Charting the Course in MEDICAL Preemption

When the Supreme Court bolstered defendants' federal preemption arguments in medical device cases, defendants heralded it as the end of medical device litigation. But recent cases give plaintiff lawyers room to navigate.

By || **Mitchell M. Breit, Hunter J. Shkolnik, and Yvonne M. Flaherty**

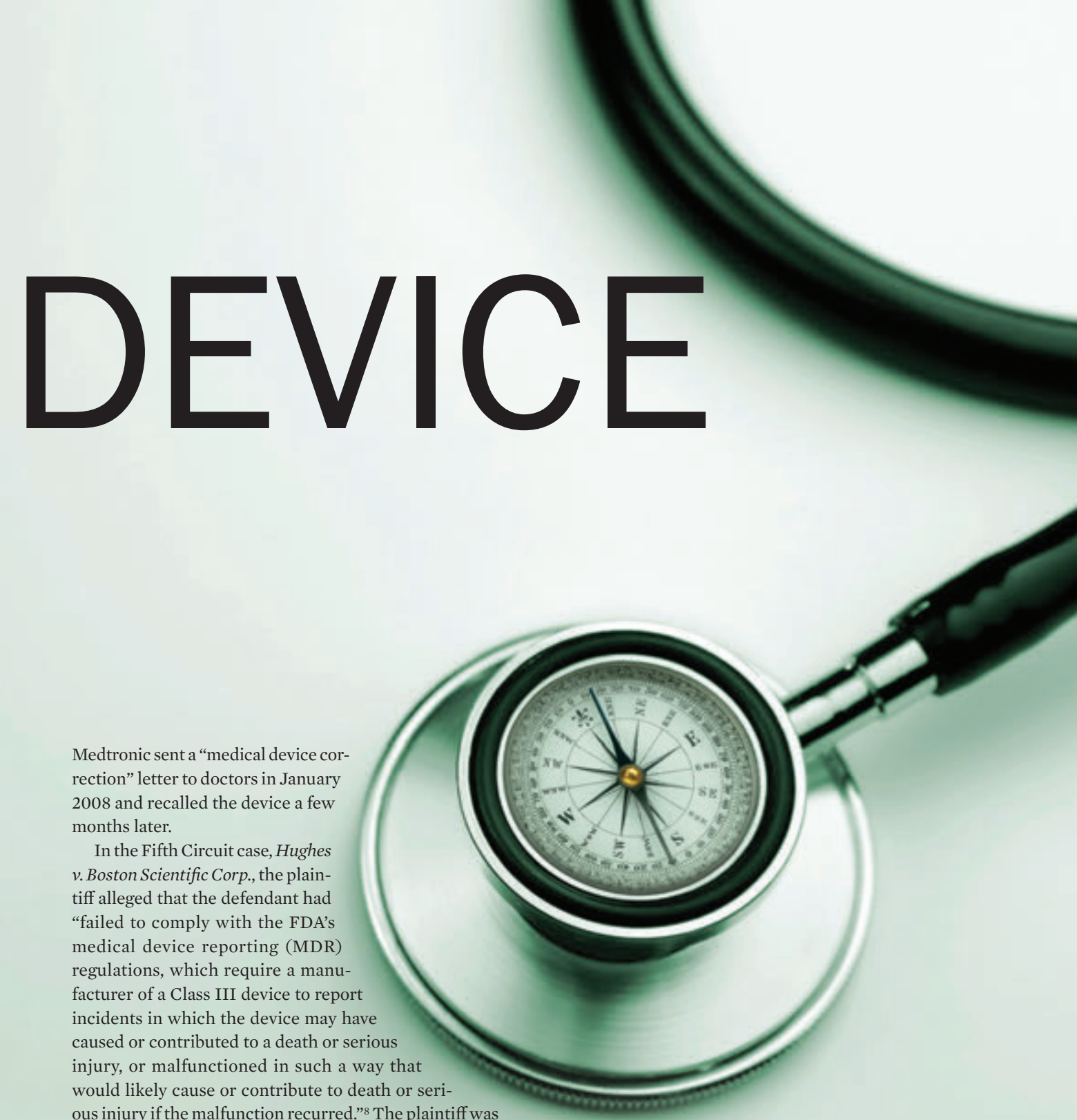
THE SUPREME COURT'S 2008 decision in *Riegel v. Medtronic, Inc.*, considerably altered the medical device litigation landscape by arming defendants with a more powerful preemption defense.[1] The years since that decision and the pleading standards set forth in *Bell Atlantic Corp. v. Twombly*[2] and *Ashcroft v. Iqbal*[3] have not produced good results for plaintiffs. Motions to dismiss have become de rigueur.

