510(k) Medical Device Trials

Effective Use of FDA Evidence

By John Q. Lewis and Sarah Bunce

Using FDA evidence to provide context for your company story is effective in defending product liability claims.

At first blush, you are excited. In-house counsel for a medical device manufacturer has requested that your team lead the defense against a series of product liability lawsuits involving a medical device cleared through the United States Food and Drug Administration's ("FDA") 510(k) clearance process. Discovery will move quickly, trials are on the horizon, and you feel up to the task.

The plaintiffs' counsel appear to be relying on an all-too-familiar playbook. They uniformly allege that their plaintiffs experienced serious complications as a result of a medical device. They say that the medical device's design was ill-conceived and untested and that the warnings were deficient and minimized safety risks. Plaintiffs also assert that after the device came to the market your client knew about growing concerns about safety and failed to take action in time to prevent the harm to the plaintiffs.

Each plaintiff also seeks punitive damages. They allege that the company "chose to use the 510(k) loophole" in an effort to "rush" the device to the market. Plaintiffs proclaim that this is a case of "profits over safety" and use other similar tag lines. The allegations strike at the moral fiber of the company and its employees.

Lawsuits attacking medical devices cleared through the 510(k) clearance process are common. Indeed, most medical device product liability trials involve devices with 510(k) clearance for two major reasons. First, the vast majority of medical devices marketed today are 510(k) devices, as opposed to devices approved through the premarket approval (PMA) process or the investigational device exemption (IDE) process. *See Thorn v. Thoratec Corp.*, 376 F.3d 163, 167 (3d Cir. 2004) ("The number of medical devices that receive PMA review each year is dwarfed by the number of those that are marketed pursuant to cleared Section 510(k).") (internal quotations omitted). *Compare* U.S. Food and Drug Admin., Medical Devices, March 2014 PMA Approvals, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm398315.htm (last visited July 24, 2014) (noting approval of two original PMAs

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in Mar. 2014), *with* U.S. Food and Drug Admin., Medical Devices, March 2014 501(k) Clearances, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm392350.htm (last visited July 24, 2014) (listing clearance of 222 traditional and abbreviated 510(k) premarket notifications in March 2014). In addition, PMA devices and IDE devices largely are insulated from product liability litigation as a result of federal preemption. *E.g.*, *Brown v. DePuy Orthopaedics, Inc.*, 978 F. Supp. 2d 1266 (M.D. Fla. 2013) (dismissing strict liability and negligence claims involving a PMA device as expressly preempted); *Berish v. Richards Med. Co.*, 928 F. Supp. 185 (N.D.N.Y. 1996) (granting summary judgment on negligence, strict liability, and warranty claims involving an IDE device based on federal preemption).

You know from years of trial experience that you will need to find objective validation of a client's decision making to defend against plaintiffs' claims. In medical device litigation, the most powerful objective bystander is the FDA. Evidence of how the FDA interacted with and oversaw a company and its products provides context for a jury to understand and assess a company's conduct and decision making. Evidence of FDA involvement also arms jurors with an objective measure to understand the risks, benefits, and safety profile of a medical device.

Plaintiffs' counsel often resist the admission of FDA evidence, believing that such evidence adversely affects their affirmative corporate conduct case. Some fear that jurors will defer to FDA determinations on market clearance and postmarket FDA inaction. Others believe that jurors will find it hard to award punitive damages in the face of the FDA's lack of enforcement with regard to a company or a product.

Recent history supports this view. In 2013, for example, four significant trials involving 510(k) medical devices went to verdict. In two trials, FDA evidence was barred, and the juries returned plaintiff verdicts. In the two other trials, FDA evidence was admitted, and the juries returned defense verdicts. Other factors no doubt affected those outcomes, but FDA evidence, or a lack thereof, was a factor in each of those verdicts.

After your initial investigation, you determine that your case will benefit from the admission of FDA evidence at trial. The miraculously prompt response to your Freedom of Information Act (FOIA) request turned up a well-drafted 510(k) reviewer memorandum confirming that the FDA reviewer was engaged and thorough and considered safety aspects of the device's design. You also know that the company reported product complaints reasonably promptly to the FDA, and at no time did the FDA raise postmarket product-specific safety concerns with the company. While the FDA picture is not perfect—FDA audits resulted in some generic "483" observations and the FDA convened an industry panel to discuss emerging safety issues with respect to this class of devices—the upside of the FDA evidence outweighs the downside risk.

