Admissibility Hurdles for 510(k) Evidence in Medical Device Litigation

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I. Introduction

As a general rule, a product's compliance with applicable regulations is properly considered as evidence in determining whether that product is defective. In recent years, plaintiffs in medical device litigation have attempted to carve out an exception to this rule, specifically in the context of devices that are marketed pursuant to a regulatory process known as 510(k) clearance. This effort to exclude 510(k) evidence has gained traction in courts across the country, potentially resulting in juror confusion regarding device manufacturers' compliance with the governing regulatory framework. This paper examines the recent trends in admissibility of 510(k) evidence and the arguments at the source of the debate.

II. Background

A. The Medical Device Amendments of 1976

In 1976, Congress amended the Federal Food, Drug and Cosmetic Act to provide for the safety and effectiveness of medical devices intended for human use. The resulting Medical Device Amendments (the "MDA" or the "Act") classifies medical devices into three categories based on the risk they pose to the public. A device that "does not present a potential unreasonable risk of illness or injury" is designated Class I and is subject to only minimal regulation in the form "general controls." *See* 21 U.S.C. §360c(a)(1)(A). Devices that are potentially more harmful, and for which "the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device," are designated Class II and must comply with federal performance regulations known as "special controls." 21 U.S.C. §360c(a)(1)(B). Finally, a device that either "presents a potential unreasonable risk of illness or injury," or that is "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," is designated Class III. 21 U.S.C. §360c(a)(1)(C).

B. Process for Ensuring Device Safety and Effectiveness

"Before a new Class III device may be introduced to the market, the manufacturer must provide the FDA with a 'reasonable assurance' that the device is both safe and effective." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). The process of establishing this reasonable assurance, known as "premarket approval," or the "PMA" process, is rigorous. *Id*. Manufacturers must submit detailed information about the device to the FDA for review.

However, not all Class III devices have received premarket approval "because of two important exceptions to the PMA requirement." *Id*. "First, Congress realized that existing medical devices could not be withdrawn from the market while the FDA completed its PMA analysis for those devices. The statute therefore includes a 'grandfathering' provision which allows pre-1976 devices to remain on the market without FDA approval until such time as the FDA initiates and completes the requisite PMA." *Id*. at 477-78. "Second, to prevent manufacturers of grandfathered devices from monopolizing the market while new devices clear the PMA hurdle, and to ensure that improvements to existing devices can be rapidly introduced into the market, the Act also permits devices that are 'substantially equivalent' to pre-existing devices to avoid the PMA process." *Id*. at 478.

"Although 'substantially equivalent' Class III devices may be marketed without the rigorous PMA review, such new devices, as well as all new Class I and Class II devices, are subject to the requirements of §360(k)." *Id*. "That section imposes a limited form of review on every manufacturer intending to market a new device by requiring it to submit a 'premarket notification' to the FDA," a process which is also known as the "§510(k) process," named after its section in the original Act. "If the FDA concludes on the basis of the §510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis" – at least until the FDA begins the PMA process for the underlying pre-1976 device to which the new device is "substantially equivalent." *Id*.

C. *Medtronic, Inc. v. Lohr*: Contrasting 510(k) and PMA

The U.S. Supreme Court's opinion in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476-77 (1996), rooted in an analysis of whether certain state law claims were preempted under 21 U.S.C. §360k(a), quickly became the touchstone for any examination of the FDA's regulatory scheme for medical devices in federal court. In considering the FDA's processes for ensuring device safety and effectiveness, *Lohr* starkly contrasted the 510(k) process with the more rigorous PMA process. The Court explained: "The §510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the §510(k) review is completed in an average of only 20 hours. As one commentator noted: 'The attraction of substantial equivalence to manufacturers is clear. [Section] 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly.'" *Id*. at 478-79 (internal citation omitted).

Lohr further provided: "[T]he 510(k) process is focused on equivalence, not safety. As a result, substantial equivalence determinations provide little protection to the public. These determinations simply compare a post-1976 device to a pre-1976 device to ascertain whether the later device is no more dangerous and no less effective than the earlier device." *Id*. at 493 (internal citation and quotation omitted).

III. Plaintiffs' Post-*Lohr* Admissibility Arguments

Although the preemption analysis in *Lohr* had nothing to do with the admissibility of evidence, some plaintiffs have deliberately used the *Lohr* Court's 510(k) criticisms out of context in an effort to exclude evidence of a manufacturer's compliance with the 510(k) process. Specifically, plaintiffs argue that because 510(k) is not a "safety" regulation, compliance with that process lacks relevance to demonstrate that the manufacturer performed sufficient testing or complied with applicable safety regulations. Plaintiffs similarly argue that the FDA rubberstamps 510(k) clearances, so evidence of compliance with this section cannot be relevant to any issue of safety or effectiveness. Additionally, Plaintiffs may seek to exclude 510(k) evidence on grounds that it will confuse or mislead the jury regarding a product's FDA history, or that it will create a mini trial on the manufacturer's compliance or non-compliance with the 510(k) process.

