Glennen v. Allergan, Inc.

GINGER PIGOTT* AND KEVIN COLE**

WHY IT MADE THE LIST

Prescription medical device manufacturers defending personal injury actions have a wide variety of legal defenses not available to claims brought against manufacturers of other products. Traditional tort claims like strict liability and negligence are often limited or entirely unavailable. As a result, plaintiffs have increasingly turned to novel theories of liability in an effort to get around these robust defenses. And, likewise, those in the industry and their lawyers remain vigilant against attempts to expand tort liability. One of the creative theories advanced by the plaintiffs' bar has been dubbed the "failure to train" claim, and *Glennen v. Allergan, Inc.*[1] presents a recent and excellent discussion of why such claims also fail. In deciding *Glennen*, the California Court of Appeal took a rare opportunity to address failure to train claims involving devices approved pursuant to the Food and Drug Administration's (FDA) Premarket Approval process. *Glennen* is the most recent in a series of cases addressing how state law failure to train claims might run afoul of federal preemption, both express and implied. With little case law on point, *Glennen* will likely guide courts elsewhere.

DISCUSSION

Federal Regulation of Medical Devices

In analyzing the *Glennen* decision, it is helpful to first understand Congress' statutory scheme for the regulation of medical devices. Many of the readers here will know the background, but for those just joining us, a brief overview of medical device regulation provides the framework to understand preemption as applied in medical device cases.

In 1976, Congress enacted the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act (FDCA), which gave FDA specific authority to regulate general medical devices.[2] In this framework, Congress sought to find a balance that would make medical devices readily available for treatment while ensuring that those

---

* Ginger Pigott is Vice-Chair of Greenberg Traurig LLP's global Pharmaceutical, Medical Device & Health Care Litigation Practice, and she focuses her practice on the defense of complex medical device and pharmaceutical products liability litigation.

** Kevin J. Cole is a litigation attorney in the Los Angeles office of Greenberg Traurig. Before joining Greenberg Traurig, Kevin served as a law clerk for Judge Eric L. Clay of the U.S. Court of Appeals for the Sixth Circuit, and also as an assistant prosecuting attorney.

[1] 202 Cal. Rptr. 3d 68 (Ct. App. 2016).

[2] *Id.*; *see also* Riegel v. Medtronic, Inc., 552 U.S. 312, 316 (2008) (explaining that Congress passed the MDA in order to "impose[ ] a regime of detailed federal oversight" to govern medical devices).

devices are safe for patient use.[3] To that end, the MDA provides "for the safety and effectiveness of medical devices intended for human use,"[4] while at the same time "encourag[ing] their research and development."[5]

The MDA divides medical devices into three classes. Class I devices pose little threat to public health and safety and are subject only to general controls on manufacturing.[6] Class II devices are more complex and must comply with specific standards known as "special controls."[7] Class III devices present a potential unreasonable risk of illness or injury.[8] As a result, these devices must "complete a thorough review process with the FDA before they may be marketed."[9]

This review, known as the Premarket Approval (PMA) process, is indisputably thorough.[10] The manufacturer must give FDA a "reasonable assurance" that the product is safe and effective.[11] The process by which FDA determines whether a manufacturer has provided a "reasonable assurance," is—to quote the Supreme Court—a "rigorous" one.[12] Indeed, "[t]he FDA spends an average of 1,200 hours reviewing each application, and grants premarket approval only if it finds there is a reasonable assurance of the device's safety and effectiveness."[13]

After completing its review, FDA either grants or denies PMA.[14] When FDA grants PMA, it may impose post-approval requirements such as restrictions on "the sale, distribution, or use of the device" and "[c]ontinuing evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use."[15] After obtaining PMA, a manufacturer may not change the device's design or labeling without FDA's consent.[16]

Federal Preemption

In addition to a framework for regulation, most readers will be familiar with federal preemption for medical devices, including express and implied preemption principles. The following is a very brief overview.

---

3 *See* Medtronic, Inc. v. Lohr, 518 U.S. 470-74 (1996) (explaining Congress' intent in enacting the MDA).

