Sample Prescription Drugs and the "Learned Intermediary": Liability without Preemption

Susan Poser
Prescription Drug Samples and the “Learned Intermediary”:
The Case for Liability Without Preemption

Susan Poser

Abstract

This is the first article that undertakes a systematic legal analysis of the issue of liability for harm from sample prescription drugs. I propose in this Article that people who suffer injuries resulting from the absence of warnings on samples of prescription drugs be permitted to sue drug manufacturers directly in tort, the learned intermediary rule notwithstanding. I show that the various rationales for the learned intermediary doctrine do not apply to sample prescription drugs. I use empirical studies to show that the drug companies’ promotion, marketing, and packaging of sample prescription drugs put patients at risk and tort law should require these companies to absorb those risks when they result in foreseeable harm. Recognition of an exception to the learned intermediary rule in the case of prescription drug samples would spread the risk of harm from unlabeled prescription drugs between physicians and the drug companies in a way that more accurately accounts for their responsibility for that risk. Moreover, recent pronouncements by the federal Food and Drug Administration concerning the preemptive effect of its drug labeling regulations should not affect this analysis. The FDA’s failure to require patient labeling on sample medication is not based on carefully considered scientific evidence. Imposing state tort liability on pharmaceutical manufacturers for failure to warn on samples of prescription drugs would not conflict with any of the FDA’s regulatory purposes or goals.
I. Introduction

In June 1992, shortly after giving birth, Mrs. Michele Vitanza visited her physician for a routine post-partum examination. She complained of a stiff neck and the physician gave her some samples of the prescription drug Ansaid, a nonsteroidal anti-inflammatory drug. The samples had been provided to the doctor earlier that year by a drug representative from the Upjohn Company. The samples were given to Mrs. Vitanza’s physician in a box that contained nine blister cards, each containing four pills, and one...
FDA-approved physician package insert describing the drug,\textsuperscript{5} contraindications, warnings, drug interactions, adverse reactions, etc. Mrs. Vitanza took enough of the pills to relieve her symptoms and put the rest in her medicine cabinet.\textsuperscript{6} More than two years later, Mrs. Vitanza’s husband had a stiff neck and, remembering that his wife had received medicine for the same symptoms, looked for and found the Ansaid tablets in the medicine cabinet.\textsuperscript{7} Mr. Vitanza had been warned by his own physician that he was severely allergic to nonsteroidal anti-inflammatory drugs and should not take them.\textsuperscript{8} The Ansaid blister card contained no warnings of this well-known allergy.\textsuperscript{9} The only information on the blister card was the following:

\begin{quote}
Complimentary Package
Not for Sale
4 Tablets Ansaid 100 mg. Tablets
FLURBIPROFEN
Each tablet contains flurbiprofen 100 mg.
Information for use and dosage--see insert.
Store at controlled room temperature 15°-30° C (59°-86° F)
Caution: Federal law prohibits dispensing without prescription.\textsuperscript{10}
\end{quote}

Although the blister pack said “see insert,” there was no package insert provided to Mrs. Vitanza when she received the samples.\textsuperscript{11} Because of his known allergy, Mr. Vitanza consulted two medical references, neither of which listed Ansaid as a nonsteroidal anti-inflammatory drug.\textsuperscript{12} He proceeded to take one Ansaid pill. Within two hours he was dead due to “a severe anaphylactic reaction to Ansaid.”\textsuperscript{13}

\textsuperscript{5} \textit{Id.} For a description of different kinds of FDA approved package inserts for prescription drugs, see \textit{infra} notes 224–39 and accompanying text.
\textsuperscript{6} \textit{Vitanza}, 214 F.3d at 75.
\textsuperscript{7} \textit{Id.}
\textsuperscript{8} \textit{Id.}
\textsuperscript{9} \textit{Id.}
\textsuperscript{10} \textit{Id.}
\textsuperscript{11} \textit{Id.}
\textsuperscript{12} \textit{Id.} Michele Vitanza’s attorney belies that this omission was because the medical reference works were published one year before Ansaid became widely available. Telephone interview with with Jonathan Levine, Esq., Partner, Silver, Golub & Teitell, Stamford Conn. (October 19, 2006).
\textsuperscript{13} \textit{Vitanza}, 214 F.3d at 75.
Michele Vitanza sued Upjohn Company for the wrongful death of her husband, claiming that Upjohn failed to warn about adverse reactions on its sample labels.\textsuperscript{14} The case was dismissed on summary judgment on the basis of the learned intermediary rule.\textsuperscript{15} The learned intermediary rule, which has been adopted in almost every state,\textsuperscript{16} holds that the manufacturer of a prescription drug has a duty to warn the prescribing physician of the risks and benefits of the drug and it is the physician in turn who has the duty to warn the patient.\textsuperscript{17} Based on this rule, the district court held that Upjohn had no duty to warn Mrs. Vitanza or her husband.\textsuperscript{18} Mrs. Vitanza appealed and the Second Circuit Court of Appeals, on its own motion, certified to the Connecticut Supreme Court the question of whether the learned intermediary doctrine should apply in this situation.\textsuperscript{19} That Court held that the doctrine did apply. The Second Circuit then upheld the summary judgment in favor of Upjohn.\textsuperscript{20}

I propose in this Article that people who suffer injuries resulting from the absence of warnings on samples of prescription drugs be permitted to sue drug manufacturers directly in tort, the learned intermediary rule notwithstanding. I will show that the various rationales for the learned intermediary doctrine do not apply to sample prescription drugs. The drug companies’ promotion, marketing, and packaging of sample prescription drugs put patients at risk and tort law should require these companies to absorb those risks when they result in foreseeable harm. Recognition of an exception to the learned intermediary rule in the case of prescription drug samples would spread the risk of harm from unlabeled prescription drugs between physicians and the drug

\begin{itemize}
\item \textsuperscript{14} Id. at 74.
\item \textsuperscript{15} Id. at 75–76. The case was dismissed after being removed to the federal district court from Connecticut state trial court. Id.
\item \textsuperscript{16} Larkin v. Pfizer, Inc. 153 S.W.3d 758, 767 (Ky. 2005).
\item \textsuperscript{17} Id. at 762.
\item \textsuperscript{18} Vitanza v. Upjohn Co., 48 F.Supp.2d 124, 132 (D. Conn. 1999).
\item \textsuperscript{19} Vitanza, 214 F.3d at 79.
\item \textsuperscript{20} Vitanza v. Upjohn Co., 271 F.3d 89, 92 (2d Cir. 2001).
\end{itemize}
companies in a way that more accurately accounts for their responsibility for that risk. In addition, I will show that recent pronouncements by the federal Food and Drug Administration concerning the preemptive effect of its drug labeling regulations should not affect this analysis.

It is hard to know how many people are harmed by sample prescription drug medication each year. In 2006, the National Academies’ Institute of Medicine reported that medication errors injure 1.5 million people annually.21 The report addressed labeling of prescription drugs and found that

> there has been a growing unease among health care providers and others about the way free samples are distributed and the resulting lack of documentation of medication use, as well as the bypassing of drug-interaction checks and counseling that are integral parts of the standard prescription process.22

Most people who believe that they are harmed by their medical care do not initiate a lawsuit.23 In the case of samples, this might be because the injury is not serious enough, or because their health insurance covers treatment associated with the harm.24 Because of the widespread adherence of courts to the learned intermediary rule, most lawyers would probably not initiate a lawsuit against a drug manufacturer based on failure to warn on a sample, particularly if the damages are not high.

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22 Id.

23 See, e.g., David A. Hyman & Charles Silver, Medical Malpractice Litigation and Tort Reform: It’s the Incentives, Stupid, 59 VAND. L. REV. 1085, 1090 (2006) (citing studies finding that as few as 10% of negligently injured patients bring lawsuits); Marilynn L. May, Daniel B. Stengel, Who Sues Their Doctors? How Patients Handle Medical Grievances, 24 LAW & SOC’Y REV. 105, 105 (1990) (“Because very few grievances are transformed into disputes, and few disputes find their way through the thickets of diversion to become legally framed and resolved, the lawsuits in medical studies represent on the tip of the iceberg.”); Randall R. Bovberg & Laurence R. Tancredi, Liability Reform Should Make Patients Safer: “Avoidable Classes of Events” are a Key Improvement, 33 J.L. MED. & ETHICS 478, 478 n.2 (2005).

24 Hyman & Silver, supra note 23, at 1114.
Someone harmed by the absence of warnings on samples of prescription drugs can sue her physician on an informed consent theory, but these cases are notoriously difficult to prove.\textsuperscript{25} They often come down to the physician’s testimony against the patients’ in a context in which the physician has many advantages in front of a jury. Once a patient admits that some communication was made, the physician can blame the patient for failing to ask for more information or to reveal her confusion.\textsuperscript{26} The physician can also simply contradict the patient’s memory of their conversation. One might not contact a lawyer in a case like \textit{Vitanza} because most people know that they should not take someone else’s prescription drugs. Yet it is well known in the medical community that sample prescription drugs are routinely taken by people, including the physician’s family and office staff, without their own doctor’s consent or even knowledge,\textsuperscript{27} and that these samples often “wind up in medicine cabinets for future use.”\textsuperscript{28} There is little doubt that a warning on the Ansaid samples would have prevented Mr. Vitanza’s death.

Although the medical community is aware of the hazards involved in the promotion, labeling, and dispensing of sample prescription drugs,\textsuperscript{29} the legal community has largely overlooked them, both in case law and the law reviews. The \textit{Vitanza} court dismissed the plaintiff’s case before she had an opportunity to demonstrate why the learned intermediary rule should not be applied in her case. Unlike other drugs, both prescription and over-the-counter, samples are routinely distributed to patients without

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\textsuperscript{27} Mary-Margaret Chren, M.D., \textit{Interactions between Physicians and Drug Company Representatives}, 107 AM J. MED. 182,182 (1999); \textit{see also} Ila M. Harris, \textit{Closing the Door on Sample Closets}, \textit{MINN. MED.}, January, 2001, at 21, 25 available at http://www.mmaonline.net/publications/MnMed2001/January/Harris.html. (reporting that 96% of physicians, residents, nurses, and office staff surveyed reported taking samples that were not prescribed for them).
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\textsuperscript{29} \textit{See infra} notes 182–88 and accompanying text.
the benefit of any written warnings from the drug company or the pharmacy, and often by a physician who was the target of aggressive and manipulative marketing by representatives of the drug company seeking to increase prescriptions of a new and expensive drug.\(^{30}\)

Because there is no pharmacist involved in the transaction when a sample is dispensed by a physician, the patient often does not receive printed information about the drug when it is dispensed, nor is she reminded of the gravity of receiving a prescription drug that a trip to the pharmacy and the receipt of the specially labeled container imparts.\(^{31}\) Knowing all of this, the pharmaceutical companies distribute millions of sample prescription drugs to physicians every year, along with a sales pitch often accompanied by gifts and free meals.

Part I of this Article reviews the current state of the law for failure to warn claims concerning prescription drugs. It addresses the ongoing debate about the learned intermediary rule and its exceptions. Part II describes the promotion of prescription drugs and the role of samples in drug marketing, including the effect of marketing on prescribing patterns, patient safety, and the price of prescription drugs. Part III demonstrates how that marketing justifies an exception to the learned intermediary rule for warnings about sample prescription drugs. Part IV addresses the potential doctrinal and prudential arguments against liability of pharmaceutical companies for inadequate labeling on sample drugs, including the role of federal preemption.

\(^{30}\) See infra Part III.

II. Warning Defects and the Learned Intermediary Rule

Michele Vitanza lost her claim against Upjohn Co. because she directed her failure to warn claim against the drug manufacturer instead of her physician. Since the dawn of modern products liability law in the 1960’s, products that are not defectively designed or manufactured can still be defective if they do not carry warnings about risks inherent in their design or use. All manufacturers of products have a duty to warn consumers about the risks of their products.32 The learned intermediary rule is an exception to that general duty insofar as the manufacturer’s duty to warn of the risk of prescription drugs is satisfied when the manufacturer warns the physician who prescribes the drug, not the ultimate consumer.

The prescription drug exception to the duty to warn the product user directly can be traced back to the advent of prescription drugs. In 1938, the Food and Drug Administration (FDA) issued regulations that for the first time drew a distinction between drugs that consumers could buy over-the-counter, and drugs for which “all representations or suggestions contained in the labeling thereof with respect to the conditions for which such drug or device is to be used appear only in such medical terms as are not likely to be understood by the ordinary individual.”33 Drugs in this latter category require a doctor’s prescription before obtaining them.34 Prior to this regulatory

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32 See Restatement (Second) of Torts § 402A (1965); Restatement (Third) of Torts: Products Liability §2, cmt. i (1998).
distinction, all non-narcotic drugs could be purchased without physician approval. These FDA regulations were codified in 1951 by the Durham-Humphrey Amendment to the Food, Drug and Cosmetics Act (FDCA), which required manufacturers to warn consumers directly about over-the-counter drugs but not prescription drugs. Fifteen years later, in Sterling Drug v. Cornish, the Eighth Circuit Court of Appeals articulated the learned intermediary rule in the context of a failure to warn claim against the manufacturer of a prescription drug for arthritis.

In 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.

Thus, the learned intermediary rule is a common law doctrine but it developed logically out of the regulatory framework for prescription and over-the-counter drugs.

Shortly before Sterling Drug, the American Law Institute (ALI) published its Restatement (Second) of Torts, including its influential section 402A, which subjected manufacturers and sellers of products to strict liability for products sold in a “defective condition unreasonably dangerous.” The comment to §402A made it clear that inadequate warnings could render a product defective: “In order to prevent the product

35 Id. at 822.
37 370 F.2d 82 (8th Cir. 1966).
38 Id. at 85. See also, Timothy S. Hall, Reimagining the Learned Intermediary Rule for the New Pharmaceutical Marketplace, 35 SETON HALL L. REV. 193, 195 (2004).
39 Sterling Drug, 370 F.2d at 85.
40 Restatement (Second) Torts, §402A (1965).
from being unreasonably dangerous, the seller may be required to give directions or warning, on the container, as to its use.\textsuperscript{41} 

It does not follow inexorably from the distinction between prescription and over-the-counter drugs that only the latter must contain warnings directed at consumers. It would be equally logical to require consumer warnings on prescription drugs, if only for the purpose of reinforcing physician warnings. The FDA does in fact require patient labeling for some prescription drugs, including oral contraceptives, intrauterine devices (IUDs), and some asthma drugs.\textsuperscript{42} The FDA has proposed rules requiring consumer warnings on virtually all prescription drugs, but those rules have never been implemented due to lobbying from the pharmaceutical industry.\textsuperscript{43}

Courts and commentators have identified three essential justifications for the learned intermediary doctrine. First, because all prescription drugs by definition pose risks to some patients and can only be obtained through a health care professional, it is the patient’s physician who is in the best position to evaluate those risks and weigh them

\textsuperscript{41} Restatement (Second) Torts § 402A, cmt. j (1965). Comment k to section 402A, specifically addressed warnings in the context of drugs, recognizing that many drugs are “unavoidably unsafe,” because they carry known risks, but that they can be made safe with the addition of warnings. The comment states:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies . . . 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 \textit{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.

Restatement (Second) Torts § 402A, cmt. k (1965).

