

**United States Court of Appeals
FOR THE EIGHTH CIRCUIT**

No. 98-3804

In re: Medtronic, Inc.,

Petitioner.

* On Application for a Writ
* of Mandamus.
*

Submitted: November 16, 1998

Filed: July 26, 1999

Before BEAM, LOKEN, and MORRIS S. ARNOLD, Circuit Judges.

BEAM, Circuit Judge.

Petitioner seeks a writ of mandamus or, in the alternative, a writ of prohibition soliciting relief from two discovery orders entered in a products liability case pending in the federal District Court for the Eastern District of Arkansas. The underlying action, Doris Adcox v. Medtronic, Inc., No. LR-C-96-333, invokes the diversity jurisdiction of the court. We earlier stayed the disputed orders and now grant a writ of mandamus.

I. BACKGROUND

Adcox, a recipient of a Medtronic heart pacemaker with an allegedly defective "lead,"¹ seeks 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.

Medtronic apparently maintains a document repository that includes copies of Medical Device Reports (MDRs) generated under regulations adopted by the federal Food and Drug Administration (FDA). The Medical Device Amendments to the Food, Drug, and Cosmetics Act (FDCA), in part, provide:

Every person who is a manufacturer or importer of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness.

21 U.S.C. § 360i(a) (emphasis added).

The statute also states that, "The Secretary may by order require a manufacturer to adopt a method of tracking a Class II or Class III device," if the device could fail under circumstances similar to those experienced by Adcox. See id. at § 360i(e). A pacemaker lead is, as we understand it, a Class III medical device. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 477 (1996). In addition to this specific rulemaking and order authority, the FDCA also provides the FDA with general rulemaking power pursuant to 21 U.S.C. § 371(a) (authority vested in secretary to promulgate regulations for enforcement of the FDCA).

¹A lead is an electrical cable used to carry information between the heart and the generator portion of the pacemaker.

Based upon this statutory authority, and to further congressional policy adopted by the Act, the FDA has established a voluntary system of medical device reporting by healthcare professionals, and, in conjunction with this system, has promulgated 21 C.F.R. § 20.63(f) which provides:

(f) The names and any 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 shall not be disclosed by the Food and Drug Administration or by a manufacturer in possession of such reports in response to a request, demand, or order. Information that would identify the voluntary reporter or persons identified in the report includes, but is not limited to, the name, address, institution, or any other information that would lead to the identities of the reporter or persons identified in a report. This provision does not affect disclosure of the identities of reporters required by a Federal statute or regulation to make adverse event reports. Disclosure of the identities of such reporters is governed by the applicable Federal statutes and regulations.

(1) *Exceptions.* (i) Identities may be disclosed if both the voluntary reporter and the person identified in an adverse event report or that person's legal representative consent in writing to disclosure, but neither FDA nor any manufacturer in possession of such reports shall be required to seek consent for disclosure from the voluntary reporter or the person identified in the adverse event report or that person's legal representative; or

(ii) Identities of the voluntary reporter and the person who experienced the reported adverse event may be disclosed pursuant to a court order in the course of medical malpractice litigation involving both parties; or (iii) The report, excluding the identities of any other individuals, shall be disclosed to the person who is the subject of the report upon request.

(2) *Preemption.* No State or local governing entity shall establish or continue in effect any law, rule, regulation, or other requirement that permits or requires disclosure of the identities of the voluntary reporter or other person identified in an adverse event report except as provided in this section.

The validity of this regulation constitutes the fighting issue in this discovery dispute. This is because the district court has 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." Adcox v. Medtronic, Inc., No. LR-C-96-333 (E.D. Ark. Oct. 28, 1998) (order granting discovery). As noted by the district court, the contact, in the form of a proposed letter prepared by Adcox's lawyers and apparently approved by the court, gives the (4000 or so) lead recipients an opportunity to waive their physician/patient privilege. Adcox contends that the purpose of this letter is to gather evidence to help her prove the liability of Medtronic. Medtronic, on the other hand, contends that the purpose of the letter is to allow Adcox's lawyers to identify and solicit additional plaintiffs for the underlying lawsuit since the district court has denied class action status. The record, including Medtronic's stipulations concerning the lead's faulty condition, tends to support the idea that plaintiff identification is a primary purpose, if not the primary purpose, of the letter.

Because the orders of the district court require Medtronic to violate the federal regulation, 21 C.F.R. 20.63(f), we asked the government to file a response if it wished to do so. It has now responded in support of Medtronic, urging this court to grant the requested writ.

II. DISCUSSION

We almost never issue a writ of mandamus in a district court discovery dispute because, as noted by respondent Adcox, such an order may issue only "in those

exceptional circumstances amounting to a judicial usurpation of power." In re Ford Motor Co., 751 F.2d 274, 275 (8th Cir. 1984). "The remedy of mandamus is a drastic one, to be invoked only in extraordinary situations." Allied Chem. Corp. v. Daiflon, Inc., 449 U.S. 33, 34 (1980). Petitioner Medtronic, respondent Adcox and the government all concede that in this circuit we are controlled by the five guidelines outlined in In re Bieter Co., 16 F.3d 929 (8th Cir. 1994).² Here, we think the requirements of Bieter have been met because all guidelines, except guideline four, have been established.