But new, creative approaches to pleading and discovery are cause for some optimism, and several courts have paved the way for a likely showdown in the Supreme Court. There are some bright spots that refute the notion—prematurely heralded by our defense colleagues—that *Riegel, Twombly,* and *Iqbal* signaled the end of medical device litigation.

Last January, the Ninth Circuit decided *Stengel v. Medtronic, Inc.*,[4] setting the stage for Supreme Court attention by following the Fifth and Seventh Circuits in a widening circuit split, specifically with the Sixth and Eleventh Circuits.[5] The court held that the plaintiffs' claim of state law negligence (for Medtronic's failure to report known risks to the FDA) was neither expressly nor impliedly preempted by the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act.[6]

Richard Stengel had a Medtronic SynchroMedEL pump implanted in his abdomen to control spinal pain, but an inflammatory mass formed on the tip of the pump's catheter, causing permanent paraplegia. The Ninth Circuit noted that before Stengel was paralyzed, Medtronic had become aware of the risk of paralysis but had failed to inform the FDA, notwithstanding its obligations under the MDA to do so. The court observed that "the FDA discovered the risks, and discovered that Medtronic already knew about them, when it inspected a Medtronic facility in late 2006 and early 2007," and it "sent a warning letter to Medtronic in July 2007, stating that the company had misbranded its Class III device by concealing known risks."[7]

DEVICE



Medtronic sent a "medical device correction" letter to doctors in January 2008 and recalled the device a few months later.

In the Fifth Circuit case, *Hughes v. Boston Scientific Corp.*, the plaintiff alleged that the defendant had "failed to comply with the FDA's medical device reporting (MDR) regulations, which require a manufacturer of a Class III device to report incidents in which the device may have caused or contributed to a death or serious injury, or malfunctioned in such a way that would likely cause or contribute to death or serious injury if the malfunction recurred."[8] The plaintiff was severely burned when the defendant's product, a Hydro ThermAblator, leaked during an ablation procedure.

Discovery revealed previous reportable events that the ablator had caused and that had not been communicated to the FDA. While deposing one of the defendant's representatives, plaintiff counsel elicited an admission that the FDA had previously directed the defendant by letter to change its reporting methodology, and that change resulted in a significant increase in the number of reported burn incidents.[9]

The Fifth Circuit found that the plaintiff's failure-to-warn claims (based on the defendant's failure to comply with the MDR by not reporting previous injuries and malfunctions) were not expressly preempted because the claims were "parallel"

PEEPO/GETTY IMAGES, DNY59/GETTY IMAGES

to FDA requirements. The court noted that neither a formal finding nor an enforcement action by the FDA was a precondition to a parallel state action, but it also held that "conclusory allegations of an FDA regulatory violation are impermissible."[10]

In a subsequent Fifth Circuit case, *Bass v. Stryker Corp.*, the court evaluated whether allegations of a manufacturing defect claim based on violations of federal regulations were sufficient.[11] The court was mindful of the plaintiffs' need to specify what went wrong in the manufacturing process and the FDA standards that the defendant allegedly violated. The court held:

> The key distinction between complaints that are sufficient to withstand a motion to dismiss and those that are not is not reliance on CGMPs [current good manufacturing practices], but rather the existence of a manufacturing defect caused by a violation of federal regulations and allegations connecting a defect in the manufacture of the specific device to that plaintiff's specific injury.[12]

The panel went to great pains to point out that if a plaintiff can show that FDA processes and procedures were not followed, and such deviations caused injury, the plaintiff's claims are parallel under *Riegel*. The key to the court's analysis was evidence of the defendant's own recall and an FDA warning letter sent to the company.

In *Bausch v. Stryker Corp.*, the Seventh Circuit was sensitive to the plaintiffs' plight. It held that the "plaintiffs could not be expected to plead their claims with greater specificity without discovery to obtain access to confidential government and company documents."[13] While noting that there are no special pleading requirements for Class III medical device claims, but that the *Iqbal* and *Twombly* plausibility standard applies, the court provided a road map for plaintiffs seeking to plead medical device claims with greater specificity:

> In applying that standard to claims for defective manufacture of a medical device in violation of federal law, moreover, district courts must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law. Formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim.[14]

There is no precise road map to obtain this information. But two things are certain: A thorough presuit investigation is critical, and device manufacturers will oppose the vast majority of your pretrial discovery requests. These practice pointers may help you gather information relevant to a manufacturer's violations of federal regulations and establish a viable parallel claim.

