No. 98-3804 EALR

IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

IN RE: MEDTRONIC, INC., PETITIONER

ON PETITION FOR A WRIT OF MANDAMUS OR WRIT OF PROHIBITION
TO THE DISTRICT COURT FOR THE EASTERN DISTRICT OF ARKANSAS,
WESTERN DIVISION

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE IN SUPPORT OF THE PETITIONER, URGING THE COURT TO GRANT THE WRIT

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Pursuant to Rule 29, Fed. R. App. P., and the invitation of the Court, the United States submits this brief as amicus curiae to address the application of federal law and regulation to the discovery order under challenge in this litigation.

INTEREST OF THE UNITED STATES

The discovery order at issue concerns the use of information in reports about possible serious defects in a medical device (heart pacemakers). Vigorous reporting about adverse events related to the use of regulated medical devices, drugs and biologic products (blood products, vaccines, venoms, etc.) is an essential tool to protect the public health.[1] In order to

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[1] See 21 U.S.C. 355(e) & (k), 21 C.F.R. 314.80 (drugs); 21 U.S.C. 360i, 21 C.F.R. Part 803 (devices); 42 U.S.C. 262(d), 21 C.F.R. 600.80 & 606.170(b) (biologics) (establishing reporting and recordkeeping requirements for purposes of determining whether public health actions – such as manufacturer recalls,

maximize reporting of such events and to prevent such reports from being deterred by privacy concerns or the prospect of involvement in litigation, federal law imposes strict restrictions on the use of adverse event reports in private lawsuits.

Of particular relevance to this case, a federal statute, 21 U.S.C. 360i(b)(3), prohibits reports from certain sources concerning serious adverse events involving medical devices ("device user reports")[2/] from being admitted in evidence "or otherwise used" in private litigation, unless the reporter knew the information to be false. In addition, a federal regulation, 21 C.F.R. 20.63(f), protects certain information in adverse event reports that are voluntarily made by health professionals and medical patients. The regulation, relying in part on §360i, prohibits the Food and Drug Administration (FDA) or "a manufacturer in possession of such reports" from disclosing,

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public health alerts, or new labeling requirements — may be necessary for such products).

[2/] The prohibition of §360i(b)(3) covers reports by a "device user facility" (a "hospital, ambulatory surgical facility, nursing home, or outpatient treatment facility which is not a physician's office," 21 U.S.C. 360i(b)(6)(A)), or by an employee or formal affiliate of the facility, or by a "physician who is not required to make such a report," of information that suggests that a device either has "caused or contributed to the death of a patient of the facility" or "may have caused or contributed to the serious illness of, or serious injury to, a patient of the facility." 21 U.S.C. 360i(b)(1).

without consent, "information that would identify the voluntary reporter or any other person associated with an adverse event involving a human drug, biologic, or medical device product * * * in response to a request, demand, or order," §20.63(f), and it further provides that "neither FDA nor any manufacturer in possession of such reports shall be required to seek consent [of the voluntary reporter or person identified in the report] for disclosure." §20.63(f)(1)(i). (Both the statute and the regulation are set out in full in the Addendum to this brief.)

In the underlying products liability action, petitioner Medtronic, Inc. ("Medtronic"), a heart pacemaker manufacturer, has been directed by the district court to contact some 4,000 or so patients who received certain Medtronic pacemaker leads and for whom Medtronic apparently filed Medical Device Reports ("MDRs") with the FDA.[3/] Medtronic has been directed to offer each lead recipient the opportunity to waive physician/patient privilege by contacting plaintiff's counsel, who could then obtain any

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[3/] See 21 C.F.R. Part 803 (Medical Device Reporting).

information from them that might be relevant to this action. Pet. Add. iii; Pet. Add. ii (Form Letter).[1]

It is highly probable that the records from which Medtronic is to draw the names of persons to receive the court-ordered correspondence may come within the scope of either 21 U.S.C. 360i(b)(3) or 21 C.F.R. 20.63(f), or both. That is, they may either be reports made under §360i(b)(1)[2] by a device user facility, its employee or affiliate, or a physician who is not required to make such a report; and/or they may contain information that would identify a voluntary reporter or other person associated with an adverse event. To the extent any such reports are involved, the United States has a substantial interest in enforcing both the statute and the regulation, as applicable. Both the statute and the regulation are designed to preserve and enhance the reporting of information essential to the statutorily-required post-approval safety surveillance of regulated products, by shielding the reporting process from the pressures of private litigation. See H.R. Rep. 101-808 at 21 (1990), reprinted in 1990 U.S.C.C.A.N. 6305, 6314-15 (explaining

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[1] "Pet. Add." refers to the Addendum to the Petition filed by Medtronic in this Court.

