

SAY WHAT YOU MEAN: THE DISCOVERABILITY OF MEDICAL DEVICE ADVERSE EVENT REPORTS

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To facilitate its task of ensuring the safety of medical devices in the United States, the Food and Drug Administration (FDA) collects “adverse event reports” regarding illnesses or injuries that may have been caused by the use of a medical device. Hospitals and similar institutions are required by a federal statute to report life-threatening and other serious illnesses or injuries to the FDA, but anyone may voluntarily report less serious incidents as well. To encourage reporting, the aforementioned statute and the FDA’s regulatory scheme take certain measures to protect the identities of individuals who make the reports. The statute generally disallows the use of mandatory reports in civil litigation, including barring their admission as evidence. Separately, the FDA’s regulation prohibits the FDA or other parties from divulging any information in a voluntary report that could be used to identify a subject or reporter. The information contained in both types of reports, however, remains useful to litigants bringing suit against device manufacturers, and production of the reports often is requested during discovery. But allowance of this type of disclosure could have a chilling effect on the reporting that Congress and the FDA have tried to encourage, and thus, inquiry is needed as to the proper treatment to be accorded discovery requests for adverse event reports.

This Note draws a clear distinction between mandatory reports, governed by the statute, and voluntary reports, governed by the regulation, and explores the problematic treatment that these provisions have been given. Beginning with a discussion of the statute and regulation, this Note details the competing interests which courts have sought to balance in their interpretations of these rules. It then proceeds to a deeper analysis of the case law, arguing that the flawed interpretations advanced by many courts are out of touch with con-

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gressional and FDA intent and are suboptimal solutions to the balancing of interests presented. The proposed solution would treat the two types of reports separately. Mandatory reports' inadmissibility limits the value that they could have to litigants, and thus, courts should concentrate on protecting reporters' identities by disallowing discovery of the reports. On the other hand, the admissibility of voluntary reports, coupled with the plain language of the regulation, necessitates courts' allowance of disclosure of these reports, as long as appropriate measures are taken to protect the identities of reporters. The Note concludes that, in any case, Congress and the FDA should amend the statute and the regulation, respectively, to establish their preferred solutions to this question, and end the confusion created by the disparate treatment given by courts.

I. INTRODUCTION

In 1970, more than three million women used intrauterine contraceptive devices (IUDs) as their primary method of birth control.¹ One model of IUD, the “Dalkon Shield,” was particularly popular; between 1971 and 1974, 2.2 million Dalkon Shields were sold.² As early as January 1973, though, deaths involving the Dalkon Shield were reported.³ By mid-1974, A.H. Robins Company, the manufacturer and distributor of the Dalkon Shield, sent letters to 120,000 physicians and pulled the Dalkon Shield from the market; however, the product was not recalled, and an estimated 100,000 Dalkon Shields were still in use in 1978.⁴ By that time, scientists had linked the Dalkon Shield to several types of injuries, including “death, pregnancy, septic abortion, spontaneous abortion, tubal pregnancy, perforation of the uterine wall, and pelvic infection.”⁵ The Dalkon Shield made history over thirty years ago, but medical device recalls are not a thing of the past. In 2009 alone, more than 2350 medical devices were recalled nationwide in the United States,⁶ including over 170 Class III recalls, in which devices involved risks of “serious health problems or death.”⁷

1. See John M. Van Dyke, *The Dalkon Shield: A “Primer” in IUD Liability*, 6 W. ST. U. L. REV. 1, 1 (1978).

2. *Id.* at 1–2.

3. *Id.* at 2.

4. *Id.*

5. *Id.* 2 at n.6.

6. The Food and Drug Administration maintains a database of medical device recalls which can be searched on its website. *Medical & Radiation Emitting Device Recalls*, U.S. FOOD & DRUG ADMIN., <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm> (last visited Mar. 6, 2011). Searches of the database reveal that there were a total of 2360 device recalls in 2009. *Id.* (search month by month using “Date Posted”).

7. See *id.*; see also *Medical Device Recalls*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/default.htm> (last updated Sept. 20, 2010). Class I medical device recalls, of which there were 160 in 2009, are described as including “a reasonable chance that the product will cause serious health problems or death.” *Medical Device Recalls, supra*; see *Medical & Radiation Emitting Device Recalls, supra* note 6 (select “Recall Class” 1 and “Date Posted” from 1/1/2009 through 12/31/2009). Notably, more than 2000 Class II medical device recalls

Thirty years later, the United States has made significant inroads in the area of medical device safety. In modern times, injuries involving medical devices often must be reported to the Food and Drug Administration (FDA) whether or not the medical device actually caused the injury.⁸ For example, if a young man with an artificial replacement knee breaks his leg, the FDA likely must be notified regardless of whether the device *caused* him to break his leg—whether the artificial knee broke spontaneously or his leg was hit by a car.⁹ Given continuing advances in medical technology,¹⁰ one would expect that the volume of these “adverse event reports” only will increase as time goes on. Perhaps due to the ever-increasing number of medical devices on the market, the FDA has come to rely on adverse event reports to keep tabs on the safety of medical devices.¹¹

Not surprisingly, these reports are coveted by plaintiffs’ attorneys. When people believe they are injured—and perhaps, in some cases, even if they do not—they regularly seek out these reports as evidence that manufacturers knowingly or purposefully left potentially dangerous medical devices on the market.¹² A confusing combination of legislation, regulation, and court precedent, however, makes it unclear whether these reports are discoverable and, if so, whether they are discoverable in their entirety. This Note seeks to determine whether medical device adverse event reports should be discoverable in litigation, both as a general matter and under the law as it stands presently.

This issue rarely is litigated¹³ and is unlikely to be litigated moving forward because the law in this area is unclear and courts differ in their interpretations of that law. Device manufacturers and distributors, when faced with the option of litigating an unclear matter or settling out of

took place in 2009, each including “a possibility that the device will cause temporary or reversible health problems, or . . . a remote chance that the device will cause serious health problems.” *Medical Device Recalls*, *supra*; see *Medical & Radiation Emitting Device Recalls*, *supra* note 6.

8. See 21 U.S.C. § 360i(b)(1), (5)–(6).

9. See *id.*

10. See, e.g., Michael Rosen, *Global Medical Device Market Outperforms Drug Market Growth*, WTN NEWS (June 2, 2008), <http://wistechology.com/articles/4790/> (explaining that the top twenty-five medical device manufacturers’ revenues increased an average of ten percent between 2006 and 2007 and discussing the growth of the industry).

11. *Reporting Serious Problems to FDA*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm> (last updated Sept. 21, 2010) (“In order to keep effective medical products available on the market, the FDA relies on the voluntary reporting of [adverse] events.”).

12. See, e.g., *In re Medtronic, Inc.*, 184 F.3d 807, 808–09 (8th Cir. 1999); *Adcox v. Medtronic, Inc.*, 131 F. Supp. 2d 1070, 1072 (E.D. Ark. 1999).

13. For example, only four published court opinions discuss the statutory provision pertaining to the admissibility of mandatory adverse event reports. See *In re Medtronic*, 184 F.3d at 811; *Chism v. Ethicon Endo-Surgery, Inc.*, No. 4:08CV00341-WRW, 2009 WL 3066679, at *1 (E.D. Ark. Sept. 23, 2009); *Contratto v. Ethicon, Inc.*, 225 F.R.D. 593, 595–99 (N.D. Cal. 2004); *Adcox*, 131 F. Supp. 2d at 1074–76. Two other cases reference, but do not discuss, the relevant provision. See *Butler v. Aaron Med. Indus., Inc.*, No. C03-00896 HRL, 2004 WL 2271604, at *4–*5 (N.D. Cal. Oct. 6, 2004); *Sylvester v. Mentor Corp.*, 663 So. 2d 176, 181 (La. Ct. App. 1995).

court—often in suits alleging serious injury or death¹⁴ and not uncommonly in multidistrict lawsuits¹⁵—understandably tend to err on the side of caution by settling out of court.¹⁶ Therefore, academic consideration of this issue—though largely lacking¹⁷—is incredibly important. The purpose of this Note is to remedy the dearth of academic commentary in this area.

Part II of this Note provides background information on mandatory and voluntary medical device adverse event reports, including definitions, statutory and regulatory language, and a brief overview of relevant court decisions. Part III attempts to discern congressional and regulatory intent regarding the discoverability of medical device adverse event reports and notes where courts may have erred in applying rules in both areas. Part IV recommends steps courts should take to apply the law as it exists presently, as well as steps Congress and the FDA should take to clarify their respective wishes in this area. Specifically, Congress and the FDA should amend the language of the relevant statute and regulation, respectively, to clarify whether adverse event reports are discoverable; until that time, courts should rule that voluntary reports are discoverable in redacted form, whereas mandatory reports are not discoverable at all.

II. BACKGROUND

Before deciding whether adverse event reports are, or should be, discoverable, it is helpful to consider several introductory matters. This Part presents the nuances separating mandatory from voluntary adverse event reports. After briefly highlighting judicial decisions relating to both mandatory and voluntary reports, this Part concludes with a discussion of relevant procedural considerations, including the interests of various parties, alternative means of accessing information contained in adverse event reports, and other ways in which parties might argue over the admissibility and discoverability of medical device adverse event reports.

14. In *Contratto v. Ethicon, Inc.*, for example, a plaintiff was seriously injured by a substance used to reduce adhesions following surgery. *Contratto*, 225 F.R.D. at 594.

15. See, e.g., *In re Rezulin Prods. Liab. Litig.*, No. CIV.00 CIV.2843 LAK, 2002 WL 24475 (S.D.N.Y. Jan. 10, 2002).

16. In January 2008, for example, a manufacturer of implantable cardiac defibrillators reached a \$240 million class action settlement. *Case Center: Guidant Defibrillators*, LIEFFCABRASER.COM, <http://www.lieffcabraser.com/cases.php?CaseID=295> (last visited Mar. 6, 2011).

17. To date, only one commentator has discussed the discoverability of medical device adverse event reports. Bonnie L. Mayfield, *Preventing Manufacturer Compelled Disclosure of Confidential Information Contained in Voluntarily Submitted Adverse Event Reports*, 19 AM. J. TRIAL ADVOC. 265 (1995). Notably, Ms. Mayfield discusses tactics defense lawyers can use in arguing that these reports should not be discoverable, rather than approaching the issue from a theoretical or academic standpoint. See *id.* at 271–84. Furthermore, her analysis of the relevant statute is less robust than that of the present Note: she cites to 21 U.S.C. § 360i(b)(3) only once, and quickly dismisses that section as insufficient to block discovery of medical device adverse event reports. See *id.* at 267–68. Therefore, further examination is needed.