These arguments require courts to draw a false distinction, for admissibility purposes, between 510(k) clearance and other FDA regulatory processes, and they flout the general rule that "a product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective…." Restatement (Third) of Torts: Prod. Liab. §4 (1998). Nonetheless, plaintiffs in device cases have gained some traction in excluding evidence relating to a product's 510(k) clearance. Although recent rulings are a mixed bag, with appellate precedent affirming exclusion, some trial courts still find in favor of the general rule that a manufacturer's compliance with applicable regulations is properly considered in an analysis of product defect claims.

IV. Admissibility Trends

A. Appellate Decisions Excluding 510(k) Evidence

Plaintiffs arguing for the exclusion of 510(k) evidence received a boost from the Eleventh Circuit in *Eghnayem v. Boston Scientific Corp*., 873 F.3d 1304, 1318 (11th Cir. 2017). In affirming a final judgment in favor of the plaintiff who alleged injuries caused by a transvaginal mesh prescription medical device, the court explained: "[I]t is clear that the district court did not abuse its discretion when it concluded that the 510(k) review process is not relevant to a product's safety." *Id*. The court further agreed with the district court's explanation that, "if 510(k) does not go to a product's safety and efficacy – the very subjects of the plaintiff's products liability claims – then evidence of [the manufacturer's] compliance with 510(k) has no relevance to the state law claims in this case." *Id*.

Following the *Eghnayem* decision, the Fourth Circuit affirmed a district court's decision to exclude 510(k) evidence in another transvaginal mesh case. In *Campbell v. Boston Scientific Corp*., 882 F.3d 70, 77 (4th Cir. 2018), the court noted: "The district court concluded that the 510(k) evidence was at best of questionable relevance, and that it was 'inadmissible because of its potential to confuse the issues and mislead the jury' even if marginally relevant." *Id*. Boston Scientific argued that prior decisions excluding 510(k) evidence on grounds that it is not relevant to the issue of consumer safety were flawed because they "fail[ed] to address the distinction between 510(k) clearance based on a predicate device that was grandfathered in when the process was created and clearance based on a predicate device that itself received a thorough safety evaluation." *Id*. The court disagreed, reasoning that "[a]dmitting evidence on these grounds would invite a battle of the experts regarding the exact meaning of 510(k) approval in these circumstances, and would risk…jury confusion[.]" *Id*.

B. Subsequent Trial Court Decisions

1. Excluding 510(k) Evidence

On the heels of these appellate decisions, some trial courts have excluded 510(k) evidence on the bases that (1) 510(k) evidence is relevant only to show equivalence, not safety, and/or (2) the probative value of 510(k) evidence is substantially outweighed by the danger of confusing the jury regarding the meaning of 510(k) clearance. *See Kaiser v. Johnson & Johnson*, No. 2:17-cv-114, 2018 WL 1358407 (N.D. Ind. Mar. 16, 2018) ("While it may seem counterintuitive that this aspect of the FDA's clearance process does not speak to the safety of the device, that is the generally accepted interpretation of the §510(k) process by courts in this country."); *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig*., MDL No. 2327, 2018 WL 3608496, at *4 (S.D.W.V. July 24, 2018) ("I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit…. Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value."); *McGinnis v. C.R. Bard, Inc*., No. BER-L-017543-14, 2018 WL 2456581 (N.J. Sup. Feb. 8, 2018) ("The FDA 510(k) clearance process is not equivalent to a premarket approval process. The premarket approval process determines a medical device's safety and efficacy.").

2. Admitting 510(k) Evidence

Despite these decisions, trial courts in other jurisdictions have recently admitted 510(k) evidence. For instance, in *In re Bard IVC Filters Prods. Liab. Litig*., 289 F. Supp. 3d 1045, 1047 (D. Ariz. 2018), the court denied the plaintiff's motion in limine to exclude evidence of 510(k) clearance. The court reasoned that, as a matter of substantive state law, analysis of the plaintiff's design defect claim "incorporates negligence princi-

ples and the concept of reasonableness." *Id*. Given this consideration, the court found that "evidence of Bard's compliance with the 510(k) process, while certainly not dispositive, is nonetheless relevant to the reasonableness of Bard's conduct and whether the company defectively designed the G2 filter." *Id*. The court readily disposed of the plaintiff's argument that "the 510(k) process focuses on device equivalence, not device safety," reasoning that, while that may be true, "this does not render evidence of the 510(k) process irrelevant to Bard's conduct." *Id*. at 1048. On the contrary, "[t]he FDA grants 510(k) clearance only where the device 'is as safe and effective as a [predicate device] and does not raise different questions of safety and efficacy than the predicate device.'" *Id*. (quoting Safe Medical Devices Act of 1990, Pub. L. No. 101-629, §12(a)(1)(A)(ii)).

