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**COMPANY REPRESENTATIVES IN THE OPERATING & TREATMENT ROOM:
HOW TO NAVIGATE THE EVER-EXPANDING THEORIES OF
LIABILITY FOR MEDICAL DEVICE & PHARMACEUTICAL
COMPANIES.**

Michael J. Summerhill & Aaron M. Chandler***

INTRODUCTION

Modern surgeries invariably involve personnel above and beyond the surgeon, nurses and anesthesiologists. Frequently, representatives of pharmaceutical companies, surgical instrument companies and medical device companies attend surgeries to observe the use of the company's products or calibrate the product for use by the surgeon¹. For some products, the company representative is a necessary part of the surgery without which the surgery could not proceed.² As a result of this now common practice, medical device and pharmaceutical companies can be subject to many more theories of liability besides the traditional product-specific theories of product liability (whether strict product liability or negligence). Indeed, following the U.S. Supreme Court's decision in *Riegel v. Medtronic*³ that further limited the product-specific claims available to plaintiff's lawyers, the creative plaintiff's bar can be expected to advance these theories with greater regularity as these companies remain attractive deep-pocket defendants.

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¹ NAESPE (n/k/a/ Heart Rhythm Society) Policy Statement, *The Role(s) of the Industry Employed Allied Professional* (March 2001), available at <http://www.hrsonline.org/Policy/ClinicalGuidelines/upload/Role%20of%20Industry%202001.pdf> (recognizing the increasing importance of company representatives during implant surgeries).

² See, e.g., John J. Hayes, *The Role of Industry in the Implantation and Follow-up of Devices: A Practitioner's Perspective*, 7 *Cardiac Electrophysiology Rev.* 5, 58 (2003) (noting that physicians cannot be expected to be familiar with the myriad of devices on the market and that as a result, physicians depend on having personnel who are knowledgeable about the device present during implant surgeries).

³ 128 S. Ct. 999 (2008). In *Riegel*, the Supreme Court held that the pre-emption clause contained in the Medical Device Amendments of 1976 to the Federal Food Drug and Cosmetic Act bars state common-law claims challenging the safety or effectiveness of a medical device given pre-market approval by the FDA.

This article will discuss the various theories under which a medical device or pharmaceutical company may incur liability due to a representative's presence in the operating/treatment room, and suggest the best practices to position that company for an effective defense. The theories of liability can generally be placed into two main categories: (1) claims alleging liability based on the representative's mere presence in the operating/treatment room; and (2) claims alleging liability based on the actions or omissions of the company representative. While the case law addressing these theories is not yet well-developed, thereby giving the plaintiff's bar ample room within which to maneuver specific fact patterns, there is substantial and well-developed case law giving medical device and pharmaceutical companies numerous defenses. These defenses sound in (1) the learned intermediary doctrine; (2) the informed consent doctrine; (3) the strong public policy in favor of the doctor-patient relationship and prohibiting any interference in that relationship; (4) the prohibition on the unlicensed practice of medicine; and, at least with respect to medical devices, (5) the federal practice of medical doctrine as set forth in the Medical Device Amendments to the Federal Food Drug and Cosmetic Act.

I. PRIVACY IMPLICATIONS ARISING FROM A REPRESENTATIVE IN THE TREATMENT ROOM.

Medical device and pharmaceutical companies should first recognize that liability can, under certain circumstances, be imposed merely because of the representative's presence at the time of treatment. While such liability can generally be avoided altogether with an appropriate patient consent, it is important to understand under what circumstances a consent is either advisable or required. As an initial matter, local law should always be consulted to determine if there are any state statutes or regulations prohibiting a representative's presence. Even if the local law is silent, the company representative should be familiar with the policies of the hospital or clinic at which the treatment will occur. For example, both the American College of Surgeons and the Association of peri-Operative Registered Nurses ("AORN") have issued statements outlining policies regarding the presence of health care industry representatives in the operating room.⁴

⁴ American College of Surgeons, *Statement on Health Care Industry Representatives in the Operating Room*, available at

The American College of Surgeons requires that “[t]he patient should be informed of the presence and purpose of the [health care industry representative] in the [operating room] and give written, informed consent. This should be documented within the medical records.”⁵ Absent a valid consent, patients have sought to impose liability on medical device and pharmaceutical companies based on the representative’s presence under an invasion of privacy theory.

A. Invasion of Privacy

The first reported decision to impose liability because of the presence of a third-party during treatment is the Michigan Supreme Court’s decision in *De May v. Roberts*.⁶ While *De May* did not involve either a medical device or pharmaceutical company representative, it serves as the basis for an invasion of privacy claim against third-parties who are present during medical treatment. In *De May*, the physician made a house call to assist in the birth of a child and brought with him a “young unmarried man” who was “utterly ignorant of the practice of medicine.”⁷ The doctor explained to the patient and the patient’s husband that the man was there “to help carry [the doctor’s] things.”⁸ Neither the patient nor the husband objected to the man’s presence. In upholding liability against the “young unmarried man” for invasion of privacy, the court stressed that the plaintiff had a legal right to privacy during such a “sacred” occasion and “[t]he fact that at the time, she consented to the presence of [the layman] supposing him to be a physician, [did] not preclude her from maintaining an action and recovering substantial damages upon afterwards ascertaining his true character.”⁹ The court reasoned that the plaintiff and her husband could reasonably presume that the layman “was an assistant physician, a competent and proper person to be present,”¹⁰ and that a clear and

http://www.aorn.org/PracticeResources/AORNPositionStatements/Position_HealthCareRepresentative/; Association of periOperative Registered Nurses, *AORN Statement on the Role of the Health Care Industry Representative in the Operating Room*, available at <http://www.aorn.org/about/positions/industryrep.htm>.

⁵ American College of Surgeons, *Statement on Health Care Industry Representatives in the Operating Room*, available at http://www.facs.org/fellows_info/statements/st-33.html.

⁶ 9 N.W. 146 (1881).

⁷ *Id.* at 146.

⁸ *Id.* at 147.

⁹ *Id.* at 149.

¹⁰ *Id.* at 146.

certain statement as to the layman status was required to put the plaintiff and her husband on notice.¹¹ The *De May* court's reasoning, therefore, is consistent with the American College of Surgeon's stated requirements, that the patient be informed of the true nature of the company's representatives, *i.e.*, who they are and why they are there.

