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## Unlabeled Drug Samples and the Learned Intermediary: The Case for Drug Company Liability without Preemption

SUSAN POSER\*

### I. INTRODUCTION

In June 1992, shortly after giving birth, Michele Vitanza visited her physician for a routine post-partum examination.<sup>1</sup> She complained of a stiff neck and the physician gave her some samples of the prescription drug Ansaid, a nonsteroidal anti-inflammatory drug.<sup>2</sup> The samples had been provided to the doctor earlier that year by a drug representative from the Upjohn Company.<sup>3</sup> The samples were given to Mrs. Vitanza's physician in a box that contained nine blister cards,<sup>4</sup> each containing four pills, and one Food and Drug Administration (FDA)-approved physician package insert describing the drug,<sup>5</sup> 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.<sup>6</sup> 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.<sup>7</sup> Mr. Vitanza had been warned by his own physician that he was severely allergic to nonsteroidal anti-inflammatory drugs and should not take them.<sup>8</sup> The Ansaid blister card contained no warnings of this well-known allergy.<sup>9</sup> The only information on the blister card was the following:

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.<sup>10</sup>

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<sup>1</sup> Vitanza v. Upjohn Co., 214 F.3d 73, 75 (2d. Cir. 2000). All of the facts of this case that follow are taken from this opinion.

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> *Id.* For pharmaceutical purposes, a blister card is a card that is attached to clear plastic bubbles inside of which are individual pills.

<sup>5</sup> *Id.* For a description of different kinds of FDA approved package inserts for prescription drugs, see *infra* notes 224-239 and accompanying text.

<sup>6</sup> Vitanza, 214 F.3d at 75.

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

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

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.<sup>14</sup> The case was dismissed on summary judgment on the basis of the learned intermediary rule.<sup>15</sup> The learned intermediary rule, which has been adopted in almost every state,<sup>16</sup> 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.<sup>17</sup> Based on this rule, the district court held that Upjohn had no duty to warn Mrs. Vitanza or her husband.<sup>18</sup> 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.<sup>19</sup> That Court held that the doctrine did apply. The Second Circuit then upheld the summary judgment in favor of Upjohn.<sup>20</sup>

This article proposes 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. The article will discuss the rationales for the learned intermediary doctrine in the context of prescription drug samples and demonstrate that the doctrine should not apply to sample prescription drugs. Research shows that in many instances, drug companies’ promotion, marketing and packaging of sample prescription drugs put patients at risk. Tort law should require these companies to absorb that risk when it results in foreseeable harm. Recognition of an exception to the learned intermediary rule in that context would spread the risk of harm from unlabeled prescription drugs between physicians and drug companies in a way that more accurately accounts for their responsibility for that risk. In addition, this article will show that recent pronouncements by FDA 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.<sup>21</sup> The report addressed labeling of prescription drugs and found that there has been a growing unease among healthcare providers and others about the way free samples are

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<sup>11</sup> *Id.*

<sup>12</sup> *Id.* Michele Vitanza’s attorney believes that this omission was because the medical reference works were published one year before Ansaïd became widely available. Telephone interview with Jonathan Levine, Esq., Partner, Silver, Golub & Teitell, Stamford Conn. (Oct. 19, 2006).

<sup>13</sup> Vitanza, 214 F.3d at 75.

<sup>14</sup> *Id.* at 74.

<sup>15</sup> *Id.* at 75–76. The case was dismissed after being removed to the federal district court from Connecticut state trial court. *Id.*

<sup>16</sup> Larkin v. Pfizer, Inc. 153 S.W.3d 758, 767 (Ky. 2005).

<sup>17</sup> *Id.* at 762.

<sup>18</sup> Vitanza v. Upjohn Co., 48 F.Supp.2d 124, 132 (D. Conn. 1999).

<sup>19</sup> Vitanza, 214 F.3d at 79.

<sup>20</sup> Vitanza v. Upjohn Co., 271 F.3d 89, 92 (2d Cir. 2001).

<sup>21</sup> Press Release, The National Academies: Institute of Medicine, Medication Errors Injure 1.5 Million People and Cost Billions of Dollars Annually; Report Offers Comprehensive Strategies for Reducing Drug-Related Mistakes (July 20, 2006), available at <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=11623>.

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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.<sup>22</sup>

Most people who believe that they are harmed by their medical care do not initiate a lawsuit.<sup>23</sup> 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.<sup>24</sup> 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. Someone harmed by the absence of warnings on samples of prescription drugs can sue his/her physician on an informed consent theory, but these cases are notoriously difficult to prove.<sup>25</sup> They often come down to the physician's testimony against the patient's 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.<sup>26</sup> The physician can also simply contradict the patient's memory of their conversation. One might not contact a lawyer in a case like *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,<sup>27</sup> and that these samples often "wind up in medicine cabinets for future use."<sup>28</sup> There is little doubt that a warning on the Ansaid samples would have prevented Mr. Vitanza's death.

Although the medical community recognizes hazards involved in the promotion, labeling and dispensing of sample prescription drugs,<sup>29</sup> the legal community has largely overlooked them, both in case law and the law reviews. The *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 (OTC), samples are routinely distributed to patients without the benefit of any written warnings from the drug company or the pharmacy, and often by a physician who was the target of aggressive market-

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<sup>22</sup> *Id.*

<sup>23</sup> 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 percent of negligently injured patients bring lawsuits); Marilyn 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).

<sup>24</sup> Hyman & Silver, *supra* note 23, at 1114.

<sup>25</sup> Nancy K. Kubasek, *Legislative Approaches to Reducing the Hegemony of the Priestly Model of Medicine*, 4 MICH. J. GENDER & LAW 375, 393-394 (1997).

<sup>26</sup> Michael J. Farrell, *Medical Malpractice: Claims Culprits, and Defenses*, 16 AM. J. TRIAL ADVOC. 65, 79 (1992).

<sup>27</sup> Mary-Margaret Chren, M.D., *Interactions between Physicians and Drug Company Representatives*, 107 AM. J. MED. 182, 182 (1999); see also Ila M. Harris, *Closing the Door on Sample Closets*, MINN. MED., (Jan., 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).

<sup>28</sup> Ellen Relkin, *Warnings in Pharmaceutical Cases: Is the Learned Intermediary Obsolete in the New Millennium?*, SF28 ALI-ABA 227, 231 (2000).

<sup>29</sup> See *infra* notes 182-188 and accompanying text.

ing by representatives of the drug company seeking to increase prescriptions of a new and expensive drug.<sup>30</sup>

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 seriousness of receiving a prescription drug that a trip to the pharmacy and the receipt of the specially labeled container imparts.<sup>31</sup> Nevertheless, 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 II 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 III 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 IV demonstrates how that marketing justifies an exception to the learned intermediary rule for warnings about sample prescription drugs. Part V addresses the potential doctrinal and prudential arguments against liability of pharmaceutical companies for inadequate labeling on sample drugs, including the role of federal preemption.

## 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 1960s, 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.<sup>32</sup> 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, FDA issued regulations that for the first time drew a distinction between drugs that consumers could buy OTC, 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."<sup>33</sup> Drugs in this latter category require a doctor's prescription before obtaining them.<sup>34</sup> Prior to this regulatory distinction, all non-narcotic drugs

<sup>30</sup> See *infra* Part III.

<sup>31</sup> See, Michele L. Hornish, *Just What the Doctor Ordered—Or Was It?: Missouri Pharmacists' Duty of Care In The 21st Century*, 65 Mo. L. Rev. 1075, 1076 (2000) (noting that "pharmacists are the last chance that the system has to correct itself"). A similar problem exists for prescription medication sold over the internet. See generally, Chester Chuang, *Is There a Doctor in the House? Using Failure-to-Warn Liability to Enhance the Safety of Online Prescribing*, 75 N.Y.U. L. Rev. 1452 (2000) (proposing abolition of the learned intermediary rule for drugs sold over the internet).

<sup>32</sup> See Restatement (Second) of Torts § 402A (1965); Restatement (Third) of Torts: Products Liability § 2, cmt. i (1998).

<sup>33</sup> Promulgation of Regulations Under the FDCA and Repeal of Certain Regulations Heretofore Promulgated Thereunder, 3 Fed. Reg. 3161-2, 3168 (Dec. 28, 1938).

<sup>34</sup> Charles J. Walsh, Steven R. Rowland, & Howard L. Dorfman, *The Learned Intermediary Doctrine: The Correct Prescription for Drug Labeling*, 48 RUTGERS L. REV. 821, 825, n.4 (1996).

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could be purchased without physician approval.<sup>35</sup> 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 OTC drugs but exempted prescription drugs if a warning was given to the physician.<sup>36</sup> Fifteen years later, in *Sterling Drug v. Cornish*,<sup>37</sup> 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:<sup>38</sup>

[I]n this case we are dealing with a prescription drug rather than a normal consumer item. In such a case the purchaser's doctor is a learned intermediary between the purchaser and the manufacturer. If the doctor is properly warned of the possibility of a side effect in some patients, and is advised of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can be avoided.<sup>39</sup>

Thus, the learned intermediary rule is a common law doctrine but it developed logically out of the regulatory framework for prescription and OTC 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."<sup>40</sup> The comment to Section 402A made it clear that inadequate warnings could render a product defective: "In order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning, on the container, as to its use."<sup>41</sup>

It does not follow inexorably from the distinction between prescription and OTC drugs that only the latter must contain warnings directed to consumers. It would be equally logical to require consumer warnings on prescription drugs, if only for the purpose of reinforcing physician warnings. FDA does in fact require patient labeling for some prescription drugs, including oral contraceptives, intrauterine devices (IUDs), and some asthma drugs.<sup>42</sup> FDA has proposed rules requiring con-

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<sup>35</sup> *Id.* at 822.

<sup>36</sup> *Id.* at 826; cf. FDA, *FDA Background: Milestones in U.S. Food and Drug Law History* (1999), <http://www.cfsan.fda.gov/mileston.html> (last visited Feb. 27, 2007) (describing important dates in the history of FDA).

<sup>37</sup> 370 F.2d 82 (8th Cir. 1966).

<sup>38</sup> *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).