\textsuperscript{42} Walsh et al., \textit{supra} note 34 at 823.

against the benefits to a particular patient.\textsuperscript{44} This view of the patient-physician relationship posits the patient in a relatively passive role, relying on the expertise of the physician to evaluate and prescribe appropriate medication.\textsuperscript{45} If the physician is fully informed by the drug company about the risks, the physician is in the best position to tailor instructions and warnings to particular patients:

\begin{quote}
It is for the prescribing physician to use his own independent medical judgment, taking into account the data supplied to him from the drug manufacturer, other medical literature, and any other source available to him, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug.\textsuperscript{46}
\end{quote}

This rationale for the learned intermediary rule parallels the independent duty of informed consent owed by a physician to a patient. The standard of care for informed consent in the vast majority of states is governed by professional practice in the community or specialty.\textsuperscript{47} Patients can sue their physician for lack of informed consent if the patient can show that other physicians would have revealed more or different information, and that the patient would have declined to take the drug if she had learned this extra information.\textsuperscript{48}

\textsuperscript{44} See Larkin v. Pfizer, 153 S.W.3d 758, 767 (Ky. 2004). See also James Barney, Dancing Towards Disaster or the Race to Rationality: The Demise of the Learned Intermediary Standard and the Pharmacists’ Duty to Warn, 39 Gonz. L. Rev. 399, 404 (2004) ("other than trusting the doctor, the patient is not exercising an individual ‘choice.’"). Hall, supra note 38 at 203 ("Training and experience allow the physician to translate the technical details concerning the potential therapeutic benefits and known risks of the drug into specific recommendation and instructions for use by the individual patient.").

\textsuperscript{45} Richard C. Ausness, Will More Aggressive Marketing Practices Lead to Greater Tort liability for Prescription Drug Manufacturers?, 37 Wake Forest L. Rev. 97, 108 (2002); Walsh et al., supra note 34 at 844.

\textsuperscript{46} Leibowitz v. Ortho Pharmaceutical Corp., 307 A.2d 449, 457 (Pa. Super. 1973). See also, Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1275 (5th Cir. 1974) (holding defendant Wyeth Laboratories liable for failing to warn plaintiffs of risks or advising them to seek the opinion and care of a medical professional).

\textsuperscript{47} David G. Owen, Products Liability Law § 22.1 (2005)

\textsuperscript{48} Owen, supra note 47 at § 22.1; Paytash, supra note 43 at 1346–47.
A second rationale for the learned intermediary rule is that drug manufacturers “lack effective means to communicate directly with each patient.”49 Drug interaction risks and other side effects might be most efficiently communicated in technical language, which the average patient would not necessarily be able to understand. The physician as learned intermediary, having the “expertise necessary to understand the warning labels adequately,”50 serves as a translator of this information into language that the patient can understand.51

Finally, many courts have contended that direct warnings from manufacturers to patients would interfere with the physician-patient relationship.52 Being bombarded with all of the possible risks of a drug might confuse patients, causing them to miscalculate the risks and benefits of the drug in their case.53 Others have argued that providing separate warnings to the patient would interfere with the trust relationship between patient and physicians, by signaling to the patient that it might be wise to rely on information from outside sources.54

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49 Larkin, 153 S.W.3d at 764.
50 Hall v. Sinn, Inc., 102 F. App’x 846, 849 (5th Cir. 2004).
52 See, e.g., Larkin, 153 S.W.3d at 764 (Kentucky Supreme Court worries that a rule requiring direct warnings from manufacturers to patients would interfere with the physician-patient relationship).
53 See Timm v. UpJohn Co., 624 F.2d 536, 538 (5th Cir. 1980); Ausness, supra note 45 at 109.
The learned intermediary rule has been adopted by 45 jurisdictions and operates essentially as an irrebuttable presumption in the vast majority of cases.55 The rule was created and continues to be justified by a vision of the physician-patient relationship in which the physician makes a completely informed decision about the appropriateness of a certain drug for a patient and the patient is reasonable in relying solely on that physician’s expertise in making this decision. Implicitly, the rule suggests that it would be insulting to the physician and even dangerous for a patient to acquire outside information about a prescription drug, even from the manufacturer, in order to be more fully informed about the risks and benefits of the drug. Also implicit is the idea that if the patient has questions about side effects of the drug over the course of treatment, she can simply contact the physician for a consultation and the drug manufacturer has no responsibility to provide an alternative source of information.

Some courts have recognized exceptions to the learned intermediary rule in situations where they considered these implicit assumptions to be absent. An early exception was for mass immunization programs in which patients were immunized against disease without the benefit of one-on-one consultation with a physician.56 Because vaccine manufacturers know that “people line up like lemmings to receive a polio shot or flu vaccination,”57 manufacturers, who often sponsored the immunization clinics, were required to provide warnings directly to the consumers. Methods of warning include advertising at the clinic58 or providing a clear informed consent form that

55 Hall, supra note 38 at 196; 2 James T. O’Reilly, FOOD AND DRUG ADMINISTRATION § 26.10 (2d ed. 1993); See also Larkin, 153 S.W.3d at 767 (listing 34 states that have explicitly adopted the rule; 2 that have implicitly adopted it; and 9 federal courts that have interpreted state law so as to adopt it).
56 Davis v. Wyeth Labs., Inc., 399 F.2d 121 (9th Cir. 1968) (applying Montana law), Reyes v. Wyeth Labs., Inc., 498 F.2d 1264 (5th Cir. 1974) (applying Texas law); Givens v. Lederle, 556 F.2d 1341 (5th Cir. 1977) (applying Florida law). See also, OWEN, supra note 47 at § 9.6.
57 OWEN, supra note 47 at § 9.6.
58 Davis, 399 F.2d at 131.
set forth the known risks. This exception to the learned intermediary doctrine is not universally recognized, however, and a majority of courts still apply the learned intermediary rule to mass immunization cases, provided that adequate warnings are given to the purchaser of the vaccine.

Several jurisdictions recognize other exceptions to the learned intermediary doctrine. In *MacDonald v. Ortho Pharmaceutical Corp.*, the Massachusetts Supreme Court held that the manufacturer of oral contraceptives had a duty to provide adequate warnings directly to the patient. The Court reasoned that because patients participate in the decision to use contraceptives more than in decisions about other prescription drugs, and because the physician generally prescribes up to a year of the drug and does not closely follow the patient despite the risks involved in oral contraceptives, direct warnings to the patient were necessary. The Court perceived that it was relatively easy for the manufacturer to articulate in lay language the risks of oral contraceptives, particularly since it was required to do so by the FDA, and that women would be inclined to reference those warnings if they had questions between office visits. Using

\[59\] Petty v. United States, 740 F.2d 1428, 1436 (8th Cir. 1984). The Childhood Vaccine Act, which created a trust fund for people injured by vaccines and provided a no-fault method to receiving compensation, also limited the availability of tort remedies. See 42 U.S.C. § 300aa-11 (1995).

\[60\] Larkin, 153 S.W.3d at 765–66 (citing Petty v. United States, 740 F.2d 1428, 1440 (8th Cir.1984); Givens, 556 F.2d at 1345-46 (5th Cir.1977); Reyes, 498 F.2d at 1276–77 (5th Cir.1974); Cunningham v. Charles Pfizer & Co., 532 P.2d 1377, 1381 (Okla.1974); Davis, 399 F.2d at 131).

\[61\] MacDonald, 475 N.E.2d 65 (Mass. 1985).

\[62\] Id. at 70.

\[63\] Id. But see, Walsh et al., supra note 34 at 863 (“Oral contraceptives are not obtained in significantly different ways than other prescription drugs.”).

\[64\] MacDonald, 475 N.E.2d at 69–70.

\[65\] Id. at 69. See also, Stephens v. G.D. Searle & Co., 602 F. Supp. 379 (E.D.Mich. 1985) (Like MacDonald, Stephens involved contraceptives); cf. Edwards v. Basel Pharmaceuticals, 933 P.2d 298 (Okl. 1997) (declining to extend similar reasoning to a case involving nicotine patches). The *MacDonald* court held that the manufacturer’s compliance with FDA regulations that required certain warnings in a package insert with oral contraceptives did not prevent the plaintiff from suing in tort for inadequate warning when the insert did not specifically mention the risk of stroke. 475 N.E.2d at 71–2.
similar reasoning, the Eighth Circuit, applying Arkansas law, declared an exception for IUD’s, but other courts have declined to follow these precedents.

In *Perez v. Wyeth Labs.*, a groundbreaking decision in 1998, the New Jersey Supreme Court carved out an exception to the learned intermediary rule for the contraceptive patch Norplant because of the manufacturer’s direct-to-consumer advertising campaign. Noting that “[o]ur medical-legal jurisprudence is based on images of health care that no longer exist,” the *Perez* court based its decision on the reality of current medical practice in which patients must take an active part in their health care because of the limitations on doctor-patient consultation time imposed by managed care organizations and the fact that studies have found that the majority of doctors fail to provide information about the risks of prescription drugs.

The court also noted that the drug companies cannot claim that patients do not take an active role in their health care decisions, or that manufacturers lack effective means to communicate with patients, when those same companies concertedly and effectively influence consumers directly through advertising. The *Perez* court held that the presumption that the learned intermediary rule applied to prescription drugs could be rebutted when direct-to-consumer advertising did not contain adequate warnings of the drug’s risks. As with other decisions finding exceptions to the learned intermediary doctrine, however, courts

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66 Hill v. Searle Labs., 884 F.2d 1064, 1070–71 (8th Cir. 1989) (applying Arkansas law). IUD’s are not prescription drugs but medical devices available only through a physician. Courts have extended the learned intermediary rule to devices and now routinely apply the learned intermediary rule to such devices. OWEN, supra note 47 at § 9.6.

67 See, e.g., Martin v. Ortho Pharmaceutical Corp., 661 N.E.2d 352, 356 (Ill. 1996) (noting that a majority of courts apply the learned intermediary rule to contraceptive cases); Paytash, supra note 43 at 1351; Walsh et al., supra note 34 at 862–63.


69 Id. at 1247. For a general discussion of this idea, see Francis B. Palumbo & C. Daniel Mullins, *The Development of Direct-to-Consumer Prescription Drug Advertising Regulation*, 57 FOOD & DRUG L.J. 423 (2002).

70 *Perez*, 734 A.2d at 1255.

71 Id. at 1256 (quoting Susan A. Casey, Comment, *Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19 WM. MITCHELL L. REV. 931, 956 (1993)).
addressing the effect of direct-to-consumer advertising on the learned intermediary rule have declined to follow Perez.\(^{72}\) In recent cases, the New Jersey courts themselves have created some limits to this exception, holding that merely placing informational brochures in physicians’ offices was not enough to invoke the exception,\(^{73}\) and limiting causation to those cases where the plaintiff can show that she actually saw and was affected by the advertising.\(^{74}\)

A growing body of scholarly work has questioned the appropriateness of the learned intermediary rule in the context of modern medical practice and drug marketing techniques. The common theme in most of this work is that the reality of modern medicine makes the learned intermediary rule an anachronism that is no longer justified and serves only to shield the drug companies from liability while saving them the cost of providing warning labels. These articles tend to focus on the changes in the doctor-patient relationship and the pharmaceutical industry’s own interference with this relationship through mass media advertising as well as the growing availability of prescription drugs on the internet.\(^{75}\) Doctors now spend less time with their patients because of the pressures from managed care organizations, and they are often reacting to patient requests for prescription drugs, rather than initiating a well-considered course of treatment. The treatment options are further limited to those drugs preferred by


\(^{73}\) *Banner v. Hoffmann-LaRoche*, 891 A.2d 1229, 1236 (N.J.Super. 2006).


\(^{75}\) See, e.g., Ausness, *supra* note 45 at 120-21; Hall, *supra* note 38 at 196–98 (calling for a complete overhaul of the learned intermediary rule in light of changes to the doctor-patient relationship and pharmaceutical marketing).
patients’ managed-care plans. Because of limitations on the patient’s choice of physicians imposed by managed-care organizations, patients are less likely to develop long-term relationships with their physicians. At the least, as Timothy Hall argues, courts should undertake a more fact-based analysis when the learned intermediary rule is invoked in order to determine if the physician was actually functioning as a learned intermediary in the transaction.

There are, however, many who continue to support the learned intermediary rule, based on the classic rationales about the expertise of the physician and the difficulty that drug companies would encounter in writing patient warnings about prescriptions drugs so that they were both useful and comprehensible to the average consumer. The learned intermediary rule is, for the most part, alive and well. In the vast number of instances, patients who believe that they were not adequately warned about the harm or side effects caused by their prescription drugs may only sue their physicians (and occasionally pharmacists) for failure to warn, a claim usually framed as lack of informed consent.

In response to the recognized exceptions to the learned intermediary rule and growing scholarly dissatisfaction with it, the recent Restatement of Torts (Third): Products Liability took a flexible approach to the rule. The Restatement endorsed the learned intermediary rule, but recognized the possibility of exceptions in circumstances where the rationale for the rule was weak. Section 6 states:

(d) A prescription drug or medical device is not reasonably safe due to

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76 Paytash, supra note 43 at 1358–60.
78 Hall, supra note 38 at 239–44.
79 Schwartz et al., supra note 54 at 160; Barney, supra note 44 at 405.
81 Owen, supra note 47 at § 22.10.
inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

(1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or
(2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.  

This Restatement justifies the basic doctrine under §6(d)(1) in the conventional way, stating: “only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy.” Yet it also recognizes that “in certain limited therapeutic relationships the physician or health-care provider has a much-diminished role as an evaluator or decision maker.”

Under Section 6(d)(1), if the manufacturer fails to warn the physician adequately, the plaintiff has a claim against the manufacturer for failure to warn the physician. Section 6(d)(2) envisions a category of exceptions when the duty to warn is owed directly to the patient because physicians are not in the best position to provide a warning to the patient. The Comments to Section 6(d)(2) recognize the exceptions to the learned intermediary rule for vaccines, contraceptives, and direct-to-consumer advertising and leave to case law whether others should be developed.

Despite the absence of evidence that the drafters of this section considered sample prescription drugs, the way in which samples are marketed and dispensed makes them particularly suitable for inclusion in the category of exceptions articulated by

82 Restatement (Third) of Torts: Products Liability § 6(d) (2006) (emphasis added).
84 Id.
85 Restatement (Third) of Torts: Products Liability, § 6, cmt. d (“[m]anufacturers of prescription drugs discharge their duty of care to patients by warning the health-care providers who prescribe and use the drugs to treat them.”).
86 Id., cmt. e.
Section 6(d)(2) of the Restatement. The Second Circuit Court of Appeals cited this section in *Vitanza* when it certified to the Connecticut Supreme Court the question of whether there should be an exception to the learned intermediary rule for harm caused by unlabeled samples.\(^87\) The learned intermediary rule provides immunity to drug companies as long as they provide adequate written warnings to physicians in the form of FDA-approved trade labeling in the sample package and patient warnings in the official Physicians Desk Reference.\(^88\) This encourages these for-profit companies to overpromote to physicians with near impunity.\(^89\)

Yet, the drug companies have reason to know that physicians “will not be in a position to reduce to the risks of harm,” from samples because the companies employ marketing techniques intended to minimize physicians’ recognition of potential harm from their drugs and to maximize distribution of the samples to patients. Moreover, the rationales for exceptions to the learned intermediary rule for contraceptives (such as the need to have a reference at home), and advertising (such as drug company interference with the doctor-patient relationship), are particularly apposite in the case of samples. The applicability of these rationales to prescription drug samples becomes clear when one examines the marketing practices of pharmaceutical companies.

Permitting a cause of action against the drug companies for inadequate labeling on sample prescription drugs would not change the duty of physicians to warn patients and obtain their informed consent when the physician distributes those samples. Physicians who are acting under a conflict of interest, or who should be aware of their own bias, whether unconscious or not, should take responsibility for it.\(^90\) Rather, the

\(^{87}\) *Vitanza v. Upjohn*, 214 F.3d 73, 78 (2d Cir. 2000).

\(^{88}\) *Ausness*, supra note 45 at 100.

\(^{89}\) See *infra* notes 174–80 and accompanying text for discussion of overpromotion.