The modern claim of invasion of privacy is set forth in Section 652B of the Restatement (Second) of Torts,¹² and the California Court of Appeals applied the Restatement formulation against a pharmaceutical company in the 2001 case of *Sanchez-Scott v. Alza Pharmaceuticals*.¹³ There, the plaintiff was a breast cancer patient who brought suit after one of the defendant's sales representatives had been present during her breast exam. At the time of the exam, the plaintiff's physician explained that the sales representative was "a person . . . who was looking at [the physician's] work."¹⁴ The sales representative was present pursuant to the defendant's "mentor[ing] program whereby its representatives . . . were directed to participate in private medical activities" of the defendant's physician-customers.¹⁵

Relying on *De May*, the court concluded that a manufacturer could be liable for invasion of privacy under the tort of intrusion. The court stressed that the tort of intrusion requires an invasion by the defendant into the plaintiff's private affairs that a reasonable person would find highly offensive.¹⁶ The court first determined that a medical examination is, as a matter of law, a private affair.¹⁷ The court then concluded that a reasonable person would find the sales representative's presence during a breast exam to be highly offensive.¹⁸ In so holding, the court rejected the defendant's argument that the plaintiff had consented to the representative's presence when she did not ask him to leave because the physician did not inform her that the representative was an employee of the defendant rather than the

¹¹ *Id.* at 147.

¹² "One who intentionally intrudes, physically or otherwise, upon the solitude or seclusion of another or his private affairs or concerns, is subject to liability to the other for invasion of his privacy, if the intrusion would be highly offensive to a reasonable person." Restatement (Second) of Torts § 652B.

¹³ 103 Cal. Rptr. 2d 410 (Cal. Ct. App. 2001).

¹⁴ *Id.* at 412-13.

¹⁵ *Id.* at 412.

¹⁶ *Id.* at 415-16.

¹⁷ *Id.* at 417 ("It cannot be easily disputed that medical examinations involve private matters.").

¹⁸ *Id.* at 418-19.

physician.¹⁹ Thus, *Sanchez-Scott*, like *De May*, essentially turned on the absence of fully informed consent.

B. Intentional Infliction of Emotional Distress

Some states, most notably New York, do not recognize a broad cause of action for invasion of privacy.²⁰ Rather, the cause of action is limited only to unwarranted publicity and the defamation of one's personality and does not protect against the wrongful intrusion into one's private activities.²¹ Even if a cause of action for invasion of privacy is unavailable, however, the cause of action for intentional infliction of emotional distress may accomplish the same result.²²

For example, in New York, the cause of action for intentional infliction of emotional distress requires "(1) [an] extreme and outrageous conduct, (2) intent to cause severe emotional distress, (3) a causal connection between the conduct and the injury, and (4) severe emotional distress."²³ The primary difference between invasion of privacy and intentional infliction of emotional distress lies in the level of offensiveness a plaintiff must prove to recover. Whereas a successful action for invasion of privacy requires conduct "highly offensive to the reasonable person," to prevail on a claim of intentional infliction of emotional distress, a plaintiff must show that the conduct was "so outrageous in character and so extreme in degree as to go beyond all possible bounds of decency and to be regarded as atrocious

¹⁹ *Id.* at 419-20.

²⁰ *Moore v. Sam's Club*, 55 F.Supp. 2d 177, 186 (S.D.N.Y. 1999) ("New York does not recognize a common law claim for invasion of privacy such as intrusion on seclusion.").

²¹ 62A Am Jur. 2d § 6 at 649-51. In the past, federal courts in New York raised the question of whether the New York State Court of Appeals might recognize such a cause of action if confronted with the issue. *See, e.g., Birnbaum v. United States*, 588 F.2d 319, 325 (2d Cir. 1978) ("[I]n light of the current jurisprudence, it is hard to believe that the New York Court of Appeals today would . . . bar an action based on intrusion upon privacy."); *Socialist Workers Party v. Att'y Gen. of the U.S.*, 642 F. Supp. 1357, 1420-21 (S.D.N.Y. 1986). More recent cases, however, suggest that courts are no longer making that prediction: "New York's highest court has consistently reminded litigants that no so-called common law right of privacy exists in New York." *Hurwitz v. United States*, 884 F.2d 684, 685 (2d Cir. 1989); *see also* *Menton v. Experian*, No. 02 CIV. 4687(NRB), 2003 WL941388, at *4 (S.D.N.Y. Mar. 6, 2003) ("[T]here exists serious question as to whether New York law recognizes this tort.").

²² 62A Am Jur. 2d § 6 at 650-51

²³ *Bender v. City of New York*, 78 F.3d 787, 790 (2d Cir. 1996).

and utterly intolerable in a civilized community.”²⁴ While there are no reported decisions addressing this cause of action in the context of a claim against a medical device or pharmaceutical company arising out of a representative’s presence in the treatment room, the courts’ analyses in *De May* and *Sanchez-Scott* would indicate that such a cause of action may very well lie in those states that do not recognize a cause of action for invasion of privacy.

C. Who Should be Liable for a Lack of Informed Consent?

As the authority makes clear, if the patient is fully informed and consents to the representative’s presence, medical device and pharmaceutical companies are well-positioned to defend any invasion of privacy or intentional infliction of emotional distress claims.²⁵ In addition, in those situations where the company representative is a necessary part of the treatment but the patient is not fully informed, medical device and pharmaceutical companies would also have very strong defenses to such claims – under an objective standard, a reasonable patient would not object to the presence of somebody who his or her doctor has determined is necessary for the treatment. Finally, even in those situations where the representative’s presence is either not medically necessary or the patient is otherwise not fully informed, medical device and pharmaceutical companies are not without viable defenses. Indeed, strong arguments can be made that only the doctor can convey information to a patient, and therefore, only a doctor can be liable when a patient is not fully informed.

Well-established law, in virtually every jurisdiction, provides that one of the primary duties arising from the doctor-patient relationship is the doctor’s affirmative duty to disclose facts related to the patient’s medical treatment. Under the doctrine of informed consent, the doctor must disclose the risks of the surgery, foreseeable results, reasonable alternatives, and any other information that a reasonable physician would convey to a patient under similar

²⁴ *Doe v. Cmty. Health Plan*, 268 A.D. 2d 183, 188 (N.Y. App. Div. 2000).