Medtronic, Adcox and the government argue at length about the policies behind the regulatory scheme, and the meaning, force and applicability of the various statutes and FDA regulations. However, we need not discuss these matters in detail because the district court held, and properly so, that "the clear language of [21 C.F.R. § 20.63(f) and] FDA's rationale for this rule, . . . demonstrate[] that FDA does seek to prevent [the] court-ordered contact by the manufacturer with an adverse event reporter or with the party identified in such report." Adcox, Order of October 28, 1998, at 2. But, despite the "plain meaning and clear intent of this regulation," the district court ordered that the contact be made. Id. at 3. This order was based upon a finding that "the regulation conflicts with Federal Rule of Evidence 501, which takes precedence over the regulation with respect to determining the limits of possible evidentiary privileges." Id. Under the facts of this case, this conclusion is clearly erroneous as a matter of law. See Bieter, 16 F.3d at 932.

²The five guidelines are: (1) the party seeking the writ has no other adequate means, such as direct appeal, to attain the relief desired; (2) the petitioner will be damaged or prejudiced in a way not correctable on appeal; (3) the district court's order is clearly erroneous as a matter of law; (4) the district court's order is an oft-repeated error, or manifests a persistent disregard of the federal rules; and (5) the district court's order raises new and important problems or issues of first impression. See In re Bieter, 16 F.3d 929, 932 (8th Cir. 1994).

To begin with, Federal Rule of Evidence 501 (Rule 501) does not support the weight placed upon it by the district court. Indeed, we think that Rule 501 is involved, at most, only peripherally in this dispute. The district court order refers only to the first sentence of the rule which states:

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.

Based upon this language, the district court concluded that "only Congress or the United States Supreme Court [and not federal executive agencies] can enact laws or rules limiting common law privileges." Adcox, Order of October 28, 1998, at 3.

Actually, however, this being a diversity case, the second sentence is the operative portion of Rule 501. It says

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.

Thus, in this case, Arkansas law dictates the scope of the physician-patient privilege that may apply. See Ark. R. of Evid. 503. Neither the district court nor any of the parties point to any authority for the proposition that federal executive rulemaking is subordinated to evidentiary rules established by state lawmakers, and we have found no precedent for such an interesting theory.

Beyond this, we do not see how the physician-patient privilege is adversely impacted at all in this situation. Arkansas Rule of Evidence 503 protects medical records and confidential communications made for the purpose of diagnosis or treatment of a patient's physical condition by a physician. The patient, here the pacemaker recipient, controls the disclosure of this information. So, if a physician files an MDR with the permission of the patient, the privilege is waived. If, on the other hand, the voluntary report is filed without the patient's knowledge, section 20.63(f) works to protect the patient's privilege while still advancing the substantial healthcare purposes carefully and accurately outlined by the government in its amicus brief to the court. This well-crafted approach does not in any way, as we see it, purport to create a new physician-patient privilege that modifies or overrules Arkansas Rule 503 or, for that matter, Federal Rule 501. In other words, Adcox's claim, as set forth in her opening brief to the court, that the FDA, through section 20.63(f) has created "a new federal FDA/Manufacturer/Physician/Patient privilege which would conflict with Federal Rule of Evidence 501 and Congress' stated intent to defer the rules of privilege to the States" is, at best, hyperbole and, at worst, misguided analysis.

Any conflicting state evidentiary rules are nullified to the extent that they directly conflict with federal statute. See Hillsborough County v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985). Federal regulations have no less preemptive effect than federal statutes where Congress has authorized an administrator to exercise his or her discretion. See Capitol Cities Cable, Inc. v. Crisp, 467 U.S. 691, 699 (1984). And, we believe that the FDA rulemaking has, in this instance, functioned well within congressional authorization. Thus, any conflict between Arkansas Rule 503, as made applicable by the second sentence of Federal Rule of Evidence 501, and section 20.63(f), must be resolved in favor of the FDA rule. However, as earlier explained, we see no substantial conflict in the application of both rules in this litigation.

Finally, 21 U.S.C. § 360i(b)(3), brought to our attention by the government, specifically provides that certain device user facility reports, as defined in the statute

"shall [not] be admissible into evidence or otherwise used in any civil action involving private parties unless the facility, individual, or physician who made the report had knowledge of the falsity of the information contained in the report." 21 U.S.C. § 360i(b)(3). Since there is no evidence of false information, the government contends that this statute directly precludes the discovery and use of the information in these facility reports, some of which, according to the government, will almost certainly be contained within the Medtronic document repository referred to above. We agree with the government's analysis of this legislation, and to the extent that compliance with any discovery order by the district court requires divulgence of the contents of reports within the scope of 21 U.S.C. § 360i(b)(3), the orders are invalid.

III. CONCLUSION

For the reasons stated above, we grant the petition for writ of mandamus. We direct the district court to vacate its discovery orders dated September 29, 1998, and October 28, 1998, and all oral modifications thereof, if any, insofar as such orders require divulgence of any information contained in or gleaned from voluntarily submitted MDRs as such documents are defined in applicable statutes and regulations. We also direct that discovery be disallowed to the extent that such discovery requires reliance upon information contained in or gleaned from device user reports within the scope of 21 U.S.C. § 360i(b)(3).

A true copy.

Attest:

CLERK, U.S. COURT OF APPEALS, EIGHTH CIRCUIT.