\(^{90}\) The medical profession itself, acknowledging the influence of drug promotion, recently called for academic medical centers to provide leadership on conflicts of interest to which physicians are subject. *See* Troyen A. Brennan et al., *Health Industry Practices*
justification for this proposal is that legal responsibility for conduct should be shared by physicians and the drug companies in a way that accords with culpability and promotes public safety.\textsuperscript{91}

\textit{III. Prescription Drug Marketing and Samples}

The pharmaceutical industry spends billions of dollars each year marketing prescription drugs. Although most consumers are aware of direct-to-consumer (DTC) advertising on television and in magazines,\textsuperscript{92} this is a far less significant feature of drug marketing than promotion to physicians.\textsuperscript{93} The primary targets of the pharmaceutical industry’s promotional activities are the physicians who prescribe the drugs and, to a lesser extent, the health care organizations and pharmacy formularies that decide which drugs to stock. The Journal of the American Medical Association recently reported that 90\% of the pharmaceutical industry’s $21 billion annual marketing budget was spent on direct marketing to physicians.\textsuperscript{94} The New England Journal of Medicine estimated that the drug industry spends annually between $8,000 and $15,000 per physician in the United States to market drugs.\textsuperscript{95} Sometimes the marketing budget for the drug exceeds the amount spent on developing the drug.\textsuperscript{96} This makes economic sense in light of one


\textsuperscript{92} In 1997, the FDA loosened its rules on DTC advertising and permitted television advertising of prescription drugs. Palumbo & Mullins, \textit{supra} note 69 at 427.

\textsuperscript{93} In 2001, the drug industry spent $2.24 billion on DTC advertising, as compared to $27.7 billion on promotions to physicians. Palumbo & Mullins, \textit{supra} note 69 at 431. See \textit{infra} notes 113–15 and accompanying text.

\textsuperscript{94} Brennan et al., \textit{supra} note 90 at 430.

\textsuperscript{95} David Blumenthal, \textit{Doctors and Drug Companies}, 351 NEW ENG. J. MED. 1885, 1885 (2004). Blumenthal gives the example of Novartis, which reported spending 36\% of its revenues on marketing in 2001. \textit{Id}. The average in the industry is 33\%. \textit{Id}

\textsuperscript{96} 17 Am. Jur. Trials §5 (Supp. 2006) ("Studies of the introduction of almost any drug new to the market reveal a budgeting of funds for its promotion that rivals or exceeds the
study that found that for each dollar spent on “detailing” (i.e. promotion of the drug to physicians by representatives from the drug companies), the return was $10.29.97 This is more than seven times the return on DTC advertising.98

Typically, direct marketing involves a pharmaceutical drug representative ("drug rep") visiting a physician, group practice, or hospital, and providing small gifts such as pens and paper, as well as meals, to everyone in the office and free samples to the physicians, while at the same time promoting a particular prescription drug. Some physicians’ offices get lunch provided by drug reps every day.99 Other gifts to physicians include free continuing medical education, payment for travel and registration at meetings, and consulting fees.100 These contacts begin early in physicians’ careers when they are medical students and residents and continue from there.101 One study found that practicing physicians meet with drug reps on average 4 times per month.102

There are approximately 90,000 drug reps in the United States, approximately 1 drug rep for every 4.7 office-based physicians,103 and they have become increasingly sophisticated in their marketing techniques. Drug reps are salespeople whose compensation is directly linked to increases in the number of prescriptions written by

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97 Carl Elliot, The Drug Pushers, ATLANTIC MONTHLY, April 2006, at 82, 83.
98 Id.
100 Brennan et al., supra note 90 at 430.
101 Blumenthal, supra note 94 at 1886 (citing surveys reporting that medical residents receive an average of 6 gifts from pharmaceutical companies per year, including free samples, money for travel to meetings, and free lunches); MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES 127 (2005) (“This ‘food, flattery, and friendship,’ as it has been called, creates a sense of reciprocity in young doctors with long prescribing lives ahead of them. They naturally feel indebted to congenial people who keep giving them gifts.”).
103 Blumenthal, supra note 94 at 1886.
their targeted physicians. Drug companies recruit the most attractive and perky people they can find right out of college to be drug reps. The companies have found that cheerleaders make the best pharmaceutical sales reps and they have begun to develop relationships with cheerleading coaches to help their recruiting. One coach said of the recruiters, “They don’t ask what the major is . . . . Exaggerated motions, exaggerated smiles, exaggerated enthusiasm – they learn those things, and they can get people to do what they want.” As one journalist recently observed:

Drug reps today are often young, well groomed, and strikingly good-looking. Many are women. They are usually affable and sometimes very smart. Many give off a kind of glow, as if they had just emerged from a spa or salon. And they are always, hands down, the best-dressed people in the hospital.

The job of the drug rep is to convince doctors that they should prescribe their company’s drug. Seduction is “deliberate industry strategy,” the success of which is measured by increases in the number of prescriptions written for whatever drug is being promoted. The New York Times reported in 2006:

A former pharmaceutical representative, Kathleen Slattery-Moschkau, called lunch ‘incredibly effective’ in lifting pharmaceutical sales for the companies where she worked, Bristol-Myers Squibb and Johnson & Johnson. ‘We got the numbers of what the physicians were prescribing. If

104 Frank C. Woodside & Margaret M. Maggio, The Learned Intermediary Doctrine: Is It Eroding?, FED. LAW., Dec. 2005, at 28, 31; AVORN, supra note 96 at 303 (reporting that bonuses alone can be up to $50,000 per year for the drug rep who “moves enough product.”).


106 Id.

107 Elliot, supra note 97 at 82. Drug representatives used to be called “detail men,” a reference to “detailing” which meant providing doctors with information about the company’s drugs. See id.; Woodside & Maggio, supra note 104 at 31. Given the current demographics of the profession, drug rep seems more accurate.

108 Elliot, supra note 97.

109 See also, Melody Peterson, Suit Says Company Promoted Drug in Exam Rooms, N.Y. TIMES, May 15, 2002 at C1. (reporting on unsealed court documents showing that drug representatives persuaded doctors to allow them into the examining rooms to speak with patients.).
I brought in lunch one week, I could see the following week if that lunch had an impact,’ Ms. Slattery-Moschkau said.\textsuperscript{110}

In addition to lunch, drug reps make their case through interpersonal appeal and gifts, including the gift of prescription drug samples. One physician and Fellow of the American College of Physicians noted:

I have watched reps ‘rearrange’ our drug sample cabinet, placing their wares in front while relocating the competition out of sight — and hopefully out of mind. Drug-labeled pens, pads, coffee mugs, calendars, letter openers and penlights are standard issue in most of our offices. As a gastroenterologist, I expect to discover any day that our toilet paper has been embossed with a drug company’s logo.\textsuperscript{111}

This seduction also takes place at the organizational level. Pharmaceutical companies often provide continuing medical education to physicians, and sponsor annual meetings of physician specialists.\textsuperscript{112} Some companies offer discounted prices to managed care organizations for their drugs if those organizations agree to give their drugs “favorable treatment” in their formularies.\textsuperscript{113}

Recent scandals have resulted in drug companies cutting down or eliminating their more extravagant gifts, like free trips to resorts for “educational conferences.”\textsuperscript{114} One scandal involved drug companies inducing physicians to switch patients to their drugs by providing drugs cheaply so that the physicians could charge Medicare the market price, and pocket the difference.\textsuperscript{115} In another, a company paid physicians

\begin{footnotes}
\footnote{Saul, \textit{Drug Makers Pay for Lunch as They Pitch}, supra note 99.}
\footnote{Blumenthal, supra note 94 at 1886}
\footnote{Id.}
\footnote{Saul, \textit{Drug Makers Pay for Lunch as They Pitch}, supra note 99.}
\end{footnotes}
$1,000 for each new prescription of its drug.116 These practices demonstrate the lengths to which drug companies are willing to go to get physicians to prescribe their drugs.

In 2002, the Office of the Inspector General ("OIG") of the Department of Health and Human Services issued its first ever "draft guidance" to the pharmaceutical industry signaling that the many of these gifts might violate federal fraud and kickback statutes.117 In anticipation of the OIG’s guidelines, the Pharmaceutical Research and Manufacturers of America ("PhRMA"), the trade association for the pharmaceutical industry, issued its own Code on Interactions with Healthcare Professionals.118 This Code reaffirmed the premise for drug detailing, stating in its Preamble that its mission is to help patients and that implementing that mission requires “ensuring that healthcare professionals have the latest, most accurate information available regarding prescription medicines.”119 The code permits modest "occasional meals" in connection with the provision of information about drugs and gifts that benefit patients, including samples, as well as smaller items such as pens and notepads with the company’s logo, if they are valued at less than

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116 Douglass & Onisile, supra note 115 at 34. (discussing Biovail). Daniel Higgins describes “switching arrangements” in which the drug companies provide incentives for physicians or formularies to switch the prescriptions drugs that they prescribe or offer. The Inspector General found these practices to be “suspect under the anti-kickback statute.” Higgins, supra note 115 at 5.
$100.00. The samples, however, only trigger the $100 limit if they have monetary value to the physician, which would not be the case if the physician provides the samples to patients for free. Thus, even with the new guidelines, drug reps are not limited in the number of samples that they can distribute to physicians. As some have observed, this Code only elevated the importance of getting the most return out of smaller gifts.

The PhRMA Code ties the provision of free meals to its mission of “ensuring that healthcare professionals have the latest, most accurate information available regarding prescription medicines.” Yet drug reps are not experts in pharmacology and often provide information to physicians that “does not educate at all: it is often inaccurate and clearly intended to promote rather than educate.” A study published in the Journal of the American Medical Association found that that 11% of statements made by pharmaceutical representatives about drugs were inaccurate and the inaccuracies were generally not recognized by physicians As one observer stated

The average juror . . . would be astounded if he were to examine the volume of drug information which manufacturers unleash upon the

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120 Dana Katz, Arthur L. Caplan, Jon F. Merz, *All Gifts Large and Small: Toward an Understanding of the Ethics of Pharmaceutical Industry Gift-Giving*, 3 AM. J. OF BIOETHICS 39, 40 (2003). Interestingly, the Code appears to be intentionally ambiguous about prohibiting conduct. Its language is written in terms of items that “may” be offered and items that “should not” be offered. This contrast with other ethics codes that articulate prohibited conduct with the terms “may not” or “must not.”

121 See Ung & Robins, *supra* note 117 at 35.

122 Saul, *Drug Makers Pay for Lunch as They Pitch*, *supra* note 99 (“Doing business over lunch is a common practice in many fields, but drug makers have honed it to perfection.”).

123 Pharmaceutical Research and Manufacturers of America, PhRMA-Principles and Guidelines, http://www.phrma.org/principles_and_guidelines/ (last visited February 9, 2007)


physician. Manufacturers want to push waves of information at the physician with the clear expectation that the physician cannot, and will not, absorb all of it. Furthermore, the size of the type-face of the product information is purposely small. Also, an advertising agency will emphasize the beneficial uses, rather than the side effects, adverse reactions and contraindications. The manufacturer’s motive, however, is not deception but profit.\textsuperscript{126}

Also in response to the OIG’s proposed guidelines, the American Medical Association, the American College of Physicians, and the Accreditation Council for Continuing Medical Education issued new or revised guidelines.\textsuperscript{127} These guidelines limit gifts from pharmaceutical companies to small gifts that are intended for office use, education, or patient care.\textsuperscript{128} They permit sample distribution, in some cases even approving of their use by physicians and their families, despite awareness of the dangers of sample prescription drugs, particularly to non-patients like Mr. Vitanza.\textsuperscript{129}

Samples are the lynchpin of prescription drug marketing.\textsuperscript{130} In 2000, the drug companies spent almost $4 billion on samples alone and in 1999 they distributed (through their representatives) 766 million samples, which averages to 1,500 samples for every physician in the United States.\textsuperscript{131} In 2004, drug companies spent $27.7 billion on promotion of which $15.9 billion was spent on free drug samples and $7.3 billion on

\textsuperscript{126} Farrell, supra note 26 at 60.
\textsuperscript{127} Studdert et al., supra note 119 at 1894–97. The other organizations issuing similar new or revised guidelines were Accreditation Council for Continuing Medical Education and the American College of Physicians.
\textsuperscript{128} Id.
\textsuperscript{129} Id. at 1897. When physicians and their staffs use the drug samples they are then receiving a gift of value that should raise ethical issues about conflicts of interest. The AMA Code circumvents this issue by permitting such use if it is on a short-term or trial basis. See Leonard J. Weber, Profits Before People? Ethical Standards and the Marketing of Prescription Drugs 89 (2006)
\textsuperscript{130} Angell, supra note 101 at 129 (“Free samples are the most important gifts.”); Weber, supra note 130 at 90 (“Drug samples are the most important gifts provided to physicians by pharmaceutical company sales reps not only because of their large dollar value, but also because the samples are likely to have a significant impact on the practice of medicine.”).
\textsuperscript{131} Harris, supra note 27.
small gifts such as notepads, pens, and lunches for physicians and office staff.\textsuperscript{132} A survey of physicians across the United States in 2001 found that 92\% had accepted free samples from drug companies.\textsuperscript{133}

For a variety of reasons, free samples are an extremely effective marketing strategy for increasing the sale of prescription drugs. First, the sample is a gift to the doctor, which consciously or unconsciously triggers in many physicians a sense of gratitude and obligation.\textsuperscript{134} When drug reps pitch a prescription drug to a physician they can give the physician a sample at the same time, thereby encouraging and permitting the physician to put this new knowledge into action immediately. Second, samples are most frequently distributed for the newest and most expensive drugs. Providing a sample allows the physician in turn to be the giver of a valuable gift to patients.\textsuperscript{135} Some doctors say that giving away free samples helps them to bond with their patients.\textsuperscript{136}

Third, and most important, if the sample works for a patient, or is perceived to work, that patient is more likely to request the full prescription of that particular drug (as opposed to a generic or a different drug) and the physician is more likely prescribe that drug.\textsuperscript{137} Coupling free sample distribution with free lunches and some notepads and pens to reinforce brand recognition, creates a strong inducement to prescribe particular drugs. One trial lawyer observed that these gifts make physicians think of drug representatives as friends and the drug companies who sponsor these gifts as “surrogate ‘Santa Claus’.”

thus making it less likely that physicians will realize the drug reps might not have their or
their patients’ best interests in mind.\textsuperscript{138}

Anecdote and now many studies have verified the effectiveness of drug
promotion tied to sample distribution. Pharmaceutical companies collect data on the
prescribing practices of physicians, so drug reps are able to track the success of their
promotions.\textsuperscript{139} They know which doctors are “early prescribers” (known as ‘cowboys’
among drug reps)\textsuperscript{140} who tend to prescribe new drugs soon after they are released.
Drug reps visit these doctors early and often.\textsuperscript{141}

Numerous studies have demonstrated the effectiveness of distributing samples
and other gifts for increasing the volume of prescriptions. One researcher, after
reviewing 29 studies on the effects of contact between drug reps and physicians
concluded that these interactions affect prescribing behavior.\textsuperscript{142} This researcher found
that “[a]ccepting samples was associated with awareness, preference and rapid
prescription of a new drug, and a positive attitude toward the pharmaceutical
representative.”\textsuperscript{143} This finding has been confirmed by many others.\textsuperscript{144} One study
looked at internal medicine residents’ attitudes toward samples and found that access to
samples affected their prescribing behavior by making them more likely to prescribe

\begin{itemize}
\item \textsuperscript{138} Farrell, \textit{supra} note 26 at 72.
\item \textsuperscript{139} Stephanie Saul, \textit{Doctors Object as Drug Makers Learn Who’s Prescribing What}, N.Y.
\item \textsuperscript{140} 17 Am. Jur. Trials §5 (Cumm. Supp. 2006); Dana & Lowenstein, \textit{supra} note 118 at
252. The data on prescribing practices provided by the pharmacies is paid for by
market research firms who then sell it to the drug companies. \textit{AVORN}, \textit{supra} note 96 at
294.
\item \textsuperscript{141} \textit{Id.}
\item \textsuperscript{142} Wazana, \textit{supra} note 102 at 375–76. \textit{See also}, Phyllis Maguire, \textit{No Easy Answers
When Managing Financial Conflicts}, ACP OBSERVER, June 2005,
hp://www.acponline.org/shell-cgi/printhappy.pl/journals/news/jun05/finance.htm (last
visited Feb. 27, 2007).
\item \textsuperscript{143} \textit{Id.}
\item \textsuperscript{144} See, \textit{e.g.}, Brennan et al., \textit{supra} note 90 at 431 (“The rate of drug prescriptions by
physicians increases substantially after they see sales representatives, attend company-
supported symposia, or accept samples.” (footnotes omitted)); Harris, \textit{supra} note 27.
(citing numerous studies); Chren, \textit{supra} note 27 at 1893 (same).
\end{itemize}
those drugs and less likely to recommend over-the-counter medication than residents
without such access. As one writer observed, “‘[a]t the critical moment – the ‘point-of-
decision,’ to quote the marketers’ jargon – the drug is there, and it’s free.’” Another
study found that physicians who met with representatives of pharmaceutical companies
were five times more likely than other physicians to request that drugs made by those
companies be added to a hospital formulary.