²⁵ See, e.g., *Sanchez-Scott*, 103 Cal. Rptr. 2d at 418 (“The maxim of law that one who consents to an act is not wronged by it applies to the tort of invasion of privacy” such that “[i]f voluntary consent is present, a defendant’s conduct will rarely be deemed highly offensive to a reasonable person so as to justify tort liability.”) (quotations and citations omitted).

circumstances.²⁶ The doctor's duty of disclosure is unique to doctors and is governed by his/her medical judgment.²⁷ As a result, the doctor, need not, and invariably should not, disclose all risks and consequences. Rather, the law requires a doctor to "exercise discretion in prudently disclosing information in accordance with his patient's best interests."²⁸ In fact, courts recognize that there may be circumstances in which physicians, in the exercise of their discretion, determine not to convey certain information to a patient:

As the expert testimony revealed in the present case, *excessive disclosure of remote risks would tend to do more harm than good to the patient*. A doctor has a special relationship with his patient. This relationship not only vests the doctor with the responsibility of disclosure, but also requires the doctor to exercise discretion in prudently disclosing information in accordance with his patient's best interests. *To disclose more than that which is material would run counter to the responsibility assumed through the doctor-patient relationship*.²⁹

²⁶ *Goldberg v. Ruskin*, 128 Ill. App. 3d 1029, 1040 (Ill. App. Ct. 1984) ("We also believe that the physician-patient relationship does create an affirmative duty to disclose facts."); *see also Hahn v. Mirda*, 147 Cal. App. 4th 740, 749 (Cal. Ct. App. 2007) ("Under the doctrine of informed consent, a doctor does have a duty to disclose to his patient all material information that is necessary to make an informed decision about a proposed treatment."); *State v. Presidential Women's Ctr.*, 937 So.2d 114, 116 (Fla. 2006) ("Under the doctrine of informed consent, a physician has an obligation to advise his or her patient of the material risks of undergoing a medical procedure."); American Med. Ass'n, *Code of Medical Ethics* § 8.08 (2004-2005 ed.) ("The patient's right of self-decision can be effectively exercised only if the patient possess enough information to enable an intelligent choice."). In Texas, the duty of disclosure has been codified. *See* Tex. Civ. Prac. & Rem. Code Ann. §§ 74.102-103 (Vernon Supp. 2008).

²⁷ *See, e.g., Buckner v. Allergan Pharm., Inc.*, 400 So.2d 820, 823 (Fla. Ct. App. 1981) ("The extent of disclosure is a matter of medical judgment."); *Hatfield v. Sandoz-Wander, Inc.*, 124 Ill. App. 3d 780, 788 (Ill. App. Ct. 1984) ("It is the doctor's decision as to which facts should be told to the patient, and the extent of disclosure is a matter of medical judgment.") (emphasis added).

²⁸ *See, e.g., Miceikis v. Field*, 37 Ill. App. 3d 763, 768 (Ill. App. Ct. 1976) ("[A doctor's duty of disclosure] requires the doctor to exercise discretion in prudently disclosing . . .").

²⁹ *Miceikis*, 37 Ill. App. 3d at 768 (citations omitted)(emphasis added); *Hatfield*, 124 Ill. App. 3d at 788-89 (a physician may "indeed exercis[e] his judgment in withholding certain information [from a patient]"); James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 101 (1998) (hereinafter "*Off-Label Use*")

Because of the delicate considerations involved in a physician's decision to disclose information, and because of the real danger that others may convey information to the patient that the physician has determined the patient should not be told, third-parties like medical device and pharmaceutical companies have strong arguments that they cannot have a duty to disclose. Illinois courts, for example, have consistently held that even hospitals do not have a duty to specify what information physicians convey to their patients because such a duty would interfere in a physician's discretion and impinge on the physician-patient relationship.³⁰ If a hospital does not have a duty to disclose facts or otherwise specify what facts a physician discloses to a patient, medical device and pharmaceutical companies have strong arguments that they cannot have such a duty either. Otherwise, the medical device or pharmaceutical company runs the risk of infringing on the doctor's discretion by conveying information to the patient that the physician has determined the patient should not be told. Thus, even if the patient is not fully informed of the specifics regarding a company representative in the treating room, the company has strong arguments that liability for the failure to disclose rests with the doctor only because to hold otherwise would necessarily require the company representative to exercise medical judgment regarding what information should be told to the patient.

II. LIABILITY BASED ON THE ALLEGED ACTIONS OR OMISSIONS OF THE COMPANY REPRESENTATIVE.

In addition to claims based on invasion of privacy, a few courts around the country have considered the analogous issue of whether

("Just as there is a limit to the amount of information physicians can be expected to digest and explain, there is likewise a limit to what patients can absorb, particularly in what are often trying and emotional circumstances. The last thing the patient needs is irrelevant and potentially misleading information."); American Med. Ass'n, *Code of Med. Ethics* § 8.08 (2004-2005 ed.) (providing that physicians should not disclose information to a patient when "disclosure poses such a serious psychological threat of detriment to the patient as to be medically contraindicated").

³⁰ See Tobias v. Winkler, 156 Ill. App. 3d 886, 895-96 (Ill. App. Ct. 1987) (noting that hospitals, in "limited circumstances," may have a duty to ensure that physicians who use their facilities secure patients' informed consent, but hospitals cannot have a duty to mandate what physicians actually tell patients because "it is within the doctor's discretion to determine what to disclose to a patient in a particular situation"); Salandy v. Bryk, 864 N.Y.S.2d 46, 49 (N.Y. App. Div. 2008) ("[I]t is the duty of the physician, not the hospital, to obtain the patient's informed consent.").

liability can attach to a medical device or pharmaceutical company for the actions or omissions of the company representative who is either present in the operating room or otherwise has knowledge of the doctor's use of the company's product. Generally speaking, these cases fall into two categories: (1) where the plaintiff alleges that the medical device or pharmaceutical company had a duty to prevent the doctor from using its product either through conduct or warnings; and (2) allegations of the unauthorized practice of medicine. Not surprisingly, these cases, in one degree or another, address the same interrelated legal principles, namely, issues of medical judgment, interference in the physician-patient relationship, the learned intermediary doctrine, voluntary undertaking and compliance with federal regulatory requirements.

A. No Duty to Prevent Physician Misuse of a Company's Product.

The Fifth Circuit was one of the first courts to address the issue of whether a pharmaceutical company has a duty to affirmatively prevent a doctor's misuse of the company's products. In *Swayze v. McNeil Labs., Inc.*,³¹ the plaintiff was the mother of a boy who died as a result of an overdose of the defendant's anesthetic. Contrary to the manufacturer's instructions, a registered nurse anesthetist ("RNA"), rather than the surgeon or anesthesiologist, determined the patient's dosage and administered the anesthetic. The plaintiff alleged, and the facts revealed, a state wide practice of RNAs administering anesthetics without physician supervision. The plaintiff further alleged that because of the frequency with which its representatives either observed surgeries or communicated with doctors, the defendant knew or should have known of this statewide practice and therefore had a duty to prevent the misuse. Specifically, the plaintiff alleged that because of its knowledge of the misuse, the manufacturer had a duty to (1) warn the patients directly of the risk of misuse; (2) take additional steps to enforce the requirement that only a physician administer the anesthetic; or (3) withdraw the anesthetic from the market altogether. The trial court granted the defendant's motion for a directed verdict and the Fifth Circuit affirmed.

