THE SHIFTING LANDSCAPE OF MEDICAL DEVICE PREEMPTION

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Introduction

Medical device product liability is a complex field, both scientifically and legally. Since the landmark 2008 Supreme Court decision in *Riegel v. Medtronic*, we have known that at least some tort claims for some defective medical devices are preempted by federal law. Recent decisions in lower courts around the nation, however, suggest the scope of that preemption is narrower than initially believed. As a result, lawyers who previously believed that preemption barred a vast majority of medical device claims may need to reevaluate their positions.

Overview of Medical Device Regulation

In 1938, Congress passed the Food, Drug & Cosmetics Act which gave the Food & Drug Administration authority to regulate the safety of food, drugs, and cosmetics. In 1976, Congress expanded FDA’s mission to include medical devices with the passage of the Medical Device Amendments of 1976 (“MDA”). Under the MDA, FDA regulates medical devices pursuant to three classifications based upon the potential risk of the device. The three classifications are made up of 16 sub-classifications (called “panels”) based upon the device’s intended use and indications for use. The following is a simplified overview of medical device classifications:

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1 The next several pages attempt to provide litigators a very basic understanding of the medical device regulatory environment. We have attempted to summarize (in lay terms to the extent possible) the portions most relevant to litigators of a 1,000 page statute implemented by approximately 4,500 pages of regulations. Please understand that those pages are replete with exceptions, exemptions, exceptions to the exemptions, and exemptions from the exceptions.
Class I Devices

Class I devices are products that present minimal potential harm to the patient. They are generally simple in design, have a basic manufacturing process, and have a demonstrated history of safe use. Class I devices include products such as bandages, tongue depressors, and simple handheld surgical instruments. Most Class I devices do not require any type of advance approval from FDA. Manufacturers, however, are typically required to comply with a set of regulations called “General Controls.” General Controls are standard requirements (i.e., not specific to any particular device) that provide for a minimal level of safety and FDA oversight. General Controls primarily require the device manufacturer to:

- Register the device with FDA;
- Register the facilities that manufacture and distribute the device;
- Comply with FDA’s regulations governing the manufacturing process, known as “Current Good Manufacturing Practices”;
  - Comply with FDA regulations governing the device’s labeling (i.e., 21 C.F.R. 801, 809); and
- Report any adverse events associated with the device.

FDA currently estimates that approximately 47% of medical devices are Class I devices.

Class II Devices

Class II devices are products for which FDA has determined that General Controls alone would not provide a sufficient assurance of safety. Class II devices are
generally more complicated than Class I devices and present a greater risk to the patient. Class II devices include products such as powered wheelchairs, surgical drapes, some automatic medication infusion pumps, and certain simple, non-life sustaining implants (such as radio frequency identification chips). Most Class II devices must receive advance FDA approval through one of the approval processes discussed below. Manufacturers of Class II devices must comply with not only General Controls but also “Special Controls.” Special Controls are a more stringent set of standard regulations governing manufacture and marketing of the device. Special Controls include:

- More stringent labeling requirements;
- Mandatory performance standards;
- Postmarket surveillance; and
- Additional guidance from FDA depending upon the type of device.

FDA currently estimates that approximately 43% of medical devices are Class II devices.

**Class III Devices**

Class III devices, not surprisingly, present the greatest risk to the patient. FDA has determined that General and Special Controls would not provide a sufficient assurance of safety for these devices. Class III devices typically support or sustain life, or present an unreasonable risk of potential injury. Class III devices include products such as pacemakers, artificial heart valves, and total joint replacements. Class III devices must receive advance FDA approval pursuant to one of the approval processes discussed below. In addition to General and Special Controls, most Class III devices are
subject to device-specific manufacturing and labeling requirements. Only about 10% of medical devices are Class III devices.