As with many instances of conflict of interest, the bias created in physicians by
pharmaceutical promotions tends to be unintentional and unconscious. When asked
in general terms, physicians deny that gifts from drug reps affect their prescribing
practices, while also tending to believe that accepting gifts might affect their
colleagues’ decision-making. Physicians are particularly adamant that small gifts, like
samples and office trinkets, are harmless, and that accepting them is not ethically
problematic. Yet, studies have found that small gifts can be just as effective as large
ones in creating a sense of obligation in the recipient.

Social science research reveals an interesting paradox in physicians’ attitude
toward samples. When asked specifically about samples, residents and physicians
acknowledge that samples influence their prescribing patterns. For example, in one

145 Laurie Barclay, Access to Drug Samples May Influence Resident Physician
146 WEBER, supra note 129 at 85–86 (quoting KATHERINE GREIDER, THE BIG FIX: HOW
THE PHARMACEUTICAL INDUSTRY RIPS OFF AMERICAN CONSUMERS 76 (2003)).
147 Bob Goodman, Do Drug Company Promotions Influence Physician Behavior? 174
148 Dana & Loewenstein supra note 118 at 254. Susan L. Coyle, Physician-Industry
citing studies). See also, MICHAEL S. PRITCHARD, PROFESSIONAL INTEGRITY: THINKING
149 Dana & Loewenstein, supra note 118 at 253–54.
150 Id. at 254.
151 Allan S. Brett, Wayne Burr, Jamaluddin Moloo, Are Gifts From Pharmaceutical
Companies Ethically Problematic? A Survey of Physicians, 163 ARCHIVES OF INTERNAL
MED. 2213, 2216 (2003).
152 Id.
153 Blumenthal, supra note 94 at 1887.; Katz et al., supra note 120 at 40.
survey of residents and faculty at an academic medical institution, respondents indicated that drug samples did influence their choice of drugs for patients. In another survey, researchers found that over 90% of physicians whose practices used samples said they would dispense a sample that was not their first choice of drug if they had that drug in their sample closet. Another study found that 55% of surveyed family medicine residents believed that their access to samples influenced their prescribing behavior. In Wazana’s review of 29 empirical studies of interactions between physicians and drug reps, she concluded that interactions with drug reps “affect prescribing and professional behavior.” On the other hand, most physicians do not consider themselves biased and when asked whether promotional material from drug reps influences their practice, 61% percent answered in the negative.

Thus, physicians, when asked directly, admit that having samples on hand affects their prescribing habits, but at the same time they do not think that drug company promotions make them biased, even though most of them also think that such promotions do influence other physicians’ practice. These findings must be reconciled with the many studies that find that drug promotions do in fact affect prescribing practices. Reconciling them is easier if the bias created by drug promotions is unconscious – recognizable in others but not in oneself.

154 Brett et. al., supra note 151 at 2216.  
155 Harris, supra note 27 (summarizing studies). See also, Chew et al., supra note 124 at 481 (in a study of physician behavior, physicians self-reported that they would dispense samples of drugs that were not their “preferred choice” because of the perceived benefits of samples, particularly avoiding cost to patients).  
156 Chew et al., supra note 124 at 481.  
157 Wazana, supra note 102 at 376 (reviewing the literature and finding that “Samples, continuing medical education . . . and conference travel funding are felt to exert more influence (40%-50%) than promotional material does (22%)”); See also, Barclay, supra note 145 at 882.  
158 Dana & Loewenstein, supra note 118 at 254.  
159 See, e.g., Dana & Loewenstein, supra note 118 ; Brett et al., supra note 151 .  
160 Dana & Loewenstein, supra note 118 at 254.
Dana and Loewenstein have shown that physicians’ unconscious response to drug company promotions is exactly what the literature on conflict of interest would predict. That literature reveals that when people have to choose among a set of arguably fair or reasonable options, they tend to choose the one that favors their own interests, even if they are aware of the bias.\textsuperscript{161} In fact, studies have found that the more gifts a physician accepts, the less likely the physician is to believe that he or she is affected.\textsuperscript{162} Dana and Lowenstein conclude:

First, individuals are unable to remain objective, even when they are motivated to be impartial, demonstrating that self-serving bias is unintentional. Second, individuals deny and succumb to bias even when explicitly instructed about it, which suggests that self-serving bias is unconscious. Third, the studies show that self-interest affects choices indirectly, changing the way individuals seek out and weigh the information on which they later base their choices when they have a stake in the outcomes.\textsuperscript{163}

Pharmaceutical companies intentionally tap into the human predilection to reciprocate favors, and they understand that this feeling of obligation can be triggered by small gifts as well as large:

The natural tendency for people to accept gifts and kind gestures reduces their ability to choose to whom they wish to be indebted. This is how the reciprocity rule can be exploited. . . . If physicians are to reciprocate for small gifts, they cannot do so in any form they please. They are essentially compelled to reciprocate by supporting their benefactor’s products.\textsuperscript{164}

Common sense dictates that “[t]he sheer ubiquity of trinkets given by pharmaceutical companies is evidence of their effectiveness; why else would profit-minded companies

\textsuperscript{161} \textit{Id.} at 253.
\textsuperscript{162} Katz et al., \textit{supra} note 120 at 40 (citing studies).
\textsuperscript{163} \textit{Id.}
\textsuperscript{164} \textit{Id.} at 42
continue to provide them?"165 The former President of Pfizer Pharmaceuticals has even stated that "marketing 'is almost as scientific as anything we do.'"166

It is not the value of the gift but the giving of the gift that triggers the sense of obligation.167 The establishment of this "gift relationship" that creates obligation in the recipient has been well studied by social scientists and is found across cultures.168 At the same time, the pharmaceutical company that fully intends to create this sense of obligation also knows that patients will receive these drugs on a trial basis from physicians in whom they have created a bias toward dispensing, and without the written warnings that typically accompany full prescriptions.169

IV. Drug Samples and the Learned Intermediary Rule

The fact that the pharmaceutical companies intentionally create unconscious bias in physicians, with the purpose of increasing sales through distribution of gifts and free samples, weakens the justification for the learned intermediary rule in this context. The same bias that makes physicians more inclined to distribute samples of drugs that have been promoted to them also makes them less likely to be objective in learning about and then articulating the risks of those drugs to their patients. This is because physicians befriended by drug reps may take the information and misinformation provided by these

165 Dana & Loewenstein, supra note 118 at 254.
166 Katz et al., supra note 120 at 42.(quoting ERIC CLARK, THE WANT MAKERS: THE WORLD OF ADVERTISING: HOW THEY MAKE YOU BUY 208 (1989)).
167 Id. at 41 (citing research in sociology and anthropology exploring gift-giving and reciprocity).
168 Coyle, supra note 148 at 398 (citing research).
169 The written instructions and warnings provided to patients at the pharmacy are regulated by state law and state Pharmacy Boards. Provision of written instructions is common. Email from Professor Charles Krobot, Associate Dean for Academic Affairs, University of Nebraska College of Pharmacy to Susan Poser, Associate Professor of Law, University of Nebraska College of Law (December 1, 2006) (on file with author). See also, ABOOD & BRUSHWOOD, supra note 80 at 111 (noting that many pharmacies voluntarily provide written drug information when dispensing prescriptions).
“friends” in the best possible light, underestimating the risks and over estimating the benefits of the drugs. This bias is heavily promoted and reinforced by the drug reps who befriend the physicians and downplay the risks of the drugs, knowing they are protected against a failure to warn claim as long as they provide a written warning in the sample box and in the physician’s desk reference.170

It should not be surprising that patients receive minimal, and perhaps in some cases incorrect, information when receiving samples. Research involving observations of 1600 physician-patient interactions in family practice found that samples were distributed in almost 20% of office visits but “detailed patient education regarding these drugs was rarely observed in patient encounters.”171 When such education was observed, it almost always consisted of verbal instructions about dosing without discussion of drug interactions or information about other matters, such as whether the drug should be taken with meals.172

Thus, the evidence suggests that physicians are distributing samples without giving adequate warnings because they are both misinformed and they unconsciously feel obligated to those who have given them gifts, bought lunch for their staff, and paid for their continuing legal education.173 If true, this conduct is clearly negligent and physicians should be held responsible for it, as informed consent law dictates. But the law should also recognize the negligence, or even recklessness, of the drug companies who intentionally create a situation that they know will result in patients receiving

170 The unconscious nature of this bias is ironically illustrated by the AMA’s own recently revised ethics guidelines which explicitly permit gifts of drug samples despite the studies just discussed, and condones their use by physicians and their families. Studdert et al., supra note 119 at 1897.
171 Backer et al., supra note 135 at 811.
172 Id. at 815.
173 Wazana, supra note 102 at 373 (10% of continuing medical education is paid for by drug companies).
samples of prescription drugs without proper oral instructions and written instructions or warnings.

Courts already recognize that intentionally creating bias in physicians in the context of drug detailing can vitiate otherwise proper written warnings to physicians. A claim of overpromotion is a variation on the universally recognized claim of a patient against a drug company if the company does not adequately warn the physician. A patient can sue a prescription drug manufacturer directly for warning defect is she can demonstrate that the drug company or its representatives promoted its product “in such a fashion as to obscure or lessen the seller’s cautionary warnings.”\textsuperscript{174} Even if a drug manufacturer properly distributes FDA-approved warnings to physicians, it can still be held liable for failure to warn if the drug reps act in such a way as to contradict or minimize the importance of those warnings.\textsuperscript{175}

For example, in \textit{Salmon v. Parke, Davis & Co.},\textsuperscript{176} the court held that a claim for overpromotion was stated when a drug rep’s gift to a physician of a promotional calendar did not include a warning of the serious side effects of the drug it was advertising. This conduct presented a question of fact as to whether the absence of the warning on the calendar was significant enough to nullify written warnings that accompanied the drug itself and were in the possession of the physician:

It is foreseeable that a calendar might remain on a physician’s desk as a constant reminder to prescribe a drug long after the sample and its

\textsuperscript{174} M. Stuart Madden, \textit{The Enduring Paradox of Products Liability Law Relating to Prescription Pharmaceuticals}, 21 PACE L. REV. 313, 330 (2001); See also Hill v. Searle Labs., 884 F.2d 1064, 1071 n.13 (8th Cir. 1989) (noting that over-promotion may cause the physician to rely on that promotion rather than information from package inserts and warnings), Stevens v. Parke, Davis & Co., 9 Cal.3d 51 (1973) (same) ;; Caraker v. Sandoz Pharmaceuticals Corp., 172 F.Supp.2d 1018, 1030 (S.D.Ill. 2001) (“the overpromotion theory is simply that by over-promoting a product, the over-promoter has de-emphasized or diluted the full effect of the warnings.”); Love v. Wolf, 38 Cal.Rptr. 183 (1964) (same).


\textsuperscript{176} 520 F.2d 1359 (4th Cir. 1975).
warning had been removed. A jury could infer, therefore, that the absence of a warning on an advertisement for the use of a drug as potentially dangerous as chloromycetin was a form of overpromotion which nullified the effect of even a valid warning on the package.\footnote{177}

This claim is a species of negligent marketing and has been stated on other kinds of facts, such as when a drug company promotes a prescription drug for off-label use.\footnote{178} If a jury were to find this to be overpromotion, then the patient who suffered harm could get damages from the manufacturer directly for failure to warn because the manufacturer did not fulfill its duty to the physician to warn adequately.\footnote{179} The patient-plaintiff in such a case is essentially a third party beneficiary of the drug company’s duty to the physician to warn of the drug’s risks. This is a question of fact, which must be decided on a case-by-case basis.\footnote{180}

Unlike the overpromotion theory, which is a claim that the drug company failed adequately to warn the physician, the exception to the learned intermediary rule for cases involving the duty to warn of risks from sample prescriptions drugs is a claim that the drug company has an independent duty to warn the consumer of the risks from samples of prescription drugs. The practice of drug promotion is so intimately linked to sample distribution that the plaintiff should not have to demonstrate the connection in every situation. Rather, the widespread conduct and its implications for patient safety should be enough to vitiate the learned rule entirely in this context and give rise to a duty to warn. To put it simply, the physician’s possession of the sample \textit{per se} indicates that promotion has taken place.

The fact that drug companies place unlabeled samples into the chain of distribution while at the same time attempting to manipulate physicians into carelessly

distributing them to patients nullifies the standard justifications for the learned intermediary rule. As discussed above, these justifications include (1) that the physician is in the best position to evaluate the risks and benefits of the drug to the patient; (2) that the drug companies lack effective means to communicate risk; and (3) that direct warnings would interfere with the doctor-patient relationship.\textsuperscript{181}

Even though the physician has the duty to obtain informed consent from the patient, the physician is not necessarily in the optimal position to evaluate the risks and benefits of prescription drug samples. The likelihood that other factors, both conscious (the desire to continue receiving attention and gifts) and unconscious (a sense of obligation to drug reps) play a part in physicians’ decision to give a sample, indicate that the physician is not in the best position to warn about risks when distributing drug samples. This is part of the reason that some healthcare organizations now ban samples, and in some cases, drug reps as well. Many organizations, including the Mayo Clinic, Kaiser Permanente, Stanford University, the Universities of Michigan, Pennsylvania, and Wisconsin, and even some private practices,\textsuperscript{182} have instituted such bans. Many others have called for such bans and some states have considered passing

\textsuperscript{181} See, supra notes 44–54 and accompanying text.
\textsuperscript{182} Saul, Drug Makers Pay for Lunch as They Pitch, supra note 99 (University of Pennsylvania and University of Michigan Health System have banned meals provided by drug reps.); Charles Schmidt, Managing the Pharma Freebies, MODERN DRUG DISCOVERY, Sept. 2002, at 23 (Albany Medical Center, in Albany, N.Y. has banned drug samples, as has Boston University Medical Center); Fred Charatan, Hospital Bans Free Drug Samples, 174 WEST J. MED. 236, 236 (2001) (the University of Wisconsin Hospital has instituted a voucher program to replace free samples); Bonnie Darves, Too Close for Comfort? How Some Physicians are Reexamining Their Dealings with Drug Detailers, ACP OBSERVER, July 2003, http://www.acponline.org/journals/news/jul-aug03/drug.htm (last visited Feb. 27, 2007) (noting that many hospitals and physicians’ offices have banned what they call “drug detailing,” the practice of allowing drug reps. to meet with doctors and explain the benefits of their firm’s drugs); See also, Wazana, supra note 102 (identifying general concerns in the medical industry over relationships between doctors and pharmaceutical reps.).
laws banning samples.183 The drug company, which creates the physician’s conflict between her duty to her patient, on the one hand, and her own interests and those of the drug company, on the other, should bear some of the risk of the conflict. It is not that the drug company is in the best position to evaluate the needs of the patient. Rather, the drug company, by intentionally interfering with the physician’s capacity for independent judgment through its marketing practices, acts in such a way as to prevent the physician from being in the best position to evaluate the needs of patients.184

Applying the learned intermediary rule to harm from sample prescription drugs encourages the companies to attempt to influence physicians with the single goal of increasing prescriptions and without concern for the health of the patient or the absence of the safety net of written warnings from the pharmacy.185 Drug companies benefit by doctors and patients not hearing about or reading a litany of side effects. Their goal in giving samples is to hook the patient on the brand-name drug so that they subsequently request full prescriptions of that drug. As Jerry Avorn has pointed out, “[i]t’s not helpful to pretend that pharmaceutical companies are bound by a different set of economic rules that are somehow gentler or nobler than those that determine the fates of companies that sell oil, food, or hair care products.”186 As discussed above, some states require pharmacies to include medication guides with prescription drugs, and in states without such regulation, many pharmacies do so voluntarily.187 This extra layer of warning is

183 Charatan, supra note 182 at 236–37; Brennan et al. supra note 90 at 431–33 (proposing that samples be banned in academic medical centers and replaced with vouchers for low-income patients).
184 Michael Davis, Conflict of Interest in 1 BUSINESS & PROFESSIONAL ETHICS JOURNAL 17, 21 (1982) (defining conflict of interest as the professional having an interest that interferes with the professional’s ability to exercise professional judgment).
185 Katz et al., supra note 119 at 42 (“the main objective of drug company gift-giving is to create relationships and interests on the part of recipient physicians that conflict with their primary obligation to act in the best interest of their patient.”).
186 AVORN, supra note 96 at 302.
187 See ABOOD & BRUSHWOOD supra note 80 at 112; supra note 169 and accompanying text.
absent when a patient receives a sample directly from a physician, and that absence benefits the drug companies. Pharmacists play a key role in the safety of prescription drugs, a role from which they are excluded when samples are dispensed by physicians.

