UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHN KUBICKI & KAREN KUBICKI ON BEHALF OF CAROLINE KUBICKI,

Plaintiffs,

v. **Civil Action No. 12-734 (KBJ/JMF)**

MEDTRONIC *et al.*,

Defendants.

MEMORANDUM OPINION

Currently pending and ready for resolution are the following two motions: 1) Plaintiffs' Motion for Relief [#86] and 2) Defendants Unomedical Devices S.A. de C.V.'s and Unomedical A/S's Motion for Protective Order [#89].

BACKGROUND

The gravamen of the plaintiffs' complaint is that on September 9, 2007, Caroline suffered permanent brain damage as a result a hypoglycemic event (over delivery of insulin), caused by her use of the Medtronic MMT-522 Pump ("the 522 Pump"), a device designed to manage Type I diabetes in individuals requiring insulin therapy, in conjunction with the Paradigm Infusion Set Model MMT-396 ("the 396 Infusion Set"), a device designed to connect an insulin pump to an individual's body. Id. ¶¶ 2, 14, 15, 16, 24, 27, 37.

The plaintiffs assert six theories of liability against the defendants: [1] 1) negligence (Counts I-VI); 2) strict liability / Restatement of Torts § 402(A) (Counts VII-XII); 3) express

[1] The Medtronic defendants will be referred to collectively as "Medtronic" and the Unomedical defendants collectively as "Unomedical."

warranties (Counts XIII-XVIII); 4) failure to warn – Restatement of Torts § 388 (Counts XIX-XXIV); 5) punitive damages (Counts XXV-XXX); and 6) damages (Count XXXI).

DISCUSSION

I. The Unsuccessful Meet and Confer

Beginning on August 15, 2014, counsel for the parties began to meet and confer to prepare for the Rule 30(b)(6) deposition of the defendants by defining the topics for those depositions. [#89-1] at 23. On September 22, 2014, the parties conferred with Judge Ketanji Jackson by telephone and she then directed them to meet and confer regarding their differences. Id. The parties did so, but were unable to reach any final agreement.

According to Medtronic, although plaintiffs previously agreed to withdraw their demand for information about "the corporate entities and individuals responsible for calculating and monitoring Medtronic's sales, market share and profits information," they now seek to expand that topic to include "'information concerning sales, market share and profits.'" [#88-3] at 19. In addition, Medtronic also contends that, although it offered to "consider a more reasonable request for adverse event information tailored to the devices and claims at issue in the case," plaintiffs rejected its proposal and instead insisted on "all adverse events for all models of insulin pumps in the Paradigm family, and all models of Paradigm Quick-set infusion sets, for a period covering 15 years." Id. at 19-20. Finally, Medtronic contends that, although it provided plaintiffs with an additional outline of its proposal, plaintiffs did not respond and instead filed the instant motion. Id. at 20.

According to Unomedical, the parties reached agreement as to certain issues but could not agree on the definition of the following terms in the Rule 30(b)(6) deposition notices: 1) "Relevant Time Period"; and 2) "Paradigm Infusion Set." Id. at 25-26. Unomedical further

contends that the parties were unable to agree as to whether the depositions would include testimony as to the following topics: 1) "Unomedical's relationship 'with any other entity' having 'any role in connection' with the [Infusion Set]"—Unomedical offered to provide testimony regarding such entities in the distribution and sale of the device (the one Caroline used) in the United States but not as to activities outside of the United States by entities other than the named defendants; 2) "Unomedical's policies and procedures for recording or memorializing communications or interactions with regulatory agencies beyond the United States"—Unomedical agreed to provide testimony as to "its procedures for memorializing communications between Unomedical and the FDA related to the design, manufacturing, and marketing" of the device (the one Caroline used) but not as to foreign regulators; and 3) "the identity of 'corporate entities and individuals,' . . . "who might calculate or monitor sales, market share, and profits not only as to the subject infusion set, but also as to other irrelevant infusion sets."[2] Id. at 26-28. At some point thereafter, the meet and confer process broke down and the instant motions were filed.