**Overview of Medical Device Approval**

The Medical Device Amendments of 1976 created two processes for medical device approval. The first approval process is known as Premarket Approval (“PMA”). The second approval process is called a “Premarket Submission,” but it is typically known as a “510(k) submission” after the applicable section of the FDCA. Below is a brief description of these two approval processes.

**Premarket Approval**

PMA is rigorous review process, roughly analogous to the New Drug Application process for prescription drugs. After the device manufacturer prepares and submits an application, FDA’s Office of Device Evaluation reviews the application for completeness. The Office of Surveillance and Biometrics then conducts a statistical review of the data contained in the application. Finally, the Office of Compliance reviews the manufacturing information for compliance with a set of regulations known as Quality System Regulation (found at 21 C.F.R. 820). If FDA determines that the manufacturer has satisfied all three steps, FDA accepts the application as “filed.”

Once an application is deemed “filed,” FDA begins to assess whether the proposed device itself is safe and effective for its intended use. This review includes (among other things): an analysis of the clinical and non-clinical studies conducted by
the manufacturer; inspections of the manufacturing facilities; and audits of the manufacturer’s data.

By law, FDA has 180 days to approve or deny a PMA. In practice, however, FDA does not start the clock until an application is accepted as “filed.” And even then, FDA restarts the clock each time a “filed” application is amended (often at FDA’s request), which is common. As a result, a typical PMA takes much longer than 180 days.

**510(k) Approval**

When it passed the MDA in 1976, Congress did not want to cease the sales of medical devices already on the market. So the MDA included a “grandfather” clause that would exempt devices already in use from the PMA process. This provision allowed for a device on the market to remain on the market unless FDA promulgated regulation requiring the specific device to undergo PMA.²

This “grandfather” clause created a second problem, though: a manufacturer of a grandfathered device would, in effect, be granted a monopoly on its device until another manufacturer completed the slow and costly PMA process to gain approval of a competitor device. So Congress included a second exception to the PMA process called a “Premarket Submission.” This second exception is known as a “510(k) submission” because it appears in that specific section of the FDCA.

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² Regulations requiring a specific “grandfathered” device to undergo PMA are subject to the hurdles of notice and comment rulemaking that some of us painfully learned in our Administrative Law classes. For reasons beyond the scope of this paper, such regulations have been few and far between.
The 510(k) process allows for streamlined approval of a device which is “substantially similar” to a device that was “grandfathered” when the MDA was passed in 1976. Although originally intended as a narrow exception to the PMA requirement, 510(k) remains the primary approval mechanism to this day. This is, in part, because the MDA allows for “piggybacking” of 510(k)-approved devices. In other words, suppose Device A is sold in 1976 and is thus exempted from the PMA process by virtue of the “grandfather” clause. In 1977, Device B is approved through the 510(k) process because FDA determines that Device B is substantially similar to Device A (Device A is referred to as the “predicate device”). In 1978, Device C may be approved on the basis that it is substantially similar to Device B. (Here, Device B becomes the “predicate device” to Device C). Imagine this iterative process continuing annually until 2001. Device Z may be quite different than Device A.

During the 510(k) process, FDA does not necessarily make a determination regarding safety and effectiveness. Instead, FDA only makes a determination as to whether the device is substantially similar to the predicate device. A finding of substantial similarity involves the following:

1. The device has the same intended use as the predicate device; and

   either one of:

2(a). The device has the same technological characteristics as the predicate device; or

2(b). The device does not raise different question of safety and effectiveness than the predicate device, and data indicates
that the difference does not diminish the device’s safety and effectiveness.

Decisions on 510(k) submissions are made within 90 days.

**Federal Preemption of State Law Claims**

In medical device litigation, federal preemption of state law claims is a constellation of complicated, and sometimes conflicting, court opinions.

The MDA includes a preemption clause which states (in pertinent part):

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device . . . any requirement . . . which is different from, or in addition to, any requirement applicable under [the Food, Drug & Cosmetics Act] to the device[.]