As one pharmacist explained:

Prescriptions are checked for proper dosing, drug-drug interactions, and disease interactions. Patients receive a printout about the medication, which includes detailed instructions for proper administration (including whether to take with food or on an empty stomach and whether or not to separate doses from other medications), side effects, warnings, and what to do in case of a missed dose. Pharmacists often provide additional instructions on proper use, as with inhalers or nasal sprays, for example. When a physician provides a sample, much of this information is neglected. The drug sample may interact with the patient’s other medications or the patient may not understand the proper administration (e.g., with or without food), proper use (e.g., inhalers), and warnings (e.g., avoid driving). In addition, there is often no instruction label, so patients may forget dosage or how often to take the medication. Patients also do not receive a drug leaflet or any other printed information. If the physician does not record the sample in the patient’s chart, there may be no documentation that the patient received the drug at all. This could be crucial in the case of a severe adverse reaction or drug allergy because patients often do not know the names of their medications.188

Drug companies should also be barred from claiming that they lack effective means to communicate the risk of samples, the second standard justification for the learned intermediary rule.189 Some drug manufacturers do in fact provide prescribing information with the sample,190 while others make implicit claims that they do. For example, one study found that 62% of the labels on the inside package of sample prescription drugs referred the user to “enclosed prescribing information” but that for 27.3% of those samples, no such information was included with the packaging of that individual sample or group of samples.191 This study included samples of some very common prescription drugs including Augmentin, Celebrex, Cipro, Coumadin, Paxil, 

188 Harris, supra note 27.
189 See supra notes 49–51 and accompanying text.
191 Id.
Prozac, Viagra, and Zithromax. The FDA only requires that a package insert be included in the larger packaging of the samples from which individual samples are removed and distributed. Furthermore, the package insert, as will be discussed below, is not intended for patients. It is trade labeling that is written in technical language and printed in very small font. Yet the drug companies purport in their inside labeling of individual samples to be directing the user to this insert. Thus, the drug companies hold themselves out to patients as capable of providing warnings, going so far as to direct users to utilize these warnings, without actually providing the warnings.

Pharmaceutical companies have many options for warning patients of risks. In the research discussed above, 31% of the samples studied included patient instruction pamphlets inside the individual boxes of samples. The drug companies can write these warnings, or use the resources that pharmacists use when they provide written information to patients about prescription drugs (most of which are probably written by the drug companies anyway).

Finally, it is implausible to claim that the learned intermediary rule in this context protects the doctor-patient relationship and that providing warnings on sample prescription drugs would interfere with that relationship. The promotion techniques used by drug reps are intended to interfere with that relationship by creating an unconscious

192 Id. at 2088.
193 See infra notes 228–31 and accompanying text.
194 Abood and Brushwood, in discussing voluntary provision of patient information by pharmacies state that not all pharmacies provide such information, and they continue

This lack of provision of written information to patients by pharmacists is difficult to understand because materials are available from several sources, including the American Pharmaceutical Association, the United States Pharmacopeial Convention (USPC), the American Society of Health System Pharmacists, and the National Community Pharmacists Association . . . . The USPC publishes a four-volume set of books known as the USP-Dispensing Information. This publication provides drug information for both the pharmacist and the patient.

ABOOD & BRUSHWOOD, supra note 80 at 112.
bias and sense of obligation in physicians. The risk of unlabeled samples is then imposed on a public that is largely not aware of drug company aggressive promotions to physicians and the bias it creates.

For these reasons, sample prescription drugs present a stronger case for an exception to the learned intermediary rule than either DTC advertising or contraceptives. Fundamentally, the learned intermediary rule addresses the issue of who is the “more efficient purveyor of information” to the patient. Advertising does not necessarily prevent the physician from remaining the most efficient purveyor of information. Even when DTC advertising is seen by the patient, the patient still has to ask the physician for the drug and receive a prescription, so the physician arguably remains the more efficient conveyer of information about the risks and side effects of the drug.

DTC advertising, if it is misleading, misleads people into thinking they need a drug or misleads them about the safety of a drug. This type of advertising is aimed at the patient, which should not affect the physician’s decision-making and communication process, except to the extent that it might require the physician to discuss a drug that she might not otherwise have considered if the patient requests it, and perhaps disappoint a patient who had requested a particular drug. The physician is arguably an equal or stronger counterweight to the influence of advertising because she is seeing the patient in-person and know that particular patient’s condition.

Doctors are not the most efficient purveyors of information as to samples, however. Marketing to physicians is intended to affect, even interfere with, their

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195 See supra notes 153–69 and accompanying text.
196 Katz et al., supra note 120 at 42 (“Patients tend to be aware that physicians accept gifts, unaware whether their own physicians accept gifts, and feel that gifts are more influential and less appropriate than do their physicians”).
197 Ausness, supra note 45 at 106–7.
198 Id.; see also Paytash supra note 43 at 1356 (noting that most courts do not see DTC advertising as something that should create an exception to the learned intermediary rule, but that at least one court has suggested, in dicta, that it could).
relationship with their patients and create a bias in favor of using a drug which the
patient, presumably unaware of the pressures on the physician, is not in a position to
counter. It is, of course, likely that drug companies will advertise a drug in the mass
media while at the same time promoting it to physicians. For those drugs, the physician
is in a doubly difficult position when it comes to warnings.

The case for an exception to the learned intermediary rule for drug samples is
also stronger than the case for contraceptives. In *MacDonald*, discussed above, the
court emphasized the fact that patients on oral contraceptives are likely to have
questions about side effects between annual office visits and therefore need warnings
written in clear, lay language to which they can refer. But in that case, as with most
prescription drugs, some written warnings were made available to the patient. There
was an FDA-required medication insert, and possibly voluntary or state-mandated
warnings and instructions that accompanied the drug when it was dispensed at the
pharmacy.

Sample prescription drugs are distributed to patients in an entirely different
context. The drug companies know that samples are not individually labeled and that
they are separated from the insert that is included in the sample box. They also know
that the safety net of pharmacy warnings will not be present. It is common knowledge
that people often do not use all of the samples that they are given and they place them
in medicine cabinets where, unlike other prescription and over-the-counter drugs, they
remain without instructions and warnings to alert others to their contents and risks.

There are both legal and prudential objections that might be raised to the
proposition that the law should carve out an exception to the learned intermediary rule

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199 Together, of course, these influences could be considered overwhelmingly against
patient interests by “heighten[ing] the tension between current marketing practices and
good patient care.” Brennan et al., *supra* note 90 at 431.
201 *See infra* note 247 and accompanying text.
for harm resulting from prescription drug samples. On the legal side, even if a court were persuaded by the claims in this article about the advantages of the exception for samples, the drug companies would still be able to raise a claim of regulatory compliance and preemption.²⁰² That is, even without the shield of the learned intermediary rule, the drug companies should not be liable for failure to warn of the risks from prescription drug samples because they complied with federal regulations regarding the labeling of samples and, additionally, imposing liability would interfere with the federal scheme of prescription drug regulation. On the prudential side, there are several potential objections, including the relative fault of physicians in these situations, and the downsides of a liability rule that might lead drug companies either to increase warnings on samples or eliminate the distribution of samples entirely. These downsides include expense, waste, overwarning, and the loss of the benefits to doctors and patients, particularly poor patients, of free samples. Finally, one might object that addressing the problem of unlabeled samples through liability in tort is not the optimal or most efficient way to deal with the problem of marketing of prescription drugs. I will address each of these in turn.

V. The Regulatory Compliance & Preemption Defenses

Even if a judge-made exception to the learned intermediary doctrine were recognized, drug manufacturers might still raise two related legal defenses: regulatory compliance and preemption. Under the “regulatory compliance” defense,²⁰³ the drug company can claim that its compliance with federal regulations renders its conduct not negligent. That is, compliance with FDA regulations constitutes not the minimal

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²⁰² For a discussion of these defenses, see infra Part V.
acceptable conduct but rather the extent of the duty to label prescription drugs. The preemption defense is that the FDA regulates warning labels on prescription drugs and specifies the type of instructions and warnings that must be placed on individual samples. Any decision by a state court that drug manufacturers should have placed warning labels on drug samples beyond FDA requirements should be preempted by the FDA regulations because such a decision would conflict with Congress’s regulatory scheme.

Neither of these related defenses should prevent a finding that drug manufacturers have a duty to warn patients of the risks of prescription drug samples. Regulatory compliance is usually considered good evidence of reasonable conduct, but is not dispositive on the issue. The Restatement (Third) of Torts: Products Liability confirms this widely adopted view of regulatory compliance in general, and as it applies to government-mandated warnings on prescription drugs, by recognizing that compliance with such warnings does not necessarily preclude state tort liability.

The proposition that FDA approval of drug warnings preempts state law claims for inadequate warnings has gained traction in recent years both in the courts and among some scholars. In the Preamble to a recent revision of drug labeling rules, the FDA itself stated that it intends its regulations to preempt state law claims. Upon

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205 Restatement (Third) of Torts: Products Liability § 4(b) (1997) states:

a product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, but such compliance does not preclude as a matter of law a finding of product defect

206 Restatement (Third) of Torts: Products Liability §6 cmt. b (1997).

207 This “preemption by preamble” is a growing phenomenon among federal agencies and appears also in recent regulations by the Consumer Product Safety Commission and the National Highway Traffic Safety Administration. See Catherine M. Sharkey,
closer inspection, however, the case of drug samples can be distinguished from even the most expansive view of federal preemption in the drug-labeling context. The overriding reason why preemption and regulatory compliance should not prevent claims against drug manufacturers for failing to warn is that the FDA’s attention to sample prescription drug labeling is cursory and not an integral part of its prescription drug labeling scheme.

Before discussing the role that these defenses might play in the context of litigation involving harm from a sample prescription drug, it is useful to review briefly how Congress and the FDA regulate sample prescription drugs.

A. Federal Regulation of Prescription Drug Samples

Prescription drugs are regulated by the FDA acting under the authority of the Food, Drug, and Cosmetic Act of 1938208 (FDCA) as amended by the Prescription Drug Marketing Act of 1987 (PDMA).209 The PDMA’s attention to drug samples is primarily to outlaw their sale and to limit their distribution with the aim of shutting down the black market in prescription drugs.210 Under the law, “No person may sell, purchase, or trade or offer to sell, purchase, or trade any drug sample.”211 The Act defines a drug sample as “a unit of a drug, subject to subsection (b) of this section (section (b) defines prescription drugs), which is not intended to be sold and is intended to promote the sale

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of the drug.\textsuperscript{212} Distribution of samples (as opposed to sale) is limited by the Act to manufacturers and authorized distributors,\textsuperscript{213} and the provision of samples by certain health care providers to patients is not considered distribution under the Act.\textsuperscript{214} Thus, Congress implicitly acknowledged the legality and ubiquity of samples as promotional material and sought in the PDMA to prevent them from getting into the wrong hands.

The statute sets out the requirements for the distribution of drug samples to physicians, health care professionals, and health care entities such as hospitals or pharmacies.\textsuperscript{215} These requirements include a written request for the sample by a practitioner licensed to prescribe, and execution of a written receipt by the recipient that is returned to the drug manufacturer. The Act also contains requirements for the proper storage and inventory of drug samples.\textsuperscript{216}

\begin{flushleft}
\textsuperscript{212} \textit{Id.}
\textsuperscript{214} \textit{Id.}
\textsuperscript{215} \textit{Id.}
\textsuperscript{216} \textit{Id.}
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The pertinent provisions state in full:

(d) Distribution of drug samples

(1) Except as provided in paragraphs (2) and (3), no person may distribute any drug sample. For purposes of this subsection, the term "distribute" does not include the providing of a drug sample to a patient by a—

(A) practitioner licensed to prescribe such drug,
(B) health care professional acting at the direction and under the supervision of such a practitioner, or
(C) pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample pursuant to paragraph (2) or (3).

(2) The manufacturer or authorized distributor of record of a drug subject to subsection (b) of this section may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or other health care entities. Such a distribution of drug samples may only be made

(i) in response to a written request for drug samples made on a form which meets the requirements of subparagraph (B), and
(ii) under a system which requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and the return of the receipt to the manufacturer or authorized distributor of
(3) The manufacturer or authorized distributor of record of a drug subject to subsection (b) of this section may, by means other than mail or common carrier, distribute drug samples only if the manufacturer or authorized distributor of record makes the distributions in accordance with subparagraph (A) and carries out the activities described in subparagraphs (B) through (F) as follows:

(A) Drug samples may only be distributed—
   (i) to practitioners licensed to prescribe such drugs if they make a written request for the drug samples, or
   (ii) at the written request of such a licensed practitioner, to pharmacies of hospitals or other health care entities. A written request for drug samples shall be made on a form which contains the practitioner's name, address, and professional designation, the identity of the drug sample requested, the quantity of drug samples requested, the name of the manufacturer or authorized distributor of record of the drug sample, the date of the request and signature of the practitioner making the request.

(B) Drug manufacturers or authorized distributors of record shall store drug samples under conditions that will maintain their stability, integrity, and effectiveness and will assure that the drug samples will be free of contamination, deterioration, and adulteration.

(C) Drug manufacturers or authorized distributors of record shall conduct, at least annually, a complete and accurate inventory of all drug samples in the possession of representatives of the manufacturer or authorized distributor of record. Drug manufacturers or authorized distributors of record shall maintain lists of the names and address of each of their representatives who distribute drug samples and of the sites where drug samples are stored. Drug manufacturers or authorized distributors of record shall maintain records for at least 3 years of all drug samples distributed, destroyed, or returned to the manufacturer or authorized distributor of record, of all inventories maintained under this subparagraph, of all thefts or significant losses of drug samples, and of all requests made under subparagraph (A) for drug samples. Records and lists maintained under this subparagraph shall be made available by the drug manufacturer or authorized distributor of record to the Secretary upon
Apart from making it explicitly legal, the provision of free drug samples by health care practitioners to patients is not addressed in the statute. Federal law also prohibits the introduction into commerce of any drug that is misbranded.\footnote{217} Misbranding includes labeling that is false or misleading.\footnote{218} Although drugs are considered misbranded if they are packaged without certain information such as the name of the manufacturer and a statement of the contents, there is an exception for “small packages,” as determined by the FDA.\footnote{219} Thus, with the exception of rather stringent statutory language intended to prevent a market in prescription drug samples, Congress itself did not focus on samples in its statutory scheme concerning the distribution and labeling of prescription drugs.

