DISTRICT COURT OF APPEAL OF THE STATE OF FLORIDA
FOURTH DISTRICT

HOWMEDICA OSTEONICS CORP.,
Petitioner,

v.

JOYCE TROWBRIDGE, JAY TROWBRIDGE, et al,
Respondents.

No. 4D16-2374

[January 25, 2017]

Petition for writ of certiorari to the Circuit Court for the Seventeenth Judicial Circuit, Broward County; Patti Englander Henning, Judge; L.T. Case No. 14-90000 (26).

Jennifer A. McLoone, Hildy M. Sastre and Daniel B. Rogers of Shook, Hardy & Bacon L.L.P., Miami, and Dennis M. O'Hara, Steven Y. Leinicke and Jordan S. Cohen of Wicker Smith O'Hara McCoy & Ford, P.A., Fort Lauderdale, for petitioner.

Jonathan M. Streisfeld, Jan Douglas Atlas and Melissa A. Gunion of Kopelowitz Ostrow Ferguson Weiselberg Gilbert, Fort Lauderdale, and Raymond Valori and Daniel Harwin of Freedland Harwin Valori, Fort Lauderdale, for respondents.

PER CURIAM.

Petitioner, Howmedica Osteonics Corporation (HOC), seeks certiorari review from a trial court's order that denied its request to redact identifying information from reports and related documents of health care providers who reported "foreign adverse events" associated with a medical device. Certiorari lies to protect privileged or protected material to avoid the irreparable harm of wrongful disclosure. *See, e.g., Rosen v. McCobb*, 192 So. 3d 576 (Fla. 4th DCA 2016).

We grant the petition and quash the order. On remand, the trial court shall redact any identifying information from the reports and related documents. Federal law mandates that identifying information of *voluntary* reporters of adverse events involving medical devices be kept

confidential. The controlling federal regulation does not distinguish between foreign and domestic reporters. *See* 21 C.F.R. § 20.63(f) (2016).

This petition arises from a consolidated proceeding pending in the trial court involving many plaintiffs who allege they sustained personal injuries from hip-implant medical devices manufactured by HOC that were subsequently recalled. The specific issue concerns production of adverse event reports and related documents furnished to HOC by foreign *voluntary* reporters. Although the trial court's order did not differentiate between the report itself and the underlying related documents, we further hold that any information that identifies the voluntary reporter must be redacted.

Congress mandates that medical device manufacturers and importers report to the Food and Drug Administration (FDA) adverse events with a medical device. 21 U.S.C. § 360i(a). A "device user facility" is also required to report adverse events to the FDA and the manufacturer (if known). 21 U.S.C. § 360i(b). HOC is a mandatory reporter and is required to report to the FDA information received "from any source" that reasonably suggests that a device it markets: "(1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and this device or a similar device that you market would likely cause or contribute to a death or serious injury, if the malfunction were to recur." 21 C.F.R. § 803.50(a); *see also* 21 C.F.R. § 803.10(c).

By contrast, voluntary reporters are physicians, consumers, or others who voluntarily report adverse events associated with medical devices to the FDA and manufacturers. The FDA regulation that controls redaction of identifying information from voluntary reporters is 21 C.F.R. § 20.63 entitled, "Personnel, medical, and similar files, disclosure of which constitutes a clearly unwarranted invasion of personal privacy." Applicable to this case is subpart (f) which requires that:

> (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.

The regulation provides for three limited exceptions not applicable to this case. *See* 21 C.F.R. § 20.63(f)(1).

Nothing within the text of this regulation limits the "identity" protection to domestic voluntary reporters. *See State v. Burris,* 875 So. 2d 408, 410 (Fla. 2004) (noting that courts will not look behind plain language when a statute is clear.). We are not persuaded by respondents' non-binding authority that suggests otherwise because the federal district courts in those cases did not analyze the issue of foreign voluntary reporters. *See In re Mentor Corp. ObTape Transobturator Sling Products Liab. Litig.*, 632 F. Supp. 2d 1370 (M.D. Ga. 2009)[1]; *see also Contratto v. Ethicon, Inc.*, 225 F.R.D. 593, 594 (N.D. Cal. 2004) (noting that defendants "conceded that they have no grounds to protect complaints by patients or foreign users, and withdrew such documents from the scope of their protective order").

As further support, we note that this regulation was adopted because the success of the "adverse event reporting system depends substantially on the guarantee of confidentiality given the identity of the reporter under FDA regulations." *See Contratto,* 225 F.R.D. at 596 (citing Protecting the Identities of Reporters of Adverse Events and Patients; Preemption and Disclosure Rules, 59 Fed. Reg. 3944, 3946 (proposed Jan. 27, 1994)). Limiting the identity protection to domestic voluntary reporters would not facilitate that success.

We also agree with HOC that the identity protection extends to the report's related documents. *See In re Mentor Corp.,* 632 F. Supp. 2d 1370 at 1379 (accepting the FDA's expansive interpretation of its regulation providing that section 20.63(f) applies to related documents that may or may not be transmitted to the FDA); *but see Contratto,* 225

[1] At issue in *Mentor* were documents from France and from American physicians. None of the documents had been made the subject of an FDA adverse report. The federal district court concluded that the documents that contained only the names of foreign physicians were to be produced in their entirety because the manufacturer did not cite authority for the proposition that any reports by these physicians were subject to FDA regulations. 632 F. Supp. 2d at 1375.

F.R.D. at 599 n.8 (declining to extend protection to certain documents but noting that plaintiff was not seeking "identities").

Consequently, we quash the trial court's order that required HOC to "produce unredacted identifying information for health care providers who reported foreign adverse events." On remand, the trial court shall redact any information that identifies the voluntary reporter from the reports and related documents.

We recognize that the parties entered into various stipulations after the trial court entered the order under review. We decline to consider those stipulations as they were neither considered nor adopted by the trial court. The trial court can consider any specific redactions that plaintiffs contend are outside the scope of the regulation and/or the parties' stipulations.

Petition granted, order quashed, and remanded with instructions.

CIKLIN, C.J., MAY and GERBER, JJ., concur.

* * *

Not final until disposition of timely filed motion for rehearing.