4 Pub. L. No. 94-295, preamble, 90 Stat. 539 (May 28, 1976).

5 S. Rep. No. 94-33, 94th Cong., 2d Sess. 2 (1976), reprinted in 1976 U.S.C.C.A.N. 1070, 1071.

6 *Lohr*, 518 U.S. at 476-77.

7 *Id.* at 477 (quotations omitted) (citing 21 U.S.C. § 360c(a)(1)(B)).

8 *Id.*

9 Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 344 (2001).

10 *Lohr*, 518 U.S. at 477.

11 *Id.*

12 *Riegel*, 552 U.S. at 317 (quoting *Lohr*, 518 U.S. at 477).

13 *Id.* at 317-18 (internal citations and quotations omitted).

14 *Id.*, 552 U.S. at 319.

15 21 C.F.R. § 814.82(a)(1)-(2).

16 *Riegel*, 552 U.S. at 319.

Express Preemption in Brief

In enacting the MDA, Congress recognized that state laws, as well as lawsuits brought by individuals, could undermine FDA's authority relating to the approval and regulation of medical devices by imposing different or additional requirements on medical device manufacturers. As a result, the statute governing medical devices includes an express preemption clause that prohibits states from imposing "requirements" that are "different from, or in addition to" federal requirements placed on medical devices.[17] The Supreme Court has also explained that state law causes of action of general applicability seek to enforce state "requirements" and thus are preempted by federal standards.[18]

Implied Preemption in Brief

In addition to express preemption, conflict and implied preemption principles also apply to limit claims available to plaintiffs. Such was the case in *Buckman*, where the Supreme Court considered the question of a state law "fraud-on-the-FDA" claim and found that it was impliedly preempted.[19] *Buckman* explained that a plaintiff cannot bring a state law cause of action claiming that a defendant defrauded a federal agency because federal law gives federal agencies—not states or private plaintiffs—the authority to police their own processes.[20] In barring claims by individuals to enforce requirements of the statute, the *Buckman* decision cites the "no private right of action" provision found in 21 U.S.C. § 337 (a), concluding that actions for alleged violations of federal requirements are not available to private litigants.[21] Plaintiffs cannot stand in the shoes of FDA.

Ashley Glennen's State Law Complaint

The *Glennen* case involved the Lap-Band Adjustable Gastric Banding System (Lap-Band), a medical device designed to help clinically obese patients lose weight by limiting the amount of food they eat.[22] The Lap-Band was intended for use by severely obese patients.[23]

In March 2000, BioEnterics, a subsidiary of a company that later merged with Allergan, filed an application with FDA seeking PMA of the Lap-Band.[24] FDA approved the application in June 2001.[25] As a condition for approval, FDA required that the Lap-Band's labeling "specify the requirements that apply to the training of practitioners who may use the device as approved in this order."[26] In complying with that requirement, BioEnterics prepared a brochure for the Lap-Band which made clear

---

17 21 U.S.C. § 360k(a)(1); *see also Riegel*, 552 U.S. at 316.

18 *Riegel*, 552 U.S. at 323-24 (includes negligence, strict liability, breach of warranty, among others).

19 *Buckman*, 531 U.S. at 347.

20 *Id.* at 350.

21 *Id.* at 349, n.4 (citing 21 U.S.C. § 337(a)).

22 *Glennen*, 202 Cal. Rptr. 3d at 70.

23 *Id.*

24 *Id.* at 71.

25 *Id.*

26 *Id.*

that surgeons using the device "must, among other things . . . participate in a training program for the LAP-BAND System authorized by BioEnterics Corporation or an authorized BioEnterics distributor (this is a requirement for use)."[27] FDA's approval order did not contain any additional requirements concerning the training of physicians.[28]

In January 2003, Ashley Glennen's surgeon implanted the Lap-Band.[29] After the surgery, however, Glennen suffered serious injuries—the Lap-Band eroded into her stomach and liver, causing a portion of her stomach and small intestine to die, and also resulting in brain damage due to hemorrhage during an attempted surgical removal.[30] In September 2012, Glennen sued Allergan for negligence,[31] alleging Allergan failed to adequately train physicians how to use the Lap-Band.[32] After a couple of iterations of the complaint where arguments by Allergan whittled down the causes of action, Allergan again demurred to Glennen's Second Amended Complaint (the California equivalent of a motion to dismiss). Allergan's motion primarily sought to apply express preemption to the claims.[33] The trial court agreed and dismissed Glennen's case, and Glennen appealed.