21 U.S.C. § 360k(a). Not surprisingly, this clause has been the subject of years of litigation. At its the most basic, the statute seems to simply provide that a state may not establish a requirement that conflicts with a federal requirement. But it is important to gleam the precise nature of the “requirements” the statute is concerned with. The forbidden state requirements must be “with respect to a device.” The federal requirements, which a state may not contradict, must also be “applicable to the device” at issue. This very fine point will become important as we examine the case law.
Medtronic v. Lohr

In Medtronic, Inc. v. Lohr, the Supreme Court addressed whether the MDA’s preemption provision preempted state law tort claims regarding a defective pacemaker approved through the 510(k) process. 518 U.S. 470 (1996). The Court explained that the only federal requirements applicable to 510(k) devices are “general federal regulations governing the labeling and manufacture of all medical devices.” Id. at 497. The Court then concluded that when Congress used the phrase “requirements applicable to the device” in the preemption clause, it did not intend to give preemptive effect to the “general federal regulations governing . . . all medical devices.” See Id. at 500. Accordingly, the Court held that as the term “requirements” is used in the statute, there were no federal requirements for the state common law to conflict with. Therefore, the state law claims were not preempted —there was nothing for them to conflict with and thus be preempted by.

A plurality of the Court went one step further, finding that as the term “requirements” is used in the MDA preemption clause, there were no state requirements either, because “the general state common-law requirements in this suit were not specifically developed ‘with respect to’ medical devices.” Id. at 501 (emphasis added). According to four justices, not only were there no federal requirements, but there were no state requirements that could conflict with federal requirements anyway.
**Riegel v. Medtronic**

In *Riegel v. Medtronic*, the Court addressed preemption of state law claims involving a heart catheter approved through PMA. 552 U.S. 312 (2008). The Court held that in contrast to 510(k) approval, PMA approval does impose requirements “applicable to the device” which preempt conflicting state requirements. *Id.* at 323.

The *Riegel* Court then dispelled the uncertainty created by the plurality opinion in *Loehr* by holding that state common law causes of action for negligence and strict liability do impose “requirements” as the term is used in the MDA preemption clause. *Id.* at 323–324. Since the state law claims at issue asserted that Medtronic was liable “notwithstanding compliance with the relevant federal requirements,” they were preempted. *Id.* at 330. The *Riegel* Court, therefore, left only one remaining avenue to recovery for victims of defective PMA devices. Under the MDA’s preemption clause, state law claims regarding PMA approved devices are preempted only if they have the effect of imposing a requirement “which is different from, or in addition to” those imposed by federal law. *Id.*; 21 U.S.C. § 360k(a). The Court noted that the MDA preemption clause “does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.” *Riegel* 552 U.S. at 330. As a result, the lower courts have spent the last five years wrestling with the issue of what constitutes a parallel claim regarding a defective PMA device.
Parallel Claims Post-*Riegel*

In the wake of *Riegel*, it was largely predicted that litigation regarding defective PMA devices was all but dead. After five years of decisions from lower courts, however, it now appears that the only claims that are preempted—under all circumstances—are design defect claims. Here’s why: When a manufacturer obtains Premarket Approval of a device, FDA expressly approves the device’s design. Once a device receives Premarket Approval, in fact, the manufacturer is forbidden from making any change to the design that would affect its safety or effectiveness. 21 U.S.C. § 360e(d)(6)(A)(i). Therefore, imposing liability based upon a device’s design would necessarily impose a requirement that is “different from, or in addition to” the federal requirements.

Under the right circumstances, however, virtually all other common law product liability claims for defective PMA devices can probably survive a preemption challenge under the right factual circumstances.

- In *Bausch v. Stryker Corp.*, the Seventh Circuit held that claims for defective manufacture of a PMA hip replacement “are not expressly preempted by federal law to the extent they are based on defendants’ violations of federal law.” 630 F.3d 546, 556.