<sup>39</sup> *Sterling Drug*, 370 F.2d at 85.

<sup>40</sup> Restatement (Second) Torts, § 402A (1965).

<sup>41</sup> 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 *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).

<sup>42</sup> Walsh et al., *supra* note 34 at 823.

sumer warnings on virtually all prescription drugs, but those rules have never been implemented due to lobbying from the pharmaceutical industry.<sup>43</sup>

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 healthcare professional, it is the patient's physician who is in the best position to evaluate those risks and weigh them against the benefits to a particular patient.<sup>44</sup> 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.<sup>45</sup> 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:

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.<sup>46</sup>

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.<sup>47</sup> 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 he/she had learned this extra information.<sup>48</sup>

A second rationale for the learned intermediary rule is that drug manufacturers "lack effective means to communicate directly with each patient."<sup>49</sup> 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,"<sup>50</sup> translates this information into language that the patient can understand.<sup>51</sup>

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<sup>43</sup> See Prescription Drug Product Labeling; Medication Guide Requirements, 60 Fed. Reg. 44,182 (Aug. 24, 1995) (to be codified at 21 C.F.R. pts. 201, 208, 314, & 601); Catherine A. Paytash, Note, *The Learned Intermediary Doctrine and Patient Package Inserts: A Balanced Approach to Preventing Drug-Related Injury*, 51 STAN. L. REV. 1343,1344 (1999); *infra* Part V.A.

<sup>44</sup> 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.").

<sup>45</sup> 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.

<sup>46</sup> *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).

<sup>47</sup> DAVID G. OWEN, PRODUCTS LIABILITY LAW § 22.1 (2005)

<sup>48</sup> OWEN, *supra* note 47 at § 22.1; Paytash, *supra* note 43 at 1346-1347.

<sup>49</sup> *Larkin*, 153 S.W.3d at 764.

<sup>50</sup> *Hall v. Sinn, Inc.*, 102 F. App'x 846, 849 (5th Cir. 2004).

<sup>51</sup> See Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 157-159 (1997) (explicating similar rationales for the learned intermediary rule).

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Finally, courts have suggested that direct warnings from manufacturers to patients would interfere with the physician-patient relationship.<sup>52</sup> 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.<sup>53</sup> Others have argued that providing separate warnings to the patient would interfere with the trust relationship between patient and physician, by signaling to the patient that it might be wise to rely on information from outside sources.<sup>54</sup>

The learned intermediary rule has been adopted by 45 jurisdictions and operates essentially as an irrebuttable presumption in the vast majority of cases.<sup>55</sup> 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 possibly 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, he/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. One early exception was for mass immunization programs in which patients were immunized against disease without the benefit of a one-on-one consultation with a physician.<sup>56</sup> Because vaccine manufacturers know that "people line up like lemmings to receive a polio shot or flu vaccination,"<sup>57</sup> manufacturers, who often sponsored the immunization clinics, were required to provide warnings directly to the consumers. Methods of warning include advertising at the clinic<sup>58</sup> or providing a clear informed consent form that sets forth the known risks.<sup>59</sup> 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.<sup>60</sup>

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<sup>52</sup> 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).

<sup>53</sup> See Timm v. UpJohn Co., 624 F.2d 536, 538 (5th Cir. 1980); Ausness, *supra* note 45 at 109.

<sup>54</sup> Ausness, *supra* note 45 at 110 (citing Swayze v. McNeil Labs, Inc., 807 F.2d. 464, 471 (5th Cir. 1987); Dunkin v. Syntex Labs, Inc., 443 F. Supp. 121, 123 (W.D. Tenn. 1977); West v. Searle & Co., 806 S.W.2d 608, 613 (Ark. 1991); Tracy v. Merrell Dow Pharms. Inc., 569 N.E.2d 875, 879 (Ohio 1991)). See also, Victor E. Schwartz, Phil Goldberg, *A Prescription for Drug Liability and Regulation*, 58 OKLA. L. REV. 135, 161 (2005) (stating that imposing a duty to warn patients directly would weaken the relationship between doctor and patient).

<sup>55</sup> 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).

<sup>56</sup> 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.

<sup>57</sup> OWEN, *supra* note 47 at § 9.6.

<sup>58</sup> Davis, 399 F.2d at 131.

<sup>59</sup> 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).

<sup>60</sup> Larkin, 153 S.W.3d at 765-766 (citing Petty v. United States, 740 F.2d 1428, 1440 (8th Cir. 1984); Givens, 556 F.2d at 1345-1346 (5th Cir. 1977); Reyes, 498 F.2d at 1276-1277 (5th Cir. 1974); Cunningham v. Charles Pfizer & Co., 532 P.2d 1377, 1381 (Okla. 1974); Davis, 399 F.2d at 131).



Several jurisdictions recognize other exceptions to the learned intermediary doctrine. In *MacDonald v. Ortho Pharmaceutical Corp.*,<sup>61</sup> the Massachusetts Supreme Court held that the manufacturer of oral contraceptives had a duty to provide adequate warnings directly to the patient.<sup>62</sup> 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.<sup>63</sup> The Court perceived that it was relatively easy for the manufacturer to articulate in lay language the risks of oral contraceptives, particularly because it was required to do so by FDA,<sup>64</sup> and that women would be inclined to reference those warnings if they had questions between office visits.<sup>65</sup> Using similar reasoning, the Eighth Circuit, applying Arkansas law, declared an exception for IUDs,<sup>66</sup> but other courts have declined to follow these precedents.<sup>67</sup>

In *Perez v. Wyeth Labs.*,<sup>68</sup> 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 (DTC) advertising campaign. Noting that "[o]ur medical-legal jurisprudence is based on images of healthcare that no longer exist,"<sup>69</sup> the *Perez* court based its decision on the reality of current medical practice in which patients must take an active part in their healthcare 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.<sup>70</sup> The court also noted that drug companies cannot claim that patients do not take an active role in their healthcare decisions, or that manufacturers lack effective means to communicate with patients, when those same companies concertedly and effectively influence consumers directly through advertising.<sup>71</sup> The *Perez* court held that the presumption that the learned intermediary rule applied to prescription drugs could be rebutted when DTC advertising did not contain adequate warnings

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<sup>61</sup> 475 N.E.2d 65 (Mass. 1985).

<sup>62</sup> *Id.* at 70.

<sup>63</sup> *Id.* *But see*, Walsh et al., *supra* note 34 at 863 ("Oral contraceptives are not obtained in significantly different ways than other prescription drugs.").

<sup>64</sup> MacDonald, 475 N.E.2d at 69–70.

<sup>65</sup> *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 (Okla. 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 71–72.

<sup>66</sup> Hill v. Searle Labs., 884 F.2d 1064, 1070–1071 (8th Cir. 1989) (applying Arkansas law). IUDs 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.

<sup>67</sup> *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 862–863.

<sup>68</sup> 734 A.2d 1245 (N.J. 1998).

<sup>69</sup> *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).

<sup>70</sup> Perez, 734 A.2d at 1255.

<sup>71</sup> *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)).

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of the drug's risks. Apart from one recent decision by the Supreme Court of West Virginia, courts addressing the effect of DTC advertising on the learned intermediary rule have declined to follow *Perez*.<sup>72</sup> In recent cases, the New Jersey courts themselves have created some limits to this exception, holding that merely placing informational brochures in physicians' waiting rooms was not enough to invoke the exception,<sup>73</sup> and limiting causation to those cases where the plaintiff can show that she actually saw and was affected by the advertising.<sup>74</sup>

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 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.<sup>75</sup> 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 patients' managed-care plans.<sup>76</sup> Because of limitations imposed by managed-care organizations on patients' ability to choose their physicians, patients are less likely to develop long-term relationships with their physicians.<sup>77</sup> 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.<sup>78</sup>

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 prescription drugs that are both useful and comprehensible to the average consumer.<sup>79</sup> 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 physi-

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<sup>72</sup> The Supreme Court of West Virginia decided in June 2007 not to adopt the learned intermediary rule in a prescription drug product liability case because it found the rationale for the rule "outdated and unpersuasive," particularly in light of the pervasiveness of DTC advertising. *State ex. rel. Johnson and Johnson v. Karl*, 647 S.E. 2d 899, 906 (W.Va. 2007). For cases declining to follow *Perez*, see, e.g., *In re Meridia Products Liability Litigation*, 328 F.Supp.2d 791 (N.D. Ohio 2004); *In re Norplant Contraceptive Products Liability Litigation*, 215 F.Supp.2d 795 (E.D. Tex. 2002).

<sup>73</sup> *Banner v. Hoffmann-LaRoche*, 891 A.2d 1229, 1236 (N.J. Super. 2006).

<sup>74</sup> *Appleby v. Glaxo Wellcome, Inc.*, No. Civ. 04-0062 (RBK), 2005 WL 3440440, at \*5 (D.N.J. Dec. 13, 2005). See also, John B. Reiss, Mark C. Levy & Allison B. Newhart, *Analyzing the Laws, Regulations, and Policies Affecting FDA-Regulated Products*, 61 FOOD & DRUG L.J. 279, 289-291 (2006) (suggesting that a consumer must at least show that he or she saw and was influenced by the advertising).

<sup>75</sup> See, e.g., Ausness, *supra* note 45 at 120-121; Hall, *supra* note 38 at 196-198 (calling for a complete overhaul of the learned intermediary rule in light of changes to the doctor-patient relationship and pharmaceutical marketing).

<sup>76</sup> Paytash, *supra* note 43 at 1358-1360.

<sup>77</sup> See *id.*; Chester Chuang, *Is There a Doctor in the House: Using Failure-to-Warn Liability to Enhance the Safety of Online Prescribing*, 75 N.Y.U. L. Rev. 1452 (discussing stats on the changing nature of the doctor-patient relationship).

<sup>78</sup> Hall, *supra* note 38 at 239-244.