The court concluded that under the learned intermediary doctrine, the manufacturer had no duty to warn the patient directly.³²

³¹807 F.2d 464 (5th Cir. 1987).

³²*Id.* at 471.

The court stressed that the doctor-patient relationship imposes upon the doctor, not the manufacturer, the responsibility for ensuring the propriety of the patient's medical care; and if the physician fails to fulfill his or her obligations under that relationship – for example by failing to supervise the RNAs working under his or her supervision – the physician is liable.³³ The court reasoned that to hold otherwise would interfere with the physician-patient relationship:

When the physician-patient relationship does exist, as here, we hesitate to encourage, must less require, a drug manufacturer to intervene in it. [The physician] took responsibility for [the patient's] care, both during the operation and for some time afterwards. A special relationship, between physician and patient, thus formed; this relationship receives special protection in law, and, at the same time, creates a great responsibility for every physician. In this case, this relationship encompassed much more than the dosage of anesthetic [the patient] would receive. Although in retrospect this decision, or failure of decision, dwarfed all others, it was an integral part of [the physician's] responsibility to [the patient]. He assumed the role of "learned intermediary," and the burdens thereof. The facts of this case may reveal a practice in Mississippi of physicians allowing [RNAs] too much discretion in a role they are not trained to play; but it is the physicians who have undertaken the responsibility of supervising [RNAs], and that responsibility cannot be shunted onto, or shared with, drug manufacturers.³⁴

The court also rejected the plaintiff's contention that the manufacturer should have taken steps to enforce its warnings. The court reasoned that "[i]t is both impractical and unrealistic to expect drug manufacturers to police individual operating rooms to determine which physicians adequately supervise their surgical teams."³⁵ Finally, the court rejected the plaintiff's contention that the manufacturer should have removed the anesthetic from the market because "[t]he problem here lies with individual physicians" not the drug itself, and the

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

manufacturer cannot “control the individual practices of the medical community, even if it is the prevailing practice...”³⁶

Similarly, the 2003 case of *Labzda v. Purdue Pharma L.P.*³⁷ also dealt with whether a pharmaceutical company had an affirmative duty to stop a physician from misusing its drugs. The facts, however, are far more egregious than *Swayze*. The plaintiff’s son died from an overdose of narcotics prescribed by the physician, and the plaintiff alleged that the defendant knew the physician was prescribing narcotics in violation of the Controlled Substances Act. The facts revealed that the defendant’s sales representative was aware that: (1) the physician had been over-prescribing the narcotic; (2) some of the physician’s employees were also patients; (3) local pharmacies had complained to the representative about the excessive prescriptions written by the physician; (4) the physician was prescribing the narcotic for himself; and (5) the physician would see up to 48 patients a day from all over south Florida, many waiting 3-4 hours to obtain a prescription for the narcotic. As a result, the representative informed her supervisors about her concerns that the physician was inappropriately prescribing the narcotic.

The plaintiff alleged that the defendant negligently sold and distributed the narcotic to the physician because it had an affirmative duty to curtail the inappropriate prescriptions to reduce the potential for abuse of its product. The court rejected the plaintiff’s contentions and granted the defendant’s motion for judgment on the pleadings. The court concluded that the physician’s duties to “inform himself of the qualities and characteristics” of the products he prescribes to his patients and “to exercise an independent judgment” based on his knowledge of the patient’s medical condition and the drug cannot be shifted to the manufacturer.³⁸ The court reasoned that a manufacturer simply cannot have a duty to “interfere with the physician-patient

³⁶*Id.* at 472. The court’s decision prompted a dissent that focused on the manufacturer’s knowledge of the misuse and argued that if the manufacturer knows the drug is being administered by an RNA the learned intermediary doctrine does not apply because there is no learned intermediary between the patient and manufacturer. However, the dissent would arguably contravene the vast majority of law in this field because it argued generally for the complete “reversal” of the learned intermediary doctrine as well as the existence of a “moral” duty to warn the patient directly. *Id.* at 474 (Goldberg, J., dissenting).

³⁷ 292 F. Supp. 2d 1346 (S.D. Fla. 2003).

³⁸ *Id.* at 1354.

relationship, even if [the manufacturer is] aware that the product may have been prescribed inappropriately.³⁹

The Illinois Appellate Court followed this same logic and reasoning in the context of a medical device in the 2006 decision in *Kennedy v. Medtronic*.⁴⁰ In *Kennedy*, the decedent was the victim of a cardiac surgeon who placed a pacemaker lead into the wrong side of the patient's heart. Because the surgeon was retired and had given up his hospital surgical privileges, the surgery was performed in his office under local anesthesia with a dentist observing the decedent's vital signs. The Medtronic representative provided the pacemaker and leads, attended the surgery, and during the surgery, checked the leads to be sure they were properly calibrated – *i.e.* that once placed into the patient's heart, the leads were able to properly detect and regulate the heart's electrical pace.

Eventually, a subsequent doctor discovered the retired surgeon had improperly inserted the lead. The decedent underwent another procedure to remove and replace the improperly implanted lead, but died shortly thereafter. His daughter sued Medtronic claiming “that Medtronic owed [the deceased] a duty to refrain from providing a pacemaker ..., and participating in the [surgery], once [the representative] discovered the procedure was being performed in a setting that was not part of a hospital with adequate qualified personnel, and which lacked proper [medical equipment].”⁴¹ In the alternative, the plaintiff alleged that under section 324A of the Restatement (Second) of Torts, by sending a representative to the surgery, Medtronic had voluntarily assumed a duty of care for the decedent.

The court affirmed the trial court's summary judgment for Medtronic. First, the court ruled that in simple negligence, no duty of care existed for two reasons: 1) plaintiff's injuries were not reasonably foreseeable to Medtronic because the surgeon admitted to violating the applicable standard of care and Illinois law does not impose a duty to anticipate the negligence of third-parties;⁴² and 2) the burden and

³⁹ *Id.* at 1355. See also *Buckner v. Allergan Pharm., Inc.*, 400 So.2d 820, 823-24 (Fla. App. Ct. 1981) (holding that because a physician's duty of disclosure to a patient “is a matter of medical judgment,” a drug manufacturer cannot have a duty to warn patients directly even if the manufacturer knows the physician did not inform the patient of specific product risks).

⁴⁰ 851 N.E. 2d 778 (Ill. App. Ct. 2006).

⁴¹ *Id.* at 785.

