Physician Suits Against Pharmaceutical And Medical Device Manufacturers: Friend Turned Foe?

By Edward J. Sebold and John Q. Lewis

[Editor’s Note: Edward J. Sebold is a partner with the Jones, Day, Reavis & Pogue law firm in its Cleveland, Ohio office. John Q. Lewis is an associate with the Firm. Mr. Sebold and Mr. Lewis frequently represent drug and device manufacturers, including some of the manufacturers referred to in this article. The views expressed in this article are those of Mr. Sebold and Mr. Lewis, and do not necessarily reflect the views or opinions of their law firm or their clients. Replies to this commentary are welcome. Copyright 2002 the authors.]

I. Introduction

Pharmaceutical and medical device manufacturers are all too familiar with the regulatory risks and with the potential for product liability claims from patients whenever a product is manufactured and sold. The Food and Drug Administration (FDA) has sweeping powers to regulate manufacturers before and after a product is brought to market. Plaintiffs’ lawyers have not hesitated to bring individual and mass tort product liability lawsuits at the first sign of any reported problem with a medical product. As if manufacturers did not have enough to be concerned about, they must also be cognizant of another litigation risk — claims from physicians alleging losses or harm to their medical practice resulting from their use of a manufacturer’s product.

Traditionally, drug and device manufacturers and physicians had a strong relationship. Manufacturers provide physicians with useful product information and often sponsor conferences where physicians can learn more about the manufacturers’ products. In addition, manufacturers assist in the funding of clinical research and employ knowledgeable sales representatives who provide valuable insights to the physicians about their products.

The strength of this relationship often carries over to the field of products liability. When a patient claims that a drug is defective or a device has malfunctioned, manufacturers are generally reluctant to cross-claim against the prescribing physician. Manufacturers might assert that a physician’s misuse of a product broke the chain of causation between the company and any alleged problem experienced by the patient, but that assertion does not necessarily require a separate claim against the physician by the manufacturer. Similarly, a manufacturer might argue that the chain of causation on a patient’s failure to warn claim was broken by showing that a physician, as the learned intermediary, was fully aware of the alleged risk, and decided to use the drug or device anyway. For the most part, however, any attempts by manufacturers to “blame” physicians are relatively benign and generally do not expose physicians to liability.

Most of the time, manufacturers can count on the prescribing physician to support the efficacy of their products. After all, a learned intermediary is expected to know the risks and benefits of the products she prescribes and to weigh those factors before prescribing the products. Legal principles such as comment k to § 402A of the Restatement (Second) of Torts and more recently § 6(c) of the Restatement (Third) of Torts enshrine the notion that drugs and devices have inherent risks that cannot be eliminated and that a product is not defective where the physician knowingly accepts those risks.
in prescribing it. Physicians may also recognize that they have more in common with the interests of the drug and device manufacturers than they do with the plaintiffs attorneys who, when not busy suing manufacturers, might be spending their time bringing medical malpractice claims.

Yet, physicians are becoming more willing to blame drug and device manufacturers for perceived problems with their products and to bring their own lawsuits claiming that an allegedly defective drug or device has harmed their practice. The concept certainly is not new. But increased exposure associated with these physician lawsuits may affect the way business is done between drug and device manufacturers and the physicians who purchase or use their products.

The reasons why physicians choose to assert claims against drug and device manufacturers are not always clear. In some cases, physicians may be feeling economic pressure in their practices (or personal lives) and view a lawsuit against a deep pocket manufacturer as a potential moneymaker. Other physicians may have been subject to malpractice claims from their patients arising from the allegedly defective products. Still others may believe that something is defective with a product and view a lawsuit against the manufacturer as a means to challenge the efficacy of a product. Physicians may also sense a willingness on the part of manufacturers to “blame” the doctors when problems occur with a drug or device. These physicians may simply believe they are returning the favor when suing manufacturers.

Whatever the reason, manufacturers must now be aware of this “other” potential litigant, and consider this litigation risk in the context of the many other issues when designing, manufacturing and marketing their products. This article reviews several representative physician-versus-manufacturer suits and, in analyzing these court decisions, proposes potential ways for manufacturers to reduce the risk of these claims.