Court Ruling

The California Court of Appeal affirmed, agreeing that federal law preempted Glennen's negligence claim.[34] The court's decision was based on two lines of reasoning. First, it held that Glennen's claim—that the training standards for physicians fell below what is required under California state law for compliance with the duty of care—was not the standard that FDA would apply in connection with the training requirements it imposed on physicians.[35] As a result, Glennen's negligence claim was expressly preempted by the MDA because it imposed requirements different than, or in addition to, the applicable federal requirements.[36] The court separately found that Glennen's claim was impliedly preempted by federal law because it improperly sought to enforce the MDA.[37] Thus, the court concluded that Glennen failed to allege facts sufficient to state a claim, based on the application of federal preemption.

---

[27] *Id.* (internal brackets and quotation marks omitted).

[28] *Id.*

[29] *Id.*

[30] *Id.*

[31] The obvious statute of limitations question must have been addressed by an argument regarding the discovery rule, but it is not mentioned in the published decision beyond noting the original complaint which sued two doctors and a surgical center, was later dismissed.

[32] *Id.* at 70-71.

[33] *Id.*

[34] *Id.* at 84.

[35] *Id.* at 81-82.

[36] *Id.* at 79-80.

[37] *Id.* at 83-84.

Rationale for Decision

The cornerstone of the court's decision was the now familiar concept of express preemption. The court, in a detailed analysis of the MDA and the Supreme Court's decisions interpreting it, explained that because FDA imposes specific requirements on Class III devices, state law claims that would impose different or additional requirements on those devices are preempted. The problem for Glennen, as the court saw it, was that her claim fell squarely within the scope of express preemption.

In her suit against Allergan, Glennen did not dispute that the Lap-Band had been approved through FDA's rigorous PMA process or that the requirements under the MDA have preemptive force under the Supremacy Clause.[38] Nor did Glennen apparently dispute, even indirectly, that state common law causes of action—like the one she filed against Allergan—seek to enforce state requirements and would be preempted by federal requirements.[39] Indeed, the question before the court—and the only question—was whether Glennen's negligence claim was preempted by the MDA because it imposed requirements different than, or in addition to, the applicable federal requirements.[40]

Glennen did not allege that Allergan failed to comply with FDA's training program requirement. There was no dispute whether Allergan had established a physician training program or whether the surgeon who implanted the Lap-Band into Glennen's body had completed that training. Rather, Glennen's claim was that something additional was required. Not only did Allergan need to create a training program, it also—according to Glennen—needed to "implement current good manufacturing practices," which included adopting and implementing "a quality policy as required by [the FDA's Quality System Regulation (Quality System Regulation)]," and ensure that surgeons "who completed the program were skilled in the implantation of Lap-Bands."[41] However, as the court noted, when FDA approved the Lap-Band, it did not mandate these additional requirements.[42]

For her part, Glennen argued that the requirements that formed the basis of her claim were not different from, or in addition to, the requirements imposed by FDA's PMA order.[43] Rather, her position was that even if the MDA expressly preempted her federally derived claim, she could still bring claims that paralleled the federal requirements.[44] This argument presumably rested on the Supreme Court's suggestion in *Riegel* that the tension between FDA's requirements and those created by state law is avoided where the state requirements correspond to the federal ones.[45] In *Riegel*, for example, the Supreme Court stated that the MDA's preemption provision did not "prevent a State from providing a damages remedy for claims premised on a violation

---

[38] *Id.* at 76.

[39] *Id.*; *see also Riegel*, 552 U.S. at 323-24.

[40] *Id.*

[41] *Id.* at 80.

[42] *Id.* at 79-82.

[43] *Id.* at 76.

[44] *Id.*

[45] *Riegel*, 552 U.S. at 330 (declining to address, in the first instance, whether plaintiffs' claims were "parallel" to federal requirements).

of FDA regulations; the state duties in such a case [are] 'parallel[].'"[46] But, the Court did not explain what constitutes a parallel claim.