⁴² *Id.*; see also *Ward v. K Mart Corp.*, 136 Ill. 2d 132, 152 (1990) (“[A] party need not anticipate the negligence of others.”). Consistent with well-established Illinois law,

consequences of imposing a duty on Medtronic would be “substantial” because it would require Medtronic to interfere in the doctor-patient relationship:

We also find the burden and consequences of imposing the duty proposed by plaintiff to be substantial. It would be a significant burden to require Medtronic to monitor the conditions under which a doctor performs surgery. . . . Moreover, a central aspect of the learned intermediary doctrine, as first adopted by our supreme court in *Kirk*, is that a licensed physician, such as Dr. Salvador, has the knowledge of his patient’s medical history and background, and, therefore, he is in a better position, utilizing his medical judgment, to determine a patient’s needs and what medical care should be provided. It would be unreasonable, and potentially harmful, to require a clinical specialist such as [Medtronic’s] to delay or prevent a medical procedure simply because she believes the setting is not appropriate or the doctor is unqualified. To hold otherwise would place a medical device manufacturer, such as Medtronic, in the middle of the doctor-patient relationship.⁴³

Second, the court ruled Medtronic’s representative, by providing the pacemaker and leads and attending the surgery, had not voluntarily undertaken a duty under 324A to do anything more than her clearly defined role of insuring the leads were properly calibrated. Because there was no contention that the representative performed that role negligently, liability under section 324A did not exist.⁴⁴

The *Swayze*, *Labzda* and *Kennedy* decisions make clear that liability for a doctor’s misuse of the company’s products cannot extend to the company itself. Whether a doctor’s use of a drug or medical device constitutes a “misuse” is dependent upon the medical standard of care. It is not a matter of judgment for a lay company representative. These cases further make clear that whether a particular medical procedure is within the standard of care requires an evaluation of the patient’s medical condition of which the company has no knowledge

the *Kennedy* court concluded that the patient’s injuries were not reasonably foreseeable.

⁴³ *Kennedy*, 851 N.E. 2d at 786.

⁴⁴ *Id.* at 786-87.

and, under modern privacy laws, is prohibited from knowing.⁴⁵ Finally, these cases make clear that a pharmaceutical or medical device company cannot have a duty to supervise a doctor's use of the company's products or otherwise prevent a doctor's use of those products because to do so would require the company to interfere in the doctor-patient relationship and exercise medical judgment, all of which the manufacturer is prohibited from doing. In other words, these decisions support the argument that whether the "use" of a device rises to the level of a "misuse" is a matter of medical judgment, committed to the sound discretion of doctors.

For example, many off-label uses of medical devices (the use of a medical device to treat a condition other than a condition for which it is intended) could arguably be considered a misuse.⁴⁶ Under the federal "practice of medicine doctrine," however, a licensed physician may use an FDA approved device for any procedure or treatment that the physician deems is in the patient's best interest:

Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.⁴⁷

The logical extension of any duty to prevent physician misuse, therefore, would require the medical device company to warn a patient, and to refuse to sell a device, if a surgeon's contemplated use of the

⁴⁵ See also, e.g., *Paulsen v. Illinois Dep't of Prof'l Regulation*, 739 N.E.2d 536, 542 (3d Dist. 2000) ("Whether a particular medical procedure is within the standard of care cannot be determined in a vacuum. Rather, such a determination can only be made with reference to the individual patient's condition at the time the procedure is performed.").

⁴⁶ For example, in *McCleary v. Medtronic Sofamor Danek USA, Inc., et al.*, the plaintiff alleged that the medical device manufacturer was liable for allowing or otherwise not preventing the physician from using a medical device in a manner that was contrary to the manufacturer's written instructions and warnings. See, e.g., *McCleary v. Medtronic Sofamor Danek USA, Inc.*, No. 01 L 11121 (Cir. Ct. DuPage County, Ill. [DATE] 2006).

⁴⁷ 21 U.S.C. § 396 (2006); see also John J. Smith, *Physician Modification of Legally Marketed Medical Devices: Regulatory Implications Under the Federal Food, Drug, & Cosmetic Act*, 55 FOOD & DRUG L.J. 245, 251 (2000) ("As applied to medical devices, the [practice of medicine] doctrine implies that a licensed physician may use any legally marketed device for any indication that he or she feels is appropriate, even if that indication is not approved specifically for that product (commonly known as 'off-label' use).").

device is contraindicated, *i.e.*, “off-label.” However, under the federal practice of medicine doctrine, a manufacturer who limits a physician’s use of a device in such a manner “threatens to impinge upon a physician’s discretion in determining the manner in which medical devices are to be used from a medical, as opposed to a regulatory, perspective.”⁴⁸

Moreover, medical device or pharmaceutical companies have strong arguments that they have no duty to provide warnings directly to the patient. The physician’s duty of disclosure within the context of the physician-patient relationship (see *supra*) serves as a basis of the learned intermediary doctrine.⁴⁹ Under the doctrine, a medical device or pharmaceutical company has no duty to warn a patient directly of any dangers inherent in the use of a device or drug.⁵⁰ Rather, a manufacturer’s duty to warn extends only to the prescribing physician, who, in turn, as a “learned intermediary” exercising both professional judgment and discretion, conveys relevant and pertinent warnings to the patient.⁵¹ The learned intermediary doctrine, as its nomenclature suggests, is based on the notion that a physician is learned and

⁴⁸ *Baker v. Smith & Nephew Richards, Inc.*, No. 95-58737, 1999 WL 811334, at *12 n.33 (Tex. Dist. June 7, 1999).

⁴⁹ See *AYH Holdings, Inc. v. Avreco, Inc.*, 826 N.E.2d 1111, 1130 (Ill. App. Ct. 1st Dist. 2005) (“[T]he learned intermediary doctrine is a special rule created based on the doctor-patient relationship, where the doctor is in the best position to warn the patient.”); *Spensieri v. Lasky*, 723 N.E.2d 544, 549 (N.Y. 1999) (“The learned intermediary doctrine focuses on the scope of a drug manufacturer’s duty to warn of the dangers of using the drug in question. That duty is fulfilled by giving adequate warning to the prescribing physician. The physician must then balance the risks and benefits of various drugs and treatments and act as an ‘informed intermediary’ between manufacturer and patient.”) (citations omitted); *Morgan v. Wal-Mart Stores, Inc.*, 30 S.W.3d 455, 462 (Tex. App. 2000) (“According to [the learned intermediary] doctrine, the manufacturer of a prescription drug has a duty to adequately warn the prescribing physician of the drug’s dangers. The physician, relying on his medical training, experience, and *knowledge of the individual patient*, then chooses the type and quantity of drug to be prescribed.”) (emphasis added).