Similarly, in *In re Cook Medical, Inc., IVC Filters Mktg., Sales Practices and Prod. Liab. Litig*., No. 1:14-ml-02570, 2018 WL 6617375, at *1-2 (S.D. Ind. Dec. 18, 2018), the court denied the plaintiff's motion to exclude evidence of the product's 510(k) clearance, explaining that the applicable test for design defect cases under state law "incorporates the concept of reasonableness, *i.e.*, whether the manufacturer acted reasonably in choosing a particular product design," and holding that "[a] factor the jury may consider in determining whether a manufacturer acted reasonably is whether it complied with federal regulations." *Id*. at *1. The court further found that the probative value of the evidence outweighed any prejudicial effect. However, the court additionally held that the defendant would not "be permitted to present evidence or argument that the [device] was approved by the FDA or that clearance of the device through the 510(k) process constitutes a finding by the FDA that the device is safe and effective." *Id*. at *2.

V. Defense Strategy: How to Proceed

A. The "Equivalence, Not Safety" Myth

As the preceding cases demonstrate, the chief obstacle in advocating for the admissibility of 510(k) evidence is the misconception that 510(k) clearance is unrelated to a device's safety or effectiveness. To counter this argument, manufacturers should rely on post-*Lohr* regulatory and case law developments to clarify the review process for 510(k) applications.

1. *Otero v. Zeltiq Aesthetics*: Making the Case for Safety

For example, in *Otero v. Zeltiq Aesthetics, Inc*., No. 17-3994, 2018 WL 3012942, at *1 (C.D. Cal. June 11, 2018), the plaintiffs sued the developer of a non-surgical, fat-reduction procedure known as "CoolSculpting." The plaintiffs argued the developer's "representations that CoolSculpting is 'FDA-cleared' and 'FDA-cleared, safe and effective'" were misleading "because they imply that the device satisfied the [PMA] process rather than simply the Section 510(k) premarket notification clearance procedure." *Id*. at *2. In evaluating these claims, the court questioned the plaintiffs' reliance on *Lohr*. The *Otero* court reasoned: "Although *Medtronic* [*v. Lohr*] observed that obtaining Section 510(k) clearance is not as onerous as the 'rigorous' PMA process, the Supreme Court did not find that the former has no bearing on a device's safety and effectiveness." *Id*. at *3. "In fact, [*Lohr*] acknowledged that 'the FDA may well examine §510(k) applications…with a concern for the safety and effectiveness of the device.'" *Id*. (quoting *Lohr*, 518 U.S. at 493).

The *Otero* court further explained, "[t]he Supreme Court later clarified that 'the FDA simultaneously maintains the exhaustive PMA and the more limited §510(k) processes in order to ensure…that medical devices are *reasonable safe and effective*….'" *Id*. (quoting *Buckman Co. v. Plaintiffs' Legal Comm*., 531 U.S. 341, 349-50 (2001)) (emphasis added). Additionally, the court found the language of the relevant FDA regulations themselves to belie the argument that safety and effectiveness are not criteria of the 510(k) clearance process. "Indeed, the FDA's regulations provide that if the agency has found that a device is substantially equivalent

to – but has 'technological characteristics' that are different from – a predicate device, then that means the agency concluded that 'the data submitted…contains information, including clinical data if deemed necessary by the Commissioner, that demonstrates that the device is as safe and effective as a legally marketed device.'" *Id.* (quoting 21 C.F.R. §807.100(b)(ii)(B)).

Given these considerations, together with the "special controls" applicable to Class II devices such as CoolSculpting, the court concluded: "[A]lthough a substantial equivalence determination does not amount to the FDA's endorsement of a medical device…the agency's classification of a device as Class II does indicate that certain 'special controls' provide 'reasonable assurance of the safety and effectiveness of the device.'" *Id.* (quoting 21 U.S.C. §360c(a)(1)(B)). Thus, according to the *Otero* court, "[i]t follows that [the] representation that CoolSculpting is 'safe and effective' is *not* 'a claim that can only be made if the procedure was 'FDA approved' and not 'FDA cleared.'" *Id.*

Although the case did not evaluate the admissibility of evidence relating to 510(k) clearance in the product defect context, *Otero* paves the way for other courts to acknowledge the safety considerations inherent in the 510(k) process.