Case Investigation

Freedom of Information Act requests. Freedom of Information Act (FOIA) requests are helpful in cases where it is difficult to obtain documentation directly from a defendant. Numerous documents may be obtained, including portions of the FDA's Premarket Approval (PMA) files, Investigational Device Exemptions (IDE), and other device-related submissions (such as the Master File, also known as an MAF).[15] Inspection reports and related communications also may be available through a FOIA request.

Plaintiff lawyers who have submitted FOIA requests to the FDA frequently voice frustration over delays in the agency's response. By narrowing the scope of your requests—such as submitting multiple targeted FOIA requests, rather than one all-encompassing request—you will significantly expedite the FDA's response time. The more specific your request, the more prompt the response will be.[16]

Establishment inspection reports. These reports, also known as EIRs, provide details regarding inspections of the manufacturer's facilities and outline observations of possible violations. FDA Form 483 is generated following the inspection, and it is issued to the manufacturer when the investigator has observed "any conditions that in their judgment may constitute violations of the Food, Drug, and Cosmetic (FD&C) Act and related acts."[17]

The agency advises that "companies are encouraged to respond to the FDA Form 483 in writing with their corrective action plan (CAPA) and implement the corrective action plan expeditiously."[18] The FDA will then consider the EIR and CAPA to determine whether a warning letter is warranted. Thus, your FOIA request should include the EIR, Form 483, any related CAPAs,[19] and any associated warning letters. The EIR and Form 483 frequently identify exhibits and addenda, so you should specifically request copies of these documents in the FOIA request, because they are not always provided.

PMA file. Portions of the PMA file also may be available through a FOIA request, although many portions are deemed confidential and will not be produced. Historically, the PMA file (including supplements and addenda) takes significantly longer to obtain from the FDA than the EIRs and warning letters. This is because of the volume of the PMA and its supplements, as well as the extensive redaction of information that is required before releasing this information.

Federal regulations set forth when, and what types of, information the FDA may disclose to the public with respect to the PMA.[20] The information that may be disclosed includes "any adverse reaction report, product experience report, consumer complaint, and other similar

data and information."[21] Details regarding design, engineering, or manufacturing specifications, as well as quality control measures, are unlikely to be obtained through a FOIA request because they contain trade secrets and are not required to be publicly disclosed.[22]

522 studies. The FDA may require a Class III medical device manufacturer to conduct postmarket surveillance studies, also known as 522 studies, if device failure would be reasonably likely to have serious adverse health consequences. This includes devices that are expected to have significant use in pediatric populations, are intended to be implanted in the body for more than one year, or will be a life-sustaining or life-supporting device used outside a health care facility. Certain information regarding the 522 studies may be obtained via the FDA's website,[23] but once the FDA approves the manufacturer's 522 Study Plan, the contents of the original submission and any amendments, supplements, or reports may be disclosed per FOIA.

MAUDE database. The FDA maintains the Manufacturer and User Facility Device Experience (MAUDE), an online database of MDRs of "suspected device-associated deaths, serious injuries, and malfunctions" that it uses to monitor device performance and detect potential safety issues. The database "houses MDRs submitted to the FDA by mandatory reporters (manufacturers, importers, and device user facilities) and voluntary reporters such as health care professionals, patients, and consumers."[24] The FDA publishes the adverse events and MDRs in the MAUDE database and updates the report monthly.[25]

MAUDE has limitations**,** but the general public may access and search it to obtain safety data.[26] Device manufacturers are obligated to timely report adverse events to the FDA, and a company's failure to do so may support certain failure-to-warn claims; the FDA also frequently cites any such failures in its EIR or Form 483.

FDA advisory committees. To assist the FDA in its mission, and to supplement its limited technical resources, the agency uses 49 committees and panels to gain independent expert advice on scientific, technical, and policy matters. Plaintiff lawyers should always be on the lookout for any advisory committee reports for the product in question. The FDA may seek advice on scientific matters from any appropriate FDA advisory committee to determine where a product approval should be withdrawn or where other agency action may be warranted, including stronger labeling, limitations on use, and identification of product hazards.

Much can be learned from committee reports and deliberations, but recent revelations of ties between drug and device manufacturers and committee members have raised questions about the objectivity of committee scientists and experts. In any event, these reports and meeting minutes can provide information that is invaluable in framing the issues and drafting a complaint.

Case law now suggests that preemption is an AFFIRMATIVE DEFENSE, so the issue often is addressed in summary judgment motions, as was the case in *Riegel*.

Public filings, reports, and presentations. Frequently, the existence of an investigation or CAPA is revealed in reports and disclosures to stockholders and corporate boards. Many of these reports are available on corporate websites and in mandatory filings.