In light of this, you suspect that your opponent will seek to exclude FDA evidence, similar to the strategies used recently by other plaintiff attorneys in mesh and hip replacement litigation. You will need to come up with a game plan to fend off plaintiffs' *in limine* motions seeking to exclude this evidence and to prepare your FDA presentation for trial. You decide to implement a two-part plan.

Step One: Getting the FDA Evidence Admitted

Experience teaches you that evidentiary admissibility battles require advanced planning. You must first understand your opponents' potential arguments. Then you must head off as many of those arguments through fact and expert witness discovery as you can. You do not want to be pondering a response to plaintiffs' FDA arguments for the first time after receiving their motions *in limine*.

Plaintiffs' attorneys often argue that FDA evidence, particularly evidence related to 510(k) clearance, is irrelevant and unfairly prejudicial. Citing *Medtronic Inc. v. Lohr* and *Riegel v. Medtronic Inc.*, plaintiffs contend that devices cleared through the 510(k) process have never been formally reviewed for safety and efficacy. 518 U.S. 470, 493 (1996) ("The design of… 'substantially equivalent' devices has never been formally reviewed under the MDA for safety or efficacy."); 552 U.S. 312, 323 (2008) ("[D]evices that enter the market through §510(k) have 'never been formally reviewed under the MDA for safety or efficacy'…." (quoting *Lohr*)). Because the 510(k) clearance process does not determine whether a medical device is "safe and effective," so the argument goes, evidence that a medical device was cleared through that process proves nothing that would bear on any issue to be tried in product liability litigation. Plaintiffs go on to say that such evidence will confuse and mislead a jury into concluding that an FDA clearance letter means that the device has been determined to be safe and effective, contrary to U.S. Supreme Court law.

In medical device litigation, the most powerful objective bystander is the FDA.

These arguments are contrary to the FDA's pronouncements. For example, FDA guidance documents confirm that "the principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review." FDA Guidance: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications 6 (Dec. 27, 2011) (covering the 510(k) process). The FDA website further states that a "510(k) is a premarket submission made to the FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device [] that is not subject to a PMA." *See* http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketnotification510k/default.htm. The FDA considers safety and efficacy in the review of every 510(k) submission. It is not misleading to argue as much to a jury.

These arguments also are contrary to case law. The U.S. District Court for the District of Minnesota, for example, has held that what constitutes reasonable care with respect to negligence claims depends on the surrounding circumstances, including a company's interactions with the

FDA. *See Huggins v. Stryker Corp.*, No. 09-1250, 2013 U.S. Dist. Lexis 41260, at *43 (D. Minn. Mar. 25, 2013). Indeed, FDA evidence can both support and rebut a claim of negligence. *See In re Levaquin Prods. Liability Litig.*, No. 08-1943, 2010 U.S. Dist. Lexis 124647, at *3–4 (D. Minn. Nov. 24, 2010). And courts there also allow witnesses "to testify to the general nature of the approval and regulatory process, the FDA's general expectations with respect to testing and marketing of new products, [defendant's] actions in that respect, and [an expert's] opinion as to whether those actions were reasonable or appropriate." *Lillebo v. Zimmer Inc.*, No. 03-2919, 2005 U.S. Dist. Lexis 2563, at *15 (D. Minn. Feb. 16, 2005). *See also Block v. Woo Young Medical Co.*, 2013 WL 1414449 (D. Minn. Mar. 28, 2013) (same reasoning); *In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 2007 WL 1964337 (D. Minn. June 29, 2007) (finding admissible testimony as to the general nature of the medical device approval and regulatory processes, including compliance with FDA regulations).

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Courts around the country have ruled in similar fashion. *See, e.g., Strum v. DePuy Orthopaedics, Inc.*, 2013 WL 3184765 (Ill. Cir. Mar.8, 2013) (denying plaintiff's motion to exclude FDA evidence with respect to a 510(k) medical device); *Miller v. Stryker Instruments*, 2012 WL 1718825 (D. Ariz Mar. 29, 2012) (same); *Musgrave v. Breg, Inc.*, 2011 WL 4620767 (S.D. Ohio Oct. 3, 2011) (holding that plaintiffs "cannot keep the jury from hearing the fact that the FDA cleared a general indication" for the use of the 510(k) medical device).