<sup>79</sup> Schwartz et al., *supra* note 54 at 160; Barney, *supra* note 44 at 405.

cians (and occasionally pharmacists<sup>80</sup>) for failure to warn, a claim usually framed as lack of informed consent.<sup>81</sup>

In response to the recognized exceptions to the learned intermediary rule and growing scholarly dissatisfaction with it, the recent *Restatement (Third) of Torts: 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 inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

(1) prescribing and other healthcare 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 healthcare providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.*<sup>82</sup>

This Restatement justifies the basic doctrine under Section 6(d)(1) in the conventional way, stating: “Only healthcare 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.”<sup>83</sup> Yet it also recognizes that “in certain limited therapeutic relationships the physician or healthcare provider has a much-diminished role as an evaluator or decision maker.”<sup>84</sup>

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.<sup>85</sup> 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 DTC advertising and leave to case law whether others should be developed.<sup>86</sup>

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 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.<sup>87</sup> The learned intermediary rule provides immunity to drug companies as long as they provide 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.<sup>88</sup>

<sup>80</sup> RICHARD R. ABOOD & DAVID B. BRUSHWOOD, *PHARMACY PRACTICE AND THE LAW* 112 (3d ed. 2001).

<sup>81</sup> OWEN, *supra* note 47 at § 22.10.

<sup>82</sup> Restatement (Third) of Torts: Products Liability § 6(d) (2006) (emphasis added).

<sup>83</sup> Restatement (Third) of Torts: Products Liability § 6 cmt. b (2006).

<sup>84</sup> *Id.*

<sup>85</sup> Restatement (Third) of Torts: Products Liability, § 6, cmt. d (“[m]anufacturers of prescription drugs discharge their duty of care to patients by warning the healthcare providers who prescribe and use the drugs to treat them.”).

<sup>86</sup> *Id.*, cmt. e.

<sup>87</sup> *Vitanza v. Upjohn*, 214 F.3d 73, 78 (2d Cir. 2000).

<sup>88</sup> Ausness, *supra* note 45 at 100.

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The learned intermediary rule creates a situation in which drug companies have no legal disincentive to overpromote to physicians.<sup>89</sup> Yet, 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 apparent when one examines the marketing practices of pharmaceutical companies.

Permitting a cause of action against a drug company 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.<sup>90</sup> Rather, the justification for this proposal is that legal responsibility for conduct should be shared by physicians and drug companies in a way that accords with culpability and promotes public safety.<sup>91</sup>

### III. PRESCRIPTION DRUG MARKETING AND SAMPLES

The pharmaceutical industry spends billions of dollars each year marketing prescription drugs. Although most consumers are aware of DTC advertising on television and in magazines,<sup>92</sup> this is a far less significant feature of drug marketing than promotion to physicians.<sup>93</sup> The primary targets of the pharmaceutical industry’s promotional activities are the physicians who prescribe the drugs and, to a lesser extent, the healthcare organizations and pharmacy formularies that decide which drugs to stock. The *Journal of the American Medical Association (JAMA)* recently reported that 90 percent of the pharmaceutical industry’s \$21 billion annual marketing budget was spent on direct marketing to physicians.<sup>94</sup> 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.<sup>95</sup> Sometimes the marketing budget for the drug exceeds the amount spent on developing the drug.<sup>96</sup>

<sup>89</sup> See *infra* notes 174–180 and accompanying text for discussion of overpromotion.

<sup>90</sup> 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 That Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers*, 295 *JAMA* 429, 431 (2006).

<sup>91</sup> See generally, John C.P. Goldberg, *Twentieth-Century Tort Theory*, 91 *Geo. L.J.* 513, 521–529 (2003) (describing the ascendancy of compensation-deterrence theory in tort).

<sup>92</sup> In 1997, FDA loosened its rules on DTC advertising and permitted television advertising of prescription drugs. Palumbo & Mullins, *supra* note 69 at 427.

<sup>93</sup> In 2001, the drug industry spent \$2.24 billion on DTC advertising, as compared to \$27.7 billion on promotions to physicians. Palumbo & Mullins, *supra* note 69 at 431. See *infra* notes 113–115 and accompanying text.

<sup>94</sup> Brennan et al., *supra* note 90 at 430.

<sup>95</sup> David Blumenthal, *Doctors and Drug Companies*, 351 *NEW ENG. J. MED.* 1885, 1885 (2004). Blumenthal gives the example of Novartis, which reported spending 36 percent of its revenues on marketing in 2001. *Id.* The average in the industry is 33 percent. *Id.*

<sup>96</sup> 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 budget for scientific development of the drug.”); JERRY AVORN, *POWERFUL MEDICINES, THE BENEFITS, RISKS AND COSTS OF PRESCRIPTION DRUGS* 305 (2004) (reporting that pharmaceutical companies employed 86,226 people in marketing and 51,588 in research and development).

This makes economic sense in light of one study that found that for each dollar spent on “detailing” (i.e., promotion of the drug to physicians by representatives from drug companies), the return was \$10.29.<sup>97</sup> This is more than seven times the return on DTC advertising.<sup>98</sup>

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.<sup>99</sup> Other gifts to physicians include free continuing medical education, payment for travel and registration at meetings, and consulting fees.<sup>100</sup> These contacts begin early in physicians’ careers when they are medical students and residents and continue from there.<sup>101</sup> One study found that practicing physicians meet with drug reps on average four times per month.<sup>102</sup>

There are approximately 90,000 drug reps in the United States, approximately 1 drug rep for every 4.7 office-based physicians,<sup>103</sup> 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 their targeted physicians.<sup>104</sup> Drug companies recruit the most attractive and perky people they can find right out of college to be drug reps. Some 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.<sup>105</sup> 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.”<sup>106</sup> 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.<sup>107</sup>

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<sup>97</sup> Carl Elliot, *The Drug Pushers*, ATLANTIC MONTHLY, (Apr. 2006), at 82, 83.

<sup>98</sup> *Id.*

<sup>99</sup> Stephanie Saul, *Drug Makers Pay for Lunch as They Pitch*, N.Y. TIMES, (July 28, 2006) at A1.

<sup>100</sup> Brennan et al., *supra* note 90 at 430.

<sup>101</sup> Blumenthal, *supra* note 94 at 1886 (citing surveys reporting that medical residents receive an average of six 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.”).

<sup>102</sup> Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?* 283 JAMA 373, 374 (2000). A more recent study based on a national survey of 3167 physicians and published in 2007, found that 94 percent of physicians have some type of relationship with drug companies, 83 percent receive free food or beverages, and 78 percent of physicians receive free drug samples. Eric Campbell, et al., *A National Survey of Physician-Industry Relationships*, 356 NEW ENG. J. MED. 1742-1750 (2007).

<sup>103</sup> Blumenthal, *supra* note 94 at 1886.

<sup>104</sup> 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”).

<sup>105</sup> Stephanie Saul, *Gimme an Rx! Cheerleaders Pep Up Drug Sales*, N.Y. TIMES, (Nov. 28, 2005) at A1.

<sup>106</sup> *Id.*

<sup>107</sup> 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.

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The job of the drug rep is to convince doctors that they should prescribe their company's drug. Seduction is "deliberate industry strategy,"<sup>108</sup> the success of which is measured by increases in the number of prescriptions written for whatever drug is being promoted.<sup>109</sup> 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 I brought in lunch one week, I could see the following week if that lunch had an impact," Ms. Slattery-Moschkau said.<sup>110</sup>

In addition to lunch, drug reps make their case through interpersonal appeals 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.<sup>111</sup>

Marketing also takes place at the organizational level. Pharmaceutical companies often provide continuing medical education to physicians, and sponsor annual meetings of physician specialists.<sup>112</sup> 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.<sup>113</sup>

Recent scandals have resulted in drug companies cutting down or eliminating their more extravagant gifts, like free trips to resorts for "educational conferences."<sup>114</sup> 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.<sup>115</sup> In another, a company paid physicians \$1,000 for each new prescription of its drug.<sup>116</sup>

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<sup>108</sup> Elliot, *supra* note at 97.

<sup>109</sup> 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.)

<sup>110</sup> Saul, *Drug Makers Pay for Lunch as They Pitch*, *supra* note 99.

<sup>111</sup> Michael Kirsch, *Is There an Ethical Doctor in the House?*, ACP OBSERVER, (Oct. 1997), <http://www.acponline.org/journals/news/oct97/ethicdr.htm> (last visited Feb. 27, 2007).

<sup>112</sup> Blumenthal, *supra* note 94 at 1886

<sup>113</sup> *Id.*

<sup>114</sup> Saul, *Drug Makers Pay for Lunch as They Pitch*, *supra* note 99.

<sup>115</sup> One of these cases settled for \$875 million. Daniel Higgins, *What Providers Need to Know about the New OIG Guidelines on Pharmaceutical Marketing*, THE HEALTH LAWYER, (Dec. 2002) at 1, 1; David L. Douglass & Olabisi A. Onisile, *Pharmaceutical Marketing Practices: Providers Beware*, THE HEALTH LAWYER, (Aug. 2004) at 31, 34 (reporting on the Lupron investigations in 2003); ANGELL, *supra* note 101 at 130–132 (same).

<sup>116</sup> Douglass & Onisile, *supra* note 115 at 34. (discussing Biovail). Daniel Higgins describes "switching arrangements" in which 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.

In 2002, the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) issued its first ever “draft guidance” to the pharmaceutical industry signaling that the many of these gifts might violate federal fraud and kickback statutes.<sup>117</sup> 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.<sup>118</sup> 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.”<sup>119</sup> 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 \$100.<sup>120</sup> 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.<sup>121</sup> 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.<sup>122</sup>

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.”<sup>123</sup> 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.”<sup>124</sup> A study published in *JAMA* found that that 11 percent of statements made by pharmaceutical representatives about drugs were inaccurate and the inaccuracies were generally not recognized by physicians<sup>125</sup> 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 physician.

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<sup>117</sup> Diane Ung & Lena Robins, *DHHS Tailors Compliance Program Guideline for Pharmaceutical Manufacturers*, DRUG BENEFIT TRENDS, (Nov. 2002), at 34, 35; Higgins, *supra* note 115 at 1; Editorial, *Drugmakers' Gifts to Doctors Finally Get Needed Scrutiny*, USA TODAY, (Oct. 14, 2002), at A14.