II. Theories Of Liability

Physicians have asserted a wide array of liability theories against drug and device manufacturers. In several cases, physicians have alleged that manufacturers were liable under negligence and strict product liability theories. In others, physicians have contended that manufacturers have violated state deceptive trade practice acts. Physicians have also asserted claims for fraud, breach of contract, and breach of warranty against manufacturers. On the “creative” side, most recently, in the Sulzer hip prosthesis litigation, an independent practice association of physicians alleged that the device manufacturer tortiously interfered with the business relationship between the association and its network physicians and, in turn, with the relationship between those physicians and their patients. Some of these theories premise liability on the allegation that manufacturers allegedly failed to reveal the FDA status of a particular drug or device. As discussed below, these claims have met with varying degrees of success.

A. ‘Traditional’ Tort Theories

Physicians who have sued manufacturers have asserted negligence and strict liability causes of action. Although recovery on these theories of liability generally is reserved for the actual patients, or persons physically injured by the product, physicians have had mild success in averting dismissal of these claims. Strict application of tort law doctrines, however, would call into question the propriety of these holdings.

1. The Economic Loss Rule

Physicians alleging traditional product liability claims against manufacturers have an initial hurdle: the economic loss rule. Because physicians suing manufacturers likely would not have suffered any personal injuries, their claims generally seek losses solely for harm to their practice, i.e., business or so-called “economic” losses. Most jurisdictions preclude recovery of economic loss under negligence or strict liability claims.

Notwithstanding this apparently well-established general rule, physicians have managed to circumvent the economic loss rule by a physician against a manufacturer, Oksenholt v. Lederle Labs., 656 P.2d 293 (Ore. 1982), the Oregon Supreme Court permitted a physician suit to go forward
under negligence and misrepresentation theories, though the physician sought losses to his “professional reputation and, consequently, to his earning capacity, and that it caused him to be exposed to a claim for damages for his patient’s loss of vision.” Id. at 296. Seemingly ignoring the economic loss rule, the court held that “[i]f proved, both impairment of earning capacity and lost income are legally cognizable damages that may have stemmed from the torts alleged.” Id. at 298.

On the other hand, a recent federal court decision in Texas granted summary judgment to a medical device manufacturer, holding that the economic loss rule was an alternative ground to dismiss a physician’s product liability claims. Barnett v. Mentor Corp., et al., 133 F. Supp. 2d 507 (N.D. Tex. 2001). In that case, the physician sought to recover damages for replacement surgeries he claimed were necessary because of defects in breast prostheses manufactured by the defendant and, as well, sought damages for harm to his professional reputation and surgical practice. Id. at 509-10. The Court ruled that “[a]fter reviewing the relevant case law” the physician’s product liability claims failed because “the economic loss doctrine prohibits a plaintiff from recovering such economic losses under any product liability theory.” Id. at 513-14.

2. Traditional Tort Defenses
In addition, physicians proceeding under a product liability theory face the same problems their patients would if asserting a claim against the manufacturer — they must prove that the product is defective. This can be difficult in the medical device and prescription drug arena. Proving that a drug or device is defective often requires complex and expensive proof heavily dependent on expert testimony.

Here, the Barnett decision is again illustrative. The Court’s primary reason for granting summary judgment for the manufacturer in that case was the physician’s failure to prove that any of the alleged 41 implants at issue actually were defective. Barnett, 133 F. Supp. 2d at 510 (“[t]his court finds that Barnett has not presented competent summary judgment evidence to controvert Mentor’s evidence that the implants were not defective”).

No black-and-white rule governs physician suits alleging traditional tort-based product liability claims against manufacturers. Although manufacturers should always consider asserting the economic loss rule, it should not be counted on entirely as a safe haven. To defend against these claims, manufacturers should also look to other commonly-asserted defenses to product liability lawsuits, such as lack of proof of defect, product misuse, and lack of causation. Restatement (Second) § 402A comment k and Restatement (Third) § 6(c).

B. Consumer Protection And Deceptive Trade Practice Claims
Physicians have also asserted claims under state consumer protection statutes. Not surprisingly, differently worded statutes have produced varying results in these cases. In many instances, these statutes protect only “consumers” and physicians purchasing drugs or devices for use in their practice may not qualify as consumers. Many state statutes mirror the federal Magnuson Moss Warranty Act, which limits claims to products used “for personal, family or household purposes” and, thus, do not encompass pharmaceuticals and medical devices. In other cases, however, the consumer protection statute at issue was broad enough to encompass the type of business-related purchase by a physician.