[2] Because the defect at issue here involves heart pacemakers, it clearly satisfies §360i's standard of seriousness for triggering a report.

§360i(b)(3)); 59 Fed. Reg. 3944 (Jan. 27, 1994) (explaining proposed rule 21 C.F.R. 20.63(f)).

Neither the district court nor the parties considered whether the use of Medtronic's MDRs to contact lead recipients for purposes of this litigation violates 21 U.S.C. 360i(b)(3). This error must be corrected. Moreover, the district court's order frankly and directly violates 21 C.F.R. 20.63(f), both by requiring a manufacturer to seek a patient's consent to waive confidentiality, and by inevitably leading to the disclosure of voluntary reporters' identities without their consent. This, too, was clear legal error. Because critical federal public health policy interests are sacrificed if these provisions are not enforced in the discovery process, the United States has a substantial interest in their enforcement by writ of mandamus in this case.

STATEMENT OF THE ISSUE

The United States will address the following issue:

Whether a writ of mandamus should issue to compel the district court to comply with 21 U.S.C. 360i(b)(3) and 21 C.F.R. 20.63(f).

In re Bieter Co., 16 F.3d 929 (8th Cir. 1994)

Hillsborough County Florida v. Automated Med. Lab., Inc., 471 U.S. 707 (1985)

Capital Cities Cable, Inc. v. Crisp, 467 U.S. 691 (1984)

Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984)

Fed. R. Evid. 501

STATEMENT OF THE CASE

Plaintiff Doris Adcox, a recipient of a Medtronic pacemaker with a defective lead that had to be surgically replaced, brought the underlying products liability action against Medtronic in federal district court, invoking the court's diversity jurisdiction. Pet. App. 3-5. Other recipients of this particular pacemaker and related models had also had to have it replaced due to defective leads, following Medtronic's report of the problem to FDA and issuance of an Urgent Health Safety Alert to hospitals and physicians. Pet. App. 5-6; 11. Plaintiff served discovery requests on Medtronic seeking names of patients, physicians and hospitals that also were involved with the defective pacemakers, and the names of any physicians who reported problems with the pacemakers to Medtronic. Pet. App. 84-90. Medtronic opposed the discovery request as violating 21 C.F.R. 20.63 and the Arkansas patient/physician privilege. Pet. App. 95-157; 165-182; 201-203; 228-230.[6]

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[6] Medtronic also pointed out that plaintiff can obtain the substance of the relevant adverse event reports with the information identifying the patient and voluntary reporter redacted. See id. & 21 C.F.R. 20.111 (FDA Freedom of

The district court agreed that discovery of patient and physician information is prohibited by 21 C.F.R. 20.63 and the Arkansas patient/physician privilege, and accordingly Medtronic could not be required to disclose such information directly. Pet. App. 281. However, by order issued October 28, 1998, the court concluded that Medtronic could be directed to send a letter to recipients of Medtronic pacing leads for whom Medtronic "apparently filed a Medical Device Report" with FDA, to notify them of the present action and offer them "an opportunity to waive their physician/patient privilege" by contacting plaintiff's counsel, whereupon "Plaintiff would be free to obtain any information from the letter recipients 'relevant to the subject matter involved in the pending action' even if the information arguably would not be admissible." Pet. Add. iii; Pet. Add. ii (Form Letter).

The district court acknowledged that the "plain meaning" and "clear intent" of 21 C.F.R. 20.63(f) would prohibit such correspondence, but concluded that the regulation was invalid because it conflicted with Federal Rule of Evidence 501, which provides that state law will govern privilege issues in diversity cases. Pet. Add. v-vi. In addition, the court held

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Information Act regulation permitting release of redacted reports).

that because §20.63(f) only expressly mentions "adverse event reports," it is not even implicated with respect to lead recipients who can be identified in Medtronic's "complaint files." Pet. Add. vii-viii.

This Court stayed the discovery order pending resolution of Medtronic's petition for mandamus or prohibition. After receiving the parties' briefs, the Court solicited FDA's views on the matter.

SUMMARY OF THE ARGUMENT

1. To the extent compliance with the present discovery order requires Medtronic to rely on information from device user reports within the scope of 21 U.S.C. 360i(b)(3), the order flatly violates federal law. The statutory prohibition against such reports being admitted into evidence or "otherwise used" in private civil litigation comfortably embraces the use of such reports as a discovery tool in the manner allowed by the district court. Since it is virtually certain that some such reports are involved here, unless mandamus issues to prevent this illegal use of them, a federal statute and the important congressional policies it embodies are rendered a nullity in a way not correctable by any other means. Mandamus is therefore plainly appropriate. See In re Bieter Co., 16 F.3d 929 (8th Cir. 1994).