Achieving admission of FDA evidence in your case is far from a slam dunk. Some recent courts have sided with plaintiffs and barred defendants from admitting FDA evidence generally or the fact of 510(k) clearance specifically. *See, e.g., Cisson v. C.R. Bard Inc.*, No. 11-cv-00195 (S.D.W.V. June 27, 2013) (barring 510(k) clearance and FDA evidence under Fed. R. Evid. 403).

While these decisions are difficult to square entirely, a common thread has emerged. When courts and the parties' arguments focused on the relevance of FDA evidence to a device's defectiveness, admission of FDA evidence happened less often. When courts and the parties' arguments focused on the relevance of the FDA evidence to corporate conduct, negligence concepts, or the mindset of corporate employees, admission of the FDA evidence was more likely to result.

Rulings in a 2010 trial in *In re: Mentor ObTape Transobturator Sling Products Liability Litigation*, MDL No. 2004, present a representative case study. In a pretrial ruling, the court found that FDA evidence was irrelevant and inadmissible, but it left open the possibility that the plaintiffs could "open the door" to such evidence depending on assertions made during the trial. *Id.*, May 3, 2010 Pretrial H'rg. During trial, the plaintiffs put the defendant's corporate conduct at issue by proffering evidence that the company did not report adverse events from the field. The court found that under the circumstances the company's interactions with the FDA, including the reporting of clinical performance and adverse events to the FDA, were relevant and admissible. *Id.*; June 3, 2010 Trial Proceedings.

To bolster your chances of admitting FDA evidence, you should do two things. First, spend time during discovery cultivating facts that you learned during your investigation, specifically that the company employees placed great weight on FDA actions and inactions with respect to your particular device. These FDA interactions colored the mindset of the company's employees and gave them some level of comfort that they were making the right decisions for the right reasons. This evidence rebuts plaintiffs' argument that company employees disregarded safety concerns or had ill motives.

Second, hire a regulatory expert, preferably a former FDA employee and 510(k) reviewer, to assist you with navigating the regulatory waters. He or she will come in handy at trial, to be sure, but this expert also will assist you with understanding the regulatory framework for the specific medical device at issue. The expert will conduct FOIA requests to help you obtain and analyze critical "FDA awareness and interaction" documents such as the 510(k) reviewer memorandum, as well as panel hearing transcripts and evidence of other FDA activities related to this class of devices. These documents may provide insight into any issues or concerns that the FDA had with your device or the class of devices. A regulatory expert is invaluable to helping you understand these documents and showing that the FDA's regulatory oversight with respect to your company's medical device is broad and deep.

Eventually, at the motion *in limine* stage, the plaintiffs do as you predicted and file a motion to preclude evidence of 510(k) clearance specifically and FDA evidence generally. The plaintiffs, citing *Lohr*, argue that 510(k) clearance demonstrates nothing about the safety or the efficacy of the product, and therefore it is irrelevant. The plaintiffs also argue that 510(k) clearance evidence and FDA "inaction" with respect to the medical device at issue would unfairly prejudice the plaintiffs because a jury allegedly will be misled to believe that the FDA's activities are conclusive findings about the safety of the product.

In thinking about your response, start with the applicable state law. Some states have enacted statutes creating rebuttable presumptions that an FDA-approved product is not defective or unreasonably dangerous. For example, the Indiana Product Liability Act provides a rebuttable presumption "that the product that caused the physical harm was not defective and that the manufacturer or seller of the product was not negligent" if the manufacturer can demonstrate that the product, at the time of sale, "complied with applicable codes, standards, regulations, or specifications established, adopted, promulgated, or approved by the United States or by Indiana, or by an agency of the United States or Indiana." Ind. Code §34-20-5-1. *See also* Fla. St. Ann. §768.1256(1).

Your next stop is a review of the applicable state law jury instructions. You have learned over time that the best response to a relevance argument is to cite pattern instructions requiring a jury to consider the very type of evidence that your opponent seeks to exclude. Given the body of law on the admissibility of FDA evidence, you particularly want jury instructions that require consideration of negligence concepts such as reasonableness and prudence of a manufacturer. *See*, *e.g.*, Minnesota, CIVJIG 75.20, Design Defect (manufacturer has duty to use reasonable care in designing a product); Minnesota, CIVJIG 75.25, The Duty to Warn (manufacturer has duty to provide reasonably accurate warnings).