A. Mandatory Medical Device Adverse Event Reports

1. Plain Language and Definitions

Congress defines what constitutes a “mandatory” adverse event report, including the parties to whom mandatory reporting requirements apply, in 21 U.S.C. § 360i(b).¹⁸ The statute dictates that certain institutions must report serious injuries, serious illnesses, and deaths to the FDA, the device manufacturer, or both.¹⁹ These institutions—or “device user facilit[ies]”—include hospitals, ambulatory surgical facilities, nursing homes, and outpatient treatment facilities.²⁰ “Serious illness[es]” and “serious injur[ies]” are defined as illnesses or injuries, respectively, that are “life threatening,” “result[] in permanent impairment of a body function or permanent damage to a body structure,” or “necessitate[] medical or surgical intervention” to prevent the same.²¹ Thus, reports of serious injuries, illnesses, or deaths—reported by “device user facilit[ies],” as defined in the statute—constitute “mandatory” adverse event reports.²² By way of example, any problem with an implanted device—an artificial joint or a pacemaker lead—likely requires a mandatory report, as surgery likely is required to fix the problem.

Congress also explains in this statute a purpose for which mandatory adverse event reports cannot be used.²³ Specifically, Congress dictates that no mandatory report made by a device-user facility, an individual employed by or affiliated with such a facility, or a “physician who is not required to make such a report,” “shall be admissible into evidence or otherwise used in any civil action involving private parties,” unless the reporter knew that information in the report was false.²⁴ Congress likely created this exception for cases alleging fraudulent adverse event reporting, to ensure that the key, if not only, evidence of such fraud would be admissible.²⁵ Therefore, it seems Congress intended that mandatory medical device adverse event reports would not be available for use in civil litigation between private parties, with the possible exception of cases involving fraudulent or falsified adverse event reports.

18. 21 U.S.C. § 360i(b) (2006).

19. *Id.* § 360i(b)(1)(A)–(B). Device user facilities must report deaths to the FDA “and, if the identity of the manufacturer is known, to the manufacturer of the device.” *Id.* § 360i(b)(1)(A). Serious illnesses or injuries must be reported “to the manufacturer of the device or to the [FDA] if the identity of the manufacturer is not known.” *Id.* § 360i(b)(1)(B).

20. *Id.* § 360i(b)(6)(A).

21. *Id.* § 360i(b)(6)(B).

22. Although Congress did not distinguish between “mandatory” and “voluntary” medical device adverse event reports, this distinction is very real: Congress did not discuss voluntary reports in 21 U.S.C. § 360i, meaning that the provisions of that statute necessarily apply only to reports that *must* be made under the statute. *See id.* § 360i.

23. *Id.* § 360i(b)(3).

24. *Id.*

25. Congress did not state this proposition directly, but the idea flows intuitively from the statement that mandatory adverse event reports should not be excluded from evidence if the reporter “had knowledge of the falsity of the information contained in the report.” *Id.*

Even if those reports are not *admissible*, however, Congress failed to explain whether they are *discoverable*, leading courts to reach different conclusions on the matter. The distinction is crucial. Regardless of admissibility, requiring defendants to produce adverse event reports imposes a burden on medical device manufacturers and allows plaintiffs access to information that, at least arguably, Congress tried to prevent them from getting. The “or otherwise used” language probably means *something*; the question is whether it refers to discovery in particular.

2. Overview of Case Law

Perhaps even more important than the plain language of 21 U.S.C. § 360i(b)(3), at least in the eyes of litigants, are the ways in which courts have interpreted that language. Unfortunately, those interpretations have not been consistent. To date, only four published federal court opinions have discussed the discoverability of medical device adverse event reports under 21 U.S.C. § 360i(b)(3).²⁶ The only federal appellate court to consider the issue ruled that mandatory adverse event reports are not discoverable.²⁷ District court decisions vary. Whereas one district court ruled that the reports are discoverable,²⁸ another district court—in separate opinions issued in different years—alternately ruled that the reports were and were not discoverable.²⁹ The discoverability of mandatory adverse event reports under 21 U.S.C. § 360i(b)(3) accordingly remains unsettled.

B. Voluntary Medical Device Adverse Event Reports

1. Plain Language and Definitions

Congress has not passed legislation relating to nonmandatory (or “voluntary”) adverse event reports. Rather, by focusing only on reports that various entities “shall” make,³⁰ Congress left the FDA to promulgate regulations regarding other reports. In response, the FDA created 21 C.F.R. § 20.63, which regulates the disclosure of information in personnel, medical, and similar files.³¹ Specific to adverse event reports, subsection (f) of the regulation dictates that neither the FDA nor manufacturers may disclose “[t]he names and any information that would identify the *voluntary* reporter or any other person associated with an adverse

26. See cases cited *supra* note 13.

27. *In re Medtronic, Inc.*, 184 F.3d 807, 811 (8th Cir. 1999).

28. *Contratto v. Ethicon, Inc.*, 225 F.R.D. 593, 595–99 (N.D. Cal. 2004) (discoverable); see discussion *infra* Part III.B.3.

29. *Chism v. Ethicon Endo-Surgery, Inc.*, No. 4:08CV00341-WRW, 2009 WL 3066679, at *1 (E.D. Ark. Sept. 23, 2009) (discoverable); *Adcox v. Medtronic, Inc.*, 131 F. Supp. 2d 1070, 1074–76 (E.D. Ark. 1999) (not discoverable); see discussion *infra* Parts III.B.2, 4.

30. See, e.g., 21 U.S.C. § 360i(b)(1)(A), (B) (requiring that device user facilities “shall . . . report” information).

31. 21 C.F.R. § 20.63 (2010).

event.”³² Identities may be disclosed in three scenarios, however: (1) if both the voluntary reporter and the person identified in the report consent in writing to disclosure; (2) if the disclosure is pursuant to a court order in a medical malpractice suit involving both the reporter and the subject; or (3) if the subject of the report requests it, albeit with other identities excluded.³³

As if to highlight the distinction between mandatory and voluntary reports, the FDA clarifies that the regulation “does not affect disclosure of the identities of reporters *required* by a Federal statute or regulation to make adverse event reports,” and that “[d]isclosure of the identities of such reporters is governed by the applicable Federal statutes and regulations.”³⁴ Thus, the regulation seems to apply only to voluntary reports, and serves not to prevent discovery of voluntary adverse event reports, but rather to prevent disclosure of identities within those reports.

2. Overview of Case Law

For the most part, courts at all levels—federal appellate courts,³⁵ federal district courts,³⁶ and even state courts³⁷—agree with the general proposition that the regulation does not permit disclosure of medical device adverse event reports in unredacted form. In one decision, however, a federal district court ruled that 21 C.F.R. § 20.63(f) “clearly prevents discovery of reports sent voluntarily by device user facilities and doctors.”³⁸ Thus, although courts generally agree on the subject of voluntary adverse event report discoverability, some discord remains.

C. Other Background Considerations

1. Competing Interests

At least three groups have an interest in the discoverability of medical device adverse event reports: consumer plaintiffs, defendant manu-

32. *Id.* § 20.63(f) (emphasis added).

33. *Id.* § 20.63(f)(1).

34. *Id.* § 20.63(f) (emphasis added).

35. *See, e.g., In re Medtronic, Inc.*, 184 F.3d 807, 810 (8th Cir. 1999); *York v. Am. Med. Sys., Inc.*, No. 97-4306, 1998 WL 863790, at *2–*4 (6th Cir. Nov. 23, 1998).

36. *See, e.g., In re Panacryl Sutures Prods. Liab. Cases*, No. 5:08-MO-1959-BO, 2010 WL 3062811, at *1 (E.D.N.C. Aug. 3, 2010); *In re Mentor Corp. Obtape Transobturator Sling Prods. Liab. Litig.*, 632 F. Supp. 2d 1370, 1374–79 (M.D. Ga. 2009); *Contratto v. Ethicon, Inc.*, 225 F.R.D. 593, 597–98 (N.D. Cal. 2004); *In re Rezulin Prods. Liab. Litig.*, No. CIV.00 CIV.2843 LAK, 2002 WL 24475, at *1 (S.D.N.Y. Jan. 10, 2002); *In re Rezulin Prods. Liab. Litig.*, No. 00 Civ. 2843, 2000 WL 1801846, at *1 (S.D.N.Y. Dec. 7, 2000). The Southern District of Illinois also discussed 21 C.F.R. § 20.63 as it pertains to preemption of tort litigation. *See Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1036 (S.D. Ill. 2001). The district court’s discussion and interpretation do not bear on the discoverability of medical device adverse event reports, and therefore are not pertinent to the present issue. *Id.*

37. *See, e.g., Low v. Hoffmann-La Roche, Inc.*, No. 2001-61586, 2003 WL 25318131, ¶14 (Dist. Ct. Tex. Feb. 4, 2003).

38. *Adcox v. Medtronic, Inc.*, 131 F. Supp. 2d 1070, 1074 (E.D. Ark. 1999).

facturers, and government overseers.³⁹ Very generally, consumer plaintiffs likely favor broad discoverability of medical device adverse event reports, mandatory *and* voluntary, because such reports may be useful in proving, for example, that a device manufacturer knew that a device posed a risk to the public but failed to recall the device. Even when adverse event reports are not admissible, knowledge of previous adverse events may prompt plaintiffs' attorneys to ask questions of expert witnesses that they otherwise may not.⁴⁰ Defendant manufacturers, meanwhile, likely favor narrow discoverability because reports regarding previous injuries caused by the same or similar medical device(s) could be used as evidence of negligence. These reports also could provide plaintiffs' attorneys with lists of potential plaintiffs for future litigation.⁴¹ Finally, government overseers likely care less about discoverability as an end than discoverability as a means. For example, the government might prefer narrow discoverability as a means to protect reporters or broad discovery as a means to ensure that plaintiffs can recover from manufacturers who legitimately injure them. Although no interest necessarily represents the right view, recognizing these competing interests serves to highlight the importance of finding the right outcome and creating a system that reaches that outcome consistently.