The recent Third Circuit decision in Balderston v. Medtronic Sofamor Danek, Inc., et al., 285 F.3d 238 (3d Cir. 2002) illustrates a claim that failed because the physician did not have standing under the operative consumer protection statute. There, Dr. Balderston brought solely a consumer protection law claim against bone screw manufacturers, Medtronic Sofamor Danek and DePuy AcroMed. He alleged, among other allegations of misrepresentation, that the manufacturers concealed the regulatory status of the bone screws, exposing Dr. Balderston to malpractice lawsuits and otherwise harming his professional practice.

The District Court granted the manufacturers’ motion to dismiss primarily because Dr. Balderston was not a “purchaser” of the bone screws. The Court’s alternative holding concluded that, even if Dr. Balderston had purchased the bone screws, his claim failed because his
purchase of the bone screws would not have been for “personal, family, or household purposes” as required by Pennsylvania’s Consumer Protection Law. The Third Circuit affirmed the District Court’s holding and reasoning on both issues, holding that Dr. Balderston was not a “purchaser” and that, because he used the bone screws only “in his medical practice,” he could not assert a claim under the Consumer Protection Law.10

The decision in In re Dow Corning Corp., No. 95-20512, 2000 Bankr. LEXIS 1579 (E.D. Mich. Nov. 3, 2000) also addressed whether physicians were purchasers of medical devices, albeit in a different context. There, the doctors brought claims under the Texas Deceptive Trade Practices Act (DTPA) and the issue was whether the doctors had standing to bring their claims as “consumers” under the DTPA. The record was murky as to whether each doctor had actually purchased breast prostheses from the defendant manufacturer. The Court held that those doctors who had no evidence of a purchase and those doctors who merely received implants through a purchase by a related professional associate or hospital, were not “consumers” under the DTPA. Doctors who had actually purchased the implants at issue had standing to sue under the DTPA.11

In contrast to the Balderston decision are physician-based suits under broadly worded consumer protection statutes. For instance, the Washington Supreme Court permitted a consumer-protection-based claim by a physician in Washington State Physicians Ins. v. Fisons Corp., 858 P.2d 1054 (Wash. 1993).12 There, a physician had cross-claimed against a drug manufacturer in a lawsuit originally involving a medical malpractice claim against the physician. The physician's cross-claim was based, in part, on Washington’s consumer protection statute, which creates a private right of action for “[a]ny person who is injured in his or her business or property by a violation of RCW 19.86.020 . . .” Rev. Code Wash. § 19.86.090.13

Thus, manufacturers defending physician consumer protection law claims initially should focus on the wording of the particular state statute. Depending on this language, physician claims may be precluded or barred because the physician is either not a purchaser or not a consumer, as defined. Alternatively, manufacturers should turn their attention to the legislative purpose of the statute and the case law interpreting it to support their argument that the statute is not intended to protect sophisticated parties such as physicians. If these hurdles are overcome by the physician, manufacturers must then turn to the substantive and statutory defenses associated with any product liability or consumer protection claim, including the adequacy of the representations made by the manufacturer about its product and the lack of product defect.

C. Other Fraud And Contract-Based Claims

Physicians have asserted claims for fraud, breach of contract and breach of warranty against manufacturers. The success of these claims often turns on the nature of the representations allegedly made by the manufacturer to the physician. While manufacturers have argued that a physician’s independent professional judgment and sophisticated knowledge should preclude fraud claims, they have not always been successful.14 The United States Supreme Court’s decision in Buckman v. Plaintiffs’ Legal Committee, 531 U.S. 341 (2001), however, has the potential to take the teeth out of at least those claims premised upon a manufacturer’s alleged fraud on federal regulatory agencies.15

More recently, an independent practice association of physicians brought tortious interference with contractual relations claims against a manufacturer of hip implants. Hill Physicians Medical Group, Inc. v. Sulzer Orthopedics, Inc., Case No. 2001-027765 (Alameda Cty. Cal.). The association contracts with health maintenance organizations to provide care to their members. The association, in turn, provides the care by subcontracting with a network of physicians. The association filed suit against the hip implant manufacturer after physicians in the network allegedly were required to replace defective hip implants. The association asserted that a lack of compensation for the remedial procedures required it to replace the implants and adversely affected its contractual relations with its physicians. In addition, the necessity for remedial surgeries as a result of the alleged defects in the implants purportedly harmed the
relationship between individual patients and the network physicians providing their care. The case, still pending, confirms that physician suits against manufacturers do not appear to be disappearing any time soon.