2. Mandamus is also necessary and appropriate to compel the district court to comply with 21 C.F.R. 20.63(f), because the policies it effectuates also cannot be vindicated in any other way. The regulation is a proper exercise of FDA's statutory authority to police the ongoing safety of regulated products, which requires a vibrant adverse event reporting system undeterred by concerns about privacy and involvement in litigation. FDA has determined that both aspects of §20.63(f) at issue here — the prohibition against unconsented disclosure of voluntary reporter- or patient-identifying information in adverse event records, and the prohibition against requiring FDA or a manufacturer to seek such consent — are essential to protect privacy and ensure that the threat of being haled into the quagmire of litigation does not chill reporting of adverse events. That judgment is entitled to deference.

Evidence Rule 501 has no effect on the regulation's validity. Rule 501 simply addresses the choice of privilege law for cases in federal courts, which for civil cases in which state law supplies the rule of decision, like this one, normally requires application of the state law of privilege. However, where the requirements of federal law validly preempt inconsistent state law, including any relevant state law of privilege, state law must give way, and Rule 501 does not

provide otherwise. Since FDA's regulation is a proper exercise of its delegated authority, under standard principles of federal law supremacy and preemption it must be enforced over the discovery order at issue here.

ARGUMENT

I. MANDAMUS LIES TO REQUIRE COMPLIANCE WITH 21 U.S.C. 360i(b)(3).

This Court will issue a writ of mandamus to correct a discovery order "when a court clearly fails to apply the proper legal standard and issues an order that, if complied with, will result in irremediable harm." In re Bieter Co., 16 F.3d 929, 933 (8th Cir. 1994). The failure even to consider the impact of 21 U.S.C. 360i(b)(3) in fashioning the discovery order here plainly meets this standard.[2/]

Section 360i(b)(3) embodies a policy judgment by Congress to shield medical device user reporting from the burdens and pressures of potential involvement private litigation, in order to ensure the freest possible flow of information about serious

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[2/] Indeed, it meets four of the five considerations noted in In re Bieter, 16 F.3d at 932 (citing cases), for granting mandamus relief ("no other adequate means, such as direct appeal, to attain relief"; "damage[] or prejudice[] * * * not correctable on appeal"; "clearly erroneous as a matter of law"; and "rais[ing] * * * issues of law of first impression"). The only criterion it does not meet is that it does not appear to be "an oft-repeated error, or * * * persistent disregard of the federal rules."

adverse events. See H.R. Rep. 101-808 at 21, supra, at 6315 ("providing [these] protections for those persons and entities doing the reporting is intended to encourage full reporting by device users"). Moreover, the broad and comprehensive terms prohibiting device user reports from being "admissible into evidence or otherwise used" in private civil litigation (unless the reporter knew it was false) creates a statutory privilege that is binding on federal courts, preempting any state law of privilege that might otherwise apply in a diversity case such as this one (see infra Points II.A & B.1). Fed. R. Evid. 501; C. Wright & K. Graham, Federal Practice & Procedure: Evidence § 5437 at 894-95 (1980) (a statutory privilege is created when, beyond providing that certain material is "confidential" or is "not admissible" in evidence, the statute requires consent or forbids the material from being "used for any purpose in any suit or action for damages"). Any discovery order that allows such a use irremediably nullifies Congress's policy and privilege. And, since by definition §360i(b)(3) applies in private litigation where the government is unlikely to be a party, enforcement of this privilege to protect critical federal interests necessarily falls to the court. Accordingly, mandamus lies to require the district court to take care that it does not violate 21 U.S.C. 360i(b)(3).

II. MANDAMUS LIES TO REQUIRE COMPLIANCE WITH 21 C.F.R. 20.63(f).

Insofar as information in voluntarily-submitted adverse event reports is involved, the discovery order also does irremediable violence to the policies and purposes of 21 C.F.R. 20.63(f), by requiring Medtronic to take actions contrary to the regulation's prohibitions against making contacts and revealing identities without consent, that FDA has determined will discourage voluntary adverse event reporting. Such damage to a vital source of public health information plainly cannot be corrected on appeal. The district court's refusal to enforce the regulation is also clearly erroneous as a matter of law. Mandamus is therefore warranted to enforce FDA's regulation as well.