2. *Baseline Availability*

Regardless of whether mandatory or voluntary adverse event reports are discoverable, nearly all of these reports are available to the general public, albeit in redacted form, on the Internet. The FDA publishes the Manufacturer and User Facility Device Experience (MAUDE) database, which contains redacted voluntary and mandatory adverse event reports dating back as far as 1991.⁴² The ready availability of this data, however, does not negate the problem of discoverability at issue here. For example, using MAUDE, it is not possible to determine with any certainty whether an individual adverse event report is "mandatory" or "voluntary," meaning that plaintiffs have no indication whether information contained in those reports may be admitted into evidence un-

39. This assertion supposes that Congress and the FDA, as "government overseers," share the same interests. If it is the case that Congress and the FDA do not share the same interests, then at least four groups have an interest in the discoverability of medical device adverse event reports.

40. For example, if a plaintiff can discover an adverse event report, yet is precluded from admitting it as evidence at trial, the plaintiff potentially could develop much of the same evidence by, for example, questioning a defendant's expert witness(es) regarding the injuries discussed in the report.

41. These reports could not be used to generate additional claims unless identities were not redacted; however, if unredacted reports were produced—purposefully or inadvertently—those reports could allow plaintiffs' attorneys to convince others to bring claims, or even to certify a class on behalf of those injured by a particular medical device or class of devices.

42. *MAUDE - Manufacturer and User Facility Device Experience*, U.S. FOOD & DRUG ADMIN., <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM> (last updated Feb. 28, 2011).

der 21 U.S.C. § 360i(b)(3).⁴³ Furthermore, even if *all* MAUDE reports were admissible into evidence, plaintiffs still might request discovery of manufacturer files relating to specific adverse events because those files may contain more information than MAUDE reports.⁴⁴

3. *Procedural Reality*

At least one commentator has argued that even if voluntary adverse event reports are *discoverable*, those reports are not *admissible* because they are “irrelevant.”⁴⁵ For example, a defense attorney may argue that, under Federal Rule of Evidence 403, the reports create unfair prejudice that outweighs their probative value, meaning the reports are likely to mislead and confuse a jury.⁴⁶ Additionally, the reports may create undue delay and rely on inadmissible hearsay.⁴⁷ These arguments, however, do not appear in any published judicial decision regarding the discoverability of adverse event reports, meaning that either defense attorneys are not raising them or courts are not buying them, and therefore should be accorded little weight. For the sake of predictability, if nothing else, a rule regarding the discoverability of adverse event reports is needed.

4. *Enforcement*

To further incentivize reporting, Congress created civil penalties for failure to report a medical device adverse event.⁴⁸ Additionally, Congress defined failure to report an adverse event as a “prohibited act”⁴⁹ subject to first-violation penalties of up to a \$1000 fine and/or one year in

43. The amount of information published in an individual MAUDE report varies directly with the amount of information provided by an adverse event reporter. This effect may be exacerbated by the extent to which a manufacturer (if known) chooses to supplement that information. Therefore, it may be impossible to determine whether an adverse event actually *caused* a serious injury or serious illness in many, if not most, cases. At best, one could guess that some reports—for example, those involving implantable devices—must be mandatory reports. But even then, a report filed by a user, rather than a device user facility, would be a voluntary report.

44. In at least one case, a plaintiff sought discovery of adverse event reports—despite the existence of the MAUDE database—in an effort to identify putative class members. See *Adcox v. Medtronic, Inc.*, 131 F. Supp. 2d 1070 (E.D. Ark. 1999).

45. Mayfield, *supra* note 17, at 278–80. First, note that Ms. Mayfield’s argument must relate only to *voluntary* adverse event reports, because the one point that 21 U.S.C. § 360i(b)(3) is clear on is that mandatory adverse event reports are not admissible into evidence. 21 U.S.C. § 360i(b)(3) (2006). Ms. Mayfield concludes that reports are not precluded from *production*, and that this argument therefore is relegated to *admission*. Mayfield, *supra* note 17, at 277–78. The issue of relevance, however, can, in and of itself, be relevant to a judicial determination regarding discovery: if the redacted reports will not be admissible later, there may be less justification to burden the defendant manufacturer or distributor by compelling production of those reports now. See discussion *infra* Part IV.A.1.

46. Mayfield, *supra* note 17, at 281–83.

47. *Id.* at 281–84.

48. See 21 U.S.C. § 333(f)(1)(A) (Supp. III 2010) (“[A]ny person who violates a requirement of this chapter which relates to devices shall be liable to the United States for a civil penalty in an amount not to exceed \$15,000 for each such violation, and not to exceed \$1,000,000 for all such violations adjudicated in a single proceeding.”).

49. 21 U.S.C. § 331(e) (2006).

prison⁵⁰ and subsequent-violation penalties of up to a \$10,000 fine and/or three years in prison.⁵¹ Congress's own action reveals the belief that further incentive to report is needed: if Congress felt these threatened penalties were enough to achieve full reporting by device user facilities, there would be no need to further incentivize that reporting by preventing the admission or use of adverse event reports in civil litigation. Thus, once again, further investigation of whether those reports should be discoverable is warranted here.

III. ANALYSIS

The plain language of 21 U.S.C. § 360i(b)(3) leaves unanswered whether mandatory medical device adverse event reports are discoverable, rather than admissible, in civil litigation. To answer the question, it is necessary to consider legislative and regulatory intent, and may be helpful to examine how courts have answered the question, as well. This Part examines Congress's intent for the discoverability of mandatory reports, as well as how courts have applied 21 U.S.C. § 360i(b)(3). It then discusses the FDA's intent regarding voluntary reports, as well as how various courts have applied 21 C.F.R. § 20.63(f). For the sake of being comprehensive, this Part also discusses ways in which courts may have erred in interpreting and applying both the statute and regulation, as well as the confusion courts have experienced in applying both.

A. Congressional Intent for Mandatory Reports

Given that the plain language of 21 U.S.C. § 360i(b)(3) does not address the discoverability of mandatory adverse event reports, attention should be directed to the statutory context and legislative intent surrounding that provision. In order to understand the context and intent behind 21 U.S.C. § 360i(b)(3), it is helpful to understand the progression of legislation leading up to, and following, the enactment of that section in its current form.

1. Medical Device Amendments of 1976⁵²

21 U.S.C. § 360i originated well before mandatory reporting schemes.⁵³ In 1976, inspired in part by concern over extensive public injury resulting from use of the Dalkon Shield, Congress amended the Food, Drug, and Cosmetic Act of 1938 with the goal of giving the FDA "authority to require that all medical devices are safe and effective be-

50. *Id.* § 333(a)(1).

51. *Id.* § 333(a)(2).

52. Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified in scattered sections of 21 U.S.C.).

53. *See id.* sec. 2, § 519, 90 Stat. at 564-65.

fore they are allowed in the marketplace.”⁵⁴ Specifically, the Conference Report for the Medical Device Amendments of 1976 explained that the legislation envisioned three classes of medical devices based on risk incident to use.⁵⁵ Class I devices were devices for which “general controls”—rules pertaining to adulteration, misbranding, registration, and so on—were sufficient to assure adequate consumer protection, or for which there was no unreasonable risk of illness or injury.⁵⁶ Class II devices were devices for which general controls were insufficient to protect consumer health and for which sufficient information exists to establish and apply a performance standard to ensure consumer safety.⁵⁷ Finally, Class III devices were those for which insufficient information exists to determine that general controls or a performance standard would protect consumer health and whose purported use includes supporting human life or preventing impairment of health, or includes a potentially un-reasonable risk of illness or injury.⁵⁸ Devices created or placed into commerce after the enactment of the amendments were to be treated as Class III devices, unless and until classified otherwise.⁵⁹ Whereas Class I medical devices were assumed to be relatively safe so long as they did not violate other statutory sections pertaining to medical devices, manufacturers and distributors of Class II medical devices had to demonstrate compliance with to-be-established “performance standards,” and Class III medical devices had to receive premarket approval.⁶⁰

The stated and shared purpose of both the House and Senate for the Medical Device Amendments of 1976 was “to assure the safety and effectiveness of medical devices.”⁶¹ Although relatively short—particularly in comparison to the Conference Report in which it appears—this statement of purpose seemingly sums up the intent of Congress in passing the amendments quite well.⁶² Recognizing Congress’s desire for the FDA to effectively regulate the medical device market

54. S. REP. NO. 94-33, at 1 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1070. The Senate report also noted that medical device technology had advanced greatly since the original definition of “device” in the 1938 Act, further necessitating the proposed amendments. *See id.* at 2–3, 5–6, *reprinted in* 1976 U.S.C.C.A.N. 1070, 1072, 1074–75.

55. *See* Medical Device Amendments sec. 2, § 513(a)(1), 90 Stat. at 540–41; H.R. REP. NO. 94-1090, at 3–4 (1976) (Conf. Rep.), *reprinted in* 1976 U.S.C.C.A.N. 1103, 1107–08.

56. Medical Device Amendments sec. 2, § 513(a)(1)(A), 90 Stat. at 540–41; H.R. REP. NO. 94-1090, at 3 (Conf. Rep.), *reprinted in* 1976 U.S.C.C.A.N. 1103, 1107.

57. Medical Device Amendments sec. 2, § 513(a)(1)(B), 90 Stat. at 541; H.R. REP. NO. 94-1090, at 3 (Conf. Rep.), *reprinted in* 1976 U.S.C.C.A.N. 1103, 1107–08.

58. Medical Device Amendments sec. 2, § 513(a)(1)(C), 90 Stat. at 541; H.R. REP. NO. 94-1090, at 3–4 (Conf. Rep.), *reprinted in* 1976 U.S.C.C.A.N. 1103, 1108.

59. Medical Device Amendments sec. 2, § 513(f), 90 Stat. at 544–46; H.R. REP. NO. 94-1090, at 7–8 (Conf. Rep.), *reprinted in* 1976 U.S.C.C.A.N. 1103, 1108–09.

60. *See* Medical Device Amendments sec. 2, § 513(a)(1), 90 Stat. at 540–41; H.R. REP. NO. 94-1090, at 3–4 (Conf. Rep.), *reprinted in* 1976 U.S.C.C.A.N. 1103, 1107–08.

61. H.R. REP. NO. 94-1090, at 1 (Conf. Rep.), *reprinted in* 1976 U.S.C.C.A.N. 1103, 1103.

62. Indeed, the one-sentence purpose adequately justifies every element of the Medical Device Amendments of 1976, as well as the Conference Report that accompanied the Act. *See generally* Medical Device Amendments, Pub. L. No. 94-295, 90 Stat. 539; H.R. REP. NO. 94-1090 (Conf. Rep.), *reprinted in* 1976 U.S.C.C.A.N. 1103.

helps to clarify the environment in which the mandatory reporting scheme was created.