**D. Damages**

The damages claimed by physicians fall into three general categories. First, physicians often seek to recover the replacement value for a failed medical device. This is a traditional warranty type of recovery — a product breaks or fails and the manufacturer is responsible for replacing it. Whether the physician has standing to seek this type of recovery depends, in part, on whether the physician actually purchased the product as opposed to the hospital where the surgery was performed, and whether the physician ultimately replaced the product at no charge to the patient as opposed to passing the replacement cost to the patient. Moreover, some medical device manufacturers provide free replacement products. When that occurs, of course, the physician or hospital has not sustained any loss associated with the cost of the device itself.

A second category of damages sought by physicians is costs associated with replacing the medical device, e.g., the operating room expenses and surgeon time. In addition, a surgeon might claim that the replacement surgery cost him the opportunity to perform another surgery or otherwise make money in his medical practice.

Third, physicians often assert that an allegedly defective product has harmed their medical practice by damaging their relations with patients. This type of damage could include discontinued patient relationships, harmed professional reputations, and loss of referrals. As well, physicians have alleged that being forced to participate in litigation, through depositions and court appearances, harms their practices.

Aside from the economic loss rule, discussed above, courts rarely have discussed available damages in physician lawsuits against manufacturers. As in claims by patients, manufacturers should demand strict proof of damages alleged by physicians. Many of the alleged categories of damages, such as lost referral business, may be quite difficult to prove. And, as discussed above, these damages constitute “economic losses” which are generally not recoverable for tort-based claims.

**III. A ‘Prescription’ For Reducing Manufacturers’ Exposure**

Regardless of the physicians’ motives for suing manufacturers, these suits reflect a breakdown in what should be a natural alliance between manufacturer and prescribing physician. To rebuild this alliance and, perhaps more importantly, to reduce exposure to liability from physician-based suits, manufacturers should consider taking the following steps.

First, manufacturers should, of course, make sure that their instructions and warnings are as clear and thorough as necessary. Most product insert warnings have been approved for distribution only after rigorous internal and regulatory review. To ensure that labeling is clear to physicians, manufacturers may wish to consult with a representative group of physicians during the labeling review process. Manufacturers should be prepared to discuss the product warning approval process in any physician-based lawsuit. In addition, manufacturers should consider identifying the product’s current regulatory status in the product literature. And, as part of a postmarket product review of medical literature, manufacturers should be alert to unconventional uses of their product in the field.

Second, manufacturers should consider using or bolstering disclaimers associated with the product. While disclaimers and limitations of liability may be ineffective against personal injury plaintiffs, the same should not be true when these liability-limiting tools are used against sophisticated physicians who should read and be familiar with product warnings accompanying the product. Disclaimers of warranties and limitations on consequential damages go to the heart of the damages a physician is likely to seek in a suit against a manufacturer. If the liability limitations are found enforceable, then the manufacturer has gone a long way to negating any meaningful recovery for the physician.

Third, although it seems self-evident, manufacturers should strive to monitor field performance of their
products. For instance, manufacturers should consider providing replacement devices free or at cost. This not only promotes goodwill, but also creates an incentive to report alleged problems with the products. In this way, manufacturers can monitor product trends and nip problems in the bud. Medical device manufacturers are generally required to review returned products for signs of problems and complaint trends. Conducting these reviews and providing feedback to doctors not only fulfills a manufacturer’s regulatory requirements, it may also help to build a record to defend against later lawsuits by a doctor.

Fourth, manufacturers should closely and carefully monitor their relationships with physicians. Manufacturers should instruct their representatives to take care in what they tell physicians about acceptable uses of the product and techniques for employing the products. Monitoring return and complaint rates from physicians is also another early warning mechanism. Likewise, if physicians are having problems paying for products or running into credit problems, this may be a sign of a physician with an incentive to sue the manufacturer. As part of the monitoring process, manufacturers should be mindful of physicians who are making unorthodox uses of their products.

Finally, manufacturers should seek common ground with physicians whenever possible. For instance, when medical devices fail, the failure is often not the fault of the manufacturer or the physician. Instead, patient specific factors and inherent risks are frequently the most likely causes of device malfunctions. If manufacturers and physicians recognize these facts, they will go a long way to rebuilding their traditional alliance. In the process, manufacturers lessen any perception among physicians that they are being blamed for the performance of a drug or device.

While none of these “prescriptions” can guarantee a complete avoidance of physician suits, they will go a long way toward that end.

