . . shall be misbranded . . . (f) Unless its labeling bears (1) adequate directions for use . . . ."

"Labeling includes labels, and . . . other written, printed or

115. See Section I B of text supra.
116. This happened quite frequently to the author during his course of employment as a detailman.
120. Willig, supra note 10, at 222.
graphic matter upon any article or any of its containers or wrappers, or accompanying such article.”

“Adequate directions for use” is partially defined in Title 21, Section 1.106(a) of the Code of Federal Regulations in the following way:

“Adequate directions for use” means directions under which the layman can use a drug or device safely and for the purposes for which it is intended. Directions for use may be inadequate [thus rendering the drug misbranded] because (among other reasons) of omissions, in whole or in part, or incorrect specification of:

1. Statements of all conditions, purposes, or uses for which such drug... is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in its oral, written, printed or graphic advertising...

At first blush, it seems that this rule allows the FDA to examine a detailman’s oral statements in determining whether he has “misbranded” his company’s product. This provision, however, applies only to sales made directly to the consumer, where no physician’s prescription is required. Furthermore in U.S. v. Various Articles of Device, Judge Gray of the Southern District of California stated:

It is... my conclusion that the [oral] representations made by the salesman... did not cause any of [the defendant’s] articles to be misbranded in violation of the Food, Drug, and Cosmetic Act.

In effect, the FDA has removed the detailman’s oral statements from its jurisdiction in a clause which follows that part of § 1.106(a)(1) quoted above:

“Except that such statements shall not refer to conditions, uses or purposes for which the drug... can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.

The same commentator argues that “any oral statements which tend to show actual labeling as being incomplete, false, or misleading,

125. Id. at 897.
in the case of new drugs, is a potential basis for action under Section 505(e). But this statement is likewise unsubstantiated. Section 505(e) also applies only to written statements. Nor is Section 502(n) pertinent in regard to the detailman's function, because this section deals with written advertising statements. This section requires, in the words of William Goodrich, former Assistant General Counsel of the Department of Health, Education and Welfare, that "every prescription drug advertisement and any other descriptive matter issued to promote sales must contain a true statement of the formula, the established name of the drug along with any trade name used, and such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required by [the] regulations."

Before the Drug Amendments of 1962 were enacted into law, the FDA had jurisdiction over drug labeling, not advertising. False advertising was the province of the FTC. One of the evils which the amendments sought to remedy was described by a distinguished physician in 1964:

Doctors are being systematically brainwashed by expensive advertising in the paper of medical journals, by the daily influx of mountains of advertising mail, by free throwaway

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“educational” pamphlets published by commercial agencies for the promotion of drug sales, by visiting detailmen, who go from door-to-door of physicians’ offices leaving elaborate samples of new drugs and valueless combinations of old drugs, together with reams of impressive but biased literature. It is utterly impossible for most busy physicians to separate the wheat from the chaff in this enormous volume of information and misinformation.

The original version of the Drug Amendments sought to extend FDA control over oral and written promotional statements, but as enacted the amendments pertained solely to written material. Absent such a rule, promotional statements by detailers cannot be easily categorized as either labeling or advertising. Therefore, FDA control does not cover exaggerated claims that might be made by some drug salesmen who are more concerned with sales figures than with their employer’s duty to adequately warn physicians of product dangers. Statutory and regulatory control does, however, extend to the product literature that the detailman leaves with the physician in addition to any promotional posters or cards used to capture the physician’s interest during the product presentation. This literature must conform to regulatory provisions. Violations of these provisions may render a drug misbranded and may provide grounds for the FDA to withdraw the manufacturer’s new drug application.