<sup>118</sup> PhRMA, PhRMA-Principles and Guidelines, [http://www.phrma.org/principles\\_and\\_guidelines/](http://www.phrma.org/principles_and_guidelines/) (last visited Feb. 9, 2007); Jason Dana & George Lowenstein, *A Social Science Perspective on Gifts to Physicians From Industry*, 290 JAMA 252, 252 (2003); David M. Studdert, Michelle M. Mello, & Troyen A. Brennan, *Financial Conflicts of Interest in Physicians' Relationships with the Pharmaceutical Industry—Self-Regulation in the Shadow of Federal Prosecution*, 351 NEW ENG. J. MED. 1891, 1891 (2004).

<sup>119</sup> PhRMA, PhRMA-Principles and Guidelines, [http://www.phrma.org/principles\\_and\\_guidelines/](http://www.phrma.org/principles_and_guidelines/) (last visited Feb. 9, 2007).

<sup>120</sup> 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.”

<sup>121</sup> See Ung & Robins, *supra* note 117 at 35.

<sup>122</sup> 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.”).

<sup>123</sup> PhRMA, PhRMA-Principles and Guidelines, [http://www.phrma.org/principles\\_and\\_guidelines/](http://www.phrma.org/principles_and_guidelines/) (last visited Feb. 9, 2007).

<sup>124</sup> Chren, *supra* note 27 at 182 (citing various studies). *Cf.*, Chew et al., *A Physician Survey of the Effect of Drug Sample Availability on Physicians' Behavior*, 15 J. GEN. INTERNAL MED. 478, 482 (2000) (85 percent of responding physicians agreed that drug samples deprive patients of important counseling and drug interaction screening by pharmacists).

<sup>125</sup> M.G. Ziegler, P. Lew & B.C. Singer, *The Accuracy of Drug Information From Pharmaceutical Sales Representatives*, 273 JAMA 1296, 1296 (1995).

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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.<sup>126</sup>

Also in response to the OIG's proposed guidelines, the American Medical Association (AMA), the American College of Physicians, and the Accreditation Council for Continuing Medical Education (ACCME) issued new or revised guidelines.<sup>127</sup> These guidelines limit gifts from pharmaceutical companies to small gifts that are intended for office use, education or patient care.<sup>128</sup> 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.<sup>129</sup>

Samples are the lynchpin of prescription drug marketing.<sup>130</sup> In 2000, 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.<sup>131</sup> 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 small gifts such as notepads, pens and lunches for physicians and office staff.<sup>132</sup> A survey of physicians across the United States in 2001 found that 92 percent had accepted free samples from drug companies.<sup>133</sup>

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.<sup>134</sup> 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.<sup>135</sup> Some doctors say that giving away free samples helps them to bond with their patients.<sup>136</sup> Third, and most important, if the sample works for a patient,

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<sup>126</sup> Farrell, *supra* note 26 at 60.

<sup>127</sup> Studdert et al., *supra* note 119 at 1894–1897. The other organizations issuing similar new or revised guidelines were ACCME and the American College of Physicians.

<sup>128</sup> *Id.*

<sup>129</sup> *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)

<sup>130</sup> 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.”).

<sup>131</sup> Harris, *supra* note 27.

<sup>132</sup> Karen Springen, *Saying No to Big Pharma*, NEWSWEEK, (Oct. 5, 2006), <http://www.msnbc.msn.com/id/15143275/site/newsweek/print/1/displaymode/1098>.

<sup>133</sup> Blumenthal, *supra* note 94 at 1886.

<sup>134</sup> See *infra* notes 153–169.

<sup>135</sup> Elisabeth L. Backer et al., *The Value of Pharmaceutical Representative Visits and Medication Samples in Community-Based Family Practices*, 49 J. OF FAM. PRAC. 811, 814 (2000).

<sup>136</sup> Harris, *supra* note 27.



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 to prescribe that drug.<sup>137</sup> Coupling free sample distribution with free lunches and some notepads and pens to reinforce brand recognition creates a strong inducement to prescribe particular drugs.<sup>138</sup>

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.<sup>139</sup> They know which doctors are “early prescribers” (known as “cowboys” among drug reps)<sup>140</sup> who tend to prescribe new drugs soon after they are released. Drug reps visit these doctors early and often.<sup>141</sup>

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.<sup>142</sup> 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.”<sup>143</sup> This finding has been confirmed by others.<sup>144</sup> 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 those drugs and less likely to recommend OTC medication than residents without such access.<sup>145</sup> 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.”<sup>146</sup> 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.<sup>147</sup>

As with many instances of conflict of interest, the bias created in physicians by pharmaceutical promotions tends to be unintentional and unconscious.<sup>148</sup> When asked in general terms, physicians deny that gifts from drug reps affect their pre-

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<sup>137</sup> Jennifer Fisher Wilson, *Prescribing Under Pressure*, ACP OBSERVER, (Oct. 1997), <http://www.acponline.org/journals/news/oct97/pressure.htm> (last visited Feb. 27, 2007); Michelle Meadows, *Saving Money on Prescription Drugs*, FDA CONSUMER MAGAZINE, (Sept. 2005), at 18, available at [http://www.fda.gov/fdac/features/2005/505\\_save.html](http://www.fda.gov/fdac/features/2005/505_save.html) (info on price of generics vs. name brand drugs).

<sup>138</sup> Farrell, *supra* note 26 at 72.

<sup>139</sup> Stephanie Saul, *Doctors Object as Drug Makers Learn Who's Prescribing What*, N.Y. TIMES, (May 4, 2006), at A1.

<sup>140</sup> 17 Am. Jur. Trials § 5 (Cumm. Supp. 2006); Dana & Lowenstein, *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 drug companies. AVORN, *supra* note 96 at 294.

<sup>141</sup> *Id.*

<sup>142</sup> Wazana, *supra* note 102 at 375–376. See also, Phyllis Maguire, *No Easy Answers When Managing Financial Conflicts*, ACP OBSERVER, (June 2005), <http://www.acponline.org/shell/cgi/printhappy.pl/journals/news/jun05/finance.htm> (last visited Feb. 27, 2007).

<sup>143</sup> *Id.*

<sup>144</sup> See, e.g., Brennan et al., *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, *supra* note 27. (citing numerous studies); Chren, *supra* note 27 at 1893 (same).

<sup>145</sup> Laurie Barclay, *Access to Drug Samples May Influence Resident Physician Prescribing*, 118 AM. J. MED. 881, 882 (2005).

<sup>146</sup> WEBER, *supra* note 129 at 85–86 (quoting KATHERINE GREIDER, THE BIG FIX: HOW THE PHARMACEUTICAL INDUSTRY RIPS OFF AMERICAN CONSUMERS 76 (2003)).

<sup>147</sup> Bob Goodman, *Do Drug Company Promotions Influence Physician Behavior?* 174 WEST. J. MED. 232 (2001).

<sup>148</sup> Dana & Lowenstein *supra* note 118 at 254. Susan L. Coyle, *Physician-Industry Relations. Part I: Individual Physicians*, 136 ANNALS INTERNAL MED. 396, 397 (2002) (citing studies). See also, MICHAEL S. PRITCHARD, PROFESSIONAL INTEGRITY: THINKING ETHICALLY, 60–66 (2006).

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scribing practices,<sup>149</sup> while also tending to believe that accepting gifts might affect their colleagues' decisionmaking.<sup>150</sup> Physicians are particularly adamant that small gifts, like samples and office trinkets, are harmless,<sup>151</sup> and that accepting them is not ethically problematic.<sup>152</sup> Yet, studies have found that small gifts can be just as effective as large ones in creating a sense of obligation in the recipient.<sup>153</sup>

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 survey of residents and faculty at an academic medical institution, respondents indicated that drug samples did influence their choice of drugs for patients.<sup>154</sup> In another survey, researchers found that over 90 percent 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.<sup>155</sup> Another study found that 55 percent of surveyed family medicine residents believed that their access to samples influenced their prescribing behavior.<sup>156</sup> 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."<sup>157</sup> 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.<sup>158</sup>

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.<sup>159</sup> Reconciling them is easier if the bias created by drug promotions is unconscious—recognizable in others but not in oneself.<sup>160</sup>

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.<sup>161</sup> 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.<sup>162</sup> Dana and Loewenstein conclude:

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<sup>149</sup> Dana & Loewenstein, *supra* note 118 at 253–254.

<sup>150</sup> *Id.* at 254.

<sup>151</sup> 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).

<sup>152</sup> *Id.*

<sup>153</sup> Blumenthal, *supra* note 94 at 1887.; Katz et al., *supra* note 120 at 40.

<sup>154</sup> Brett et. al., *supra* note 151 at 2216.

<sup>155</sup> 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).

<sup>156</sup> Chew et al., *supra* note 124 at 481.

<sup>157</sup> 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 percent-50 percent) than promotional material does (22 percent)"); *See also*, Barclay, *supra* note 145 at 882.

<sup>158</sup> Dana & Loewenstein, *supra* note 118 at 254.

<sup>159</sup> *See, e.g.*, Dana & Loewenstein, *supra* note 118; Brett et al., *supra* note 151.

<sup>160</sup> Dana & Loewenstein, *supra* note 118 at 254.

<sup>161</sup> *Id.* at 253.

<sup>162</sup> Katz et al., *supra* note 120 at 40 (citing studies).

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.<sup>163</sup>

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.<sup>164</sup>

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 continue to provide them?"<sup>165</sup> The former president of Pfizer Pharmaceuticals has even stated that "marketing 'is almost as scientific as anything we do.'"<sup>166</sup>

It is not the value of the gift but the giving of the gift that triggers the sense of obligation.<sup>167</sup> The establishment of this "gift relationship" that creates obligation in the recipient has been well studied by social scientists and is found across cultures.<sup>168</sup> At the same time, the drug rep who creates 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.<sup>169</sup>

#### IV. DRUG SAMPLES AND THE LEARNED INTERMEDIARY RULE

The fact that the pharmaceutical companies market prescription drugs in a way that creates 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

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<sup>163</sup> *Id.*

<sup>164</sup> *Id.* at 42

<sup>165</sup> Dana & Loewenstein, *supra* note 118 at 254.

<sup>166</sup> 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)).