Next, focus on the plaintiffs' complaint and the law of common sense. As noted, the plaintiffs' complaint is littered with allegations that the company rushed the product to market, ignored safety concerns postmarket, and sought to hide reported adverse events and safety concerns from the outside world. With help from your regulatory expert, demonstrate that FDA reviewers undertook careful and deliberate review of the manufacturer's 510(k) application, the FDA on several occasions undertook review of adverse events associated with this class of devices and published public notices, and the FDA received numerous adverse events from the manufacturer over time. From fact discovery of company witnesses, establish that these FDA-related facts affected the company's challenged decision making and directly rebut the allegations in the plaintiffs' complaint.

Lastly, address the plaintiffs' Federal Rule 403 argument head-on by arguing that *not* admitting the FDA evidence will result in prejudice. Plaintiffs inevitably argue that defendant should have done more—more testing, more reporting, more warnings—but without FDA evidence, a jury has no context from which to understand why a defendant took the actions it took. A jury deserves the complete regulatory picture to assess a defendant's conduct properly. And, as you point out, any potential harm or prejudice can be mitigated through a limiting instruction, informing a jury of the proper limits on the use of the evidence.

In the end, your brilliant arguments and advanced planning win the day, and the court denies the plaintiffs' motion. For that reason—and because outlining strategies on what to do when FDA evidence is excluded would require a separate article—you are off to trial with FDA evidence in your toolbox. And, through it all, you avoided debating whether 510(k) clearance demonstrates that the device at issue is safe and effective.

Step Two: Using FDA Evidence at Trial

You understand that you must avoid two things at trial: (1) overplaying FDA evidence, for instance, by sloppily using words such as 510(k) "approval" instead of "clearance" to the point that the court reconsiders its decision to admit the evidence; and (2) letting FDA evidence subsume the rest of your defense. Indeed, FDA evidence can negate the plaintiffs' attack on the company's decision making. But at the end of the day, the defense strategy is to play even on the corporate story so that your jury focuses on the specific defenses associated with the individual plaintiff in your case.

Early on in your case, you will present your regulatory expert witness. Generally, this witness will provide the "rules of the road" to the jury and opine about whether the company followed those rules both in advance of bringing the product to market and afterward. Along the way, this witness will impress upon the jury that the FDA fulfilled its watchdog duties and the company appropriately relied on FDA guidance in its product safety analyses.

To start, your regulatory expert will provide an overview of the FDA and its structure. The FDA is the federal agency with sole authority to regulate the introduction of medical devices into the U.S. market. The Center for Devices and Radiological Health, the center to which the FDA has delegated authority to regulate medical devices, employs scientists, epidemiologists, clinicians, and engineers—smart people with substantive knowledge regarding the benefits and risks of medical devices. Most of these individuals develop subspecialties within their fields, which allow them to become the foremost experts with respect to their assigned product lines.

The regulatory expert also will describe the two basic regulatory pathways that have been established to bring medical devices to market: the premarket approval process and the 510(k) premarket notification process. The premarket approval process involves the submission of a premarket approval application demonstrating that a company's device is safe and effective. Most Class III devices other than Class III preamendment devices require premarket approval before commercial distribution is permitted. *See* U.S. Food and Drug Admin., Medical Devices, Premarket Approval (PMA), http://www.fda.gov/Medicaldevices/Deviceregulationandguidance/Howtomarketyourdevice/Premarketsubmissions/Premarketapprovalpma/Default.Htm (last visited July 24, 2014).

The FDA is the federal agency with sole authority to regulate the introduction of medical devices into the U.S. market.

In contrast, under the 510(k) premarket notification process, Class II and some Class III devices may be marketed if it is established that the new device is "substantially equivalent" to a legally marketed predicate device. A new device is deemed substantially equivalent only if it is at least as safe and effective as the predicate device. *See* U.S. Food and Drug Admin., Medical Devices, Premarket Notification (510k), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm (last visited July 24, 2014). Under either pathway, the FDA considers the safety and the efficacy of the device.

Your jury will hear that the 510(k) premarket notification process is the workhorse of the two regulatory processes: the number of devices cleared through the 510(k) process far exceeds the number of devices approved through the premarket approval process. For example, in March of 2014, clearance decisions were rendered on 255 premarket notifications; only

74 premarket approval applications were approved. *See* U.S. Food and Drug Admin., March 2014 501(k) Clearances, *supra*; U.S. Food and Drug Admin., March 2014 PMA Approvals, *supra*.

Your expert also will clarify that the FDA, not a manufacturer, determines the appropriate pathway to market. For instance, the 510(k) pathway is the prescribed pathway for Class II devices, and manufacturers don't have an option to file a PMA application for Class II devices. And FDA guidance documents exist to outline 510(k) requirements for manufacturers.