Under the authority of the FDCA and PDMA, the FDA further regulates samples and the labeling of prescription drugs. Its most stringent regulation of samples picks up on the PDMA’s prohibition on the sale of samples and its concern with a black market. The FDA specifies many aspects of the transaction between drug manufacturers and health care practitioners, including the content of the request and receipt and who must sign for them.\footnote{220} There are different regulations for distribution by mail as opposed to in-person by representatives of drug companies;\footnote{221} provisions on the proper storage and

\begin{itemize}
  \item \textbf{(D)} Drug manufacturers or authorized distributors of record shall notify the Secretary of any significant loss of drug samples and any known theft of drug samples.
  \item \textbf{(E)} Drug manufacturers or authorized distributors of record shall report to the Secretary any conviction of their representatives for violations of subsection (c)(1) of this section or a State law because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.
  \item \textbf{(F)} Drug manufacturers or authorized distributors of record shall provide to the Secretary the name and telephone number of the individual responsible for responding to a request for information respecting drug samples.
\end{itemize}

\footnote{217}{21 U.S.C. § 33(a) (2000).}
\footnote{218}{21 U.S.C. § 352(a) (2000).}
\footnote{219}{21 U.S.C. § 352(b) (2000).}
\footnote{220}{See Romanski, supra note 209 at 653–54.}
\footnote{221}{Niezgoda & Richardson, supra note 210 at 769–64.}
handling of samples;\textsuperscript{222} and rules about donation of drug samples to charity.\textsuperscript{223} These regulations follow logically from Congress’ stated concern with a black market in sample prescription drugs.

There are several kinds of FDA-approved labeling for prescription drugs. The first goes by several names, including “professional labeling”, “package insert,” “direction circular,” or “package circular.”\textsuperscript{224} This is the labeling that is written for the physician to educate the physician about the drug so that the physician can prescribe the drug appropriately and properly counsel patients.\textsuperscript{225} These labels accompany drugs when the manufacturer sends them to the pharmacy, and they also must be put in the Physician’s Desk Reference (PDR), the standard reference source about prescription drugs for physicians.\textsuperscript{226} Under the learned intermediary rule, it is with this kind of labeling that the drug manufacturer fulfills its duty to warn the physician and the pharmacist. The content of these inserts must be in 8-point type.\textsuperscript{227}

“Trade labeling” is the labeling that is “on or within the package from which a prescription drug is to be dispensed.”\textsuperscript{228} Trade labeling must also accompany packages of samples when they are distributed to physicians.\textsuperscript{229} The FDA has found that

\textsuperscript{222} 21 C.F.R. § 203.32 (2006).
\textsuperscript{225} Id.
\textsuperscript{226} Ausness supra note 45 at 100; Victor E. Schwartz & Phil Goldberg, A Prescription For Drug Liability and Regulation, 58 OKLA. L. REV. 135, 160 (2005); Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3972 (citing studies showing that the PDR is “the most frequently used reference book in a clinical setting”).
\textsuperscript{227} Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3971.
\textsuperscript{228} Id. at 3979.
\textsuperscript{229} Id. See supra notes 87–89 and accompanying text for discussion of package inserts.
physicians tend to reference trade labeling substantially less often than other types of labeling. \textsuperscript{230} The contents of trade labeling must be in 6-point type. \textsuperscript{231}

Certain promotional materials that accompany prescription drugs must also be properly labeled in 8-point type. Promotional materials that require labeling include virtually all kinds of printed, visual, and audio matter supplied by a manufacturer that describe a drug. \textsuperscript{232} This type of labeling must also receive FDA approval. \textsuperscript{233} All of the labeling thus far described is written by drug manufacturers and addressed to healthcare providers, not patients, as part of the duty to disclose.

FDA-approved patient labeling, also known as medication guides or patient package inserts, is intended for patients and is required for certain prescription drugs. \textsuperscript{234} In the 1970’s, the FDA required medication guides for oral contraceptives. \textsuperscript{235} These were the medication guides at issue in the \textit{MacDonald} case. \textsuperscript{236} Since then, the FDA has required patient labeling for asthma inhalation medicines and IUD’s, among others. \textsuperscript{237} In 1979, and again in 1995, the FDA proposed rules requiring patient package inserts for nearly all prescriptions drugs, but in both cases the rules were eventually withdrawn

\textsuperscript{230} \textit{Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products}, 71 Fed. Reg. at 3958.
\textsuperscript{231} \textit{Id.} at 3955.
\textsuperscript{233} \textit{Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products}, 71 Fed. Reg. at 3957.
\textsuperscript{234} See, \textit{e.g.}, 28 C.F.R. § 208.1(c) (2006) (“Patient labeling will be required if the FDA determines that one or more of the following circumstances exists:(1) The drug product is one for which patient labeling could help prevent serious adverse effects (2) The drug product is one that has serious risk(s) (relative to benefits) of which patients should be made aware because information concerning the risk(s) could affect patients’ decision to use, or to continue to use, the product. (3) The drug product is important to health and patient adherence to directions for use is crucial to the drug's effectiveness.”)

\textsuperscript{235} \textit{MacDonald} v. Ortho Pharmaceutical Corp. 475 N.E.2d 65, 67 (Mass. 1985); Walsh et al., \textit{supra} note 34 at 823.
\textsuperscript{236} MacDonald, 475 N.E.2d at 67.
\textsuperscript{237} Paytash, \textit{supra} note 43 at 1354; Walsh et al., \textit{supra} note 34 at 829.
because of opposition from the pharmaceutical industry.\textsuperscript{238} Yet, in 1996, an FDA representative stated that “[i]n this day and age . . . it is inconceivable that a patient should leave the pharmacy without written advice about how to get the maximum benefit out of their medication.”\textsuperscript{239}

In January 2006, the FDA revised the labeling regulations for package inserts for prescription drugs. This is the type of labeling directed at health care providers, not patients. The changes to the regulations were designed “to make it easier for health care practitioners to find and read information important for the safe and effective use of prescription drugs.”\textsuperscript{240} The changes involved reorganization and format changes to labels; some graphics changes; and the addition of a table of contents and a ‘highlights’ section to draw attention to the most important prescribing information.\textsuperscript{241} The FDA now requires 8-point type on all types of labeling (e.g. package inserts and promotional materials) except trade labeling (e.g. the labeling that accompanies packaging of samples), which only requires 6-point type.\textsuperscript{242} This is consistent with findings that physicians tend not to consult trade labeling.\textsuperscript{243} The revised regulations were aimed at health care providers who make the decision whether to prescribe a drug and have the duty to inform the patient about the risks and benefits of the drugs.\textsuperscript{244} These revisions

\textsuperscript{238} Walsh et al., \textit{supra} note 34 at 830.
\textsuperscript{241} \textit{Id.}
\textsuperscript{243} See \textit{supra}, note 230 and accompanying text.
\textsuperscript{244} Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3922 (citing 21 U.S.C. § 353(b), which defines prescription drugs as those that have certain properties making them “not safe for use except under the supervision of a practitioner licensed by law to administer such drug.”).
were part of a larger FDA initiative to make prescription drugs safer. The initiative includes regulations promulgated in 2004 requiring bar codes on certain drugs, which are intended to permit health care practitioners to scan drugs before dispensing them in order to reduce errors in hospitals. In January 2007, the FDA issued a report announcing that it would study and improve its oversight of the safety of prescription drugs after they reach the market.

The FDA takes a much less rigorous approach to the labeling of prescription drug samples than to the labeling of prescription drugs in general. The FDA requires minimal labeling on the sample unit itself. The unit must contain a control or lot number so that it can be tracked (records of those lot numbers must then be retained by the distributor of the sample), and it must contain language indicating it is not for individual sale. The 2006 revisions of prescription drug labeling regulations address samples only insofar as the new regulations affected trade labeling. Although the FDA received comments asking them to provide more information on drug sample units, the FDA declined to make the change, citing the already existing requirement that trade labeling be included in the packaging of sample units.

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245 See, 21 C.F.R. § 201.25 (2006). The bar code requirements in the 2004 regulations do not apply to samples. 21 C.F.R. § 201.25(b)(1)(i)(A) (2006). See also, Bar Code Label Requirement for Human Drug Products and Biological Products, 69 Fed. Reg. 9120, 9123 (February 26, 2004) (codified at 21 C.F.R. Pts. 201, 606, and 610) (“We proposed to exclude prescription drug samples because most samples are given to patients at physicians’ offices, and we did not believe that physicians or patients would have or be inclined to buy bar code scanners for their own use in the immediate future.”)


248 Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3979.

249 Id. See also, 21 C.F.R. § 201.56(b) (2006). Trade labeling requirements include:

(1) Labeling on or within the package from which the drug is to be dispensed
This brief tour through the federal scheme of regulation of samples and prescription drug labeling demonstrates that neither Congress nor the FDA has made sample prescription drugs a key focus of their prescription drug labeling scheme. The focus of federal regulation of samples is on preventing a black market by prohibiting their sale and regulating their distribution to health care providers. The FDA’s labeling concerns focus primarily on getting the right kind of information in the right format to the health care providers and pharmacists so that they can make appropriate prescribing and dispensing decisions and effectively counsel patients. The package insert plays a dual role – it is both included with the prescription drug when it goes to the pharmacy so that the pharmacist knows what she is dispensing and can run drug interaction checks, and it is placed in the Physician’s Desk Reference for the physician or other health care provider. These parallel warning tracks are an important part of the FDA’s regulatory scheme. The provision of unlabeled samples to a patient disrupts rather than reinforces the FDA’s focus on providing adequate information to healthcare professionals so that they can adequately counsel patients.

B. The Preemption and Regulatory Compliance Defenses

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bears adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented. 21 C.F.R. 201.100(c) (2006).

250 For example, the new format of the package inserts includes a Patient Counseling Information Section, which is prominently displayed. U.S. Food and Drug Administration, Information for Healthcare Professionals on FDA’s New Prescribing Information for Drugs, http://www.fda.gov/cder/regulatory/physLabel/physLabel_HCP.htm (last visited February 19, 2007).
Preemption is an affirmative defense that liability based on state law should be foreclosed because it would interfere with Congress’ comprehensive scheme to regulate. Historically, the preemption analysis begins and ends with Congressional intent.\textsuperscript{251} The doctrine, rooted in the Supremacy Clause of the Constitution,\textsuperscript{252} is divided into express preemption, which bases preemption on language in the statute that shows Congress’ express intent to override state law, and implied preemption, where the courts look to the overall purposes and effects of the statute and regulatory scheme to discern if Congress intended to foreclose alternative state requirements. Implied preemption is further divided into the sometimes-overlapping categories of conflict and field preemption. Conflict preemption applies to situations where state requirements would conflict with the federal regulatory scheme, and field preemption applies in situations where the courts discern that Congress intended federal regulation to cover the entire substantive field to the exclusion of state requirements.\textsuperscript{253} The Supreme Court has clearly held that federal law can preempt not just state laws that address the same subject as federal law, but also state tort liability insofar as the latter acts as a form of regulation by imposing damages and creating strong incentives for defendants to change their conduct to avoid liability:

\begin{quote}
\text{‘[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy.’}\textsuperscript{254}
\end{quote}

\textsuperscript{251} Cipollone v. Liggett Group, 505 U.S. 504, 516 (1992); Sharkey, supra note 207 at 5 (“Congressional intent is at the heart of conventional preemption analysis.”).
\textsuperscript{252} U.S. Const. Art. VI, cl. 2 (the laws of the United States “shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.”).
Because there is no express preemption in the FDCA concerning the duty to warn on prescription drugs, preemption would have to be implied. Courts will find implied preemption of a state common law duty to warn if the drug company cannot comply with the state law duty and the federal law at the same time, or if the common law duty will be an obstacle to the implementation of Congress’ purpose in enacting the federal law. The Supreme Court has stated that federal statutes should, at least initially, be subject to a “presumption against preemption,” particularly in areas of law that the States have historically regulated.

Because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action. In all pre-emption cases, and particularly in those in which Congress has "legislated ... in a field which the States have traditionally occupied,"

The health and safety of its citizens is one of those fields traditionally occupied by state law.

Up until relatively recently, the FDA itself took the position that state tort liability was generally not preempted by prescription drug labeling regulations. In originally promulgating its rules for patient labeling of prescription contraceptives, the FDA was

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255 Hall, supra note 38 at 229.
259 Caraker, 172 F. Supp. 2d at 1032.
260 See Caraker, 172 F. Supp. 2d at 1036 ("there is evidence that the FDA has seen the utility of state products liability claims despite their approval of the prescription drug in question. See, e.g., 59 Fed.Reg. 3944, 3948 (1994) (codified at 21 C.F.R. § 20.63(f)) (‘FDA recognizes the sophistication and complexity of private tort litigation in the United States and the proposed preemption action is not intended to frustrate or impede tort litigation in this area. Indeed, FDA recognizes that product liability plays an important role in consumer protection.’) 44 Fed.Reg. 37,434, 37,447 (1979)"); This regulation section has now been amended, see 21 C.F.R. § 20.63(f) (2006); OWEN, supra note 47 at § 14.4.
aware that the regulations might be used to bolster an independent state tort duty on the
drug manufacturers to provide patient information. As a result, the FDA stated that this
labeling was “not intended to ‘affect adversely the standard of civil tort liability which is
imposed on drug manufactures and dispensers.’”261 In other words, the federal
requirements per se should not give rise to other duties.262 The FDA labeling regulation
rather serves “primarily as an informational adjunct to the physician-patient encounter
and is intended to reinforce and augment oral information given by the physician to the
patient at the time the drug is prescribed.”263 In MacDonald, the court was careful to say
that it was not basing the exception to the learned intermediary rule on the fact that
patient warnings were required by federal regulations. The court instead found
independent reasons for the duty to warn, such as the patient’s involvement in the
decision to use contraceptives and the need for written instructions and warnings
between office visits.264

This ought to mean that in the case of labeling of prescription drug samples, the
minimal FDA requirements for labeling should also not affect state tort liability by limiting
the duties owed by manufacturers to consumers of their prescription drugs under state
tort law. Seemingly in agreement, as recently as 2000, the FDA stated that its labeling
regulations did not preempt state law.265 For the most part, courts have interpreted the
FDCA not to foreclose state tort liability for failure to warn of risks from prescription
drugs, even when the drug manufacturer had complied with federal labeling

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261 Walsh et al., supra note 34 at 867, n.178 (quoting 43 Fed. Reg 4214, 4214 (1978)
(codified as 21 C.F.R. pt. 310)).
262 Id.
263 Id.
2006).
requirements. Courts have interpreted Congress’ intent in passing the FDCA and delegating rulemaking to the FDA to create minimal standards for warnings on prescription drugs, which drug companies and state law may enhance with more extensive information.

One of the reasons that courts have rejected implied preemption for prescription drug labeling is that the FDA regulations themselves permit drug manufacturers to add warnings to labels if the manufacturers discover new side effects that warrant warnings after their labels have been approved by the FDA. Under the FDA’s regulations, labels must be revised “as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been provided.” The manufacturer can make these changes without FDA approval, as long as the FDA is notified.