<sup>167</sup> *Id.* at 41 (citing research in sociology and anthropology exploring gift-giving and reciprocity).

<sup>168</sup> Coyle, *supra* note 148 at 398 (citing research).

<sup>169</sup> 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 (Dec. 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).

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the risks of those drugs to their patients. Physicians befriended by drug reps may take the information and misinformation provided by drug reps in the best possible light, underestimating the risks and over estimating the benefits of the drugs. The drug reps create this bias yet their employers are protected from the results of the physician's exercise of this bias, in the form of inadequate verbal warnings, as long as a written warning is provided in the sample box and the physician's desk reference.<sup>170</sup>

Research has shown that patients receive minimal, and perhaps in some cases incorrect, information when receiving samples. One study, involving observations of 1,600 physician-patient interactions in family practice, found that samples were distributed in almost 20 percent of office visits but "detailed patient education regarding these drugs was rarely observed in patient encounters."<sup>171</sup> 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.<sup>172</sup>

Many factors could contribute to physicians' distribution of samples without giving adequate verbal warnings. Physicians may simply be too busy to spend enough time with patients. Physicians may also be misinformed by drug reps about the relative merits of drugs, or they might unconsciously feel obligated to those who have given them gifts, bought lunch for their staff, and paid for their continuing legal education and this may affect their willingness and ability to give adequate warnings.<sup>173</sup> If any of these factors exist, this conduct is 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 drug companies who knowingly create a situation that is likely lead to patients receiving 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 if 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."<sup>174</sup> 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.<sup>175</sup>

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<sup>170</sup> 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.

<sup>171</sup> Backer et al., *supra* note 135 at 811.

<sup>172</sup> *Id.* at 815.

<sup>173</sup> Wazana, *supra* note 102 at 373 (10 percent of continuing medical education is paid for by drug companies).

<sup>174</sup> M. Stuart Madden, *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 overpromotion 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).

<sup>175</sup> *See* Mahr v. G.D. Searle & Co., 72 Ill.App.3d 540 (1979); Stevens v. Parke Davis & Co., 9 Cal.3d 51 (1973).

For example, in *Salmon v. Parke, Davis & Co.*,<sup>176</sup> 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 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.<sup>177</sup>

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.<sup>178</sup> 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.<sup>179</sup> 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.<sup>180</sup>

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 is negligent in failing 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, coupled with the drug company choosing to bypass the written warnings provided when a prescription is written, should be enough to shift the burden of proof on the learned intermediary rule in this context.

The way in which drug companies market prescription drug samples negates 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 drug companies lack effective means to communicate risk; and 3) that direct warnings would interfere with the doctor-patient relationship.<sup>181</sup>

Even though the physician has the duty to obtain informed consent from the patient, 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, suggest 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

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<sup>176</sup> 520 F.2d 1359 (4th Cir. 1975).

<sup>177</sup> *Id.* at 1363.

<sup>178</sup> See generally, Ausness, *supra* note 45 at 133-135.

<sup>179</sup> See *Love v. Wolf*, 249 Cal.App.2d 822, 823-833, 836-837 (1967).

<sup>180</sup> *Baldino v. Catagna*, 505 Pa. 239, 248 (1984); 17 Am. Jur. Trials § 5 (Cum. Supp. 2006).

<sup>181</sup> See, *supra* notes 44-54 and accompanying text.

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Wisconsin, and even some private practices,<sup>182</sup> have instituted such bans. Many others have called for such bans and some states have considered passing laws banning samples.<sup>183</sup> The drug company, which creates the physician's conflict between his/her duty to his/her patient, on the one hand, and his/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 companies' marketing techniques can interfere with the physician's capacity for independent judgment in such a way as to prevent the physician from being in the best position to evaluate the needs of patients.<sup>184</sup>

Applying the learned intermediary rule to harm from sample prescription drugs encourages drug 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.<sup>185</sup> Their goal in giving samples is to hook patients on brand-name drugs 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."<sup>186</sup> 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.<sup>187</sup> This extra layer of warning is absent when a patient receives a sample directly from a physician, and that absence benefits 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 instruc-

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<sup>182</sup> 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 Univ. Medical Center); Fred Charatan, *Hospital Bans Free Drug Samples*, 174 WEST J. MED. 236, 236 (2001) (the Univ. 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.). *See generally*, Roni Caryn Rabin, *Free Drug Samples? Bad Idea, Some Say*, N.Y. TIMES, (May 1, 2007) at D5.

<sup>183</sup> Charatan, *supra* note 182 at 236–237; Brennan et al. *supra* note 90 at 431–433 (proposing that samples be banned in academic medical centers and replaced with vouchers for low-income patients).

<sup>184</sup> 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).

<sup>185</sup> 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.").

<sup>186</sup> AVORN, *supra* note 96 at 302.

<sup>187</sup> *See* ABOOD & BRUSHWOOD *supra* note 80 at 112; *supra* note 169 and accompanying text.

tions 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.<sup>188</sup>

Drug companies do not lack effective means to communicate the risk of samples, the second standard justification for the learned intermediary rule.<sup>189</sup> Some drug manufacturers do in fact provide prescribing information with the sample,<sup>190</sup> while others make implicit claims that they do. For example, one study found that 62 percent of the labels on the inside package of sample prescription drugs referred the user to "enclosed prescribing information" but that for 27.3 percent of those samples, no such information was included with the packaging of that individual sample or group of samples.<sup>191</sup> This study included samples of some common prescription drugs including Augmentin, Celebrex, Cipro, Coumadin, Paxil, Prozac, Viagra and Zithromax.<sup>192</sup> 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.<sup>193</sup> Yet drug companies purport in their inside labeling of individual samples to be directing the user to this insert. Thus, 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 appropriate warnings.

Pharmaceutical companies have many options for warning patients of risks. In the research discussed above, 31 percent of the samples studied included patient instruction pamphlets inside the individual boxes of samples. 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).<sup>194</sup>

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<sup>188</sup> Harris, *supra* note 27.

<sup>189</sup> See *supra* notes 49–51 and accompanying text.

<sup>190</sup> Jennifer L. Dill & Joyce A. Generali, Medication Sample Labeling Practices, 57 AM. J. HEALTH-SYSTEM PHARMACISTS 2087, 2089 (2000).

<sup>191</sup> *Id.*

<sup>192</sup> *Id.* at 2088.

<sup>193</sup> See *infra* notes 228–31 and accompanying text.

<sup>194</sup> 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.

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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 interfere with that relationship by creating an unconscious bias and sense of obligation in physicians.<sup>195</sup> The risk of unlabeled samples is then imposed on a public that is largely not aware of drug company's aggressive promotions to physicians and the bias it creates.<sup>196</sup>

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.<sup>197</sup> 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 must 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.<sup>198</sup>

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 decisionmaking 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 knows 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 their relationship with their patients by creating 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.<sup>199</sup> 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 taking 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.<sup>200</sup> 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.

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<sup>195</sup> See *supra* notes 153–169 and accompanying text.

<sup>196</sup> 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").

<sup>197</sup> Ausness, *supra* note 45 at 106–107.

<sup>198</sup> *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).

<sup>199</sup> 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.

<sup>200</sup> *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65, 69–70 (Mass. 1985).



Sample prescription drugs are distributed to patients in an entirely different context. Drug companies know when samples are not individually labeled and they know that the samples are likely to be 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. With unlabeled samples, patients are not given the choice whether to read, and retain, instructions and warnings. 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 OTC drugs, they remain without special packaging, instructions and warnings to alert others to their contents and risks.<sup>201</sup>

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 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, drug companies would still be able to raise a claim of regulatory compliance and preemption.<sup>202</sup> That is, even without the shield of the learned intermediary rule, drug companies could argue that they 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. Each of these will be addressed in turn.

## V. THE REGULATORY COMPLIANCE AND 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,<sup>203</sup> 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 acceptable conduct but rather the extent of the duty to label prescription drugs. The preemption defense is that 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 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.

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<sup>201</sup> See *infra* note 247 and accompanying text.

<sup>202</sup> For a discussion of these defenses, see *infra* Part V.

<sup>203</sup> Robert Rabin refers to this as a “close cousin” of the preemption defense. Robert L. Rabin, *Keynote Paper: Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2053 (2000).

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Regulatory compliance is often considered good evidence of reasonable conduct, but is not dispositive on the issue.<sup>204</sup> The *Restatement (Third) of Torts: Products Liability* confirms this widely adopted view of regulatory compliance in general,<sup>205</sup> 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.<sup>206</sup>

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, FDA itself stated that it intends its regulations to preempt state law claims.<sup>207</sup> Upon 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 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 FDA regulate sample prescription drugs.

### A. Federal Regulation of Prescription Drug Samples

Prescription drugs are regulated by FDA acting under the authority of the FDCA<sup>208</sup> as amended by the Prescription Drug Marketing Act of 1987 (PDMA).<sup>209</sup> 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.<sup>210</sup> Under the law, "No person may sell, purchase or trade or offer to sell, purchase or trade any drug sample."<sup>211</sup> 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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<sup>204</sup> See *Restatement (Third) of Torts: Product Liability* § 4 (1997); Ellen Relkin, *Warnings in Pharmaceutical Cases: Is the Learned Intermediary Obsolete in the New Millennium?*, SF28 ALI-ABA 227, 235 (2000) ("It is . . . beyond cavil that FDA regulations constitute 'minimum standards.'") (citation omitted).

<sup>205</sup> *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.

<sup>206</sup> *Restatement (Third) of Torts: Products Liability* § 6 cmt. b (1997).

<sup>207</sup> 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, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. (forthcoming 2007) (on file with author).

<sup>208</sup> 21 U.S.C. §§ 301-399 (2000).

<sup>209</sup> Pub. L. No. 100-293, 102 Stat. 95 (1987). The PDMA was in turn amended by the Prescription Drug Amendments Act in 1992, Pub. L. No. 102-353, 106 Stat. 941 (1992). Jennifer A. Romanski, *The Final Sampling Regulations of the Prescription Drug Marketing Act Are Alive and Well: Is your Sampling Program Compliant?* 58 FOOD & DRUG L.J. 649, 649 (2003).