ENDNOTES


2. In many jurisdictions manufacturers have the option of naming physicians as “non-parties at fault,” thereby permitting a manufacturer to argue potential fault on the part of the physician without actually joining the physician as a party to the litigation. E.g., A.R.S. § 12-2506(A-B) (Arizona statute permitting non-parties to be considered by jury under comparative fault system); Fabre v. Martin, 623 So. 2d 1182, 1185 (Fla. 1993) (establishing that a party may “compare that party’s percentage of fault to all other entities who contributed to the accident, regardless of whether they have been or could have been joined as defendants”).


4. In a 1987 decision discussing the learned intermediary doctrine in a patient suit against a drug manufacturer, one court described physician suits against manufacturers as an “innovative theory of liability.” See Phelps v. Sherwood Medical Indus. and Argyle Assoc., 836 F.2d 296, 302 n.5 (7th Cir. 1987) (citing Conlee v. McGhan Medical, No. 81-4062 (Tex., Nueces Cty. Dist. Ct., Dec. 15, 1983) (Texas jury returned a $11.1 million award, including $10 million in punitive damages, against the manufacturer of inflatable breast prostheses, finding it liable for the mental anguish caused and income lost by a doctor who replaced 48 defective prostheses in his patients without charge); Kennedy v. McKesson Co., 462 N.Y.S.2d 421 (1983) (affirming recovery for dental surgeon against manufacturer and installer of an anesthesia machine for pecuniary expenses to his reputation and practice he suffered when patient died during minor surgery); Runnels v. Astra Pharmaceutical Products, Inc., Nos. 218450 and 224532 (Cal., Sacramento Cty. Sup. Ct., May 25, 1976)).

5. This article is not intended as a fifty state survey on the economic loss doctrine, but many states apply some variety of this doctrine to bar recovery in tort for purely economic losses arising from an allegedly defective product. E.g., Ohio Revised Code §§ 2307.73(A)(1), 2307.75 (a plaintiff must be entitled to compensatory damages
for physical harm before economic losses can be awarded); Nobility Homes of Texas, Inc. v. Shivers, 557 S.W.2d 77, 80 (Tex. 1977) (there can be no recovery in strict liability for purely economic loss, including damage to the product itself).

6. The Barnett decision was affirmed by the Fifth Circuit, No. 01-10328, slip op., (5th Cir. Dec. 17, 2001).


8. Dr. Balderston admitted in court pleadings that he merely "designated" the bone screws for use by his patients and that the actual patients were purchasers. See Balderston, 152 F. Supp. 2d 772, 777 (E.D. Pa. 2001).

9. 73 P.S. §§ 201-2 and 201-3.

10. 285 F.3d at 244.

11. Unlike the Pennsylvania consumer protection statute, the Texas DTPA defined consumers to include those who purchased goods solely for resale. Dow Corning, 2000 Bankr. LEXIS 1579 at *45.


13. Although the Washington statute can be fairly read to encompass a business transaction such as a physician purchase for resale, the Court seemingly ignored this reading and instead held that the physician was really akin to an ordinary consumer. Id. at 1061 (“[t]his unique relationship results in the physician being comparable to the ordinary consumer in other settings . . . the drug company targets its marketing efforts toward the physician not the patient”).

14. For instance, in Bocci v. Key Pharmaceuticals, Inc., 974 P.2d 758 (Ore. App. 1999), the court upheld a $23 million verdict in favor of a physician on a cross-claim against a manufacturer of an asthma medication. In that case, a plaintiff had brought suit against his physician and the manufacturer after he suffered permanent brain damage allegedly from taking the medication. The physician cross-claimed against the manufacturer under theories of negligence and fraud. After a verdict for the physician on his cross-claim, the manufacturer appealed, arguing that the physician had no right to rely on its representations about the drug because the physician “had a duty to exercise his own professional judgment in the treatment of his patients.” Id. at 771. The appellate court rejected the argument, holding that “[i]n short, it is incumbent upon the manufacturer to bring the warning home to the doctor.” Id. (citation omitted). Cf. Barnett, 133 F. Supp. 2d at 513 (ruling that plaintiff’s fraud and contract-based claims failed alternatively and noting Dr. Barnett is “a skilled person in the field with knowledge about the products he purchases and uses”).

15. See, e.g., James M. Beck, Buckman v. Plaintiffs’ Legal Committee and Implied Preemption Of Common Law Tort Claims Alleging Fraud Against Agencies And Violations Of Federal Law, Mealey’s Lit. Rep.: Emerging Drugs & Devices Vol. 6, Iss. 6 (3/22/02 at p.29).