2. *Safe Medical Devices Act of 1990*⁶³

Mandatory adverse event reporting was introduced through the Safe Medical Devices Act of 1990, the relevant part of which is codified at 21 U.S.C. § 360i(b).⁶⁴ In approving the Act, the House Committee on Energy and Commerce noted that, among other concerns, the FDA struggled to make itself aware of serious problems with medical devices because “hospitals often do not report potentially hazardous medical devices to the FDA or the manufacturer.”⁶⁵ Thus, it would seem that, at least in part, the intent underlying the creation of current 21 U.S.C. § 360i(b) was twofold: first, Congress wanted to create a functional and effective post-marketing surveillance program for FDA-approved medical devices; and second, Congress wanted to give the FDA more power and authority to regulate those devices where and when needed. This purpose is reflected in a Report by the House Committee on Energy and Commerce: “[P]roviding some protections for those persons and entities doing the reporting is intended to encourage full reporting by device users.”⁶⁶ Unfortunately, this House Report fails to expand on the notion that mandatory reports “may not be admitted into evidence or otherwise used in any civil actions involving private parties,” instead simply mentioning that “there is no prohibition on civil litigation about the events that are the subject of the report.”⁶⁷

The House and Senate affirmed in their Conference Report the shared purpose of establishing “a statutory requirement that medical device user facilities report serious problems with medical devices.”⁶⁸ At the same time, though, Congress clarified what it did not want the statute to do: (1) cause device user facilities to “expend resources in the investigation of each event that requires a report”; (2) suggest that “[t]he filing of a report . . . constitute[s] evidence that a device has caused a death or serious injury”; or (3) shift responsibility from the FDA and/or device manufacturers, to medical device users filing reports, “to make such de-

63. Pub. L. No. 101-629, 104 Stat. 4511 (1990) (codified in scattered sections of 21 U.S.C.).

64. *Id.* sec. 2, § 519(b), 104 Stat. at 4511–13 (current version at 21 U.S.C. § 360i(b) (2006)). Specifically, 21 U.S.C. § 360i(b) pertains to user reports. 21 U.S.C. § 360i(b). While the Act covered much more than user reports—the Act had nineteen sections, no more than three of which pertained directly to medical device reports, and only one of which pertained directly to *user* reports—the User Reports section is most pertinent to the issue at hand. See Safe Medical Devices Act, 104 Stat. 4511.

65. H.R. REP. NO. 101-808, at 14 (1990), *reprinted in* 1990 U.S.C.C.A.N. 6305, 6307.

66. *Id.* at 21, *reprinted in* 1990 U.S.C.C.A.N. 6305, 6315. The House Report additionally explains that these protections are extended “to physicians who are not otherwise required to report under the provisions of this section” for the purpose of “encourag[ing] such medical device users, who may encounter otherwise reportable problems in their private office practice [sic], to notify the FDA or the manufacturer of such problems.” *Id.*, *reprinted in* 1990 U.S.C.C.A.N. 6305, 6314.

67. *Id.*, *reprinted in* 1990 U.S.C.C.A.N. 6305, 6314.

68. H.R. REP. NO. 101-959, at 23 (1990) (Conf. Rep.), *reprinted in* 1990 U.S.C.C.A.N. 6327, 6328.

terminations.”⁶⁹ In sum, Congress apparently wanted to increase rates of reporting regarding medical device adverse events, but did not want to burden device user facilities with financial or bookkeeping responsibilities. Nor did Congress intend for adverse event reports to serve as proxies for causation in lawsuits alleging negligence.

It also is worth noting that the House and Senate stated in the Conference Report that their amendments regarding user reporting substantially followed a preceding House Bill.⁷⁰ The House Report accompanying that Bill explains that some of the protections afforded to individuals who file medical device adverse event reports exist “to encourage reporting”—not unlike whistleblower statutes—by sheltering reporting individuals “from reprisals for making a report respecting a medical device.”⁷¹

Thus, while Congress did not explain why mandatory adverse event reports are not admissible and cannot otherwise be used in civil litigation between private parties, it seems that the goal of the statute was to increase reporting among health professionals and other device users. It would stand to reason, then, that protecting those reports from admission in lawsuits was simply a means to that end.

3. *Subsequent Legislation*

Though 21 U.S.C. § 360i(b) has not been changed since its inception in 1990, Congress has passed additional legislation relating to medical device identification. In 2007, Congress enacted the Food and Drug Administration Amendments Act, which requires that the FDA promulgate a system for unique identification of medical devices, allowing the agency to track devices from manufacturing through distribution and use.⁷² Even more recently, the House of Representatives proposed a national medical device registry, wherein many in-commerce medical devices—all Class III medical devices, and any Class II medical devices that are life-supporting or life-sustaining—would be documented, tracked, and linked to other medical data using a central electronic database.⁷³

69. *Id.* at 24, reprinted in 1990 U.S.C.C.A.N. 6327, 6328.

70. *Id.* at 23, reprinted in 1990 U.S.C.C.A.N. 6327, 6328.

71. H.R. REP. NO. 101-808, at 22, reprinted in 1990 U.S.C.C.A.N. 6305, 6315.

72. Pub. L. No. 110-85, sec. 226, § 519(f), 121 Stat. 823, 854 (2007). Congress also noted that unique identifiers may include information on the lot and serial numbers of medical devices. *Id.*

73. Affordable Health Care for America Act, H.R. 3962, 111th Cong. sec. 2571 (as passed by House of Representatives, Nov. 7, 2009). Data would have included Medicare and/or Veterans Affairs data, as well as private sector health-related data. *Id.* sec. 2571(a)(1)(B), § 519(g)(3).

Following resistance to the proposed registry from industry members,⁷⁴ however, this proposed legislation died in the Senate.⁷⁵

4. Overall Intent

These legislative histories, taken holistically, provide several points for consideration moving forward. As early as 1976, Congress recognized the importance of empowering the FDA to regulate the medical device market in protecting Americans from unnecessary injuries.⁷⁶ Fourteen years later, Congress recognized that the FDA was unable to effectively regulate the medical device market because health professionals and others were not reporting injuries relating to medical devices, and Congress responded by creating a mandatory reporting scheme.⁷⁷ Therefore, although Congress chose to make mandated adverse event reports inadmissible in litigation between private parties, that choice likely reflects little more than an attempt by Congress to increase reporting rates regarding serious injuries, serious illnesses, and deaths involving medical devices. Since the Safe Medical Devices Act of 1990, Congress has passed, and briefly considered, additional legislation that would better enable the FDA to regulate medical devices effectively,⁷⁸ further stressing the concept that Congress is more concerned about the FDA's ability to regulate the medical device market than the mechanism by which that regulation is achieved.

B. The Statute as Applied by Courts

Four published federal court decisions—one appellate court decision and three district court decisions—have considered the discoverability of mandatory adverse event reports under 21 U.S.C. § 360i(b)(3). Analyzing these decisions in chronological order, this Section addresses both whether the courts applied the statute correctly and whether those applications—right or wrong, given the plain language of the statute—represent the result Congress intended in passing the statute.

1. *In re Medtronic, Inc.*⁷⁹

In 1999, in *In re Medtronic, Inc.*, the Court of Appeals for the Eighth Circuit ruled that discovery could not include information con-

74. See Sue Darcey, *House Health Reform Bill Calls for Sweeping National Device Registry*, MED. DEVICES TODAY (July 20, 2009), <http://www.medicaldevicestoday.com/2009/07/medical-devices-house-health-reform-bill-calls-for-sweeping-national-device-registry.html>.

75. See Pub. L. No. 111-192, 124 Stat. 1280 (2010) (containing no reference to a national device registry). To review the Senate Amendment that replaced the as-passed House Bill, see 92 CONG. REC. § 55150-61 (daily ed. June 18, 2010).

76. See discussion *supra* Part III.A.1.

77. See discussion *supra* Part III.A.2.

78. See discussion *supra* Part III.A.3.

79. 184 F.3d 807 (8th Cir. 1999).

tained in device user reports according to 21 U.S.C. § 360i(b)(3).⁸⁰ The court entertained a petition for a writ of mandamus from Medtronic, Inc.⁸¹ after the District Court for the Eastern District of Arkansas granted a discovery motion by Doris Adcox, who alleged that Medtronic manufactured a defective pacemaker lead.⁸² Adcox sought discovery “of the names of patients, physicians and facilities involved with other allegedly defective Medtronic pacemakers and, especially, the names of physicians who reported to Medtronic incidents similar to those experienced by Adcox.”⁸³ Specifically, the district court had ordered Medtronic “to contact the 4000 or so lead recipients for whom [Medtronic] apparently filed a Medical Device Report (MDR) with the Food and Drug Administration.”⁸⁴

On appeal, the Eighth Circuit agreed with the U.S. Department of Justice⁸⁵ and ruled that, “to the extent that compliance with any discovery order . . . requires divulgence of the contents of reports within the scope of 21 U.S.C. § 360i(b)(3), the orders are invalid.”⁸⁶ Notably, the Eighth Circuit’s analysis is among the only published federal court decisions accurately highlighting the difference between mandatory and voluntary adverse event reports.⁸⁷ Specifically, the court treated voluntary and mandatory reports as distinct classes of reports, with different rules applying to each.⁸⁸

2. Adcox v. Medtronic, Inc.⁸⁹

On remand that same year, in *Adcox v. Medtronic, Inc.*, the District Court for the Eastern District of Arkansas used the Eighth Circuit’s decision to divide Adcox’s discovery request into three categories of reports: (1) “[r]eports made and submitted directly by patients or their legal representatives”; (2) “[r]eports made and submitted by doctors when there was no death, serious harm, or serious illness caused by or contributed to by the [medical device]”; and (3) “[r]eports made and submitted

80. *Id.* at 812.

81. *Id.* at 808.

82. *Id.* A pacemaker lead is “[a]n electrically insulated conductor that carries signals between the pulse generator (pacemaker) and the heart,” such that “[s]ome leads enter the heart through a vein, and other leads attach to the outer surface of the heart.” *Cardiovascular and Pulmonary Terms Legal Glossary*, CONSULTWEBS.COM, <http://www.consultwebs.com/glossary/glossary-of-cardiovascular-and-pulmonary-terms/p/> (last visited Mar. 6, 2010).

83. *In re Medtronic*, 184 F.3d at 808.