2. The Safety Argument: Key Points

Consistent with the *Otero* analysis, one approach for countering plaintiffs' arguments that 510(k) clearance is irrelevant to product safety is to raise the Supreme Court's clarification in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349-350 (2001). That is, the *Buckman* opinion expressly recognized that "the FDA simultaneously maintains the exhaustive PMA and the more limited §510(k) processes in order to ensure…that medical devices are reasonably safe and effective[.]" *Id.* Another important consideration is that the "substantial equivalence" statute itself, 21 U.S.C. §360c(i), provides:

> For purposes of determinations of substantial equivalence…the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device…(i) has the same technological characteristics as the predicate device, or (ii) (I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information…that demonstrates that *the device is as safe and effective* as a legally marketed device, and (II) does not raise different questions of *safety and effectiveness* than the predicate device.

21 U.S.C. §360c(i)(1)(A) (emphasis added). The statute further provides: "As part of a submission under section 360(k)…, the person required to file a premarket notification under such section *shall provide an adequate summary of any information respecting safety and effectiveness*…." 21 U.S.C. §360c(i)(3)(A) (emphasis added). Thus, especially where a manufacturer receives 510(k) clearance based on a predicate device which was extensively tested for safety, manufacturers should argue that the 510(k) process affirmatively considered the safety of their substantially-equivalent device.

Finally, a court tasked with evaluating a 510(k) safety argument may be persuaded by the changes effected in the 510(k) process since its inception. In the decades since "Medtronic took advantage of §510(k)'s expedited process in October 1982," *Lohr*, 518 U.S. at 480, the 510(k) program has changed significantly. *See* FDA, CDRH Preliminary Internal Evaluations – Volume I, 510(k) Working Group Preliminary Report and Recommendations, at 34 (Aug. 2010). Recognizing the importance of product safety as an integral function of 510(k) clearance, "various statutory and regulatory modifications over time" have transformed the original premarket notification process into "a multifaceted premarket review process that is expected to assure that

cleared devices, subject to general and applicable special controls, provide reasonable assurance of safety and effectiveness…." *Id*.

According to the FDA, "[t]he 510(k) program has been strengthened and refined…in recent years, as [the Center for Devices and Radiological Health ("CDRH")] made a systematic, concerted effort to improve the program's performance, predictability, efficiency, and safety." FDA Statement, *Statement from FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., Director of the [CDRH], on Transformative New Steps to Modernize FDA's 510(k) Program to Advance the Review of the Safety and Effectiveness of Medical Devices* (Nov. 26, 2018), *available at* https://www.fda.gov/newsevents/newsroom/pressAnnouncements/ucm626572.htm (last accessed Mar. 24, 2019). Indeed, the very purpose for the existence of the CDRH within the FDA is to "assur[e] that marketed medical devices provide a reasonable assurance of safety and effectiveness, and [to assure] the safety of radiation-emitting products." FDA, CDRH Preliminary Internal Evaluations, at 3.

In sum, given the Supreme Court's more favorable view of the 510(k) process in *Buckman*, coupled with statutory and regulatory changes over time emphasizing the importance of safety and effectiveness in 510(k) review, reliance on the outdated analysis in *Lohr* should no longer carry the day in an argument regarding device safety and 510(k) clearance. A deep dive into these details may be necessary to convince a court that there is simply no basis for an exception to the general rule of statutory-compliance admissibility where a plaintiff argues 510(k) clearance is not relevant to safety.

B. Manufacturer Reasonableness

A more concise argument in favor of admitting 510(k) evidence may be the "reasonableness" argument invoked by the manufacturers in *In re Bard IVC Filters* and *In re Cook*, above. There, the court agreed with the manufacturers' arguments that compliance with the 510(k) process, although perhaps not dispositive, is nonetheless relevant to the reasonableness of the manufacturer's conduct and whether the company defectively designed the device. Notably, both of those cases relied on the applicable test for design defect cases under state law, which incorporated negligence principles and the element of reasonableness. However, this may be a useful argument in jurisdictions which similarly evaluate whether a manufacturer acted reasonably in choosing a particular product design.

VI. Conclusion

Admissibility of 510(k) evidence remains problematic. The most effective arguments in favor of admitting this evidence appear to be grounded in state laws incorporating the concept of reasonableness into an analysis of design defect. Conceptually, however, it seems that the best argument for manufacturers should be that safety and effectiveness are, in reality, integral considerations in the 510(k) clearance process. Extensive briefing may be required to provide context for the 510(k) program's inception and development over time in order to combat plaintiffs' argument that *Lohr* should serve as controlling authority on this issue. Given the recent appellate authority, the 510(k) safety argument is far from a sure winner, but manufacturers should persist with this message (where appropriate) with the goal of educating the jury on their compliance with the governing regulatory framework.