A. Federal Rule Of Evidence 501 Has No Effect On The Application Of 21 C.F.R. 20.63(f) To This Case.

Contrary to the district court's conclusion, Federal Rule of Evidence 501 has no bearing on whether FDA's regulation validly preempts inconsistent state law. Rule 501 evolved from the controversy over whether to enact a complete system of codified federal evidentiary privileges for all cases in federal court that would displace the common law rules of privilege. See C. Wright & K. Graham, Federal Practice & Procedure: Evidence § 5421. Objections were raised both to the proposal to

effectively "freeze" the development of federal law of privilege, and to supplanting state evidentiary privileges where only a state law substantive issue was at stake. Id.; see also Advisory Committee Notes to the Rule. The resulting Rule 501[8] was a compromise, providing, in the first sentence, for the continued development of a federal common law of privilege by the federal courts (except where otherwise required by the Constitution, or provided by Act of Congress or statutorily-authorized rules issued by the Supreme Court), but requiring, in the second sentence, the application of state law of privilege to state law claims or defenses in civil cases (the "state law proviso").

Since this is a state law products liability case, it falls under the second sentence of the Rule and, all things being

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[8] Rule 501 provides:

> General Rule. Except as otherwise required by the Constitution of the United States or provided by Act of Congress or in rules prescribed by the Supreme Court pursuant to statutory authority, the privilege of a witness, person, government, State, or political subdivision thereof shall be governed by the principles of the common law as they may be interpreted by the courts of the United States in the light of reason and experience. However, in civil actions and proceedings, with respect to an element of a claim or defense as to which State law supplies the rule of decision, the privilege of a witness, person, government, State, or political subdivision thereof shall be determined in accordance with State law.

equal, state law would apply to determine privilege. See Harlan v. Lewis, 982 F.2d 1255, 1258 (8th Cir.), cert. denied, 510 U.S. 828 (1993) (in a diversity medical malpractice case, Rule 501 requires physician-patient privilege to be determined under state law).

However, there is nothing in Rule 501 that surrenders the federal legislative power to preempt state law, including state law of privilege. Where federal law has preempted state law of privilege, under standard principles of federal law supremacy and preemption the federal law becomes the law of the state for purposes of Rule 501. Thus, the only relevant question is whether FDA's regulation must be given effect under standard principles of federal supremacy and preemption.

B. FDA'S Regulation Is A Valid Preemption Of Inconsistent State Law.

1. Federal Law Supremacy And Preemption.

The Supremacy Clause of the United States Constitution states that "the Laws of the United States * * * shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2. Under standard principles of federal supremacy and preemption, even where Congress has not expressly or completely displaced state regulation in a specific area, state law is

nullified to the extent it actually conflicts with federal law. See Hillsborough County Florida v. Automated Med. Lab., Inc., 471 U.S. 707, 713 (1985). Such a conflict arises "when 'compliance with federal and state regulation is a physical impossibility' or when state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress'" (id., quoting Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-43 (1963) and Hines v. Davidowitz, 312 U.S. 52, 67 (1941)), or if state law interferes with the methods by which a federal law is designed to reach its goals, see International Paper Co. v. Ouellette, 479 U.S. 481, 494 (1987); Michigan Canners & Freezers Ass'n v. Agricultural Mktg. & Bargaining Bd., 467 U.S. 461, 477 (1984).

Moreover, the Supreme Court has "held repeatedly" (Hillsborough, id. at 713) that state laws that are not otherwise inconsistent with federal law can be preempted by a federal agency acting within the scope of its congressionally delegated authority, even without express congressional authorization to preempt. The Court has "made clear" that

> Federal regulations have no less preemptive effect than federal statutes. Where Congress has directed an administrator to exercise his discretion, his judgments are subject to judicial review only to determine whether he has exceeded his statutory authority or acted arbitrarily. When the administrator promulgates regulations intended to pre-empt state law, the court's inquiry is similarly limited: If

> [h]is choice represents a reasonable accommodation of conflicting policies that were committed to the agency's care by the statute, we should not disturb it unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned.

Capital Cities Cable, Inc. v. Crisp, 467 U.S. 691, 699 (1984) (citation and internal quotation marks omitted), citing Fidelity Fed. Sav. & Loan Ass'n v. De la Cuesta, 458 U.S. 141, 153-54 (1982), and United States v. Shimer, 367 U.S. 374, 383 (1961).

In refusing to enforce 21 C.F.R. 20.63(f) notwithstanding these well-established principles, the district court appears to have been under the erroneous impression that FDA's regulation is an attempt to preempt Rule 501 itself, and not just to preempt state law of privilege that might otherwise apply in accordance with the second sentence of the Rule. See Pet. Add. v-vi (noting that an FDA regulation is not a "Congressionally enacted law or rule established by the Supreme Court," and that "there has been no * * * direct delegation [from Congress] for the FDA to override a prior, explicit Congressional act [Rule 501]." In invalidating 21 C.F.R. 20.63(f) on this basis, the district court may have had in mind a line of authority indicating that, for a federal agency to preempt otherwise applicable federal law of privilege where it would apply under the first sentence of Rule 501, the agency must have specific congressional authorization to address the question of privilege

as such. See C. Wright & K. Graham, Federal Practice & Procedure: Evidence § 5437, at 896-97 ("'Act of Congress' does not include administrative regulations purporting to create a privilege or otherwise barring judicial access to evidence. * * * [T]he better view is that Congress has not given administrative tribunals any power to create privileges that are binding on courts") (footnotes omitted). See also In re Bankers Trust Co., 61 F.3d 465, 470 (6th Cir. 1995) ("[t]o allow a federal regulation issued by an agency to effectively override the application of the Federal Rules of Civil Procedure and, in essence, divest a court of jurisdiction over discovery, the enabling statute must be more specific than a general grant of authority * * *").