Glennen, however, did not rely on *Riegel* in support of her parallel claim argument. Instead, she cited to a number of federal appellate cases, all of which the court was quick to distinguish.[47] For example, in one of the cases Glennen cited, *Bausch v. Stryker Corp.*,[48] the Seventh Circuit reversed a district court's dismissal of a plaintiff's claims for defective manufacture of a hip replacement in violation of federal law. The court concluded that state negligence claims premised on a manufacturer's failure to abide by FDA's approved manufacturing requirements survive express preemption.[49] By contrast, Glennen did not allege that the Lap-Band suffered from manufacturing defects in violation of federal law.[50]

Glennen also relied on *Stengel v. Medtronic Inc.*,[51] but as the court noted, the plaintiffs in that case alleged that the defendant violated its duty under federal law to report adverse events associated with its device to FDA, whereas Glennen did not allege failure to warn as a cause of action.[52] Likewise, in *Hughes v. Boston Scientific Corp.*,[53] another case on which Glennen relied, the Fifth Circuit explained that the plaintiff's claim was "not expressly preempted to the extent she asserts that Boston Scientific violated the state [law] duty to warn by failing to accurately report serious injuries and malfunctions of the . . . device as required by the FDA's [reporting] regulations."[54] And, just as in Glennen's claim, the Fifth Circuit in *Hughes* held that "[i]t is clear that all of [the plaintiff's] state products liability claims that purport to impose liability on Boston Scientific despite Boston Scientific's compliance with the applicable FDA design and manufacturing specifications, as approved by the FDA during the PMA process, seek to impose different or additional state duties and are expressly preempted."[55]

The court was also unpersuaded by any argument that FDA's Quality System Regulation (QSR) required device manufacturers like Allergan to train physicians in a certain way.[56] The court pointed out that Glennen's claim did not fit into that regulation, which governs the quality of "finished" manufacturing devices and has nothing to do with training of physicians.[57] As the court explained, the plain language

---

[46] *Id.*; *see also* Bates v. Dow Agrosciences LLC, 544 U.S. 431, 447-48 (2005) (describing parallel claims); *Lohr*, 518 U.S. at 496-97 (holding that state requirements that are "substantially identical to" those imposed by the MDA are not preempted).

[47] *Glennen*, 202 Cal. Rptr. 3d at 76-77 (distinguishing cases).

[48] 630 F.3d 546 (7th Cir. 2010).

[49] *Id.* at 557-58.

[50] *Glennen*, 202 Cal. Rptr. 3d at 76.

[51] 704 F.3d 1224 (9th Cir. 2013) (en banc).

[52] *Glennen*, 202 Cal. Rptr. 3d at 77.

[53] 631 F.3d 762 (5th Cir. 2011).

[54] *Id.* at 770.

[55] *Id.* at 768.

[56] *Glennen*, 202 Cal. Rptr. 3d at 78 ("In an apparent effort to align her claim with a violation of federal law, plaintiff's [complaint] alleges violations of several federal provisions contained in the FDA's 'Quality System Regulation.'").

[57] *Id.* ("Because none of the regulations on which [Glennen] relies references any requirement to train physicians in the use of a medical device, her allegations fail to state a parallel claim.").

of the QSR dispels any notion that it regulates, or that it even relates to, the training of physicians.[58]

Indeed, the QSR "govern[s] the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use."[59] The court explained that "[t]he requirements in this part are intended to ensure that finished devices will be safe and effective,"[60] and also provides that "[e]ach manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed."[61] As the court further observed, the QSR is notably silent on the issue of physician training.[62]

The court was equally unpersuaded by Glennen's argument that Allergan's training was inadequate. The court observed that other courts addressing state law failure to train claims like Glennen's concluded that the MDA expressly preempted those claims.[63] The court noted the Fifth Circuit's decision in *Gomez v. St. Jude Medical Daig. Div., Inc.*,[64] which recognized that "[t]o permit a jury to decide . . . claims that the . . . training material the FDA required and approved through the PMA process were inadequate under state law would displace the FDA's exclusive role and expertise in this area and risk imposing inconsistent obligations on" device manufacturers.[65]