Nor can the courts adequately fill this void by construing oral product presentations as either labeling or advertising. While it has been suggested that the Yarrow case has succeeded in doing so, this is not entirely accurate. A misbranded drug, within the meaning of the statute and the Code of Federal Regulations gives the government, not the aggrieved plaintiff, a cause of action against the manufacturer. The only causes of action that are available to the injured patient against the drug house are those discussed earlier—negligence, strict liability, deceit, and breach of warranty. While violations of statutory and regulatory standards may be negligence per

133. Id. at 653.
134. Id.
135. For extensive citations to and analysis of applicable regulatory provisions see Boland, supra note 118.
136. For a review of the significance of the new drug application see Rheingold supra note 73, at 959; Ferg and Morrow, supra note 121, at 386; Note, The Drug Amendments of 1962, supra note 128, at 1086-96.
137. Sterling Drug, Inc. v. Yarrow, 408 F.2d 978 (8th Cir. 1969).
138. Ruge, supra note 192, at 653.
or at least evidence of negligence, these will not furnish the plaintiff with a cause of action because these violations are criminal in nature. To state it differently, the FDA's right of action against the manufacturer whose written advertising or labeling renders a drug misbranded arises from statutory and regulatory transgressions only. No such right of action is afforded the consumer by the statute.

The rights of the injured plaintiff to pursue a civil remedy where the detailman's oral statements do not adequately warn of dangers attendant to the use of his drugs arise at common law. No such rights of action are afforded the government.

In sum, statutory provisions and administrative regulations have no application to the detailman's oral promotional claims. The statute speaks in terms of "true statements" in advertising, the regulations in terms of "full disclosure" in labeling and "fair balance" in all of the manufacturer's written statements which relate to its drug products. Only the common law actions discussed above, which are reserved solely for the injured patient, speak in terms of the "duty to warn" orally or in writing. The government, therefore, has no authority to prosecute a drug manufacturer for misbranding its products where the detailman has exaggerated the advantages of a drug or de-emphasized its risks, unless, of course, the manufacturer has done the same in its labeling or advertising.

Footnotes:


144. 21 C.F.R. 1.105(e)(6) (1972).

145. See generally 1 FRUMER & FRIEDMAN § 8.

146. In this regard, the following cases are noteworthy: United States v. Hohensee, 243 F.2d 367 (3d Cir. 1957); V.E. Irons, Inc. v. United States, 244 F.2d 34 (1st Cir. 1957), cert. denied, 354 U.S. 923 (1957); United States v. 3 Cartons, More or Less "No. 28 Formula GM" etc., 132 F. Supp. 569 (S.D. Cal. 1952); United States v. Articles of Drug, etc., 352 F. Supp. 923 (3d Cir. 1965). These are all distinguishable in that oral promotional statements were used in conjunction with written labeling and advertising as evidence of misbranding. Therefore, the detailman's oral promotional statements alone do not constitute misbranding and are not actionable under applicable federal statutes or regulations.

Furthermore, 21 C.F.R. § 1.105(e)(6) lists twenty violations which clearly render a
III. CONCLUSION

The detailman is the victim of a dual allegiance. On one hand he is interested in economic profits for his employer and himself. On the other, he must convey vital drug information to physicians so that patients may be treated safely and successfully. His position is analogous to that of the lawyer who must serve the private interests of his client on the one hand, and, uphold the law as an officer of the court on the other. Unlike the detailman, lawyers have an institutionalized mechanism in bar association ethics committees which compels them to balance what may often be conflicting allegiances. Unlike the detailman, the lawyer is licensed to practice his profession. Indeed the detailman is perhaps the only member of the health care team whose qualifications are not examined by a competent board or panel. While there are minimal training and licensing requirements for less vital health care workers, no such standards have been formulated for detailmen. If the detailman were required to be licensed, not only would the pharmaceutical industry be assured of a stable, qualified pool of personnel to promote their products, but physicians would be more apt to welcome these detailmen as reliable and convenient sources of drug information. While the threat of drug liability suits hangs over the pharmaceutical industry, this deterrent does not necessarily filter down to the detailman in the field. The threat of being brought before the Ethics Committee directly encourages the lawyer to balance his conflicting allegiances. A similar institutionalized mechanism must therefore be created for the detailman.

Unlike the remedial actions which are available to the consumer, licensure is preventive in nature. Its purpose is not to compensate the injured patient but to protect him from becoming injured. The Yarrow court’s statement that the detailman is “the most significant and efficient means” of conveying drug information is more a goal to be achieved than a finding of ultimate fact. Only if the detailman is highly trained and licensed can that goal be realized. Federal legislation along these lines is therefore imperative.

Drug misbranded. 21 C.F.R. § 1.105(e)(7) adds thirteen violations which may render a drug misbranded. These violations pertain solely to written advertising statements.