84. *Id.* at 809 (quoting *Adcox v. Medtronic, Inc.*, No. LR-C-96-333 (E.D. Ark. Oct. 28, 1998) (order granting discovery)).

85. A Department of Justice attorney and a U.S. Attorney filed an amicus brief on the government’s behalf in the appeal, by request of the circuit court, because the order of the district court required Medtronic to violate 21 C.F.R. § 20.63(f) (pertaining to disclosure of information contained in medical device adverse event reports). *Id.* at 808–10.

86. *Id.* at 811.

87. *See id.* at 811–12.

88. *Id.*

89. 131 F. Supp. 2d 1070 (E.D. Ark. 1999).

under 21 U.S.C. [§] 360i(b)(1)(A) and (B).”⁹⁰ After ruling that reports made and submitted by patients or their legal representatives did not fall within the scope of 21 U.S.C. § 360i(b)(3),⁹¹ the court proceeded to rule that reports made pursuant to 21 U.S.C. § 360i(b)(1)(A) and (B) were not discoverable under the binding precedent from the Eighth Circuit in *In re Medtronic, Inc.*⁹²

Despite the court’s acceptance of the binding Eighth Circuit holding, however, it also made its concerns very clear. First, the court questioned the policy underlying the decision to deny all discovery of mandatory adverse event reports, noting that redaction of identifying information serves just as well in terms of protecting adverse event reporters.⁹³ Second, the district court noted that similar “limiting language” in other statutes has been interpreted as meaning that such evidence “is generally not admissible in civil actions, but is, nonetheless, subject to discovery.”⁹⁴ Finally, the court argued that the Eighth Circuit’s ruling “runs counter to the FDA’s own statement[s],” noting that it is “skeptical of much of the FDA’s alleged concern for patient privacy” and labeling its view as “speculative and jaundiced.”⁹⁵

This last statement, however, is indicative of a fundamental misconception regarding the distinction between mandatory and voluntary adverse event reports. In reality, nothing the FDA has said regarding the discoverability of adverse event reports even applies to mandatory reports, as FDA regulation 21 C.F.R. § 20.63(f) concerns itself exclusively with voluntary reports.⁹⁶ Therefore, although the district court offers its interpretation of the FDA’s intent as a basis for undermining the Eighth Circuit’s decision regarding mandatory reports, that offering simply reflects the district court’s misunderstanding of the nuances it tried so carefully to highlight.⁹⁷

3. *Contratto v. Ethicon, Inc.*⁹⁸

Five years later, in *Contratto v. Ethicon, Inc.*, the Northern District of California ruled that 21 U.S.C. § 360i(b)(3) does not preclude discovery of mandatory adverse event reports, but that those reports may only be discovered in redacted form.⁹⁹ The court entertained a motion for a

90. *Id.* at 1072.

91. *Id.* at 1074. The court reasoned that “[a] patient who submits one of these reports, or instructs her lawyer to do so, obviously knows the report is being filed and thereby waives her privilege.” *Id.* The court further explained that patient-submitted reports “are discoverable, but only after redaction of reporter and patient identifying information,” in line with 21 C.F.R. § 20.63(f). *Id.*

92. *Id.* at 1074–76.

93. *Id.* at 1075.

94. *Id.* at 1075–76.

95. *Id.* at 1076.

96. 21 C.F.R. § 20.63(f) (2010); see discussion *supra* Part II.B.

97. *Adcox*, 131 F. Supp. 2d at 1072.

98. 225 F.R.D. 593 (N.D. Cal. 2004).

99. *Id.* at 599.

protective order, wherein a medical device manufacturer argued that mandatory medical device adverse event reports, as well as manufacturer files relating to those reports, were protected from disclosure under 21 U.S.C. § 360i(b)(3).¹⁰⁰ The plaintiff received Intergel¹⁰¹ after a hernia surgery, which subsequently caused serious injuries.¹⁰² Noting that adverse event reports compelled by 21 U.S.C. § 360i(b) were “mandatory” reports, the court cited both the Federal Rules of Civil Procedure¹⁰³ and Supreme Court precedent¹⁰⁴ in rejecting Ethicon’s argument that 21 U.S.C. § 360i(b)(3) prohibited discovery of adverse event reports.¹⁰⁵ Indeed, although the court agreed that the reports defendants sought to protect were covered by the statute, the court thought that “a better interpretation [of the statute] is that admissibility or discovery of [the] reports is prohibited only in civil actions involving the maker of the report.”¹⁰⁶ Separately, the court rejected the notion that 21 U.S.C. § 360i(b)(3) protects “‘complaint files’ and any documents produced by manufacturers in response to mandatory or voluntary complaints,” holding that the statute pertains “only [to] reports made by device user facilities, their staff, and physicians.”¹⁰⁷ Thus, the court entered an order that “defendants shall produce the requested documents,” but also ordered that “defendants shall redact all names and other identifying information from all documents they produce.”¹⁰⁸

In terms of statutory confusion, the Northern District of California’s decision stands alone. The court’s claim that admissibility is barred only when a reporter is party to a lawsuit does not mesh with either the Eighth Circuit or Eastern District of Arkansas decisions preceding it¹⁰⁹

100. *Id.* at 594–95. During hearings, both parties made concessions: the plaintiff conceded that some of the reports she requested were publicly available, and the defendants conceded that they had “no grounds to protect complaints by patients or foreign users.” *Id.* at 594.

101. The court described Intergel as “a substance used by medical care providers to reduce the adhesions sustained by a patient during surgery.” *Id.* Both parties agreed that “[f]or regulatory purposes . . . Intergel is classified as a medical device.” *Id.*

102. *Id.* Specifically, the Intergel hardened within the plaintiff’s body. *Id.*

103. Specifically, the court cited Rule 26(b)(1), which provides that “parties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party.” *Id.* at 595 (quoting FED. R. CIV. P. 26(b)(1) (amended 2007)).

104. The court cited *Hickman v. Taylor*, regarding the Federal Rules of Civil Procedure, which held that “[t]he way is now clear, consistent with recognized privileges, for the parties to obtain the fullest possible knowledge of the issues and facts before trial.” *Id.* (quoting *Hickman v. Taylor*, 329 U.S. 495, 501 (1947)). Additionally, the court cited *Schlagenhauf v. Holder*, in which the Supreme Court “held that the discovery rules should be accorded a ‘broad and liberal scope.’” *Id.* (quoting *Schlagenhauf v. Holder*, 379 U.S. 104, 114–15 (1964)).

105. *Id.* at 595–98. The court cited additional concerns as well, including FDA interpretations of the statute and the legislative history behind the statute. *Id.* at 596.

106. *Id.* at 595–96. The court stated that “[u]nder this interpretation, section 360i(b)(3) does not apply to a suit by a patient against the manufacturer of the product that is the subject of the report.” *Id.* at 596.

107. *Id.* at 598.

108. *Id.* at 599.

109. Neither of these decisions would have been binding, but both could have informed the court’s decision.

and seemingly violates the plain language of the statute as well.¹¹⁰ In referencing the FDA's discussion of its proposed rule for 21 C.F.R. § 20.63(f),¹¹¹ the court showed that it also was led to believe that the FDA created that regulation to supplement Congress's statute, effectively misunderstanding that the statute and regulation apply to wholly different sets of reports.¹¹² Next, the court discussed the statutory language allowing for discovery of false reports in the context of "produc[ing] an absurd result,"¹¹³ apparently missing the possibility that the provision may be intended to allow discovery of evidence in lawsuits based on allegations of fraudulent reporting.¹¹⁴ Further exemplifying its misunderstanding, the court explains that "a manufacturer would have no way of distinguishing [voluntary complaints made by patients or others unaware of the statute] from voluntary reports described in section 360i(b)(3)."¹¹⁵ Manufacturers, however, *can* distinguish mandatory from voluntary reports—voluntary reports are filed using FDA Form 3500, whereas mandatory reports are filed using FDA Form 3500A¹¹⁶—and 21 U.S.C. § 360i(b)(3) does not apply to voluntary reports.¹¹⁷

4. *Chism v. Ethicon Endo-Surgery, Inc.*¹¹⁸

In September 2009, the District Court for the Eastern District of Arkansas—the same court and the same judge that heard the *Adcox v. Medtronic* matter¹¹⁹—again entertained a motion to exclude adverse event reports.¹²⁰ The intentions of the parties were similar to those in *Contratto*, in that the plaintiffs sought to discover evidence of other similar incidents that came in the form of adverse event reports, and the defendant asserted that those reports were not discoverable.¹²¹ This time,

110. Nothing in the plain language of the statute suggests it is limited to suits involving reporters themselves. See 21 U.S.C. § 360(i)(b) (2006).

111. *Contratto*, 225 F.R.D. at 596 (citing Protecting the Identities of Reporters of Adverse Events and Patients; Preemption of Disclosure Rules, 59 Fed. Reg. 3944, 3944–46 (Jan. 27, 1994)).

112. See discussion *supra* Parts II.A.1, II.B.1. As discussed, the statute applies to mandatory reports, whereas the regulation applies to voluntary reports.

113. *Contratto*, 225 F.R.D. at 597.

114. See *supra* note 25 and accompanying text. Alternatively, if the court was focusing solely on suits involving manufacturers, the court apparently missed the possibility that the cited language would not apply.

115. *Contratto*, 225 F.R.D. at 596 n.4.

116. See *Download Forms*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm> (last updated Feb. 9, 2010). Therefore, when reports are forwarded to manufacturers, they quickly and easily can discern mandatory from voluntary reports.

117. See discussion *supra* Parts II.A.1, II.B.1.

118. No. 4:08CV00341-WRW, 2009 WL 3066679 (E.D. Ark. Sept. 23, 2009).

119. The Honorable William R. Wilson, Jr. heard both *Adcox v. Medtronic, Inc.* and *Chism, Id.*; *Adcox v. Medtronic, Inc.*, 131 F. Supp. 2d 1070, 1072 (E.D. Ark. 1999).

120. The complete title of the motion was "Motion to Exclude Product Inquiry Verification Reports, Medwatch Reports, or Other Adverse Event Reports." *Chism*, 2009 WL 3066679, at *1.