Finally, no shrinking violet, the court held that Glennen's claim was impliedly preempted by federal law, explaining that the implied preemption forbids state law claims that seek to enforce the FDCA.[66] The court observed that there was no duty under California law that required a medical device manufacturer like Allergan to train physicians in the use of its products, and Allergan did not voluntarily train physicians how to use the Lap-Band.[67] Instead, FDA required specified physician training by Allergan as a condition of its PMA for the Lap-Band.[68] Thus, but for FDA's requirement that Allergan provide training to physicians implanting the Lap-Band, Glennen would have no basis for which to allege the facts underlying her negligence claim.[69] As a result, the court explained, Glennen's claim did not "exist independently of the MDA, and . . . [was] impliedly preempted."[70] This reflects the Supreme Court's admonishments in *Buckman* that the MDA "leaves no doubt that it is the Federal Government rather than private litigants [which is] authorized to file suit for noncompliance with the medical device provisions."[71]

---

[58] *Id.* at 78-79.

[59] 21 C.F.R. § 820.1(a).

[60] *Id.*

[61] *Id.* at § 820.160(a).

[62] *Glennen*, 202 Cal. Rptr. 3d at 81.

[63] *Id.* at 82.

[64] 442 F.3d 919, 931 (5th Cir. 2006).

[65] *Id.*

[66] *Id.* at 75-76.

[67] *Id.* at 83.

[68] *Id.*

[69] *Id.*

[70] *Id.*

[71] *Buckman*, 531 U.S. at 349 n.4 (citing 21 U.S.C. § 337(a)).

IMPACT OF DECISION

Failure to train claims against medical device manufacturers are nothing new, and the case law—more often than not closing the door on such claims—has developed in two ways. First are cases where courts have explicitly refused to recognize a duty to train.[72] In such cases, the alleged failure to train is often characterized by courts as an attempt to expand the duty to warn.[73] As the Fifth Circuit put it, "[i]t is both impractical and unrealistic to expect drug manufacturers to police individual operating rooms to determine which doctors adequately supervise their surgical teams."[74] Other courts view the distinction between failure to train claims and failure to warn claims as one of "semantics only."[75]

Second are cases presenting failure to train claims for devices with an explicit requirement to undertake training. Training as a specific requirement of a PMA is relatively rare, though certainly available to FDA, particularly where a technology is new.[76] Therefore, while there is not as much precedent, most courts confronted with this kind of failure to train claim agree with *Glennen* that such claims are preempted because they would impose requirements that are different from, or in addition to federal requirements. The Fifth Circuit's decision in *Gomez*, on which the *Glennen* court relied in part, is illustrative. In that case, the plaintiff sued the manufacturer of the Angio-Seal (also a Class III device) under state law theories for, among other things, failure to train medical personnel.[77] In applying *Riegel*, the court affirmed the dismissal of the plaintiff's failure to train claim on the ground that "this state-law challenge" to FDA's requirements for the device was preempted by the MDA.[78] The court reasoned that permitting "a jury to second-guess the [FDA's requirements] by applying the [state] statutory standard for unreasonably dangerous [products] would risk interference with" the requirements approved by FDA and "would displace the FDA's exclusive role and expertise in this area."[79]

In another negligent training claim case, *Chamian v. Sharplan Lasers Inc.*,[80] the Massachusetts Superior Court provided a good example of the underlying rationale:

The fact that individuals who have received training on medical equipment subsequently misuse the equipment to the detriment of a patient, standing alone, is insufficient to establish a breach of a duty to the injured patient on the part of the entity

---

[72] *See, e.g.*, Woodhouse v. Sanofi-Aventis U.S. LLC, No. EP-11-CV-113-PRM, 2011 WL 3666595 at *3 (W.D. Tex. June 23, 2011) (allegation that defendant "failed to train, warn or educate" physicians failed to state a plausible claim because no such duty exists); Sons v. Medtronic, Inc., 915 F. Supp. 2d 776, 783 (W.D. La. 2013) ("It is well established that a medical device manufacturer is not responsible for the practice of medicine.").