- In *Hughes v. Boston Scientific Corp.*, the Fifth Circuit held that state law failure to warn claim regarding a PMA device was not preempted “to the extent that it is based on [the defendant’s] violation of applicable FDA regulations requiring accurate reporting of serious injuries and malfunctions of the . . . device.” 631 F.3d 762, 771 (5th Cir. 2011).
• The Fifth Circuit similarly allowed the plaintiff to advance a negligence per se claim, holding, “we conclude that invoking the negligence per se doctrine to support a negligence claim that is otherwise parallel to federal requirements is not expressly preempted.” *Id.* at 772.

• The Ninth Circuit has followed suit, holding that a state law failure to warn claim regarding a PMA insulin pump was not preempted. *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (The court found that “[t]he claim rests on a state-law duty that parallels a federal-law duty under the MDA”).

• Lower courts—even in other jurisdictions—have begun to follow these Circuit Court decisions. For example, a recent decision by District Court for the District of Columbia held that the plaintiff’s state law claims for a defective insulin pump were not preempted—including negligence, strict liability, express warranties, and failure to warn—to the extent they were based upon violation of the federal requirements applicable to the device. *Kubicki v. Medtronic*, 2013 U.S. Dist. LEXIS 38965 (D.D.C. Mar. 21, 2013).

Two often cited Circuit Court decisions, however, seemed at first blush to go the other way.

• In *In re Medtronic, Inc.*, the Eighth Circuit held that plaintiffs in the multidistrict litigation involving defective cardiac defibrillator leads could not proceed with their failure to warn claims. In that case, however, the
multidistrict plaintiffs “alleged that, by reason of state law, Medtronic was required to give additional warnings, precisely the type of state requirement that is ‘different from or in addition to’ the federal requirement[.]” *In re Medtronic, Inc.*, 623 F.3d 1200, 1205 (8th Cir. 2010). In *Stengel*, by contrast, the successful plaintiff’s failure to warn claim was based upon the allegation that “Medtronic had a continuing duty to monitor the product after pre-market approval and to discover and report to FDA any complaints about the product’s performance and any adverse health consequences of which it became aware and that are or may be attributable to the product.” *Stengel*, 704 F.3d 1224, 1232 (9th Cir. 2013).

- In *Wolicki-Gables v. Arrow Int’l, Inc.*, the Eleventh Circuit considered tort claims regarding a PMA approved pain medication pump. 634 F.3d 1296, 1302 (11th Cir. 2011). The court, however, did not actually rule upon substantive preemption law. Rather, the court found that the plaintiffs “failed to allege facts in their complaint demonstrating the presence of the elements of a parallel claim[.]” *Id.* (emphasis added). The plaintiffs argued simply that “the device was not designed or manufactured according to the pre-market approval or it would not have failed.” *Wolicki-Gables*, 634 F.3d 1296, 1300 (11th Cir. 2011). The Court noted that a plaintiff “must allege that the defendant violated a particular federal specification referring to the device at issue,” which the plaintiffs did not
do. *Id.* at 1301. In other words, Wolicki-Gables was a simple *Twombly* decision, as opposed to a decision on substantive preemption law.

As such, Defendants may be relying too heavily upon these decisions. (We regularly see them cited in defense briefs for substantive preemption propositions). And injured victims might not be getting the representation they deserve because of attorneys declining to enter this field based upon the headlines.

**Conclusion**

Six years ago the Supreme Court told victims of defective medical devices that if the device was approved through FDA’s Premarket Approval process, then the courthouse door would be locked unless the victim brought claims that parallel federal law. In response, victims have been doing just that. And we have seen an increasing number of those parallel claims pursued with relative success.

Of course, we have not heard the final word on the issue of medical device preemption. The *Kubicki* case is still pending at the district level. And a Petition for *Writ of Certiorari* is pending before the Supreme Court in the *Stengel* case. One thing is clear, though. For most people injured by defective PMA devices, there is still a road to recovery, albeit a rather long and steep one.