An illustrious case is Caraker v. Sandoz. The plaintiff in Caraker suffered a stroke after taking the drug Palodel, a postpartum lactation-control drug. The court held that Illinois’ common law duty to warn was not preempted by the FDCA or the FDA’s regulations about prescription drug labeling because the FDA standards were intended to be minimum standards. The FDA permitted and even encouraged state

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267 Robert Rabin correctly points out that, notwithstanding what courts say, the FDA itself does not really consider its approval of new prescription drug labeling to be providing for a bare minimum of safety. Rather, it is engaging in a risk benefit analysis in order to provide the optimal amount of information communicated in the optimal manner. Rabin, supra note 203 at 2055–56. This does not preclude states from imposing more stringent standards, but it does make language about minimal standards somewhat misleading.
269 21 C.F.R. § 314.70(c) (2006).
270 172 F. Supp. 2d 1018 (S.D. Ill. 2002).
271 Id. at 1022.
272 Id. at 1031-32.
law to require pharmaceutical companies to include known risks, even if discovered after
the labeling had been approved by the FDA. 273

This interpretation of Congress’ intent is different from courts’ interpretation of
Congress’ intent in other health and safety statutes that address warnings. For example,
in statutes dealing with medical devices, 274 nonprescription drugs, 275 and cigarettes, 276
courts have found preemption in failure to warn cases, based on the express language
of the statute.

There is a legitimate concern that imposing tort liability on drug manufacturers
who are in compliance with federal labeling requirements will lead drug companies to
overwarn, perhaps increasing the content of their warning labels to the extent that they
render all of the warnings ineffective. 277 This is a good reason for the regulatory
compliance defense for drug labeling:

273 Id.
274 Medical Device Amendment to the Food, Drug and Cosmetics Act, 21 U.S.C. §
360k(a) (2000) (“no State or political subdivision of a State may establish or continue in
effect with respect to a device intended for human use any requirement-- (1) which is
different from, or in addition to, any requirement under this chapter to the device, and (2)
which relates to the safety or effectiveness of the device or to any other matter included
in a requirement applicable to the device under this chapter.”). See Buckman v.
claim); but see Medtronic v. Lohr, 518 U.S. 470 (1996) (finding no preemption for design
defect in pacemaker under the Medical Device Amendments to the FDCA.).

general Except as provided in subsection (b), (c)(1), (d), (e), or (f) of this section, no
State or political subdivision of a State may establish or continue in effect any
requirement—(1) that relates to the regulation of a drug that is not subject to the
requirements of section 353(b)(1) or 353(f)(1)(A) of this title; and (2) that is different from
or in addition to, or that is otherwise not identical with, a requirement under this Act, the
Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair
Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

on smoking and health shall be imposed under State law with respect to the advertising
or promotion of any cigarettes the packages of which are labeled in conformity with the
provisions of this chapter.”).

277 Walsh et al., supra note 34 at 874, n.203; Howard Latin, “Good” Warnings, Bad
pharmaceutical companies have real incentives to adopt a warnings strategy that warns of nearly everything. Such a warnings strategy conflicts, however, with the FDA's regulatory goals of both reliability and brevity. Overwarning is also not in the interests of consumers because it hinders the ability of health care professionals to distinguish the relative risks posed by various drugs. Some courts have correctly recognized that the present litigation environment creates incentives for manufacturers to adopt a warnings strategy that actually hinders these goals.278

It has been shown that people who are given too many warnings tend to be unable to differentiate between the more and less significant warnings and either ignore all of them, or place too much significance on minimal risks.279 As discussed above, this is one of the main justifications for the learned intermediary rule - that physicians are more competent than patients to weigh risks appropriately, determine if the risks of the prescription drugs are worth the benefits, and communicate the decision to the patient.280 The issue of overwarning is an important consideration in the labeling of non-prescription, over the counter drugs where there is no learned intermediary and where Congress, in giving regulatory authority to the FDA, has expressly preempted state tort liability over failure to warn.281

Despite the history of non-preemption in this area, recent statements by the FDA and recent Supreme Court rulings have raised new questions about preemption. Over the past six years, the FDA has been on a campaign to have its regulations on

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279 Id.
280 See supra note 44 and accompanying text.
281 Underwarning can also present a problem. The need to find and maintain a balance in warning sometimes leads the FDA to initially approve labels that it later determines are inadequate, as is demonstrated in the recent FDA rule that will require stronger warnings on products containing acetaminophen (which can cause liver damages) and ibuprofen (which can cause gastrointestinal bleeding). See Stephanie Saul, Warnings Proposed for Over-the-Counter Drugs, N.Y. TIMES, December 20, 2006 at A18 (“The proposed warnings — about possible liver failure from acetaminophen and gastrointestinal bleeding from other medicines like aspirin, ibuprofen, naproxen and ketoprofen — follow alarms about overusing such medications.”)
prescription drug labeling preempt state law, despite the absence of express preemption in the statute and the long history of the FDA’s own position against preemption. The FDA’s new position first came to light most prominently in an amicus brief that the it filed in 2002 in the case of *Motus v. Pfizer*.282 That case involved the issue of whether Pfizer, the manufacturer of the prescription anti-depressant drug Zoloft, should have warned of the risk of suicide.283 Pfizer was sued by the wife of a man who had committed suicide shortly after he began taking Zoloft for depression. The Motus court upheld the district court’s grant of summary judgment to the defendant based on causation and never reached the preemption argument.284 But the FDA’s preemption brief has nevertheless garnered a lot of attention because it is now understood as the first salvo in the FDA’s attempt to strengthen the preemptive effect of its regulations.285

The main argument in the “Motus brief” is summed up in the following excerpt from the brief:

The FDA, the federal agency charged with regulating the manufacture, sale, and labeling of prescription drug products, has a clear interest to

282 358 F.3d 659 (9th Cir. 2004).
283 Because of the learned intermediary rule, the plaintiffs alleged that the warning about suicide should have been made to the prescribing physician, not to the patient. See *Motus*, 358 F.3d at 660.
284 *Motus*, 358 F.3d at 661. The Eastern District of Texas, however, did reach the preemption issue in *Cartwright v. Pfizer*, and found no preemption based on state law about prescription drug warnings. 369 F.Supp.2d 876, 881 (E.D.Tex. 2005).
285 This attempt is part of a larger strategy of the administration of George W. Bush to use the preemption doctrine to prevent consumers from suing drug manufacturers for product defects. See Jonathan V. O’Steen, *The FDA Defense: VIOXX and the Argument Against Federal Preemption of State claims for Injuries Resulting from Defective Drugs*, 48 ARIZ. L. REV. 67, 77 (2006) (“The Bush Administration contends that lawsuits encourage drug manufacturers to withdraw beneficial medications from the market or provide warnings that overemphasize risks, to the detriment of patients”); Robert Pear, *In a Shift, Bush Moves to Block Medical Suits*, N.Y. TIMES, July 25, 2004, at A1; Gary Young, *FDA Strategy Would Pre-Empt Tort Suits. Does It Close Off Vital Drug Data?* NAT’L L. J., March 1, 2004 at 1 (“Under the Bush administration, the U.S. Food and Drug Administration (FDA) has adopted a novel legal strategy that would, if successful, leave many consumers claiming injury from pharmaceuticals or medical devices with no recourse to tort law, critics and attorneys charge. That strategy is pre-emption, basically the nullification of state actions that conflict with or supplement FDA decisions.”).
ensure that state tort law does not undermine the agency’s authority to protect the public health through enforcement of the FDCA’s prohibition against false or misleading labeling of drug products. To require a warning of a supposed danger that FDA concludes has no actual scientific basis, no matter the warning’s language, would be to require a statement that would be false or misleading, and thus contrary to federal law.286

Notably, this statement incorporates the Supreme Court’s position that, for the purposes of preemption, tort liability for failure to warn is the functional equivalent of state regulation.287 The FDA considers it so unlikely that a drug company would not change its label after losing a lawsuit based on failure to warn and decide instead to take its chances with future juries, that the FDA simply equates one loss in a lawsuit to a state-imposed labeling requirement. Regardless, the FDA’s reasoning is fairly simple: since it is responsible for determining both what should be included on a prescription drug label and what constitutes misbranding,288 the FDA’s determination of what should be included on a prescription drug label means that anything else on that label would be misbranding per se. These determinations are an integral part of the FDA’s other main task, which is to determine which drugs are safe and effective.289 In the case of Zoloft, the FDA had weighed the evidence of a link between the drug and increased risk of suicide and decided that there was no causal connection,290 so to warn of one would amount to placing false information on a label.291 The FDA characterized this as classic

286 Brief for the United States as Amicus Curiae Supporting Defendant-Appellee at 1–2, Motus v. Pfizer Inc., 358 F.3d 659 (9th Cir. 2004) (Nos. 02-55372, 02-55498), 2002 WL 32303084 (footnotes omitted).
287 See Epstein, supra note 254 at 26; Sharkey, supra note 207 at 23, n.98.
288 See 21 U.S.C. 331(a), (b) & (k) (2000).
289 Brief for the United States, supra note 286 at 4–5. See also supra note 203 and accompanying text discussing Rabin’s point that regardless of one’s view of preemption or regulatory compliance, the FDA’s approval process for drug labels is not aimed at minimal safety.
290 Brief for the United States, supra note 286 at 2–3.
291 Despite this position in Motus, the FDA has since placed warnings about suicide by children on SSRI’s and recently held hearings to determine if it should expand those
“conflict” preemption because permitting tort liability would require the drug company to choose between following state or federal law.\textsuperscript{292} In January 2006, the FDA revised its regulations concerning the labeling of prescription drugs, as discussed above.\textsuperscript{293} In the Preamble to this rulemaking, the FDA stated that its prescription drug labeling regulations preempted state law and state tort liability related to prescription drug labeling on the grounds of conflict preemption.\textsuperscript{294} The Preamble stated:

\begin{quote}
FDA believes that under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law . . . . \textsuperscript{295}
\end{quote}

The FDA offered two overarching reasons for this blanket preemption. The first I call the “expertise” rationale, and the second is the “repose” rationale. The expertise rational is essentially that the FDA is the Congressionally designated expert on the health and safety aspects of prescription drugs.\textsuperscript{296} It engages in a rigorous process of review when approving new drugs and it carefully weighs risks and benefits when approving drug labeling and so should not be second-guessed by local juries who have none of that expertise. Thus, the 2006 final proposed rule states:

\begin{quote}
Under the act, FDA is the expert Federal public health agency charged by Congress with ensuring that drugs are safe and effective, and that their labeling adequately informs users of the risks and benefits of the product and is truthful and not misleading. Under the act and FDA regulations, the agency makes approval decisions based not on an abstract estimation of its safety and effectiveness, but rather on a comprehensive scientific
\end{quote}

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Brief for the United States, \textit{supra} note 286 at A15.
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See discussion \textit{supra} note 224 and accompanying text.
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\textit{Id.} at 3922.
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\textit{Id.} at 3934.
evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling.\textsuperscript{297}

To support this, the FDA provides a detailed explanation of the rigorous scientific process that it employs before approving prescription drugs and their labeling. The expertise rationale has been endorsed by scholars who see the tort system as a wasteful interference with this system. Richard Epstein, for example, argues that the Preamble notwithstanding, the negative social and economic consequences of permitting state tort liability for inadequate warnings when those warnings comply with FDA requirements should lead courts to have a presumption in favor, rather than against preemption.\textsuperscript{298} The most serious of these consequences include the stifling of innovation and delay in bringing much needed drugs to market.\textsuperscript{299} This is an endorsement of the expert theory because it implies that the FDA is doing all that needs to be done to protect the public in the context of prescription drugs.\textsuperscript{300}

The repose rationale focuses not on the expertise of the FDA but on the position of physicians and drug companies. It is essentially the argument that these actors are put in an impossible bind by the allowance of state damages awards for inadequate labeling on prescription drugs because they can never know what constitutes adequate labeling. As the FDA stated:

If State authorities, including judges and juries applying State law, were permitted to reach conclusions about the safety and effectiveness information disseminated with respect to drugs for which FDA has already made a series of regulatory determinations based on its considerable institutional expertise and comprehensive statutory authority, the federal system for regulation of drugs would be disrupted\textsuperscript{301}

\textsuperscript{297} Id.
\textsuperscript{298} Epstein, supra note 254 at 2–3.
\textsuperscript{299} Id. at 4.
\textsuperscript{300} Epstein does not, however, endorse \textit{Chevron} deference as the rationale for preemption because he does not believe that agency statements about preemption should be given weight. Id. at 15–16.
\textsuperscript{301} Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3969.
This argument partakes of the regulatory compliance defense, i.e., that compliance with federal regulations ought to provide an affirmative defense to failure to warn claims, as well as the expertise defense insofar as compliance should be enough because the FDA exercises its expertise so thoroughly in vetting prescription drug labels. But, as Rabin points out, the goal of state tort liability may not be only to create incentives for drug manufacturers to make their products safer. They may consider the compensatory and cost-spreading advantages of liability to be equally valuable goals.\textsuperscript{302} If that is the case, then there is no inherent inconsistency in awarding damages against a drug company for failure to warn of known risks even though the company complied with all applicable labeling requirements.

On its own, the repose rationale is both circular and proves too much. Defendants are only entitled to repose if they are led to believe that they will achieve it merely through regulatory compliance, and up until relatively recently, they had no reason for believing this in the prescription drug labeling context, as discussed above. It proves too much because it could be used in every federal regulatory context and would therefore lead to automatic preemption whenever federal regulation is present and the defendant has complied with it.

The FDA’s attempt to establish preemption by regulatory fiat, or what Sharkey has dubbed, “preemption by preamble,”\textsuperscript{303} has gotten a mixed reception by the courts that have thus far addressed it. In the past, courts have given credence to agency declarations about the non-preemptive effect of their regulations,\textsuperscript{304} so it would be consistent to also pay attention to the agency’s pro-preemption stance.\textsuperscript{305}
A few cases have addressed the 2006 FDA Preamble. In Abramowitz v. Cephalon, Inc., the New Jersey Superior Court applied the learned intermediary rule to a case involving the warnings on a prescription cancer drug, finding that the drug company had given the physician adequate warnings, but stated in dicta that even if the learned intermediary rule did not apply, the plaintiff’s claim would have been preempted and cited the 2006 Preamble to support this proposition. A similar conclusion was recently reached by the Eastern District of Pennsylvania.

Other courts, however, have been less receptive to the preemptive effect of the FDA’s Preamble. In Perry v. Novartis Pharmaceutical Corp., a more recent case from the Eastern District of Pennsylvania, the court rejected Chevron deference when the FDA was not creating or interpreting the substantive meaning of its regulations but rather “supply[ing], on Congress’ behalf, the clear legislative statement of intent required to overcome the presumption against preemption.” The court gave no credence to the statements in the Preamble and went on to find that the plaintiffs’ failure to warn claim was not preempted because the FDA had not made a specific determination that the warning about the risk of cancer from Elidel, a drug for atopic dermatitis, was not warranted, even though it had approved labeling that did not contain that warning. Another court addressing the same Preamble in litigation over the same drug treated the Preamble to Skidmore deference, which demands that the agency’s interpretations are

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307 Id. at *3. See also, Sharkey, supra note 207 at 13–18.
310 Id. at 864 (internal quotations omitted).
311 Id. at 685. It was based on the issue of the specificity of the FDA’s findings as to that particular risk that distinguished this case from Colacicco. In Colacicco, the FDA had specifically determined that there was no link between the SSRI and risk of suicide and therefore did not require it be placed on the label.
“entitled to respect” only to the extent that they have the “power to persuade.” Both
the Weiss and the Perry courts held that the Preamble was an advisory opinion, not
subject to notice and comment, and therefore not subject to Chevron deference.

There are two important implications of the FDA’s new position on preemption of
drug labeling requirements when considering the labeling of samples. First, it is still
unclear whether the FDA’s Preamble will be adopted by the courts, particularly the
Supreme Court. The Preamble has generated a lot of controversy and its merits are
being actively debated in the courts and law reviews. Second, and more significantly,
even if the Supreme Court eventually accepts the FDA’s arguments for preemption of
state tort liability for failure to warn of risks from prescription drugs, there are very good
reasons why the labeling of samples should not be preempted. The FDA’s justification
for its preemption doctrine for labeling, as articulated in the January 2006 Preamble and
the Motus, brief is focused on the content of the label, the problem of misbranding, and
the fear that state liability rules about the content of labels can create a situation where
juries act out of sympathy for plaintiffs rather than out of a true understanding of the
complex risk benefit analysis that goes into labeling decisions.