However, as is evident from their contexts, these observations concerned whether a federal agency has power to "preempt" a federal court's discovery rulings made under federal law of evidentiary privilege.[9/] They did not consider or address the standards for agency preemption of state law under the Supremacy Clause (which are well established, see Capital Cities

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[9/] Most of the cases cited in the treatise involved so-called "Touhy" regulations, see United States ex rel. Touhy v. Ragen, 340 U.S. 462 (1951), issued pursuant to an agency's general "housekeeping" authority over the conduct of employees, the performance of its business, and the custody, use and preservation of its records.

Cable, supra). Although superficially similar, the two situations are significantly different. Supremacy Clause analysis does not come into play in determining Congress's intended distribution of authority between coordinate branches of the federal government. Moreover, in the first sentence of Rule 501 Congress specifically assigned to the federal courts general authority to develop the law of evidentiary privileges where federal law claims and defenses are at issue. There thus may be some force to the view that a federal court is entitled to demand a clearer indication from Congress before giving way to an agency-created disclosure privilege in such cases.[10/] But federal court prerogatives are not at stake where the second sentence of Rule 501 requires the court to apply state privilege law for state law claims and defenses. Thus, a federal agency acting within its statutory authority does not require "super"-preemption authority to override state privilege law, but need only meet the usual requirements for overriding state law that "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," Hines v. Davidowitz, 312 U.S. at 67, or "interferes with the methods by

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[10/] If such an indication were needed here, it would be found in 21 U.S.C. 360i(b)(3), which certainly indicates that Congress intends FDA to be able to protect its adverse event reporting systems from interference by the pressures of private litigation.

which the federal statute was designed to reach [its] goal," International Paper Co. v. Ouellette, 479 U.S. at 494.

2. 21 C.F.R. 20.63(f) Meets The Standards For Preemption.

FDA's regulation readily meets these requirements. As FDA explained in introducing it, 21 C.F.R. 20.63(f) is firmly rooted in longstanding FDA policy and practice for carrying out one of its most critical statutory functions. 59 Fed. Reg. at 3944-47. Under the comprehensive system established by Congress for permitting the marketing of human drugs, biologics and medical devices, FDA's responsibilities do not end with approval after testing on a limited number of subjects, but continue with the post-approval surveillance of the safety of these products as they are more widely used. Id. Various statutory and regulatory provisions (including 21 U.S.C. 360i, discussed above) require manufacturers, and in some instances hospitals and other facilities, to maintain records of adverse experiences with FDA-regulated products and to report certain categories of adverse events to the FDA. See 21 U.S.C. 355(e) & (k), 21 C.F.R. 314.80 (drugs); 21 U.S.C. 360i, 21 C.F.R. Part 803 (devices); 42 U.S.C. 262(d), 21 C.F.R. 600.80 & 606.170(b) (biologics).[11]

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[11] See also 21 U.S.C. 356b (requirements for sponsor-conducted postmarket studies of drugs); 21 U.S.C. 360l (circumstances where Secretary may require postmarket surveillance by a device

Typically, manufacturers and others who are required to maintain records and report to FDA ("mandatory reporters") first learn of adverse events with FDA-regulated products from unaffiliated physicians or other health professionals who are not required to report to them or to the FDA ("voluntary reporters"). See 59 Fed. Reg. at 3945 & 3948. FDA itself also relies very heavily on voluntary reporters as a primary source of direct adverse event information. Id. at 3944-45. Thus, "[b]oth the voluntary and the statutorily required reporting systems for [FDA regulated products] ultimately depend on the willingness of the individual health care professionals to submit reports." Id. at 3945.

Voluntary adverse event reporting has been the initial catalyst for innumerable important public health actions by FDA (manufacturer recalls, public health alerts, additional labeling requirements, etc.). Recently, actions have been triggered by voluntary reporting of drug interactions with the popular antihistamine Seldane; potentially fatal allergic reactions to latex medical products; and potentially fatal cardiac and pulmonary effects of the diet drug combination Phen-Fen. See, e.g., 59 Fed. Reg. at 3945.[12]

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manufacturer).