The idea is not to have FDA evidence dominate your company story, but instead to provide context for your company story.

The FDA's internal 510(k) review memorandum provides a road map of the FDA's review. Assuming that particular product design features are targeted by the plaintiffs, the 510(k) application demonstrates that your client described and discussed those aspects of its design and that the FDA considered them as part of its review. Similarly, product warnings were supplied in the 510(k) package, and those were passed on by the FDA in its review as well.

The review memorandum also contains the company's interaction with the FDA during the clearance process. Questions raised by the FDA during the clearance and your client's response to those questions demonstrate that the 510(k) process is not merely a rubber stamp by the FDA and instead the reviewers are diligent in considering applications and making their determination. This confirms that the 510(k) review is meaningful and performed by scientists and clinicians in the field.

Your expert also will focus on postmarket FDA oversight. The FDA collects and analyzes adverse event reports, conducts periodic literature reviews, and regularly holds advisory committee meetings to monitor the safety and the effectiveness of devices. The FDA also has expansive audit and enforcement authority. These enforcement tools range from surprise audits and inspections, to warning letters, to seizure of products. The FDA can also require device manufacturers to conduct post-market surveillance studies, or "522 studies." Ctr. for Devices and Radiological Health, U.S. Food and Drug Admin., Strengthening Our National System for Medical Device Postmarket Surveillance (Sept. 2012), http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM301924.pdf. In wielding its enforcement power, the FDA must balance the need to protect the public health while ensuring the availability of safe and effective medical devices.

Although many defendants seek to exclude adverse events reported to the FDA, you decide to take a different route. Your client reported all adverse events to the FDA through medical device reporting. This rebuts the plaintiffs' argument that the company hid adverse events related to the product. Given the FDA's comprehensive monitoring and surveillance processes, the FDA's lack of safety-related action is consistent with the company's postmarket decision making for this device.

Of course, not all FDA evidence is "positive." Your regulatory expert may also have to grapple with FDA evidence that requires explanation. Initially, you may attempt to excise some of that evidence from the case. For instance, some of the progeny of *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), preclude the admission of FDA evidence "when it is offered only to show that the FDA was misled, or that information was intentionally concealed from the FDA." *Bouchard v. Am. Home Prods. Corp.*, 213 F. Supp. 2d 802, 812 (N.D. Ohio 2002). Likewise, as the Arkansas Supreme Court recently held, FDA warning letters have been deemed inadmissible and prejudicial. *Ortho-McNeil-Janssen Pharms., Inc., v. State*, ___ S.W.3d___ (Ark. 2014). But be careful in your efforts to present all of the good evidence and none of the bad: the court may reward your efforts by excluding FDA evidence altogether under the unwritten goose-and-gander rule. Pick your spots and narrowly tailor your request to targeted evidence at trial.

The world will not end if your jury hears about post-audit 483 observations, FDA safety updates, or other FDA evidence requiring explanation. Confronting these issues with your regulatory expert during direct is the best approach. Your expert can successfully present the "negative" evidence in a positive way, for example, by focusing on the FDA's diligence in fulfilling its regulatory oversight obligations and demonstrating the company's transparency in communicating with and responding to the FDA.

Later in the case, you will present company fact witnesses. As discovered during your investigation, these witnesses will testify regarding the importance of the FDA at many levels and across different departments—engineering, regulatory, quality, marketing, and compliance. The testimony of these witnesses will also bolster that of your regulatory expert—that the company consulted and complied with FDA guidance documents when putting together its 510(k) application, was transparent in its application with respect to its design components, responded promptly to FDA questions during the review process, and was diligent in reporting adverse events. It is through these witnesses that you can present evidence that the company's conduct was reasonable, as guided and informed by the FDA and the regulatory process.

Your closing statement provides one last opportunity to tie everything together, and the FDA evidence can be woven into the science, engineering, clinical, and plaintiff-specific arguments that you make. As you did in responding to the plaintiffs' *in limine* attacks, focus on the relevant jury instructions. Remind your jury that the reasonableness of the company's conduct should be viewed from the perspective of what the FDA required of the company to market its device. The idea is not to have FDA evidence dominate your company story, but instead to provide context for your company story.

Maybe a day or so after your defense verdict in that medical device trial, you will receive an e-mail from a colleague, saying, "You should write an article on how you used FDA evidence in the trial." You will write the article. FD