121. *Chism*, 2009 WL 3066679, at *1; see also *Contratto v. Ethicon, Inc.*, 225 F.R.D. 593, 594–96 (N.D. Cal. 2004). In *Chism*, however, the defendant further argued that the reports at issue were inadmissible hearsay. *Chism*, 2009 WL 3066679, at *1. The court ultimately rejected this argument, de-

by contrast, Judge Wilson ruled that the reports could be discoverable *and* admissible, despite the existence of 21 U.S.C. § 360i(b)(3), so long as the reports being sought (1) were delivered by the manufacturer to the FDA, rather than by device user facilities to the manufacturer; and (2) pertained to devices “substantially similar” to the device(s) at issue.¹²² Because it was unclear whether the pleadings adequately demonstrated that the devices in the requested reports were “substantially similar” to the device at issue in the present case,¹²³ however, Judge Wilson simply denied the motion in favor of a more comprehensive discussion at the pretrial conference.¹²⁴ Although the case has yet to move forward following the order entered on September 23, 2009,¹²⁵ the underlying holding is clear: if the reports being requested pertain to devices that are “substantially similar” to the device at issue in the present case, then those reports—at least, in the eyes of Judge Wilson—will be discoverable.

Perhaps in an effort to finally succeed in allowing for the discovery and admissibility of adverse event reports, Judge Wilson apparently creates a distinction where none exists. Specifically, he distinguishes reports made by device user facilities (and sent to manufacturers) from subsequent reports made by manufacturers (and sent to the FDA).¹²⁶ Nothing in the plain language or legislative history of 21 U.S.C. § 360i(b)(3), however, suggests such a distinction; rather, it is clear that reports sent from device user facilities to manufacturers or the FDA, as well as reports sent from manufacturers to the FDA, simply are separate links in the same chain.¹²⁷

C. FDA Intent for Voluntary Reports

The plain language of 21 C.F.R. § 20.63(f) implies that the regulation pertains only to voluntary adverse event reports and concerns itself more with the disclosure of identifying information than the discoverability of voluntary reports.¹²⁸ The FDA’s final rule regarding that regulation largely echoes the same points.

ciding that the reports were one or both of (i) records of regularly conducted business activity or (ii) public records or reports. *Id.* at *2.

122. *Chism*, 2009 WL 3066679, at *1.

123. Judge Wilson explained that “[t]he legislative history of § 360i supports [the] finding” that medical device reports are admissible “as long as they pass the substantially similar test, including that the device in the report operated in a similar manner as the device in [the present] case.” *Id.* at *1 & n.9.

124. *Id.* at *1, *3.

125. *Id.* at *1.

126. *Id.* at *1.

127. In the event both a device user facility and a manufacturer submit reports discussing the same event, it seems the FDA is left to reconcile differences, if any, between those reports.

128. See discussion *supra* Part II.B.1.

1. *FDA Final Rule for 21 C.F.R. § 20.63(f)*¹²⁹

The FDA's explanation of the rule in the Federal Register begins by distinguishing mandatory reports, submitted by manufacturers, distributors, and device user facilities "as required under Federal statutes"—including, by specific reference, the Safe Medical Devices Act¹³⁰—from voluntary reports.¹³¹ The FDA then explains that it relies on adverse event reports "to identify possible problems in marketed products" so that it can evaluate potential hazards and take corrective action as needed.¹³² The purpose of the final rule, the FDA explains, is to "enhance safeguards for protecting the identities of persons who voluntarily submit adverse event reports, as well as the identities of the patients experiencing those adverse events."¹³³

Importantly, the FDA rejected requests to extend the regulation's coverage to mandatory adverse event reports, noting that "[t]he policy and final rule are intended to protect *voluntary* reporting."¹³⁴ Furthermore, the FDA rejected requests to rule on the admissibility of adverse event reports, explaining that the policy "is designed to encourage voluntary adverse event reporting by health care professionals and others," and that "[t]he agency's policy regarding disclosure of voluntarily submitted adverse event reports has been, and continues to be, that such reports are publicly available after deletion of identifying information."¹³⁵

2. *Overall Intent*

Taking these comments and rationales holistically, it is clear that the FDA is not concerned with the discoverability of voluntary adverse event reports. Rather, the FDA's sole concern is protecting the identities of voluntary adverse event reporters from disclosure so that health professionals and others will continue to report adverse events in the future, allowing the FDA's postmarketing surveillance program to function effectively. At the same time, the FDA considers mandatory adverse event reports to be out of its jurisdiction, so to speak, and squarely within the control of Congress via 21 U.S.C. § 360i(b)(3).

D. The Regulation as Applied by Courts

By and large, courts interpreting 21 C.F.R. § 20.63(f) seem to agree with the general proposition that the regulation does not permit disclo-

129. Protecting the Identities of Reporters of Adverse Events and Patients; Preemption of Disclosure Rules, 60 Fed. Reg. 16,962 (Apr. 3, 1995) (codified at 21 C.F.R. § 20.63(f)).

130. *Id.* at 16,965.

131. *Id.* at 16,962.

132. *Id.*

133. *Id.*

134. *Id.* at 16,963 (emphasis added).

135. *Id.* at 16,964.

sure of medical device adverse event reports in unredacted form.¹³⁶ This general agreement holds true across various levels of courts: federal circuit courts, federal district courts, and state courts generally seem to reach the same conclusion regarding 21 C.F.R. § 20.63(f).

1. Federal Circuit Court Decisions

Two federal circuit courts have considered the implications of 21 C.F.R. § 20.63(f). In a 1998 unpublished opinion, *York v. American Medical Systems, Inc.*, the Sixth Circuit upheld a district court's ruling that 21 C.F.R. § 20.63(f) allowed for disclosure of voluntary medical device adverse event reports, but required that those reports be disclosed only in redacted form.¹³⁷ In *York*, a penile implant manufacturer was sued for a manufacturing defect and failure to warn of known risks.¹³⁸ In response to York's discovery request, manufacturer American Medical Systems moved for a protective order "to prevent disclosure of [adverse event reports], including . . . complaint and analysis documents, in unredacted form."¹³⁹

The Sixth Circuit held that 21 C.F.R. § 20.63 grants "a blanket prohibition against disclosure of confidential information by manufacturers," subject to the exceptions in the regulation.¹⁴⁰ The court further explained that the legislative history of 21 C.F.R. § 20.63 supported that construction because "the comments to § 20.63 state that the provision allowed for disclosure only in the situations outlined in the exceptions."¹⁴¹ Finally, the court clarified that "disclosure [of identifying information] is permitted pursuant to court order only when both the manufacturer and the party experiencing the adverse event are involved in the litigation."¹⁴² Thus, the court ruled that voluntary adverse event reports are discoverable, but also that the only identifying information that may be disclosed is that information pertaining to parties in the litigation.

Notably, the Sixth Circuit's holding implied that only reports pertaining to the plaintiff in the current case were discoverable; in other words, that reports other than those pertaining to the plaintiff(s) were not discoverable.¹⁴³ This holding, however, seems to stray from the intent of the FDA, as the FDA seemingly cared only about protecting confiden-

136. The opinions tend to focus more on redaction than discoverability, largely agreeing that—for parties to which the regulation applies—redaction of identifying information is required. See discussion *infra* Parts III.D.1–3. In one decision, however, a district court ruled that "[§ 20.63] clearly prevents discovery of reports sent voluntarily by device user facilities and doctors." *Adcox v. Medtronic, Inc.*, 131 F. Supp. 2d 1070, 1074 (E.D. Ark. 1999).

137. *York v. Am. Med. Sys., Inc.*, No. 97-4306, 1998 WL 863790, at *2–*5, *8 (6th Cir. Nov. 23, 1998) (unpublished disposition).

138. *Id.* at *1.

139. *Id.* at *2.

140. *Id.* at *4.

141. *Id.*

142. *Id.*

143. *Id.* at *4–*5.

tial information, rather than categorically precluding discovery of voluntarily submitted adverse event reports.¹⁴⁴

The following year, the Eighth Circuit offered its opinion in *In re Medtronic, Inc.*, discussed previously.¹⁴⁵ Turning its attention to voluntary adverse event reports, the Eighth Circuit reversed the district court and ruled that discovery orders are invalid “insofar as such orders require divulgence of any information contained in or gleaned from voluntarily submitted [adverse event reports].”¹⁴⁶

It bears special note that the Eighth Circuit’s ruling is the only *published* decision holding that voluntary adverse event reports are not discoverable.¹⁴⁷ Similar to the Sixth Circuit’s decision, this holding seems to be overbroad: the FDA apparently did not intend to preclude all discovery, but rather intended to prevent the disclosure of reporters’ and subjects’ identifying information in particular.¹⁴⁸

2. Federal District Court Decisions

At least six federal district court decisions have interpreted 21 C.F.R. § 20.63.¹⁴⁹ Looking chronologically, the first decision interpreting the regulation was *Adcox v. Medtronic*, on remand from the Eighth Circuit, discussed previously.¹⁵⁰ In *Adcox*, the court identified two primary purposes for 21 C.F.R. § 20.63: to prevent (1) “unwarranted invasions of privacy that might result if certain medical reports are disclosed”; and (2) “court ordered contact by the manufacturers with either the adverse event reporters . . . or with the parties identified . . . in the reports.”¹⁵¹ Thus, the court concluded that 21 C.F.R. § 20.63 bars discovery of voluntary reports from device user facilities and doctors¹⁵² but does not bar discovery of patient-submitted voluntary reports.¹⁵³

The *Adcox v. Medtronic* decision, however, was likely overbroad—perhaps because the Eighth Circuit’s holding, with which the district court was compelled to comply, similarly was overbroad.¹⁵⁴ Specifically,

144. See discussion *supra* Parts II.B.1, III.C.

145. See discussion *supra* Part III.B.1.

146. *In re Medtronic, Inc.*, 184 F.3d 807, 811–12 (8th Cir. 1999).

147. The court specifically held that “orders requir[ing] divulgence of any information contained in or gleaned from voluntarily submitted [reports] as such documents are defined in applicable statutes and regulations” are invalid. *Id.* Recall that *York* is an unpublished decision. See *supra* note 137.

148. See discussion *supra* Parts II.B.1, III.C.

149. In addition to the six district court decisions discussed herein, the Southern District of Illinois also discussed 21 C.F.R. § 20.63 as it pertains to preemption of tort litigation. See *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1036 (S.D. Ill. 2001). However, its discussion and interpretation are not pertinent to the present issue. See *supra* note 36.

150. *Adcox v. Medtronic, Inc.*, 131 F. Supp. 2d 1070 (E.D. Ark. 1999); see discussion *supra* Part III.B.2.

151. *Adcox*, 131 F. Supp. 2d at 1073.

152. *Id.* at 1074.