II. The Parties' Positions

As the Memorandum of Points and Authorities in Support of Plaintiffs' Motion for Relief [#86-1] and, more particularly, Plaintiffs' Reply Memorandum in Support of Motion for Relief and In Opposition to Medtronic's Cross-Motion for Protective Order [#92] make clear, plaintiffs want the Court to go much further than denominating what are the proper topics for the Rule 30(b)(6) depositions. Rather, plaintiffs seek to have the court specify the proper scope of discovery from this point on "irrespective of the mode or phase of the discovery at issue." [#92]

[2] As will be explained, plaintiffs define "Paradigm Infusion Set" to include more than the Infusion Set Caroline used.

at 2. Building on that basis, plaintiffs first want to expand the scope of discovery beyond simply information pertaining to the devices that Caroline used on September 9, 2007. Id. at 12-21.

According to plaintiffs, the predicate devices, which were first manufactured in 1999, were antecedents of the devices that Caroline used. Id. at 21. Specifically, plaintiffs contend that representations made by defendants in their submissions to the FDA, in which defendants claimed that the new devices were the substantial equivalent of predicate devices, are admissions by defendants that yield the conclusion that information about the earlier devices is relevant to or likely to lead to information relevant to the devices Caroline used. Id. at 15-21. Plaintiffs further contend that information about the successor devices is similarly discoverable. Id. at 12-21. Thus, according to plaintiffs, the scope of discovery should be fifteen years long, from 1999, when the first predicate device was introduced, to the present. Id. at 21. Finally, plaintiffs contend that the following information about the subject devices, during that same time period, is also discoverable: 1) information concerning post-manufacture and post-injury remedial events and measures; 2) information concerning defendants' communications and interactions with foreign regulatory agencies; 3) information concerning sales, market share, and profit; and 4) information concerning adverse events. Id. at 22-30.

Both Medtronic and the Unomedical protest that plaintiffs are misreading their FDA submissions and approvals and that the predicate and successor devices were different in significant ways from the two devices used by Caroline. See [#88-3] at 20-52; [#89-1] at 32-50. Rather, they insist that discovery be limited to information about the devices Caroline actually used and resist any further discovery. Id.

III. Analysis

A. Legal Standard

Rule 26 of the Federal Rules of Civil Procedure provides the following:

> Unless otherwise limited by court order, the scope of discovery is as follows: Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense—including the existence, description, nature, custody, condition, and location of any documents or other tangible things and the identity and location of persons who know of any discoverable matter. For good cause, the court may order discovery of any matter relevant to the subject matter involved in the action. Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence.

Fed. R. Civ. P. 26(b)(1).

Discovery must be limited if any of the following conditions exist:

> (i) the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive;
>
> (ii) the party seeking discovery has had ample opportunity to obtain the information by discovery in the action; or
>
> (iii) the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues.

Fed. R. Civ. P. 26(b)(2)(C).

B. <u>The Scope of this Opinion is Limited to Defining Topics for the Rule 30(b)(6) Depositions</u>

As explained above, although the parties began negotiating the topics for the Rule 30(b)(6) depositions, thereby engaging in the trading and compromising that is and should be typical of that process, plaintiffs abandoned their efforts as futile and decided instead to come to court and demand that the court not merely intervene to denominate the proper topics for those depositions but also to define the scope of discovery irrespective of what discovery device the

parties choose to use. Thus, as plaintiffs would have it, the scope of discovery, as defined by the court, applies universally to an interrogatory, a request to produce documents, or the proper topics of a deposition.

But, as defendants point out, the rules of this Court seem to require that a motion to compel or a motion for a protective order be premised on the precise discovery device that a party has used. See LCvR 26.2(d); LCvR 30.4. More to the point, a moment's thought indicates that the mandated assessment of cost and burden against utility required by Rule 26(b)(2)(C) can only be made conscientiously when the cost and burden of responding to the device being used is weighed against its utility. Surely, there is a difference between permitting certain questions in a deposition and demanding that defendants produce documents created over a fifteen year period.