[12] See also FDA's home page, www.fda.gov/medwatch/safety.htm.

Moreover, because adverse event reporting typically flows in both directions between FDA and the manufacturer as part of the adverse event reporting and investigative process, similar or identical volunteered adverse event reports will often be in the possession of both FDA and the manufacturer, regardless of who received the report first. 59 Fed. Reg. at 3945; see also id. at 3946 ("In general, the agency does not care whether the voluntary report goes directly to FDA or to the manufacturer -- as long as the event is reported"). As FDA noted in the rulemaking, many health professionals would be reluctant to volunteer this critical information to manufacturers or the FDA if they believed it could involve them or their patients in litigation, either as parties or witnesses. 59 Fed. Reg. at 3947 & 3950 (citing comments and empirical studies). FDA's ability to assure the confidentiality of patients and voluntary reporters involved in adverse event reporting -- whether the reports are held by FDA or the manufacturer -- is therefore essential to preserve an irreplaceable source of information of proven value to the fulfillment of its statutory duties.[13/] In

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[13/] The district court's offhand dismissal of FDA's concern as reflecting a "jaundiced view of the health care field" (Pet. Add. vi, n.1) is unwarranted and unsupported. The court's speculations about the likely motivations of multitudes of individual health professionals, and whether FDA is wise to take possible "selfish motivations" into account, do not displace FDA's judgment, based on long experience, as to how best to

addition, FDA is directed by statute to ensure that its reporting systems "have due regard for the professional ethics of the medical profession and the interests of patients," see 21 U.S.C. 355(k) & 360i(a), including the basic tenet of physician-patient confidentiality. 59 Fed. Reg. at 3948; see also 58 Fed. Reg. at 31597 (citing Department of HHS "policy of providing strict protection to the confidentiality of patient information").[14/]

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ensure the continued flow of information that it needs to meet its weighty public health responsibilities under the statutes it administers. See Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984).

[14/] Without effective confidentiality, FDA also may not continue to have access to the substantial amount of adverse event information concerning FDA-regulated products that comes from European sources. A European Community provision, Parliament and Council Directive 95/46, 1995 O.J. (L 281) 31, prohibits the transfer of personal health data from EC member states to other countries if the other country does not provide for adequate protection of that information. And, manufacturers could face irreconcilable requirements of reporting to the FDA under U.S. law information that they are forbidden to transmit under the EC directive.

For these reasons, beginning long before the promulgation of 21 C.F.R. 20.63(f), FDA has consistently protected the identities of both patients and voluntary adverse event reporters, although it will otherwise release the contents of the reports. See 21 C.F.R. 20.111(c)(3) (information in voluntarily submitted "[a]dverse reaction reports, product experience reports, consumer complaints, and other similar data shall be disclosed" by FDA under the Freedom of Information Act, but only after deletion of names and information that would identify "the person using the product" and "any third party involved with the report, such as a physician, hospital or other institution"). This provision (originally codified at 21 C.F.R. 4.111 (1975)) was included because the Commissioner concluded that:

> If such a pledge is not made, the possibility of persuading health professionals voluntarily to submit important adverse reaction information on marketed products to the Food and Drug Administration is substantially diminished, and indeed perhaps wholly destroyed. Such information is important to the Food and Drug Administration and to the public, since it may well lead to action by the Food and Drug Administration designed to protect the public health.

39 Fed. Reg. at 44616. Identifying information can be released only if the request for it is "accompanied by the written consent to such disclosure [by] the person who submitted the report to the [FDA] and the individual who is the subject of the

report." 21 C.F.R. 20.111(c)(3)(vi).[15]

FDA's optional forms for voluntary reporting of adverse events have also consistently assured confidentiality of information identifying patients or voluntary reporters. See 59 Fed. Reg. at 3947. In 1993, FDA implemented an improved reporting system called MEDWATCH, which continues to assure strict confidentiality for patient and reporter identities. See 58 Fed. Reg. 31596, 31598 (June 3, 1993) (see forms attached in Addendum).

In announcing MEDWATCH, FDA noted that it was aware of private litigants in state courts attempting to evade FDA's assurances of confidentiality by seeking adverse event reports from manufacturers, and that when courts were made aware of FDA's policies, such efforts were rejected. See Eli Lilly & Co. v. Marshall, 850 S.W.2d 155 (Tex. 1993); Stahl v. Rhee, 136 A.D. 2d 539, 523 N.Y.S. 2d 159 (1988); Wesley v. Rye, 490 So.2d 272 (La. 1986). See also Harris v. Upjohn Co., 115 F.R.D. 191 (S.D. Ill. 1987); and see Farnsworth v. Procter & Gamble, 101 F.R.D. 355 (N.D. Ga 1984), aff'd, 758 F.2d 1545 (11th Cir. 1985).