Lawyers who are investigating potential claims can search securities fraud filings. While many of the documents in the securities case docket may be subject to confidentiality provisions and protective orders, a review of the publicly available filings and docket can provide insight into disclosures that were (or were not) made to stockholders about FDA investigations or other product problems.

Pretrial Discovery

In prior years, it was not uncommon for a medical device manufacturer to respond to a complaint with a Rule 12 motion to dismiss on preemption grounds, relying on *Iqbal* and *Twombly*. Case law now suggests that preemption is an affirmative defense, so the issue often is addressed in summary judgment motions, as was the case in *Riegel*.

Thus, while it is critical that you conduct a thorough presuit investigation, it is equally important that you draft specific discovery requests for documents that

MORE ON PREEMPTION AND MEDICAL DEVICES

Visit the Web pages below for additional information.

AAJ SECTION
Products Liability
www.justice.org/sections

AAJ LITIGATION GROUP
Preemption Law
www.justice.org/litgroups

LITIGATION PACKET
A Guide Through Preemption
www.justice.org/litigationpackets

AAJ EDUCATION PROGRAM
Medtronic Program—2013 Annual Convention
www.PlaybackAAJ.com

are relevant to a preemption analysis. The following suggestions for early discovery—while not an exhaustive list—can help you defend against the inevitable preemption challenge. Once litigation is commenced, you should request these documents as soon as feasible.

Your discovery should include the PMA and its supplements, because you cannot obtain these documents in their entirety through an FOIA request. You can obtain a brief overview of each PMA supplement by visiting the FDA website, but the supplements frequently build on earlier submissions and refer to documents not attached to the individual supplement, so you may need to obtain the original PMA and all supplements.[27]

Keep in mind that the PMA and its supplements paint only part of the picture regarding preemption issues. For example, the manufacturer may communicate certain manufacturing changes to the FDA via annual or 30-day reports, so that not all changes are communicated in PMA supplements. Examples of manufacturing changes that may be made under a 30-day notice include automating existing processes and certain changes to the sterilization process parameters, welding, component suppliers, and quality control testing on both incoming components and finished products.[28] If the manufacturer submitted such changes via a 30-day report, that information generally will not be in the PMA supplements. Thus, you should consider these additional reports in your discovery requests.

Another item that may be appropriate for early discovery is the device master record (DMR), which each manufacturer must maintain pursuant to federal regulations. The DMR must include

- device specifications, such as appropriate drawings, composition, formulation, component specifications, and software specifications
- production process specifications, such as proper specifications for equipment, the production environment, production methods, and production procedures
- quality assurance procedures and specifications, including acceptance criteria and the quality assurance equipment to be used
- packaging and labeling specifications for the methods and processes used
- installation, maintenance, and servicing procedures and methods.

The DMR also must be maintained at a reasonably accessible location.[29]

The FDA defines the device traveler as a company form used to "identify a batch or sub-batch of in-process assemblies as they are passed from one department to another. Where needed, travelers are used to reduce mix-ups and confusion and, in general, increase the state of control of an overall manufacturing operation."[30] Note, however, that the traveler frequently is based on specifications or requirements that are contained in other files or protocols, so you should request and obtain the documents used to complete and substantiate the traveler.

Other areas ripe for early discovery include unredacted versions of documents obtained through your FOIA requests, as well as relevant quality systems regulations and good manufacturing practices, hazard analyses, failure mode effects analyses, and other process controls that may exist. These requests will likely be met with significant resistance, but if you limit the scope of these requests to what is clearly relevant to the claims alleged (rather than an "any and all" request), you will likely fare significantly better in any discovery disputes. Courts are beginning to recognize the utility of quality systems regulations and good manufacturing practices in preemption analysis.[31]

You should carefully evaluate these items' applicability and narrowly tailor your discovery requests. The information you glean in discovery can help you build claims to withstand preemption challenges.

Until the Supreme Court addresses the circuit split, there is room for plaintiff lawyers to maneuver. A well-pleaded complaint, backed up by targeted discovery, may give medical device litigators and their clients a window of hope.