153. *Id.* The court qualified this holding, however, in explaining that patient-submitted reports are discoverable “only after redaction of reporter and patient identifying information.” *Id.*

154. See *supra* text accompanying notes 145–48.

the court held that 21 C.F.R. § 20.63(f) “clearly prevents discovery of reports sent voluntarily by device user facilities and doctors.”¹⁵⁵ Again, this holding seems to conflict with the stated intent of the FDA: to prevent disclosure of reporter identifying information, rather than to preclude any discovery of voluntary reports.¹⁵⁶

Another year later, in *In re Rezulin Products Liability Litigation*, the Southern District of New York delivered the first of two pretrial orders interpreting 21 C.F.R. § 20.63.¹⁵⁷ In an unopposed appeal, the district judge reversed an order of the magistrate judge granting discovery of medical device adverse event reports pertaining to putative plaintiffs in a nonexistent class.¹⁵⁸ Instead, the district judge ruled that 21 C.F.R. § 20.63 required that only reports pertaining to *named* plaintiffs in the suit were eligible for disclosure.¹⁵⁹ Thus, the court concluded that “the only patient names to be disclosed from [the manufacturer’s adverse event report] database shall be those of individuals, if any, who are named plaintiffs” in the multidistrict litigation.¹⁶⁰ Two years later, the same court (in the same litigation) again interpreted the regulation.¹⁶¹ Fashioning an order after parties were unable to agree upon which pieces of information were discoverable in the litigation, the court made two observations regarding 21 C.F.R. § 20.63: (1) the regulation “applies only to the FDA and to pharmaceutical manufacturers and therefore, presumably, not to [doctors]”; and (2) the regulation “shields only the identities of voluntary reporters, not all physicians and health care institutions mentioned in patient records.”¹⁶² Therefore, the court concluded that the defendant could redact “[t]he names and any information that would identify the voluntary reporter or any other person associated with an adverse event involving a human drug” but could not redact “information concerning the identities of doctors and institutions who made such reports under compulsion of law or who made no such reports.”¹⁶³

The first *In re Rezulin Products Liability Litigation* decision seems to fall within the FDA’s intent for 21 C.F.R. § 20.63(f), in that it only allowed disclosure of identifying information for reports regarding named

155. *Adcox*, 131 F. Supp. 2d at 1074.

156. See discussion *supra* Parts II.B.1, III.C.

157. *In re Rezulin Prods. Liab. Litig.*, No. 00 Civ. 2843, 2000 WL 1801846 (S.D.N.Y. Dec. 7, 2000).

158. *Id.* at *1.

159. *Id.*

160. *Id.*

161. *In re Rezulin Prods. Liab. Litig.*, No. CIV.00 CIV.2843 LAK, 2002 WL 24475 (S.D.N.Y. Jan. 10, 2002).

162. *Id.* at *1.

163. *Id.* (internal quotation marks omitted). In reaching this conclusion, the court seemed to suggest that the real crux of the determination was whether the information would allow a discovering party to identify a patient. See *id.* at *1–*2. This is reflected by the court’s explanation that the parties could redact “any other information which counsel for the subpoenaed party in good faith believes may lead to discovery of the patient’s identity.” *Id.* at *2. This decision also seems to wander, albeit unwittingly, into the realm of mandatory adverse event reports, insofar as it discusses reports made “under compulsion of law.” *Id.* at *1.

plaintiffs in the suit.¹⁶⁴ The second decision, however, may have strayed from the FDA's intent: if the FDA's goal was to prevent the disclosure of identifying information generally, allowing for the disclosure of information relating to individuals *other than* reporters may have frustrated that intent.¹⁶⁵ Recall that, by its own terms, 21 C.F.R. § 20.63 applies to any person associated with a voluntary adverse event report, rather than to the voluntary reporter alone.¹⁶⁶

In 2004, the District Court for the Northern District of California considered 21 C.F.R. § 20.63 in *Contratto v. Ethicon, Inc.*, discussed previously.¹⁶⁷ In *Contratto*, the court referenced the regulation in arguing the necessity and purpose of 21 U.S.C. § 360i(b)(3), explaining that 21 C.F.R. § 20.63 was intended to foster confidentiality, rather than preclude discovery.¹⁶⁸ Notably, the court ruled that all discoverable reports, voluntary or mandatory, must be produced in redacted form.¹⁶⁹ This ruling seems to have complied with the FDA's stated intent, in that whatever disclosure was allowed did not include any information that would allow for the identification of reporters, nor of parties in the reports.¹⁷⁰

The District Court for the Middle District of Georgia interpreted 21 C.F.R. § 20.63 in July 2009, in *In re Mentor Corp. Obtape Transobturators Sling Products Liability Litigation*.¹⁷¹ In entertaining plaintiffs' motion to compel discovery, the court noted that the FDA "intended [§ 20.63] to place an affirmative duty of confidentiality on manufacturers."¹⁷² The court therefore ruled that the defendant manufacturer "may accordingly redact the names of the U.S. physicians" appearing in any reports.¹⁷³ Again, this ruling seems to fall in line with the FDA's stated intent.¹⁷⁴

The most recent decision to interpret 21 C.F.R. § 20.63 was *In re Panacryl Sutures Products Liability Cases*, decided by the District Court for the Eastern District of North Carolina in August 2010.¹⁷⁵ The court entertained the plaintiffs' motion to compel discovery and the defendants' motion for a protective order, among others.¹⁷⁶ Plaintiffs sought discovery of a list of physicians' names that had been given to a third-

164. *In re Rezulin*, 2000 WL 1801846, at *1.

165. *In re Rezulin*, 2002 WL 24475, at *1.

166. See 21 C.F.R. § 20.63 (2010).

167. *Contratto v. Ethicon, Inc.*, 225 F.R.D. 593 (N.D. Cal. 2004); see discussion *supra* Part III.B.3.

168. *Contratto*, 225 F.R.D. at 596. The court explained that confidentiality could be protected via redaction, without taking the drastic measure of precluding discovering entirely. See *id.* at 596–98.

169. *Id.* at 599. While the court did not cite 21 C.F.R. § 20.63 in offering this ruling, it must have been the primary—if not the only—consideration in determining that all discoverable reports were subject to redaction of identifying information.

170. See discussion *supra* Part III.C.

171. 632 F. Supp. 2d 1370 (M.D. Ga. 2009).

172. *Id.* at 1376.

173. *Id.* at 1379. The court noted, however, that the defendant presented no evidence, and indeed no case set favorable precedent, such that the defendant should be allowed to redact the names of *foreign* physicians. *Id.* at 1375–76.

174. See discussion *supra* Part III.C.

175. No. 5:08-MD-1959-BO, 2010 WL 3062811 (E.D.N.C. Aug. 3, 2010).

176. *Id.* at *1.

party physician serving as a consultant, where all of the identities sought were those of voluntary reporters.¹⁷⁷ Agreeing with the defendants that 21 C.F.R. § 20.63 prohibits disclosure of the identities of voluntary reporters, even when possessed by a third party, the court granted defendants' motion for protective order with respect to those identities.¹⁷⁸

It appears the Eastern District of North Carolina's decision follows the intent of the FDA. Although 21 C.F.R. § 20.63 does not discuss treatment of voluntary reporters' identities once those reports have been shared with a third party—here, a corporate consultant—the court accurately noted that “[p]laintiffs are trying to get from [the consultant] what they could not get from [d]efendants,” and that, “[i]n light of the policy of encouraging voluntary reporting, it would be inapposite to hold that 21 C.F.R. § 20.63(f) does not apply to a survey commissioned by a manufacturer or where a physician voluntarily responds to a survey undertaken by a manufacturer.”¹⁷⁹ Later in its opinion, the court held that any complaints or complaint forms the defendants were required to produce “may be redacted in order to comply with 21 C.F.R. § 20.63(f),” again in line with the FDA's intent for that provision.¹⁸⁰

3. State Court Decisions

To date, only one published state court decision has interpreted 21 C.F.R. § 20.63. In 2003, in *Low v. Hoffman-La Roche Inc.*, a Texas district court delivered a protective order, ruling that defendants may redact “names, addresses, and other identifying information pertaining to” research subjects, patients, adverse event reporters, and any other individuals whose identities would be protected under several regulations, including 21 C.F.R. § 20.63.¹⁸¹ Thus, the Texas state court followed the decisions of many federal courts in ruling that 21 C.F.R. § 20.63 requires redaction of personally identifying information from medical device adverse event reports prior to production.¹⁸² And, like so many federal courts, the Texas court seemed to fall in line with the FDA's stated intent for voluntary adverse event reports.¹⁸³

IV. RECOMMENDATION

This Part presents three considerations for each of the statute and regulation: how courts should apply the statute or regulation based on plain language; how courts should apply the statute or regulation based on stated congressional and regulatory intent; and how Congress and the

177. *Id.*

178. *Id.* at *2.

179. *Id.* at *1.

180. *Id.* at *2.

181. No. 2001-61586, 2003 WL 25318131, ¶ 14 (Dist. Ct. Tex. Feb. 4, 2003).

182. *Id.*

183. See discussion *supra* Part III.C.

FDA should amend the statute and regulation, respectively, to reflect underlying intent more clearly.

A. *Mandatory Adverse Event Reports*

1. *Applying the Statute as Written*

If mandatory adverse event reports cannot be admitted into evidence, and cannot otherwise be used in civil litigation, there can be little value added by forcing manufacturers and distributors to produce those reports, which may in some cases number into the thousands.¹⁸⁴ Conversely, the statute, on its face, does not preclude *discovery* of those reports; rather, it simply precludes admission and use of the reports at trial.¹⁸⁵ Even then, however, the merit in allowing plaintiffs access to those reports—tempered by the burden placed upon defendants in having to produce them—is particularly tenuous, given that plaintiffs have unfettered access to redacted adverse event reports via MAUDE.¹⁸⁶ Thus, it seems that mandatory adverse event reports should not be discoverable, given both the plain language of 21 U.S.C. § 360i(b)(3) and the existence of the MAUDE database. Under the statute as written, then, the Eighth Circuit in *In re Medtronic, Inc.*—followed begrudgingly by the District Court for the Eastern District of Arkansas in *Adcox v. Medtronic*—made the right decision by precluding discovery of mandatory adverse event reports.¹⁸⁷ At the very least, courts might look upon discovery cost-shifting measures favorably should defendants be forced to incur potentially extensive costs in producing mandatory adverse event reports.