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[15] See also 21 C.F.R. §§ 314.430(e)(4), 601.51(e)(3) and 803.9(b), providing parallel protections against FOIA disclosure of identities of patients and voluntary reporters identified in reports required to be submitted to FDA concerning drugs, biologics and devices, respectively. (Proposed amendments to the biologics regulations, see 63 Fed. Reg. 40,858 (July 31, 1998), will not affect this).

Because of increasing concern about the existence of this potential "back door" to undermine FDA's longstanding assurances of confidentiality and frustrate the accomplishment of the full purposes and objectives of Congress (see Hillsborough, 471 U.S. at 713), the agency determined to end doubts about any possible loophole by explicit preemption. 59 Fed. Reg. 3944 (Jan. 27, 1994) (proposed rule 21 C.F.R. 20.63(f)); 60 Fed. Reg. 16962 (April 3, 1995) (final rule).

21 C.F.R. 20.63(f) precludes FDA or a manufacturer from complying with a "request, demand, or order" to disclose information that would identify a voluntary reporter or any person named in an adverse event report. It does not affect disclosure of identities of mandatory reporters, which may or may not be permitted under other federal statutes or regulations. Id. It also does not affect the disclosure of the substance of the reports themselves, apart from identifying information. See 21 C.F.R. 20.111. It allows disclosure of patient- or voluntary reporter-identifying information with written consent by both parties or their legal representative, §20.63(f)(1)(i), or pursuant to court order in medical malpractice litigation involving both parties, §20.63(f)(1)(ii), or disclosure of the report to the person who is the subject of the report, excluding third-party identities,

§20.63(f)(1)(iii). However, "neither FDA nor any manufacturer in possession of such reports shall be required to seek consent for disclosure" from the voluntary reporter or other person named in the report. §20.63(f)(1)(i).[16] FDA determined that this supplementary prohibition was necessary to prevent ready circumvention of the confidentiality requirement and to avoid creating new disincentives to reporting. 60 Fed. Reg. at 16964 ("If third parties could request or demand that FDA or manufacturers seek consent from the voluntary reporter and/or person named in the report, the practical effect would be to eliminate the protection given by FDA's regulations").

As this recitation comprehensively demonstrates, 21 C.F.R. 20.63(f) emanates from FDA's exercise of statutory authority and represents a reasonable accommodation of competing considerations arising under policies committed to the agency's care. See Capital Cities Cable, 467 U.S. at 699. The regulation carries forward FDA's consistent policy of protecting the confidentiality of voluntary adverse event reporters and patients in order to ensure the continued availability of this essential information, while making the substance of the reports themselves freely available to the maximum extent consistent

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[16] FDA was alerted to the need for this proviso from two comments, one submitted by a drug manufacturer, and one by a drug industry association. See 60 Fed. Reg. at 16964.

with this goal.

Indeed, because a litigant has ready access to the substance of the reports and remains free to use other means apart from FDA's adverse event reporting system (or the MDR system covered by 21 U.S.C. 360i(b)(3)), such as advertising, to attempt to identify patients or medical personnel who have relevant information and (consistent with patient/physician confidentiality) wish to come forward, the regulation does not significantly intrude upon civil court processes. It only preempts state law that "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," Hines v. Davidowitz, 312 U.S. at 67, or interferes with the methods by which a federal law is designed to reach its goals, see International Paper Co. v. Ouellette, 479 U.S. at 494. There is, moreover, no indication that the accommodation it represents is not one that Congress would have sanctioned, see Capital Cities Cable, supra, particularly in light of Congress's similar action in 21 U.S.C. 360i(b)(3). Accordingly, the regulation must be given its intended preemptive effect over any inconsistent state "law, rule, regulation or other requirement."

3. The District Court's Order Is Unlawful Insofar As It Involves Information From Voluntary Adverse Event Reporting, Including Such Information Contained In "Complaint Files."

To the extent it applies to information from voluntary adverse event reports, the district court's order in this case directly contravenes FDA's regulation, both by requiring a manufacturer to seek consent for the disclosure of identifying information, and by failing to recognize that consent must be obtained from both the voluntary reporter and the "person named" in the report. The requirement that both protected parties consent to disclosure of their identities is plainly essential to prevent one party from deliberately, inadvertently or inevitably revealing the identity of the other without consent. Moreover, FDA has determined, based on long experience with adverse event reporting, that if voluntary adverse event reports become the vehicle for any type of extraneous burden or annoyance to voluntary reporters or persons associated with the adverse event, even to the extent of being notified of private litigation and being asked to waive confidentiality, some number of the reports will not be forthcoming, with unknowable but certain detriment to the public health. See Harris v. Upjohn, 115 F.R.D. at 192 (recognizing that fear of being drawn into litigation, "[u]nfounded or not," can be a deterrent to a

physician's willingness to participate in medical research).[17] Particularly in light of the high stakes involved, FDA's judgment on this point cannot be characterized as arbitrary or beyond its statutory authority and competence; accordingly, it is controlling, and bars this discovery order. See Capital Cities Cable, supra; see also Chevron, supra.