In this case, the only questions that should be addressed are those raised by the parties during their meet and confer, which of course were based on the plaintiffs' proposed 30(b)(6) deposition notice. That is the only issue that is ripe for review at this stage of discovery. While defining the scope of discovery has an obvious neatness, it disguises the principled decision that has to be made in this case—that of weighing the cost of what is actually being demanded by the 30(b)(6) deposition notices against the potential utility of the identified topics, using the factors identified in Rule 26(b)(2)(C)(i)-(iii). Trying to do that balancing as to discovery devices not yet used is to speculate as to cost against utility without knowing what those actuals costs are and how they might be made more manageable by devices available to the court such as sampling, phased discovery or cost sharing. This opinion will therefore be limited to the proper topics for the defendants' 30(b)(6) depositions and nothing more.

C. Plaintiffs May Explore the Similarities Among the Predicate and Successor Devices to Those Used by Caroline On September 9, 2007

In a case involving a medical device that must be approved by the FDA, the similarity of a new device to predicate devices is often addressed through the approval process. See 21 U.S.C. § 360e.[3] That approval may be obtained either through the premarket approval process, "a rigorous application process in which the applicant must establish that a new or modified device is both safe and effective," or through premarket notification, a process by which manufacturers obtain a "510(k) clearance," wherein they "demonstrate to the FDA that the device to be marketed is at least as safe and effective, that is 'substantially equivalent,' to an existing FDA-approved device (known as a 'predicate device')." Prather v. Abbott Laboratories, 960 F. Supp. 2d 700, 704 (W.D. Ken. 2013) (internal citations omitted).

As explained above, the first fundamental premise of plaintiffs' amended complaint is that information about the predicate devices is discoverable since each of them was similar to the devices Caroline used so that, for example, defects in the design and manufacture of the predicate devices would bear on similar defects in the devices Caroline used. It would follow, therefore, that if the defendants were aware of a defect or if the defect was brought to their attention by an FDA notice, and they did nothing to correct that defect, they might be liable to plaintiffs for their negligence and failure to warn.

Plaintiffs' second fundamental premise is that if the FDA brought to the defendants' and the public's attention some defect in a predicate device, then such a defect might bear on defendants' negligence or failure to warn Caroline about the device she used even though the warning came several years after Caroline used the device.

The amended complaint claims that had the devices Caroline used functioned properly they "would not have malfunctioned and produced an over delivery of insulin." [#51] ¶ 37.

[3] All references to the United States Code or the Code of Federal Regulations are to the electronic versions that appear in Westlaw or Lexis.

Thus, whether other devices had similar defects that malfunctioned in the way in which it is alleged that Caroline's malfunctioned is relevant to both her claim and the defendants' defense. Knowledge of a similar malfunction in a predicate device would, for example, be the premise of a claim of negligence or failure to warn and plaintiffs are therefore entitled to probe whether defendants had such knowledge and also to learn how defendants will support their defense of dissimilarity.

I appreciate that defendants argue in their briefs that the devices plaintiffs are trying to compare are dissimilar, but in my view, questions of similarity and dissimilarity are scientific questions and plaintiffs are entitled to probe defendants' scientific and technical claims of dissimilarity, rather than simply accept the arguments of counsel, even if supported by exhibits.

Furthermore, the more limited approach I am taking cannot fairly be condemned by plaintiffs as forcing them to prove their case to get discovery. Defects in any devices other than the ones Caroline used are neither relevant nor likely to lead to relevant evidence unless the devices functioned in the same way as Caroline's. Without that predicate, discovery about other devices is irrelevant and plaintiffs cannot be permitted to explore every device manufactured by defendants from 1999 to the present irrespective of whether all the devices shared a common design and malfunctioned in a fashion similar to that alleged by plaintiffs with respect to Caroline's devices.

To effectuate the limitation I am imposing, I will therefore permit plaintiff to pursue the following topics in their 30(b)(6) depositions: 1) the similarities or dissimilarities in design and usage among the predicate devices to those used by Caroline on September 9, 2007; 2) the similarities or dissimilarities in design and usage among the successor devices (to the present time) to those used by Caroline on September 9, 2007.