⁵⁰ See *Kirk v. Michael Reese Hosp. & Med. Ctr.*, 513 N.E.2d 387, 393 (Ill. 1987); *Black v. Merck & Co.*, No. CV 03-8730 NM (AJWx), 2004 WL 5392660, at *4 n.5 (C.D. Cal. Mar. 3, 2004) (“Under the ‘learned intermediary’ doctrine, a drug manufacturer has no duty to warn the ultimate consumer, the patient, so long as adequate warnings are given to the doctor.”) (citations omitted); *Cooley v. Carter-Wallace Inc.*, 102 A.D.2d 302, 211(N.Y. App. Div. (1984) (“The drug manufacturer has a duty to warn the prescribing physician, not the consumer-patient.”).

⁵¹ *Kirk*, 513 N.E.2d at 395; *Hansen v. Baxter Healthcare Corp.*, 723 N.E.2d 302, 311 (Ill. App. Ct. 1999), *aff’d*, 198 Ill. 2d 420 (Ill. 2002); *Spensieri*, 723 N.E.2d at 549; *Morgan*, 30 S.W.3d at 462.

knowledgeable in areas about which the patient will know little.⁵² This same disparity in knowledge forms the basis of the physician's duty of disclosure in the context of the physician-patient relationship.⁵³ It is for this reason that the Illinois Supreme Court has determined that patients should look to their physicians to provide relevant warnings about prescription drugs and devices.⁵⁴

Thus, when a plaintiff alleges that a medical device or pharmaceutical company should provide warnings directly to the plaintiff, whether those warnings are related to the product itself or how the doctor intends to use the product, medical device and pharmaceutical companies have strong arguments that they can never have a duty to warn a patient directly. Obviously, the learned intermediary doctrine would preclude the imposition of a duty to provide product-specific warnings, but more importantly, the policy considerations underlying the doctrine, namely the physician-patient relationship, would prohibit a manufacturer from providing any warnings to the patient. As discussed above, to hold otherwise would place the manufacturer in the middle of the physician-patient relationship.

⁵² See *Kirk*, 513 N.E.2d at 392; *Union Carbide Corp. v. Kavanaugh*, 879 So.2d 42, 44 (Fla. Dist. Ct. App. 2004) ("A learned intermediary is defined as one who has knowledge of the danger and whose position *vis-a-vis* the manufacturer and consumer, confers a duty to convey the requisite warnings to the consumer.") (quotations omitted). *Bean v. Baxter Healthcare Corp.*, 965 S.W.2d 656, 663 (Tex. App. 1998) ("In general, the physicians dispensing prescription medicine and inserting the implant better understand their dangers and propensities. Further . . . the physicians must use [their] comprehensive training and experience in conjunction with [their] knowledge of the individualized patient in determining the suitability of the medication.") (citations and quotations omitted) (alterations in original).

⁵³ See, e.g., *Goldberg*, 471 N.E.2d at 537. ("We also believe that the physician-patient relationship does create an affirmative duty to disclose facts. Such a relationship is based upon the theory that the "physician is learned, skilled and experienced in subjects of vital importance to the patient but about which the patient knows little or nothing."); *Union Carbide*, 879 So.2d at 44; *Bean*, 965 S.W.2d at 663.

⁵⁴ See *Frye v. Medicare-Glaser Corp.*, 605 N.E.2d 557, 561 (Ill. 1992) ("In our opinion, consumers should principally look to their prescribing physician to convey the appropriate warnings regarding drugs, and it is the prescribing physician's duty to convey these warnings to patients.") (citing *Kirk*, 117 Ill. 2d at 524); *Humble Sand & Gravel, Inc.*, 146 S.W.3d 170, 190-91 (Tex. 2004) ("The rationale for this 'learned intermediary' rule is not that a direct warning from manufacturers to patients is infeasible, in the practical, physical sense of that word, but that it is *better for the patient for the warning to come from his or her physician.*") (emphasis added).

B. A Company Can be Liable for its Representative's Actions, Including the Unauthorized Practice of Medicine.

While medical device and pharmaceutical companies can generally avoid liability arising out of their alleged omissions (*i.e.*, their failure to prevent physician misuse of their products), liability can attach for their actions, either under section 324A of the Restatement (Second) of Torts or because the actions amount to the unauthorized practice of medicine.

1. Liability Under Section 324A of the Restatement.

As noted above, the plaintiff in *Kennedy* alleged that by providing a representative to attend the surgery, Medtronic had voluntarily assumed a duty of care for the patient.⁵⁵ Section 324A provides:

One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of a third person or his things, is subject to the third person for physical harm resulting from his failure to exercise reasonable care to protect his undertakings, if (a) his failure to exercise reasonable care increases the risk of such harm, (b) he has undertaken to perform a duty owed by the other to the third person or (c) the harm is suffered because of reliance of the other or the third person upon the undertaking.

Obviously, liability can attach for the representative's negligent performance of his or her duties.

For example, in *Chamian v. Sharplan Lasers, Inc.*,⁵⁶ the plaintiff suffered significant facial scarring and loss of skin pigmentation from the misuse of a laser during cosmetic surgery. The manufacturer of the laser did not have an employee present during the surgery; rather, the manufacturer sold the device to a third-party distributor that leased the laser to the physician and itself provided a

⁵⁵ *Kennedy*, 851 N.E. 2d at 786.

⁵⁶ *Chamian v. Sharplan Lasers, Inc.*, No. 20000171, 2004 WL 2341569, at *7 (Mass. Super. Sept. 24, 2004).

technician to assist the physician during the surgery. In addition to the physician, the plaintiff sued the manufacturer and the distributor.

The laser at issue had various settings that controlled the strength of the beam and the duration of the actual pulse. In addition to warning against the risks of misuse, the manufacturer provided instructions and recommended settings based on the procedure the physician intended to perform. The appropriateness of the settings depended upon both the procedure to be performed and the patient's physical and medical condition, but ultimately the physician had to decide what settings were appropriate. The manufacturer also provided training to the physician and the distributor's technician. Although his job required him to program the laser as directed by the physician, the technician was also permitted to answer the physician's questions and reiterate the recommended settings as specified in the instructions. Prior to the plaintiff's procedure, the physician informed the technician what procedure he was going to perform and asked the technician to program the recommended settings. The technician, based on his prior experiences, programmed the laser for settings that were not recommended for the plaintiff's procedure. As a result, the laser burned the plaintiff's face.