Mitchell M. Breit *is a partner with Hanly Conroy Bierstein Sheridan Fisher & Hayes in New York City. He can be reached at mbreit@hanlyconroy.com.* **Hunter J. Shkolnik** *is a partner with Napoli Bern Ripka & Shkolnik in New York City. He can be reached at hunter@napolibern.com.* **Yvonne M. Flaherty** *is a partner with Lockridge Grindal Nauen in Minneapolis. She can be reached at ymflaherty@locklaw.com.*

Notes

1. 552 U.S. 312 (2008). *See* Hunter Shkolnik & Mitchell Breit, *The Beat Goes On*, Trial 16 (June 2010).
2. 550 U.S. 544 (2007).
3. 556 U.S. 662 (2009).
4. 704 F.3d 1224 (9th Cir. 2013).
5. Medtronic's writ of certiorari petition is pending in the Supreme Court. *Medtronic, Inc. v. Stengel*, No. 12-1351 (May 10, 2013). It asserted a panoply of circuit splits in its petition, including deviations on MDA preemption and parallel claims. The Fifth and Seventh Circuit decisions are *Hughes v. Boston Sci. Corp.*, 631 F.3d 762 (5th Cir. 2011) and *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010).
6. *See* 52 Stat. 1040, as amended, 21 U.S.C. §301.
7. *Stengel*, 704 F.3d at 1227.
8. *Hughes*, 631 F.3d at 762, 765–66.
9. The plaintiff learned of the increase in burn injuries through the FDA's Manufacturer and User Facility Device Experience (MAUDE) database, which can be accessed at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.
10. 631 F.3d at 772, 773.

11. 669 F.3d 501 (5th Cir. 2012).
12. *Id.* at 511, 512.
13. *Bausch*, 630 F.3d at 554 (citing the dissent in *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.,* 623 F. 3d 1200 (8th Cir. 2010)).
14. *Bausch*, 630 F.3d at 558. *See also Kubicki v. Medtronic,* 2013 WL 1739580 (D.C. Mar. 21, 2013).
15. *See* U.S. Food & Drug Admin., Master Files: Introduction to Master Files for Devices (MAFs), www.fda.gov/MedicalDevices/DeviceRegulationand Guidance/How toMarketYourDevice/Premarket Submissions/PremarketApprovalPMA/ucm142714.htm.
16. For an overview of FOIA requests directed to the FDA and additional details regarding submission of FOIA requests, see FDA Freedom of Information Act (FOIA), www.accessdata.fda.gov/scripts/foi/FOIRequest/index.cfm.
17. *See* U.S. Food & Drug Admin., FDA Form 483 Frequently Asked Questions, www.fda.gov/ICECI/EnforcementActions/ucm256377.htm.
18. *Id.*
19. *See* 21 C.F.R. §820 (2010).
20. *See* 21 C.F.R. §814.9.
21. 21 C.F.R. §814.9(f)(3).
22. 21 C.F.R. §814.9(h).
23. *See* U.S. Food & Drug Admin., Postmarket Surveillance Studies—Frequently Asked Questions (FAQs), www.fda.gov/Medical Devices/DeviceRegulationandGuidance/PostmarketRequirements/Postmarket Surveillance/ucm134497.htm.
24. *See* U.S. Food & Drug Admin., MAUDE—Manufacturer and User Facility Device Experience, www.access data.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.
25. *Id.*
26. *See e.g.* Robert G. Hauser et al., *Deaths Caused by the Failure of Riata and Riata ST Implantable Cardioverter-Defibrillator Leads,* 9 Heart Rhythm 1227–35 (Aug. 2012).
27. *See* 21 C.F.R. §§814.20(c), 814.39(c); *see also* U.S. Food & Drug Admin., *Guidance for Industry, Supplements and Approved Applications for Class III Medical Devices: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review*, 63 Fed. Reg. 98-13720 (May 21, 1998). *See also* U.S. Food & Drug Admin., Guidance for Industry—Supplements to Approved Applications for Class III Medical Devices: Use of Published Literature, Use of Previously Submitted Materials, and Priority Reviews, www.fda.gov/medicaldevices/deviceregulation and guidance/guidancedocuments/ucm080183.htm.
28. *See* U.S. Food & Drug Admin., Medical Devices, Guidance for Industry and FDA Staff, 30-Day Notices, 135-Day Premarket Approval (PMA) Supplements and 75-Day Humanitarian Device Exemption (HDE) Supplements for Manufacturing Method or Process Changes, www.fda.gov/medical devices/deviceregulationandguidance/guidancedocuments/ucm080192.htm.
29. *See* U.S. Food & Drug Admin., Device Master Record, http://tinyurl.com/qbf7hfd; *see also* 21 C.F.R. §820.180.
30. *See* U.S. Food & Drug Admin., *supra* n. 29; *see also* 21 C.F.R. §§820.60, 820.86.
31. *See Howard v. Zimmer, Inc.*, 2013 WL 2322106 (10th Cir. May 29, 2013). *See also Bausch,* 630 F.3d 546.