[73] *See, e.g.*, *Rounds v. Genzyme Corp.*, 440 F. App'x 753, 754-55 (11th Cir. 2011).

[74] *Swayze v. McNeil Labs, Inc.*, 807 F.2d. 464, 471 (5th Cir. 1987).

[75] *Rounds*, 440 F. App'x at 756.

[76] Speaking only anecdotally, very few PMA orders specify training requirements for the use of a particular device.

[77] *Gomez*, 442 F.3d at 931.

[78] *Id.* at 931-32.

[79] *Id.*

[80] 2004 WL 2341569 (Mass. Super. Ct. Sept. 24, 2004).

that provided the training. By providing training, [the defendant] did not become a guarantor of the competence of [those it trained.][81]

More recently, in *Mattingly v. Hubbard*,[82] a Kentucky trial court held that the plaintiff's failure to train claims were preempted by the MDA because they were "in addition to" FDA's requirements applicable to the device. In that case, the plaintiff argued that his negligence claims were not precluded by *Riegel* because unlike in *Riegel*, they related to the alleged inadequate training of his physician rather than FDA's approval of the device.[83] While noting the argument that "claims of negligent failure to train physicians properly is separate from the FDA approval process," the court rejected the plaintiff's argument and instead held "that such a claim would nonetheless impose an additional substantive requirement for a specific device."[84]

Similarly, in *Rollins v. St. Jude Medical*,[85] the plaintiff alleged that the manufacturer failed to train her surgeon how to use the Angio-Seal device implanted during an angiogram. The court held that the plaintiff's failure to train claim was preempted by the MDA.[86] However, the court noted that a claim by the plaintiff that the manufacturer failed to abide by the training requirements imposed by FDA could survive preemption as a parallel claim.[87]

As the case law demonstrates, courts are generally averse to failure to train claims—perhaps even viewing them as an indication of a plaintiff who lacks a better cause of action. Indeed, that may have been the case in *Glennen*, where the trial judge was sufficiently persuaded that the plaintiff's claim did not survive California's liberal pleading standards, dismissing her case on the pleadings without allowing discovery.[88]

However, the court's decision in *Glennen* was premised on more than inadequate pleading. Instead, it illustrates a growing trend among courts that—to quote from *Glennen*—"medical device manufacturers are not responsible for the practice of medicine."[89] The court's decision reflects the concern that imposing upon a medical device manufacturer a duty to train physicians in the use of its products—above and beyond what is required by FDA—not only restricts physicians in their ability to practice medicine, but also forces manufacturers to practice medicine. As *Glennen* made clear, the entire point of FDA's regulatory scheme is to prevent that outcome. And with few cases specifically on point, *Glennen* is sure to pave the way for this emerging legal doctrine in which uniform federal laws will hold sway over conflicting state law claims.

---

[81] *Id.* at *7.

[82] No. 07CI12014, 2008 WL 3895381 (Ky. Cir. Ct. July 30, 2008).

[83] *Id.*

[84] *Id.*

[85] 583 F.Supp.2d 790 (W.D. La. 2008).

[86] *Id.* at 801-02.

[87] *Id.*

[88] *See Glennen*, 202 Cal. Rptr. 3d at 70-71 (dismissing the case on the pleadings); *see also Pointe San Diego Residential Community, L.P. v. Procopio, Cory, Hargreaves & Savitch, LLP*, 125 Cal. Rptr. 3d 540, 551 (Ct. App. 2011) (discussing California's "liberal pleading rules.").

[89] *Id.* at 83.

CONCLUSION

The California Court of Appeal decision is an important step toward a consistent application of the preemption doctrine in failure to train claims—an area with few appellate court opinions. In many ways, this was an easy case. Not only does the court's decision reflect the general consensus refusing to recognize a duty to train, but the plaintiff did not have much of a case. Perhaps the analysis would have been different had the plaintiff alleged that Allergan failed to comply with FDA's requirements, or that Allergan did not establish a physician training program, or even that the surgeon who implanted the Lap-Band had not completed the required training. Instead, the plaintiff's claim was that something more was required. But the court left no doubt that it thought the training of physicians is best left only to a specific FDA requirement, and is not subject to the requirements of state law.