As against the manufacturer, the plaintiff alleged: (1) the warnings were inadequate because the manufacturer "watered them down" by stating that the final decision as to the settings to be used was the physician's to make; and (2) the manufacturer negligently trained the physician and technician. The court rejected the plaintiff's allegations, and granted the manufacturer's motion for summary judgment. The court reasoned that under the learned intermediary and sophisticated user doctrines the manufacturer had fulfilled its duty to warn. In so holding, the court stressed that "it was the physician's responsibility to exercise his clinical judgment to determine the appropriate settings based on the characteristics of the patient's skin and the objectives of the surgery."⁵⁷ The court also rejected the plaintiff's "negligent training" theories against the manufacturer, holding that "the fact that individuals who have received training on medical equipment subsequently misuse the equipment . . . , standing alone, is insufficient . . ."⁵⁸ The court emphasized that "by providing training, [the manufacturer] did not become a guarantor of the competence of either [the physician or the technician]."⁵⁹

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.*

The court, however, denied the distributor's motion for summary judgment. The court reasoned that "by [providing a technician to assist in the surgery, the distributor] assumed a duty to . . . ensure that the [representative] was knowledgeable about the equipment and competent to provide technical assistance to physicians."⁶⁰ In so holding, the court rejected the distributor's argument that the physician's negligence broke the proximate cause chain, stating that "the fact that [the physician] had the responsibility to exercise his clinical judgment to determine appropriate settings and was required by the standard of care to confirm that the settings [were appropriate] does not preclude negligence on the part [of the technician] from being a substantial contributing cause of [the injuries]."⁶¹ The court stressed that regardless of the physician's conduct, the distributor had a duty to "provide a trained and competent technician."⁶²

2. Liability for the Unauthorized Practice of Medicine.

A more nebulous issue is the notion of liability for the unauthorized practice of medicine. Most, if not all, states have a medical practices act. For example, the Illinois Medical Practice Act of 1987⁶³ prohibits the "practice [of] medicine, or any of its branches, or [the] treat[ment] [of] human ailments without the use of drugs and without operative surgery, without a valid, existing license to do so."⁶⁴ However, "[t]he legislature did not define 'the practice of medicine' in the definition section of the Medical Practices Act [and] [a] flexible definition of the practice of medicine is required in a statute intended to govern various healers from osteopaths to herb doctors."⁶⁵ New York defines the practice of medicine as "diagnosing, treating, operating or prescribing for any human disease, pain, injury, deformity, or physical condition."⁶⁶ Florida and Texas have definitions similar to New

⁶⁰ *Id.* at *8.

⁶¹ *Id.*

⁶² *Id.*

⁶³ 225 ILL. COMP. STAT. 60/1 – 63 (2008).

⁶⁴ 225 ILL. COMP. STAT. 60/3 (2008).

⁶⁵ *Siddiqui v. Illinois Dep't of Prof'l Regulation*, 718 N.E.2d 217, 224 (Ill. App. Ct. 1999) (citations omitted, alterations added).

⁶⁶ N.Y. EDUC. LAW § 6521 (McKinney 2008).

York.⁶⁷ While the question of whether an activity amounts to the practice of medicine is highly fact-dependent,⁶⁸ the case law makes clear that determinations and decisions “requiring the exercise of medical judgment” can only be made by a licensed physician:

Each and every medical problem requiring the exercise of medical judgment varies in complexity and severity, but what all cases have in common is “*an individual human being*,” a patient who has an illness or condition, whose treatment must be evaluated by one with the compassion, the authority and medical training, and the intimate knowledge of the patient’s problem and needs (including the patient’s physical and psychological [condition]), required to make the treatment decision: the physician.⁶⁹

Thus, medical device manufacturer representatives are precluded from doing anything that would involve the exercise of medical judgment.

⁶⁷ See, e.g., FLA. STAT. § 458.305(3) (2008) (“Diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition.”); TEX. OCC. CODE ANN. § 151.002(a)(13) (Vernon 2008) (“Diagnosis, treatment, or offer to treat a mental or physical disease or disorder or a physical deformity or injury by any system or method, or the attempt to effect cures of those conditions, by a person who: (A) publicly professes to be a physician or surgeon; or (B) directly or indirectly charges money or other compensation for those services.”).

⁶⁸ *People v. Rubin*, 424 N.Y.S.2d 592 (N.Y. Crim. Ct. Queens Co. 1979) (discussing the many issues to determine whether an activity is the practice of medicine).

⁶⁹ *State of Wisconsin Dep’t of Health & Social Serv. v. Bowen*, 797 F.2d 391, 412 (7th Cir. 1986) (italics in original); see also *Jackson v. Chicago Classic Janitorial & Cleaning Serv., Inc.*, 355 Ill. App. 3d 906, 912-13 (Ill. App. Ct. 1st Dist. 2005) (concluding that determinations requiring the exercise of medical judgment “can only be properly made by individuals with the necessary training and expertise.”); *NCO Financial v. Komurka*, No. E042232, (Super. Ct. Nos. RIC416929, RIC 420515), 2008 WL 541604, at *4 (Cal. Ct. App. Feb. 29, 2008) (“The decision to obtain additional medical consults for a patient in the Emergency Department is a medical decision which *can be made only by the licensed physician, as such a decision involves medical judgment.*”) (emphasis added); *Diversicare General Partner, Inc. v. Rubio*, 185 S.W.3d 842, 850 (Tex. 2005) (“The nature and intensity of care and treatment, including professional supervision, monitoring, assessment, quantities and types of medication, and other medical treatment are judgments made by professionals trained and experienced in treating and caring for patients and the patient populations in their health care facilities.”).

To do so could subject themselves to either, civil penalties, criminal penalties or both.⁷⁰

At one end of the spectrum lies *People v. Smithtown General Hospital*.⁷¹ *Smithtown* involved a hip replacement surgery. The physician enlisted the help of the general sales manager of the prosthetic hip manufacturer.⁷² During the surgery, the physician encountered a problem with the prosthetic hip. At that point, the sales manager scrubbed in to remedy the problem and finish the surgery.⁷³ The surgery lasted approximately three and a half hours, during which period the physician walked away from the operating table.⁷⁴ The court found that the physician “abdicated his role as surgeon in that operating room and permitted the judgment and skills of a layman to prevail,” that the salesman’s “involvement in the surgical procedure extended far beyond instruction as to the use or manner of implant of the device he sold,” and that “the Grand Jury could conclude that the salesman . . . unlawfully engaged in the practice of medicine without the prior consent of the patient under circumstances which did not constitute an emergency.”⁷⁵

At the other end of the spectrum lies the Texas Appellate Court’s decision in *Disbrow v. Richards, Inc.*⁷⁶ that also involved a hip replacement surgery. The plaintiff in *Disbrow* sued the manufacturer of a prosthetic hip and the manufacturer’s representative who provided the hip and surgical supplies to the surgeon when a tool supplied by the representative broke during the surgery. The plaintiff alleged that the representative – who was present in the operating room but did not scrub in and merely provided the device and surgical tools used to implant the device – was liable for the unauthorized practice of medicine. The court affirmed the trial court’s grant of the defendant’s motion for summary judgment, and concluded that the representative’s

⁷⁰ See, e.g., 225 ILL. COMP. STAT. 60/3.5 (2008) (providing civil penalties for the unlicensed practice of medicine); *Id.* at 60/59 (providing criminal penalties for the unlicensed practice of medicine); See also *Kohn v. Laidlaw Transit, Inc.*, 347 Ill. App. 3d 746, 757 (Ill. App. Ct. 2004) (“A violation of a statute designed for the protection of human life or public safety is prima facie evidence of negligence and creates a cause of action if the violation has a direct and proximate connection with the injury.”).