2. *Applying the Statute as Congress Intended*

Remembering that Congress's real purpose in passing 21 U.S.C. § 360i(b)(3) was to ensure increased adverse event reporting by health professionals and others, and that precluding admission of mandatory adverse event reports may have been nothing more than a means to achieve that end, it is less clear whether precluding discovery of mandatory adverse event reports is necessary.¹⁸⁸ Intuitively, if parties comply with rules regarding redaction of identifying information, precluding discovery of adverse event reports would be an unnecessary corollary to the existing regulatory framework.¹⁸⁹ If Congress hoped to incentivize great-

184. For example, in each of the Medtronic decisions, adverse event reports for over 4000 pacemaker lead recipients were at issue. See *In re Medtronic, Inc.*, 184 F.3d 807, 809 (8th Cir. 1999); *Adcox v. Medtronic, Inc.*, 131 F. Supp. 2d 1070, 1072 (E.D. Ark. 1999).

185. See 21 U.S.C. § 360i(b)(3) (2006).

186. See *supra* notes 42–44 and accompanying text.

187. See *In re Medtronic*, 184 F.3d at 811–12; *Adcox*, 131 F. Supp. 2d at 1076.

188. See discussion *supra* Part III.

189. Assuming perfect compliance, such a scheme theoretically would ensure that Congress's goal of protecting adverse event reporters would succeed. That said, perfect compliance may or may not be a reasonable assumption.

er adverse event reporting among health professionals and others, however, and thought that protecting the identities of reporters was the most effective means to reach that goal, it must be the case—at the very least, on the margins—that precluding discovery of mandatory adverse event reports is the right decision.

As Congress apparently saw it, preventing disclosure of adverse event reporters' identities was necessary to ensure that individuals would comply with a mandatory reporting scheme.¹⁹⁰ That being said, it necessarily is the case that preventing discovery of redacted or unredacted reports would provide reporters with greater peace of mind than preventing admission of redacted reports at trial. By way of example, if a party is entitled to discovery of mandatory adverse event reports, it must be the case that there is a better chance that the party will gain access to reporters' identities, even if that chance is slim—perhaps due to a clerical error in disclosing those identities in reports that should have been redacted, given that such discovery requests easily can reach thousands of reports¹⁹¹—than if the reports are not discoverable in the first place. Stated differently, identities cannot be disclosed, even inadvertently, if the reports are not discoverable.¹⁹² Therefore, precluding discovery of mandatory adverse event reports likely would build reporters' faith that their identities will remain confidential—at least, to a greater extent than if those reports were discoverable in redacted form—resulting in higher rates of adverse event reporting, in line with Congress's intent. Thus, although the Eighth Circuit did not explain its reasoning at great length,¹⁹³ it seems that the court made the correct decision regarding adverse event report discoverability based on Congress's underlying intent.

3. *Amending the Statute to Reflect Congressional Intent*

Congress needs to clarify its wishes. As has been demonstrated, courts do not agree on the appropriate interpretation of 21 U.S.C. § 360i(b)(3) as it relates to the discoverability of mandatory adverse event reports. If Congress truly wants to bar discovery of all mandatory adverse event reports—an understandable goal, since that approach most distinctly and effectively protects the identities of reporters—all Congress needs to do is amend the language of 21 U.S.C. § 360i(b)(3). If, however, the converse is true—if Congress did not envision barring discovery of mandatory adverse event reports, and thought that barring admission of those reports into evidence would be sufficient to protect the identities of reporters—Congress just as easily could clarify that mandatory adverse event reports *are* discoverable, again by amending

190. See *supra* notes 66, 71 and accompanying text; see also discussion *supra* Part III.A.2.

191. See *supra* note 184.

192. Particularly, and most importantly, human error could not enter the calculus.

193. See *In re Medtronic, Inc.*, 184 F.3d 807, 811 (8th Cir. 1999); see also discussion *supra* Part III.B.1.

the language of 21 U.S.C. § 360i(b)(3). That alternative makes little sense, however, given that Congress went so far as to say that such reports, in addition to not being admissible, cannot be “otherwise used” in litigation.¹⁹⁴ Either way, Congress can—and, given the disagreement among courts, should—amend the statute to clarify its intent, and that amendment seemingly should favor nondiscoverability of adverse event reports in litigation between private parties. Meanwhile, given the struggle many courts have experienced in distinguishing mandatory from voluntary adverse event reports, it would be a worthwhile endeavor to expressly relegate rules regarding voluntary reports to FDA regulations—specifically including 21 C.F.R. § 20.63—as well.

4. *In Sum*

Mandatory adverse event reports should not be discoverable for at least two reasons. First, precluding discovery of those reports serves as the best possible incentive to would-be reporters, assuring them that their identities will not—indeed, cannot—be disclosed. Some might argue that a similar result theoretically could be attained by simply requiring redaction of identifying information from mandatory reports prior to disclosure. Given the possibility of human error, however, at least on the margins—particularly in the cases of discovery requests for reports numbering easily into the thousands—the safest and most definite way to prevent disclosure of any identifying information contained in mandatory adverse event reports is to simply preclude disclosure of those reports in the first place.

Second, and perhaps more importantly, precluding discovery of mandatory adverse event reports avoids imposition of a seemingly unnecessary and definitely imbalanced burden on defendant manufacturers and distributors. Specifically, if mandatory adverse event reports cannot be admitted into evidence, nor otherwise used, in civil litigation, the benefit to plaintiffs of receiving those reports cannot approximate the burden placed upon defendants of requiring them to produce those reports. This effect is heightened in cases in which the reports are stored in a proprietary format, number into the thousands, and so on. Thus, to the extent courts label mandatory adverse event reports discoverable, those courts should consider cost-shifting measures for discovery as well.

B. *Voluntary Adverse Event Reports*

1. *Applying the Regulation as Written*

The regulation, by its plain language, explicitly applies to voluntary reports.¹⁹⁵ Concurrently, the regulation explicitly focuses on the protec-

194. 21 U.S.C. § 360i(b)(3) (2006).

195. 21 C.F.R. § 20.63(f) (2010).

tion of identities of reporters and subjects, rather than the discoverability of those reports.¹⁹⁶ Because there is no suggestion in the plain language of the regulation that voluntary reports should not be discoverable—nor, in contrast to 21 U.S.C. § 360i(b)(3), that such reports should not be admissible into evidence—there is no reason for courts to deny discovery of these reports.¹⁹⁷ Of course, reports must be produced in redacted form, unless an exception applies, to comply with the provisions of the statute; but this seemingly is the only limitation envisioned by 21 C.F.R. § 20.63(f).¹⁹⁸

This being the case, most courts have complied with the regulation as written. Indeed, with the exception of the *In re Medtronic, Inc.* and *Adcox v. Medtronic* decisions—the latter being bound by precedent to the former—all courts considering the discoverability of voluntary adverse event reports generally agree on this conclusion.¹⁹⁹

2. *Applying the Regulation as the FDA Intended*

It would seem that the FDA meant exactly what it said. Just as the plain language suggests, the FDA intended to protect the identities of voluntary reporters as a means to encourage ongoing voluntary reporting by health professionals and others when their reports fall outside the scope of 21 U.S.C. § 360i(b)(3).²⁰⁰ Thus, the same conclusion holds: courts ruling that voluntary reports are discoverable, albeit in redacted form—the conclusion reached by the vast majority of courts considering the issue²⁰¹—correctly (if sometimes inadvertently) gauged the FDA’s intent on the issue.

3. *Amending the Regulation to Reflect the FDA’s Intent*

Given that a federal appellate court construed 21 C.F.R. § 20.63(f) as barring discovery of voluntary adverse event reports,²⁰² the FDA should consider revising its regulation to clarify that voluntary adverse event reports are discoverable, albeit in redacted form.²⁰³ For the sake of clarity, the FDA also might consider listing 21 U.S.C. § 360i(b)(3) as a specific example of a “Federal statute . . . [requiring reporters] to make adverse event reports,” as well, as such clarification would highlight the

196. *Id.*

197. *See id.*; *see also* discussion *supra* Part II.B.1.

198. *See* 21 C.F.R. § 20.63(f).

199. *See* discussion *supra* Part III.D; *see also In re Medtronic, Inc.*, 184 F.3d 807 (8th Cir. 1999); *Adcox v. Medtronic, Inc.*, 131 F. Supp. 2d 1070 (E.D. Ark. 1999).

200. *See* discussion *supra* Parts II.B.1, III.C.

201. *See* discussion *supra* Part III.D.

202. *See In re Medtronic*, 184 F.3d at 811–12.

203. The listed exceptions, of course, still would apply. *See* 21 C.F.R. § 20.63(f)(1) (2010).

difference between mandatory and voluntary reports—which seemingly is lost on many courts.²⁰⁴

4. *In Sum*

Just as is the case for mandatory reports, the best and most definite way to prevent the inadvertent disclosure of identifying information in voluntary adverse event reports would be to preclude discovery of those reports as a general matter. Specific to voluntary reports, however, there is nothing suggesting that those reports cannot be admitted into evidence, nor otherwise used, in civil litigation. Therefore, the burden placed on defendants in having to produce those reports may not so significantly outweigh possible benefits to plaintiffs that discovery should be barred as a policy matter. Therefore, it seems that discovery of those reports in redacted form is acceptable—even including the risk of inadvertent disclosure of identifying information due to human error. This effect is heightened by the fact that reporters were not required to make reports in the first place.

V. CONCLUSION

More than thirty years after the Dalkon Shield caused serious injuries and deaths among the women who used it, the United States has become a much safer place in terms of medical device use and tracking. Even now, however, it is not clear whether people injured by medical devices may obtain discovery of adverse event reports relating to serious illnesses, serious injuries, or death, in civil litigation suits against device manufacturers and distributors. The issue of discovery of voluntary reports stemming from less-serious illnesses and injuries is more settled. The language of the pertinent regulation and its underlying intent are much clearer, and cases considering the issue generally have trended toward the correct outcome: deciding that voluntary adverse event reports are discoverable in redacted form. Meanwhile, Congress needs to clarify its intent regarding mandatory reports by changing the relevant statutory language to specifically preclude or allow discovery of mandatory adverse event reports, though statutory language, underlying intent, and external realities (e.g., the MAUDE database) work together to suggest that the reports should not be discoverable. Either way, nothing more than a simple adjustment to statutory language is needed. And, given the confusion experienced by courts attempting to interpret the statute, that adjustment is long overdue.

204. *Id.* § 20.63(f). For examples of instances in which courts may have blurred the line(s) between mandatory and voluntary reports, see discussion *supra* Parts III.B, III.D.