<sup>210</sup> Romanski, *supra* note 209 at 649; see also, Erica L. Niezgoda & Maureen M. Richardson, *Federal Food and Drug Act Violations*, 35 AM. CRIM. L. REV. 767, 786 (1998) (describing the criminal sanctions levied by the Act).

<sup>211</sup> 21 U.S.C. § 353(c)(1) (2000).

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

The statute sets out the requirements for the distribution of drug samples to physicians, healthcare professionals, and healthcare entities such as hospitals or pharmacies.<sup>215</sup> 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.<sup>216</sup> Apart from making it explicitly legal, the provision of free drug samples by healthcare practitioners to patients is not addressed in the statute.

Federal law also prohibits the introduction into commerce of any drug that is misbranded.<sup>217</sup> Misbranding includes labeling that is false or misleading.<sup>218</sup> 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 FDA.<sup>219</sup> 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 addressing the distribution and labeling of prescription drugs.

Under the authority of the FDCA and PDMA, FDA further regulates the labeling of prescription drugs. Its most stringent regulation of samples picks up on PDMA’s prohibition on the sale of samples and its concern with a black market. FDA specifies many aspects of the transaction between drug manufacturers and healthcare practitioners, including the content of the request and receipt of samples and who must sign for them.<sup>220</sup> There are different regulations for distribution by mail as opposed to in-person by representatives of drug companies;<sup>221</sup> provisions on the proper storage and handling of samples;<sup>222</sup> and rules about donation of drug samples to charity.<sup>223</sup> These regulations follow logically from Congress’ objective of preventing 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.”<sup>224</sup> 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.<sup>225</sup> 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

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<sup>212</sup> *Id.*

<sup>213</sup> 21 U.S.C. § 353(d) (2000).

<sup>214</sup> *Id.*

<sup>215</sup> *Id.*

<sup>216</sup> *Id.*

<sup>217</sup> 21 U.S.C. § 33(a) (2000).

<sup>218</sup> 21 U.S.C. § 352(a) (2000).

<sup>219</sup> 21 U.S.C. § 352(b) (2000).

<sup>220</sup> See Romanski, *supra* note 209 at 653–654.

<sup>221</sup> Niezgoda & Richardson, *supra* note 210 at 769–864.

<sup>222</sup> 21 C.F.R. § 203.32 (2006).

<sup>223</sup> 21 C.F.R. § 203.39 (2006).

<sup>224</sup> Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan.24, 2006) (to be codified at 21 CFR pts. 201, 314, 601).

<sup>225</sup> *Id.*

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source about prescription drugs for physicians.<sup>226</sup> 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.<sup>227</sup>

“Trade labeling” is the labeling that is “on or within the package from which a prescription drug is to be dispensed.”<sup>228</sup> Trade labeling must also accompany packages of samples when they are distributed to physicians.<sup>229</sup> FDA has found that physicians tend to reference trade labeling substantially less often than other types of labeling.<sup>230</sup> The contents of trade labeling must be in 6-point type.<sup>231</sup>

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.<sup>232</sup> This type of labeling must also receive FDA approval.<sup>233</sup> 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 the risks of prescription drugs.

FDA-approved patient labeling, also known as medication guides or patient package inserts, is intended for patients and is required for certain prescription drugs.<sup>234</sup> In the 1970s, FDA required medication guides for oral contraceptives.<sup>235</sup> These were the medication guides at issue in the *MacDonald* case.<sup>236</sup> Since then, FDA has required patient labeling for asthma inhalation medicines and IUDs, among others.<sup>237</sup> In 1979, and again in 1995, FDA proposed rules requiring patient package inserts for nearly all prescriptions drugs, but in both cases the rules were eventually withdrawn because of opposition from the pharmaceutical industry.<sup>238</sup> 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.”<sup>239</sup>

In January 2006, FDA revised the labeling regulations for package inserts for prescription drugs. This is the type of labeling directed at healthcare providers, not

<sup>226</sup> 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”).

<sup>227</sup> Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3971.

<sup>228</sup> *Id.* at 3979.

<sup>229</sup> *Id.* See *supra* notes 87–89 and accompanying text for discussion of package inserts.

<sup>230</sup> Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3958.

<sup>231</sup> *Id.* at 3955.

<sup>232</sup> 21 C.F.R. 202.1(l)(2) (2006).

<sup>233</sup> Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3957.

<sup>234</sup> See, 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.”)

<sup>235</sup> *MacDonald v. Ortho Pharmaceutical Corp.* 475 N.E.2d 65, 67 (Mass. 1985); Walsh et al., *supra* note 34 at 823.

<sup>236</sup> *MacDonald*, 475 N.E.2d at 67.

<sup>237</sup> Paytash, *supra* note 43 at 1354; Walsh et al., *supra* note 34 at 829.

<sup>238</sup> Walsh et al., *supra* note 34 at 830.

<sup>239</sup> Justina A. Molzon, *The FDA’s Perspective on the Future of Pharmacy*, 44 DRAKE L. REV. 463, 464 (1996).

patients. The changes to the regulations were designed “to make it easier for healthcare practitioners to find and read information important for the safe and effective use of prescription drugs.”<sup>240</sup> 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.<sup>241</sup> 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.<sup>242</sup> This is consistent with findings that physicians tend not to consult trade labeling.<sup>243</sup> The revised regulations were aimed at healthcare 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.<sup>244</sup> These revisions 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 healthcare practitioners to scan drugs before dispensing them in order to reduce errors in hospitals.<sup>245</sup> In January 2007, FDA issued a report announcing that it would study and improve its oversight of the safety of prescription drugs after they reach the market.<sup>246</sup>

FDA takes a much less rigorous approach to the labeling of prescription drug samples than to the labeling of prescription drugs in general. 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.<sup>247</sup> The 2006 revisions of prescription drug labeling regulations address samples only insofar as the new regulations affected trade labeling.<sup>248</sup> Although FDA received comments asking them to provide more information on drug sample units, FDA declined to make the change, citing the already existing requirement that trade labeling be included in the packaging of sample units.<sup>249</sup>

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<sup>240</sup> Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3970 (Jan. 24, 2006) (to be codified at 21 CFR pts. 201, 314, 601).

<sup>241</sup> *Id.*

<sup>242</sup> *Id.* at 3958; FDA, *FDA Guidance for Industry: Labeling for Human Prescription Drug and Biological Products—Implementing the New Content and Format Requirements*, <http://www.fda.gov/cder/guidance/6005dft.htm> (last visited Feb. 19, 2007).

<sup>243</sup> *See supra*, note 230 and accompanying text.

<sup>244</sup> 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.”).

<sup>245</sup> *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 (Feb. 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.”)

<sup>246</sup> Press Release, FDA, FDA Reinforces Commitment to Drug Safety: Progress Underway, New Initiatives Announced in Response to Institute of Medicine Recommendations (Jan. 30, 2007), available at <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01551.html>

<sup>247</sup> 21 C.F.R. § 203.38 (2006).

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

<sup>249</sup> *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 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).

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This brief tour through the federal scheme of regulation of samples and prescription drug labeling demonstrates that neither Congress nor 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 healthcare providers. FDA's labeling concerns focus primarily on getting the right kind of information in the right format to the healthcare providers and pharmacists so that they can make appropriate prescribing and dispensing decisions and effectively counsel patients.<sup>250</sup> 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 he/she is dispensing and can run drug interaction checks, and it is placed in the PDR for the physician or other healthcare provider. These parallel warning tracks are an important part of FDA's regulatory scheme. This article contends that provision of samples without warnings to a patient disrupts rather than reinforces FDA's focus on providing adequate information to healthcare professionals so that they can adequately counsel patients.

### B. *The Preemption and Regulatory Compliance Defenses*

Preemption is an affirmative defense that liability based on state law should be foreclosed because it would interfere with Congress' regulatory scheme. Historically, the preemption analysis begins and ends with Congressional intent.<sup>251</sup> The doctrine, rooted in the Supremacy Clause of the Constitution,<sup>252</sup> 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.<sup>253</sup> The Supreme Court has 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:

[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.<sup>254</sup>

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<sup>250</sup> For example, the new format of the package inserts includes a Patient Counseling Information Section, which is prominently displayed. FDA, *Information for Healthcare Professionals on FDA's New Prescribing Information for Drugs*, [http://www.fda.gov/cder/regulatory/physLabel/physLabel\\_HCP.htm](http://www.fda.gov/cder/regulatory/physLabel/physLabel_HCP.htm) (last visited Feb. 19, 2007).

<sup>251</sup> *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.”).

<sup>252</sup> 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.”).

<sup>253</sup> OWEN, *supra* note 47 at § 14.4; *Geier v. American Honda Motor Co.*, 529 U.S. 861, 869–874 (2000).

<sup>254</sup> *Cipollone v. Liggett Group*, 505 U.S. 504, 521 (1992) (quoting *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 247 (1959)). See also Richard A. Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda*, 1 J. Tort L. 5, 8 (2006), <http://www.bepress.com/jtl/vol1/iss1/art5>.

Because there is no express preemption in the FDCA concerning the duty to warn on prescription drugs,<sup>255</sup> 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.<sup>256</sup> 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.<sup>257</sup>

[B]ecause 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 ... we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.<sup>258</sup>

The health and safety of its citizens is one of those fields traditionally occupied by state law.<sup>259</sup>

Until relatively recently, FDA itself took the position that state tort liability was generally not preempted by prescription drug labeling regulations.<sup>260</sup> In originally promulgating its rules for patient labeling of prescription contraceptives, FDA was aware that the regulations might be used to bolster an independent state tort duty to provide patient information. As a result, FDA stated that this labeling was "not intended to 'affect adversely the standard of civil tort liability which is imposed on drug manufacturers and dispensers.'"<sup>261</sup> In other words, the federal requirements *per se* should not give rise to other duties.<sup>262</sup> 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."<sup>263</sup> 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.<sup>264</sup>

By analogy, this means that in the case of labeling of prescription drug samples, the minimal FDA requirements for labeling should not affect state-law duties owed

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<sup>255</sup> Hall, *supra* note 38 at 229.