⁷¹ *New York v. Smithtown Gen. Hosp.*, 93 Misc. 2d 736 (Suffolk Co. 1978).

⁷² *Id.* at 738-39.

⁷³ *Id.* at 739-40.

⁷⁴ *Id.*

⁷⁵ *Id.* at 740.

⁷⁶ *Disbrow v. Richards, Inc.*, No. 14-95-00759-CV, 1996 WL 593780 (Tex. App. Oct. 17, 1996).

participation in the surgery did not amount to the unauthorized practice of medicine because the representative was not involved in “diagnosis or treatment.”⁷⁷ Rather, the representative merely “assisted the scrub nurse get equipment in order – a service that is offered by most manufacturers.”⁷⁸

Somewhere in the middle lies *Hurley v. Heart Physicians, P.C.*⁷⁹ In *Hurley*, the Connecticut Supreme Court addressed the issue of whether a medical device manufacturer could be liable for the statements made by a representative. The plaintiff was born with a congenital heart condition requiring the use of a pacemaker. When she was fourteen, the battery of the pacemaker she had at that time needed to be replaced. According to the pacemaker’s FDA-approved manual, “[t]he physician should schedule an immediate replacement of the pacemaker” when the battery needs to be replaced.⁸⁰ According to both the doctor and the company representative, however, the plaintiff’s mother did not want her daughter to go through yet another surgery and would not agree to the surgery.

As a result of the physician’s and representative’s belief that the mother would not consent to the surgery, the physician asked the representative if there were options for extending the life of the battery. The pacemaker’s manual provided that the pacemaker’s rate could be reduced to a rate of 40 beats per minute, and the representative testified that reducing the rate would extend the battery’s life. The pacemaker manual provided, however, that “[r]ates less than 40 ppm are intended primarily for diagnostic purposes.”⁸¹ The physician decided to make the rate reduction to evaluate “[the plaintiff’s] ability to function with the pacemaker operating at a lower rate,”⁸² prolong battery life, and obtain additional information to convince the mother that a replacement surgery was required.⁸³ Shortly after the downward adjustment was made, the plaintiff suffered a sudden cardiac arrest that caused permanent brain damage.⁸⁴

The court reversed the trial court’s grant of summary judgment in favor of the manufacturer. In so doing, the court agreed with the defendant that under the learned intermediary doctrine, the

⁷⁷ *Id.* at *2.

⁷⁸ *Id.*

⁷⁹ *Hurley v. Heart Physicians*, 898 A.2d 777 (Conn. 2006).

⁸⁰ *Id.* at 780-81.

⁸¹ *Id.* at 782 n.7.

⁸² *Id.* at 778.

⁸³ *Id.*

⁸⁴ *Id.*

manufacturer had no duty to provide warnings directly to the plaintiff.⁸⁵ The court further agreed that if the representative “did nothing inconsistent with the manual,” then summary judgment would be appropriate because the plaintiff’s claims would be preempted.⁸⁶ The court stressed that in such a situation, a representative who merely recites to the doctor the information set forth in the FDA-approved manual cannot subject a manufacturer to liability. The court concluded, however, that there was a genuine issue of fact as to whether the representative’s statement that the pacemaker’s rate could be turned down in the circumstances presented was actually consistent with the manual’s statement that the pacemaker’s rate can be turned down for diagnostic purposes.⁸⁷

Although dicta, the court also discussed in detail the legal principles that weigh against the imposition of a duty upon a device manufacturer to prevent physician malpractice. As the court concluded, whether and how to use a device to treat a patient are matters of medical judgment.⁸⁸ Thus, “the learned intermediary doctrine . . . applies independent of whether the manufacturer knew or should have known of the physician’s inferior care because ‘[w]hen the physician-patient relationship does exist . . . we hesitate to encourage, much less require, a drug manufacturer to intervene in it.’”⁸⁹ Indeed, the logical extension of the *Hurley* opinion makes clear that, as the courts similarly made clear in *Disbrow* and *Chamian*, if what the representative told the physician in *Hurley* is not consistent with the FDA-approved warnings and instructions, the plaintiff would have a strong argument that the representative actually engaged in the unauthorized practice of medicine and that the representative negligently fulfilled his duties.

Disbrow, *Chamian* and *Hurley* make clear that a company cannot be held liable for the unauthorized practice of medicine merely because its representative is present in the operating/treatment room. Rather, the representative must participate in the actual treatment of the patient and/or the exercise of medical judgment. Thus, representatives should be advised that they should not, under any circumstances, exercise any modicum of medical judgment. In addition, as *Hurley*

⁸⁵ *Id.* at 786.

⁸⁶ *Id.* (italics omitted).

⁸⁷ *Id.* at 788.

⁸⁸ *Id.* at 786 (“[P]hysicians, as learned intermediaries, still ‘stand in the best position to evaluate a patient’s needs and assess [the] risks and benefits of a particular course of treatment.’”).

⁸⁹ *Id.* (quoting *Swayze*).

makes abundantly clear, a representative should never provide information other than what is set forth in the FDA-approved manual, if any.

CONCLUSION

Advancements in technology and the medical sciences have lead to an unprecedented growth in the number and use of medical devices and drugs to treat patients. These devices and drugs extend and improve the lives of millions of patients every year, and therefore, are immeasurably valuable to society. Their complexity, however, also places an increasing burden on pharmaceutical and medical device companies. Physicians are experts in the practice of medicine. They cannot possibly be expected to be an expert in the workings of the innumerable devices and drugs currently on the market, particularly with new drugs and devices entering the market every year. As a result, doctors are increasingly dependent on company representatives who are such experts. Because of the advances in technology and medial sciences, this dependency can only be expected to increase. Thus, medical device and pharmaceutical companies should be aware of the liability that can attach because of a physician's reliance on company representatives and instruct their representatives accordingly.