The labeling of samples does not present a situation in which the FDA has
considered and then rejected this type of labeling based on scientific information. The
issue of whether drug companies should be vulnerable to state tort liability for failing to
use a version of the FDA-approved warning, translated into language understandable to

(quotjng Skidmore v. Swift, 323 U.S. 134,140 (1944)).
313 Id. Advisory opinions are defined as “[a]ny portion of a Federal Register notice other
than the text of a proposed or final regulation.” 21 CFR § 10.85(d)(1) (2006). See also
314 See generally, Colacicco v. Apotex, Inc., 432 F.Supp.2d 514 (E.D.Pa. 2006); Perry,
456 F.Sup.2d 678; Weiss, 464 F. Supp. 666; Jackson, 432 F.Supp.2d 964; Epstein
supra note 254; Sharkey, supra note 207; Issacharoff & Sharkey, supra note 64.
315 Brief for United States, supra note 286; Robert B. Leflar & Robert S. Adler, The
Preemption Pentad: Federal Preemption of Products Liability Claims After Medtronic, 63
the patient, does not involve the question of the adequacy of the content of the warning and the risks and benefits of alternative warnings.\textsuperscript{316} There is no health risk involved in adding a patient warning to a drug that is otherwise essentially unlabeled and there is no evidence that a state which imposed such a requirement through liability rules would interfere with the central risk-benefit function of the FDA. In response to a query by the judge in \textit{Perry}, the FDA took the position that:

“state tort law is preempted if it imposes liability for a company’s failure to provide a warning that FDA has rejected, or would reject, as scientifically unsubstantiated, or for a company’s conduct in providing a warning that FDA deems necessary for the safe and efficacious use of a prescription drug.”\textsuperscript{317}

The case of samples would even pass Epstein’s blanket endorsement of preemption that does not rely on FDA statements. For Epstein, preemption of state tort liability is appropriate whenever the courts answer the following two questions in the affirmative:

First, are these cases in which there are alternative hazards associated with possible courses of action; second, did the agency make a considered examination of the various risks when it decided on its course of action?\textsuperscript{318}

There is no public safety issue involved in a state creating incentives for drug companies to provide warnings on their sample packages. The problem of overwarning is belied by the fact that some companies already provide patient warnings with samples. \textsuperscript{319} There is also no evidence in the FDA regulations that the decision not to require warnings on sample prescription drugs was the result of an examination of the

\textsuperscript{316} Drug companies have a lot of experience with these patient package inserts because the FDA requires them in some contexts. \textit{See supra}, notes 234–39 and accompanying text.

\textsuperscript{317} Weiss, 464 F.Supp.2d at 672 (quoting Letter to Judge Dalzell at 2, \textit{Perry v. Novartis Pharmaceuticals Corp.}, No. 05-5350 (E.D. Pa. Sept. 21, 2006)).

\textsuperscript{318} Epstein, \textit{supra} note 254 at 20.

\textsuperscript{319} \textit{See supra} notes 277-291 and accompanying text.
risks involved in providing warnings. Allowing patients to sue drug companies directly for failing to warn about risks associated with prescription drug samples would not conflict with any federal interest that is promoted by prescription drug regulation.

V. Prudential objections.

There are also prudential objections to creating an exception to the learned intermediary doctrine for prescription drug samples. The substance of these objections depends on how one thinks drug companies would react to the type of liability exposure suggested in this Article. If one believes, for example, that recognition of an exception to the learned intermediary rule for drug samples would lead the drug companies to put labels on all individual samples, then one might object to this proposal based on the cost and waste associated with labeling every sample or blister pack.

On the other hand, if one predicted that drug companies would instead stop using samples as a promotional tool, then one might object because of the benefits of contact between physicians and drug reps, and because the elimination of samples would hurt the poor who are often the beneficiaries of these free drugs. It is also possible that the drug companies would undertake some combination of these approaches, or do nothing at all and take their risks with the liability system. I will briefly address each of these objections.

It is feasible to attach labels to individual samples, and proponents of patient labeling on sample drugs have proposed labeling that would work with small packages. These include “bifold or trifold packaging design in which the product storage compartment is built directly in to the outside labeling.”320 Many sample drugs are

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320 Dill & Generali, supra note 190 at 2090. See also, Medscape.com, Ask The Experts — Is it Legal to Use Samples to Supply a Patient with Medication?
already individually boxed and contain patient information.\textsuperscript{321} There is already so much waste involved in the packaging and promotion of samples that drug companies might come out even by simply shifting their information from promotional language on the outside of the packaging to patient information on the inside.\textsuperscript{322} Or they might simply give away fewer meals, pens, and notepads. There is, in short, so much money invested in drug promotion that patient labeling on samples could easily be accomplished through a simple shift in resources.

There is also a general impression that sample prescription drugs benefit the poor because they allow physicians to give away free medicine.\textsuperscript{323} If drug companies react to liability exposure for distributing unlabeled samples by no longer distributing them, this could eliminate this source of free drugs. But it is not clear that giving free samples to private physicians has much of an effect on the poor.\textsuperscript{324} As one scholar put it, “[p]roviding samples is marketing, pure and simple.”\textsuperscript{325} If the physician is able to provide full treatment with the samples, some saving in individual cases will be realized, but if it is just a trial run for an expensive drug, then the samples may result in higher drug costs overall for individuals.\textsuperscript{326} Moreover, people who rely on charity for their prescription drugs might be more in need of written instructions and warnings because they are less likely to get the time and attention from their physicians that other patients

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\textsuperscript{321} Dill & Generali, supra note 190 at 2087.
\textsuperscript{323} See e.g. WEBER, supra note 128 at 85.
\textsuperscript{324} Harris, supra note 27.
\textsuperscript{325} WEBER, supra note 129 at 85.
\textsuperscript{326} id; Coyle, supra note 148 at 398.
\end{flushleft}
do. If drug companies want to donate prescription drugs to charity, there are many ways to do it, including vouchers that can be taken to a pharmacy.\textsuperscript{327}

Moreover, there are some beneficial collateral effects that might result from the liability rule proposed herein. First, if drug companies were to respond to recognition of an exception to the learned intermediary rule by decreasing their distribution of samples, it might lower drug costs. The notion that samples effectively counteract the high cost of prescription drugs because they are freebies has been refuted by studies showing that any savings by individuals receiving free drugs are more than compensated for by the fact that the use of samples tends to lead physicians to prescribe newer more expensive drugs.\textsuperscript{328} In fact, institutions that have banned samples have found that drug costs decrease thereafter.\textsuperscript{329} The high cost of prescription drugs is in part due to the marketing budget of the pharmaceutical industry, which in the year 2000 was $13.2 billion for advertising and promotions to physicians, which accounted for 11.8\% of the pharmaceutical industry's revenue from sales.\textsuperscript{330} One commentator dubbed these gifts a "surreptitious transfer of wealth from patients to doctors."\textsuperscript{331}

There are some benefits to physician interaction with the representatives of drug companies. Physicians are busy and it is convenient for them that someone will come to their office to tell them about the latest drugs and give them free samples.\textsuperscript{332} This might be compromised if, in reaction to liability exposure, drug companies cut down on their

\begin{footnotesize}
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\item Wilson, \textit{supra} note 137. ("many medical directors blame the sales tactics of drug reps for influencing physicians to prescribe new, expensive drugs over less expensive equally effective products."); Meadows, \textit{supra} note 137 at 18; WEBER, \textit{supra} note 129 at 84.
\item Harris, \textit{supra} note 27.
\item Id.
\item Blumenthal, \textit{supra} note 94 at 1887, 1889. In addition to being convenient, it may also be a sign of respect and professional recognition, particularly to new doctors. Katz et al., \textit{supra} note 120 at 40.
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promotional activities. But, as discussed above, a significant portion of the information that drug reps convey is misleading if not simply wrong. A recent article in the American Journal of Bioethics concluded:

Industry proponents assert that because physician-detailer interaction raises awareness of new products, the practice benefits patients. However, no evidence exists to support this claim. In contrast, research suggests that physicians rely heavily on detailers for information and that the more doctors rely on commercial sources of information, the less likely they are to prescribe drugs in a manner consistent with patient needs. Information provided by detailers is often biased, and sometimes dangerously misleading.

Not only is this information misleading, but physicians are often misled, relying on the messages imparted by drug reps, even when it differs from information from scientific sources that are available to physicians. Partly in reaction to the perceived quid pro quo of drug rep education, a practice called “academic detailing” is gaining momentum. Academic detailing involves healthcare organizations sending physicians and pharmacists to the offices of private physicians in the community to educate them about new drugs and practices. Using some of the techniques of behavioral science that drug reps use, but without the financial incentives of gifts and samples, academic detailers provide prescription drug information and prescribing suggestions to physicians. The goal of academic detailing is to counteract the influence of drug reps, improve clinical decision making by physicians, and respond to pressure to minimize health care costs. Since “no current regulatory apparatus can ensure that marketed

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333 Many physicians are only willing to see drug reps because they want the samples. Darves, supra note 182.
334 Katz et al., supra note 120 at 40.
335 Stephen B. Soumeral & Jerry Avorn, Principles of Education Outreach (“Academic Detailing”) to Improve Clinical Decision Making 283 JAMA 549, 550 (1990). This is so even though having a background in science is not required for a drug rep and is often completely lacking. Id. at 554.
336 Id. I am indebted to Professor Bob Works for bringing this to my attention.
337 Id. at 555–56.
drugs are prescribed intelligently, it is possible that a decrease in contact between
drug reps and physicians would lead to more time and attention given to academic
detailers, which would improve physician education.

VI. Conclusion

Tort rules are rules of policy and there are many good policy reasons for creating
this new exception to the learned intermediary rule. The risk created by the drug
companies through their promotional practices is born by patients who receive these
drugs from physicians in whom the drug companies have attempted to instill bias. The
unsuspecting patients do not in turn subject any of those parties to risks in return. The
risk created by the drug companies in their promotion and distribution of samples is thus
nonreciprocal insofar as the drug companies incur no risk to themselves in creating risk
to others. In fact, deceptive marketing of pharmaceutical products is helped by the
trusting relationship in which the ultimate consumer, the patient, receives the drug. The
patient is likely unaware that the sample was provided to the physician by a drug rep
who considers herself a participant in the market, where caveat emptor is the guiding
principle, even though neither the physician nor the patient is in any position to evaluate
the claims made by the drug rep. The liability shield provided by the learned
intermediary rule creates incentives for drug companies to pour more money into

338 Id.
339 Studies have found that physicians react positively to academic detailing and report
finding it helpful. See, e.g., Helene Levens Lipton, Jonathan D. Agnew, Marilyn R.
Stebbins, & R. Adams Dudley, Managing the Unmanageable: The Nature and Impact of
Drug Risk in Physician Groups, 30 J. HEALTH POL. POL’Y & L. 719, 731 (2005); AVORN,
supra note 96 at 325–26.
340 See generally, Gregory C. Keating, Reasonableness and Rationality in Negligence
Theory, 48 STAN. L. REV. 311 (1996); George P. Fletcher, Fairness and Utility in Tort
341 See WEBER, supra note 129 at 96–97 (arguing that caveat emptor should be replaced
with a standard of “due care” in marketing pharmaceuticals because of the their
importance to human health).
promoting the newest and most expensive drugs to physicians with impunity, which in turn contributes to the growing cost of prescription drugs.

Permitting a cause of action on behalf of patients against drug companies for failure to warn on sample medication would begin to address this imbalance by requiring the drug companies to absorb some of the cost of the risk that their conduct creates. This proposal in no way suggests relieving physicians of their independent duty to warn, and physicians who permit themselves to be influenced in their prescribing practices or fail to warn patients about the risks of sample drugs they distribute could still be subject to liability for failure to provide this information. This proposal only suggests that liability for the risk to patients who are not fully informed about the sample drugs they are given accurately track responsibility for creation of that risk, which requires it be shared by drug manufacturers and physicians alike. In a case like Vitanza with which this article began, accurately tracking responsibility might also require that the doctrine of comparative negligence be applied. A jury might find it reasonable to apportion some responsibility to a victim like Mr. Vitanza, who knowingly took a sample drug that was not dispensed to him.342

Recognition of an exception to the learned intermediary rule for prescription drug samples would be a salutary use of tort law to affect the conduct of an entire industry in a context where the legislative process has failed because of powerful interests in opposition.343 As in the case of tobacco, this is an instance in which tort law can serve the important function of uncovering and alerting the public to “unscrupulous and socially dangerous business practices detrimental to the public health.”344 Also like the tobacco situation, permitting plaintiffs to sue drug manufacturer’s directly for their failure to label prescription drug samples adequately is likely to uncover business conduct that is

342 Vitanza v. Upjohn Co., 214 F.3d 73, 75 (2d Cir. 2000).
343 THOMAS H. KOENIG & MICHAEL L. RUSTAD, IN DEFENSE OF TORT LAW 5 (2001)
344 Rabin, supra note 203 at 2068; KOENIG & RUSTAD, supra note 342 at 5.
dangerous to public health and safety in a context where legislative or regulatory solutions are improbable because of the power and influence of corporate interests, in this case, the drug lobby. As Senator Charles E. Grassley recently lamented, the FDA "was far too 'cozy' with drug makers." This cozy relationship is due in part to the fact that more than 25% of the FDA’s budget comes from fees collected from drug makers. These fees, negotiated with the drug companies, who get regulatory favors in exchange, including the proviso that the FDA would not spend much of it on tracking drugs after they are approved and put on the market. This is a classic case of capture in which a federal agency, although charged with regulatory oversight of an industry, is the one arm of government least capable of carrying out that charge. The power of the pharmaceutical industry is also felt at the state-level. Some state legislatures have tried to reign in drug promotion by passing laws requiring pharmaceutical companies to disclose the gifts that they make. Vermont, West Virginia, Maine and Minnesota have such laws. New York recently failed to pass such a law because of the lobbying by the Pharmaceutical Research and Manufacturers of America, the lobbying group for brand-name drug companies.

Exposure to this type of liability would force pharmaceutical companies to consider the risks to the public that they are creating through their promotional activities, something that they do not have to consider under current law because of the learned intermediary rule. They would have to determine whether it was economically beneficial

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345 Blumenthal, supra note 94 at 1889.
346 Gardiner Harris, F.D.A. Widens Safety Reviews on New Drugs, N.Y. TIMES, January 31, 2007, at A17. See also, Blumenthal, supra note 94 at 1889 (noting that it is "politically impractical for governments to adopt the kind of draconian ban on relationships between doctors and drug companies that their strongest critics favor.").
347 Harris, FDA Widens Safety, supra note 345.
349 Milt Freudenheim, Market place; a windfall from Shifts to Medicare, N.Y. TIMES, July 18, 1006, at C1; Blumenthal, supra note 94 at 1889; Katz et al., supra note 119 at 43.
350 Katz et al., supra note 119 at 43.
to put labels on all samples of prescription drugs, or only on those with particularly severe side effects or to which a significant portion of the general population might be allergic, and then suffer the liability consequences of those decisions. Other industries whose products or conduct pose direct risks to the public are required to do this calculation and there is no reason why drug companies should be exempt. Whether the way in which medicine is practiced today makes the learned intermediary doctrine anachronistic in general is a question beyond the scope of this Article. It is clear, however, that the pharmaceutical industry’s aggressive marketing techniques and inadequate labeling of sample drugs are a lethal combination. In this context, the learned intermediary rule creates incentives for the drug companies that are incompatible with public health.