The district court was further wrong in concluding that even if valid, the regulation would not protect identifying information in Medtronic's "complaint files." "Adverse event report" as used in 21 C.F.R. 20.63(f) is not a term of art limiting the regulation's scope and precluding its application to voluntary reporter- or patient-identifying information contained in a device manufacturer's Medical Device Reporting "complaint files." The "complaint files" that FDA requires device manufacturers to maintain in order to assure device safety and effectiveness, see 21 U.S.C. 360i & 21 C.F.R. 820.198, broadly encompass "any written, electronic, or oral

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[17] The disincentives to voluntary reporting are especially evident in the type of order here. A health professional whose patient receives such a contact may be called upon to quell the patient's concerns about how the patient's personal medical information came to the attention of the court, and the health professional also stands a good chance of being drawn into the litigation as a witness for trial or deposition, and/or being required to produce volumes of documents. Such daunting prospects will inevitably dampen the eagerness of health professionals to furnish adverse event information to FDA or a manufacturer in the future.

communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution." 21 C.F.R. 820.3(b) (emphasis added). Thus, such files can easily include voluntarily submitted adverse event reports within the scope of 21 C.F.R. 20.63(f) (and indeed they also could include the device user reports covered by 21 U.S.C. 360i(b)).

Device manufacturers must evaluate, and if necessary investigate and report, each complaint received, and must maintain a record of all action taken. 21 C.F.R. 820.198(a)(3), (b)-(e). Some complaints may concern events triggering mandatory reports to FDA under Medical Device Reporting requirements. Id.; see 21 U.S.C. 360i. However, a person reporting an adverse device event cannot necessarily know in advance how the report will be categorized, and has no control over how the manufacturer may file it. FDA's interest in protecting voluntary reporter and patient confidentiality, and in protecting voluntary reporting from the pressures of litigation, is therefore equally relevant to "complaint files," and 21 C.F.R. 20.63(f) applies. Moreover, this is true even for complaints volunteered by patients themselves, who might be less forthcoming with their personal medical information

if they find it could lead to their being importuned on behalf of private litigants.

Finally, there is plainly no merit to plaintiff's argument (see Opp. to Petition for Writ of Mandamus at 13-14) (which the district court did not even address) that 21 C.F.R. 20.63(f) operates "retroactively" to deprive her of vested rights. A rule of evidentiary privilege governs the process of the court, not the antecedent conduct of the parties giving rise to the suit. See Landgraf v. USI Film Prod., 511 U.S. 244, 275 (1994) ("Because rules of procedure regulate secondary rather than primary conduct, the fact that a new procedural rule was instituted after the conduct giving rise to the suit does not make application of the rule at trial retroactive"); see also id. at 291 (Scalia, J., concurring) ("A new rule of evidence governing expert testimony, for example, is aimed at regulating the conduct of trial, and the event relevant to retroactivity of the rule is introduction of the testimony").[18/]

Section 20.63(f), which became effective in July 1995, was in place long before plaintiff sought to make the prohibited use Medtronic's adverse event records as a discovery tool in this case — indeed it was in effect well before she filed this suit

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[18/] For these same reasons, the privilege established in 21 U.S.C. 360i(b)(3), enacted 1990, also does not operate "retroactively."

in 1996. The regulation does not govern any substantive right she may have to recover for the alleged conduct of Medtronic giving rise to her injuries, nor does it reach back to attach new legal consequences to that conduct or any prior conduct by the parties. See Landgraf, 511 U.S. at 270. It only affects the evidentiary procedures by which plaintiff may now seek to enforce her rights, and "[n]o one has a vested right in any given mode of procedure." Id. at 291 (Scalia, J., concurring) (internal quotation marks and citations omitted). Moreover, the applicability of 21 C.F.R. 20.63(f)'s evidentiary privilege does not depend on whether particular adverse event reporters relied on its precise terms when they made their reports (cf. Opp. to Petition for Mandamus at 18). Rather, by its plain language, the regulation imposes a present limitation on the use of all voluntary adverse event reports, to effectuate longstanding, ongoing and preemptive federal public health policies that depend on the continued flow of such reports.

CONCLUSION

For the foregoing reasons, the Court should grant mandamus and direct the district court to comply with 21 U.S.C. 360i(b)(3) and 21 C.F.R. 20.63(f).

Respectfully submitted,

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