<sup>256</sup> Caraker v. Sandoz Pharmaceuticals Corp., 172 F. Supp. 2d 1018, 1031 (S.D.Ill. 2001).

<sup>257</sup> Geier, 529 U.S. at 871-873 (2000).

<sup>258</sup> Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996) (internal citations omitted).

<sup>259</sup> Caraker, 172 F. Supp. 2d at 1032.

<sup>260</sup> See Caraker, 172 F. Supp. 2d at 1036 ("there is evidence that 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.

<sup>261</sup> 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)).

<sup>262</sup> *Id.*

<sup>263</sup> *Id.*

<sup>264</sup> MacDonald v. Ortho Pharmaceutical Corp., 475 N.E.2d 65, 71 (Mass. 1985).

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by drug manufacturers to consumers. Seemingly in agreement, as recently as 2000, FDA stated that its labeling regulations did not preempt state law.<sup>265</sup> 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 requirements.<sup>266</sup> Courts have interpreted Congress' intent in passing the FDCA and delegating rulemaking to FDA to create minimal standards for warnings on prescription drugs, which drug companies and state law may enhance with more extensive information.<sup>267</sup>

One of the reasons that courts have rejected implied preemption for prescription drug labeling is that 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 FDA. Under 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."<sup>268</sup> The manufacturer can make these changes without FDA approval, as long as FDA is notified.<sup>269</sup>

An illustrious case is *Caraker v. Sandoz*.<sup>270</sup> The plaintiff in *Caraker* suffered a stroke after taking the drug Palodel, a postpartum lactation-control drug.<sup>271</sup> The court held that Illinois' common law duty to warn was not preempted by the FDCA or FDA's regulations about prescription drug labeling because FDA standards were intended to be minimum standards.<sup>272</sup> FDA permitted and even encouraged state law to require pharmaceutical companies to include known risks, even if discovered after the labeling had been approved by FDA.<sup>273</sup>

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,<sup>274</sup> nonprescription drugs<sup>275</sup> and

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<sup>265</sup> See *Weiss v. Fujisawa Pharmaceutical Co.*, 464 F. Supp. 2d 666, 669–670 (E.D. Ky. 2006).

<sup>266</sup> *Caraker v. Sandoz Pharmaceuticals Corp.*, 172 F. Supp. 2d 1018, 1033–1034 (S.D. Ill. 2001), *Motus v. Pfizer, Inc.*, 127 F. Supp. 2d 1085, 1095 (C.D. Cal. 2000), *Cartwright v. Pfizer*, 369 F. Supp. 2d 8766 (E.D. Tex. 2005); See generally, Samuel Issacharoff & Catherine M. Sharkey, *Backdoor Federalization*, 53 UCLA L. REV. 1353, 1389 (products cases "typically present themselves as part of an incomplete federal regime.")

<sup>267</sup> Robert Rabin correctly points out that, notwithstanding what courts say, 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 2055–2056. This does not preclude states from imposing more stringent standards, but it does make language about minimal standards somewhat misleading.

<sup>268</sup> 21 C.F.R. § 201.57(e) (2006).

<sup>269</sup> 21 C.F.R. § 314.70(c) (2006).

<sup>270</sup> 172 F. Supp. 2d 1018 (S.D. Ill. 2002).

<sup>271</sup> *Id.* at 1022.

<sup>272</sup> *Id.* at 1031–1032.

<sup>273</sup> *Id.*

<sup>274</sup> Medical Device Amendment to the FDCA, 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. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) (MDA preempts fraud-on-the-FDA 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.).

<sup>275</sup> National Uniformity for Nonprescription Drugs Act, 21 U.S.C. § 379r (2000) ("(a) In 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.)").



cigarettes,<sup>276</sup> 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.<sup>277</sup> This concern also applies to the regulatory compliance defense for drug labeling:

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 healthcare 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.<sup>278</sup>

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.<sup>279</sup> 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.<sup>280</sup> The issue of overwarning is an important consideration in the labeling of non-prescription, OTC drugs where there is no learned intermediary and where Congress, in giving regulatory authority to FDA, has expressly preempted state tort liability over failure to warn.<sup>281</sup>

Despite the history of non-preemption in this area, recent statements by FDA and recent Supreme Court rulings have raised new questions about preemption. Over the past six years, FDA has routinely asserted that its regulations on prescription drug labeling preempt state law, despite the absence of express preemption in the statute and the long history of FDA's own position against preemption. FDA's new position first came to light most prominently in an amicus brief that it filed in 2002 in the case of *Motus v. Pfizer*.<sup>282</sup> That case involved the issue of whether Pfizer, the manufacturer of the prescription anti-depressant drug Zoloft, should have warned

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<sup>276</sup> *Cipollone v. Liggett Group*, 505 U.S. 504 (2002) (interpreting Public Health Cigarette Smoking Act of 1969); 15 U.S.C. § 1334(b) (2000) (“No requirement or prohibition based 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.”).

<sup>277</sup> Walsh et al., *supra* note 34 at 874, n.203; Howard Latin, “Good” Warnings, Bad Products, and Cognitive Limitations, 41 UCLA L. REV. 1193 (1994).

<sup>278</sup> W. Kip Viscusi, Steven R. Rowland, Howard L. Dorfman, Charles J. Walsh, *Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1468 (1994).

<sup>279</sup> *Id.*

<sup>280</sup> See *supra* note 44 and accompanying text.

<sup>281</sup> Underwarning can also present a problem. The need to find and maintain a balance in warning sometimes leads 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, (Dec. 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.”).

<sup>282</sup> 358 F.3d 659 (9th Cir. 2004).

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of the risk of suicide.<sup>283</sup> 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.<sup>284</sup> But FDA's preemption brief has nevertheless garnered a lot of attention as a clear statement of a policy change by FDA about the preemptive effect of its prescription drug regulations.<sup>285</sup>

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

FDA, the federal agency charged with regulating the manufacture, sale, and labeling of prescription drug products, has a clear interest to 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.<sup>286</sup>

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.<sup>287</sup> 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 FDA simply equates one loss in a lawsuit to a state-imposed labeling requirement. Regardless, FDA's reasoning is fairly simple: because it is responsible for determining both what should be included on a prescription drug label and what constitutes misbranding,<sup>288</sup> 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 FDA's other main task, which is to determine which drugs are safe and effective.<sup>289</sup> In the case of Zoloft, FDA had weighed the evidence of a link

<sup>283</sup> 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.

<sup>284</sup> 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).

<sup>285</sup> 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., (Mar. 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.").

<sup>286</sup> 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).

<sup>287</sup> *See* Epstein, *supra* note 254 at 26; Sharkey, *supra* note 207 at 23, n.98.

<sup>288</sup> *See* 21 U.S.C. 331(a), (b) & (k) (2000).

<sup>289</sup> 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, FDA's approval process for drug labels is not aimed at minimal safety.

between the drug and increased risk of suicide and decided that there was no causal connection,<sup>290</sup> so to warn of one would amount to placing false information on a label.<sup>291</sup> FDA characterized this as classic “conflict” preemption because permitting tort liability would require the drug company to choose between following state or federal law.<sup>292</sup>

In January 2006, FDA revised its regulations concerning the labeling of prescription drugs, as discussed above.<sup>293</sup> In the Preamble to this rulemaking, 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.<sup>294</sup> The Preamble stated:

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 ...<sup>295</sup>

FDA offered two overarching reasons for this blanket preemption. The first is the “expertise” rationale, and the second is the “repose” rationale. The expertise rationale is essentially that FDA is the congressionally designated expert on the health and safety aspects of prescription drugs.<sup>296</sup> 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:

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 evaluation of the product’s risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling.<sup>297</sup>

To support this, 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 consider tort liability to be 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

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<sup>290</sup> Brief for the United States, *supra* note 286 at 2–3.

<sup>291</sup> Despite this position in *Motus*, FDA has since placed warnings about suicide by children on SSRI’s and recently held hearings to determine if it should expand those warnings to include adults. Benedict Carey, *Panel to Weigh Expansion of Antidepressant Warnings*, N.Y. TIMES, (Dec. 13, 2006) at A30.

<sup>292</sup> Brief for the United States, *supra* note 286 at 15.

<sup>293</sup> See discussion *supra* note 224 and accompanying text.

<sup>294</sup> Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3967 (Jan. 24, 2006) (to be codified at 21 CFR pts. 201, 314, 601).

<sup>295</sup> *Id.* at 3922.

<sup>296</sup> *Id.* at 3934

<sup>297</sup> *Id.*

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than against preemption.<sup>298</sup> The most serious of these consequences include the stifling of innovation and delay in bringing much needed drugs to market.<sup>299</sup> This is an endorsement of the expert theory because it implies that FDA is doing all that needs to be done to protect the public in the context of prescription drugs.<sup>300</sup>

The repose rationale focuses not on the expertise of 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 FDA stated:

If State authorities, including judges and juries applying State law, were permitted to reach conclusions about the safety and effectiveness of 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<sup>301</sup>

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 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 solely 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.<sup>302</sup> 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.

FDA's attempt to establish preemption by regulatory fiat, or what Sharkey has dubbed, "preemption by preamble,"<sup>303</sup> 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,<sup>304</sup> so it would be consistent to pay attention to the agency's pro-preemption stance.<sup>305</sup>

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<sup>298</sup> Epstein, *supra* note 254 at 2–3.

<sup>299</sup> *Id.* at 4.

<sup>300</sup> Epstein does not, however, endorse 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.

<sup>301</sup> Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3969.

<sup>302</sup> *Id.*

<sup>303</sup> Sharkey, *supra* note 207 at 1–3.

<sup>304</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495–496 (1996).

<sup>305</sup> Epstein, *supra* note 254 at 30–31.

A few cases have addressed the 2006 FDA Preamble. In *Abramowitz v. Cephalon, Inc.*,<sup>306</sup> 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.<sup>307</sup> A similar conclusion was recently reached by the Eastern District of Pennsylvania.<sup>308</sup>

Other courts, however, have been less receptive to the preemptive effect of FDA's Preamble. In *Perry v. Novartis Pharmaceutical Corp.*,<sup>309</sup> a more recent case from the Eastern District of Pennsylvania, the court rejected *Chevron* deference when 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."<sup>310</sup> 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 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.<sup>311</sup> Another court addressing the same Preamble in litigation over the same drug treated the Preamble to *Skidmore* deference, which holds that the agency's interpretations are "entitled to respect" only to the extent that they have the "power to persuade."<sup>312</sup> Both the *Weiss* and the *Perry* courts, along with several others, held that the Preamble was an advisory opinion, not subject to notice and comment, and therefore not subject to *Chevron* deference.<sup>313</sup>

There are two important implications of FDA's new position on preemption of drug labeling requirements when considering the labeling of samples. First, it is still unclear whether 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.<sup>314</sup> Second, and more significantly, even if the Supreme Court eventually accepts 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.

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

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<sup>306</sup> *Abramowitz v. Cephalon, Inc.*, No. BER-1-617-04, 2006 WL 560639 (N.J. Super. Ct. Mar. 3, 2006).

<sup>307</sup> *Id.* at \*3. See also, Sharkey, *supra* note 207 at 13–18.

<sup>308</sup> See *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006).

<sup>309</sup> 456 F. Supp. 2d 678 (E.D. Pa. 2006).

<sup>310</sup> *Id.* at 864 (internal quotations omitted).

<sup>311</sup> *Id.* at 685. It was based on the issue of the specificity of FDA's findings as to that particular risk that distinguished this case from *Colacicco*. In *Colacicco*, 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.

<sup>312</sup> *Weiss v. Fujisawa Pharmaceutical Co.*, 464 F. Supp. 2d 666, 673 (E.D. Ky. 2006) (quoting *Skidmore v. Swift*, 323 U.S. 134, 140 (1944)).

<sup>313</sup> *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 *Jackson v. Pfizer*, 432 F. Supp. 2d 964 (D. Neb. 2006) and *In re Zyprexa Products Liability Litigation*, 489 F.Supp.2d 230 (E.D.N.Y. 2007).

<sup>314</sup> See generally, *Colacicco v. Apotex, Inc.*, 432 F.Supp.2d 514 (E.D.Pa. 2006); *Perry*, 456 F.Supp.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.

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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 FDA has considered and then rejected this type of labeling based on scientific information.<sup>315</sup> 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 the patient, does not involve the question of the adequacy of the content of the warning and the risks and benefits of alternative warnings.<sup>316</sup> 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 FDA. In response to a query by the judge in *Perry*, 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.<sup>317</sup>

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?<sup>318</sup>

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.<sup>319</sup> There is also no evidence in FDA regulations that the decision not to require warnings on sample prescription drugs was the result of an examination of the 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 drug

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<sup>315</sup> 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 TENN. L. REV. 691, 717 (1997).

<sup>316</sup> Drug companies have a lot of experience with these patient package inserts because FDA requires them in some contexts. *See supra*, notes 234-239 and accompanying text.

<sup>317</sup> Weiss, 464 F.Supp.2d at 672 (quoting Letter to Judge Dalzell at 2, *Perry v. Novartis Pharmaceuticals Corp.*, No. 05-5350 (E.D. Pa. Sept. 21, 2006)).

<sup>318</sup> Epstein, *supra* note 254 at 20.

<sup>319</sup> *See supra* notes 277-291 and accompanying text.

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 drug companies would undertake some combination of these approaches, or do nothing at all and take their risks with the liability system. Each of these objections will be briefly addressed.

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.”<sup>320</sup> Many sample drugs are already individually boxed and contain patient information.<sup>321</sup> 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.<sup>322</sup> 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 shift, rather than increase, in resources.

There is also a general impression that sample prescription drugs benefit the poor because they allow physicians to give away free medicine.<sup>323</sup> 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.<sup>324</sup> As one scholar put it, “[P]roviding samples is marketing, pure and simple.”<sup>325</sup> 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.<sup>326</sup> 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 than other patients. 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.<sup>327</sup>

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<sup>320</sup> 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?* <http://www.medscape.com/viewarticle/413404> (last visited Feb. 20, 2007). There is a website created by a physician that is entirely devoted to eliminating drug promotion. It also has suggestions for effective labeling of samples, see <http://www.nofreelunch.org>.

<sup>321</sup> Dill & Generali, *supra* note 190 at 2087.

<sup>322</sup> Manjunath P. Pai, Danielle M. Graci, & Joseph S. Bertino, *Waste Generation of Drug Product Samples Versus Prescriptions Obtained Through Pharmacy Dispensing*, 20 *PHARMACOTHERAPY* 593, 594–595 (2000) (reporting that the packaging of samples creates 5X as much waste as that of drugs dispensed from the pharmacy).; Dill & Generali, *supra* note 190 at 2090; Martin T. Donohoe, Letter to the Editor, *Wasted Paper in Pharmaceutical Samples*, 340 *NEW ENG. J. MED* 1600 (1999).

<sup>323</sup> See e.g. WEBER, *supra* note 128 at 85.

<sup>324</sup> Harris, *supra* note 27.

<sup>325</sup> WEBER, *supra* note 129 at 85.

<sup>326</sup> *Id.*; Coyle, *supra* note 148 at 398.

<sup>327</sup> Saul Weiner, Jill Dischler, & Cheryl Horvitz, *Beyond Pharmaceutical Manufacturer Assistance: Broadening the Scope of an Indigent Drug Program*, 58 *AM. J. HEALTH-SYST. PHARMACISTS* 146, 149 (2001).

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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.<sup>328</sup> In fact, institutions that have banned samples have found that drug costs decrease thereafter.<sup>329</sup> 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 percent of the pharmaceutical industry's revenue from sales.<sup>330</sup> One commentator dubbed these gifts a "surreptitious transfer of wealth from patients to doctors."<sup>331</sup>

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.<sup>332</sup> This might be compromised if, in reaction to liability exposure, drug companies cut down on their promotional activities.<sup>333</sup> 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.<sup>334</sup>

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.<sup>335</sup> 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

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<sup>328</sup> Wilson, *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, *supra* note 137 at 18; WEBER, *supra* note 129 at 84.

<sup>329</sup> Harris, *supra* note 27.

<sup>330</sup> Winston Chiong, *Industry-to-Physician Marketing and the Cost of Prescription Drugs*, 3 AM. J. BIOETHICS 28, 28 (2003).

<sup>331</sup> *Id.*

<sup>332</sup> Blumenthal, *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., *supra* note 120 at 40.

<sup>333</sup> Many physicians are only willing to see drug reps because they want the samples. Darves, *supra* note 182.

<sup>334</sup> Katz et al., *supra* note 120 at 40.

<sup>335</sup> Stephen B. Soumerai & 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.



to educate them about new drugs and practices.<sup>336</sup> 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 healthcare costs.<sup>337</sup> Because “no current regulatory apparatus can ensure that marketed drugs are prescribed intelligently,”<sup>338</sup> 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.<sup>339</sup>

## 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 drug companies through their promotional practices is borne by patients who receive these drugs from physicians in whom 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 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.<sup>340</sup> In fact, effective marketing of pharmaceutical products is enabled 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 himself or herself a participant in the market, where caveat emptor is the guiding principle.<sup>341</sup> The liability shield provided by the learned intermediary rule creates incentives for drug companies to pour money into 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 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 *Vitanz* 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

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<sup>336</sup> *Id.* The author is indebted to Professor Bob Works for bringing this to the author’s attention.

<sup>337</sup> *Id.* at 555–556.

<sup>338</sup> *Id.*

<sup>339</sup> 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 325–326.

<sup>340</sup> *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 Theory*, 85 HARV. L. REV. 537 (1972).

<sup>341</sup> *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).

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to apportion some responsibility to a victim like Mr. Vitanza, who knowingly took a sample drug that was not dispensed to him.<sup>342</sup>

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.<sup>343</sup> 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.”<sup>344</sup> 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 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.<sup>345</sup> As Senator Charles E. Grassley recently lamented, FDA “was far too ‘cozy’ with drug makers.”<sup>346</sup> If true, this cozy relationship may be due in part to the fact that more than 25 percent of FDA’s budget comes from fees collected from drug makers. These fees, negotiated with the drug companies, include the proviso that FDA would not spend much of it on tracking drugs after they are approved and put on the market.<sup>347</sup> 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.<sup>348</sup> 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.<sup>349</sup> New York recently failed to pass such a law because of the lobbying by PhRMA, the lobbying group for brand-name drug companies.<sup>350</sup>

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 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.<sup>351</sup> Other industries whose products or conduct pose direct risks

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<sup>342</sup> *Vitanza v. Upjohn Co.*, 214 F.3d 73, 75 (2d Cir. 2000).

<sup>343</sup> THOMAS H. KOENIG & MICHAEL L. RUSTAD, *IN DEFENSE OF TORT LAW* 5 (2001).

<sup>344</sup> Rabin, *supra* note 203 at 2068; KOENIG & RUSTAD, *supra* note 342 at 5.

<sup>345</sup> Blumenthal, *supra* note 94 at 1889.

<sup>346</sup> Gardiner Harris, *F.D.A. Widens Safety Reviews on New Drugs*, N.Y. TIMES, (Jan. 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.”).

<sup>347</sup> Harris, *FDA Widens Safety*, *supra* note 345.

<sup>348</sup> *See* John Ferejohn, *The Structure of Agency Decision Processes*, in CONGRESS: STRUCTURE AND POLICY 441, 455–559 (Matthew McCubbins & Terry Sullivan eds., (1987)).

<sup>349</sup> 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.

<sup>350</sup> Katz et al., *supra* note 119 at 43.

<sup>351</sup> *See generally* M. Stuart Madden, *The Duty to Warn in Products liability: Contours and Criticism*, 89 W.VA. L. REV. 221 (1987); Restatement (Third) of Torts: Products Liability § 2, cmt. i (1998) (“Commercial product sellers must provide reasonable instructions and warnings about risks of injury posed by products.”).

to the public are required to do this calculation. The pharmaceutical industry's aggressive marketing of unlabeled sample prescription drugs creates a potentially lethal situation for patients. In this context, the learned intermediary rule creates incentives for drug companies that are incompatible with public health.