D. Plaintiffs May Explore Information About the Policies and Procedures for Recording Communications with the FDA and Foreign Regulatory Agencies But May Not Explore Information About All Communications with These Agencies

In their 30(b)(6) deposition notices, plaintiffs seek the following information from Medtronic: "The policies and procedures of Defendants for recording or memorializing communications or interactions with the FDA, or with the regulatory agencies of the United States, Mexico, and Canada, concerning the PARADIGM INFUSION SET and PARADIGM INSULIN PUMP during the RELEVANT TIME PERIOD." [#86-16] at 10-11. From Unomedical, plaintiffs seek: "The policies and procedures of Defendants for recording or memorializing communications or interactions with the FDA, or with the regulatory agencies of the United States, Mexico, and Canada, concerning the PARADIGM INFUSION SET during the RELEVANT TIME PERIOD." [#86-17] at 10. In their motion, however, plaintiffs insist that they are "entitled to discover information concerning Defendants' interaction with foreign regulatory agencies insofar as such information concerns the subject devices." [#86-1] at 39.

The leap from the former—seeking records regarding defendants' policies for recording communications with domestic and foreign regulators regarding the subject devices—to the latter—seeking all documents exchanged with foreign and domestic regulators for 15 years—is about the size of the Grand Canyon. As I have explained, I will only consider the topics for the 30(b)(6) depositions. As I find the original description in the notices an innocuous effort to find out what documents may be available, information that cannot be terribly burdensome for defendants to answer, I will permit it. I will leave for another day, however, whether and to what extent such documents exist and are discoverable.

E. Plaintiffs May Explore Information About Adverse Event Reports But May Not Seek the Reports Themselves

In their 30(b)(6) deposition notice to Medtronic,[4] plaintiffs seek information about Adverse Event Reports in five of their topics:

> Topic No. 19: The department, division, group, committee or other collection of Defendants' employees who has responsibility for intake, processing, reporting, recording and/or memorializing Adverse Event reports for the PARADIGM INFUSION SET and PARADIGM INSULIN PUMP during the RELEVANT TIME PERIOD.
>
> Topic No. 20: The policies and procedures for the intake, processing, reporting, recording and/or memorializing of Adverse Event reports for the PARADIGM INFUSION SET and PARADIGM INSULIN PUMP during the RELEVANT TIME PERIOD.
>
> Topic No. 21: The policies and procedures for adjudicating and determining the cause of Adverse Events for the PARADIGM INFUSION SET and PARADIGM INSULIN PUMP during the RELEVANT TIME PERIOD.
>
> Topic No. 22: WITHDRAWN during meet and confer.
>
> Topic No. 23: The corporate entities and individuals responsible for adjudicating adverse events and determining what events to report to the FDA for the PARADIGM INFUSION SET and PARADIGM INSULIN PUMP during the RELEVANT TIME PERIOD.

[#86-16] at 10.

As is clear from their notices, plaintiffs do not seek the actual Adverse Event Reports. However, in their motion they do: "Plaintiffs should be entitled to discover adverse event reports for each subject device during the relevant time period." [#86-1] at 43. Plaintiffs further state that they are seeking redacted versions of the adverse event reports generated by the defendants, who are manufacturers, and not those generated devices user facilities or physicians. Id. at 44.

[4] The same topics are listed in plaintiff's notice to Unomedical, except that the only device referenced is the paradigm infusion set. See [#86-17] at 9-10.

Medtronic counters that the manufacture's reports are protected because they may themselves be based on the adverse event reports submitted by device user facilities. [#88-3] at 44-45. Furthermore, Medtronic notes that properly redacted adverse event reports are already publically available through the FDA via its MAUDE database. Id. at 46. Finally, Medtronic states that it "has already agreed to produce a witness to testify regarding its processes for collecting and reporting adverse events as they relate to the Quick-set Infusion Set MMT-396 and Paradigm Pump Model MMT-522 from the time of the FDA clearance and Premarket Approval of the devices, respectively, until the date of the subject incident on September 9, 2007." Id. at 42.

The production of adverse event reports is governed by statute, codified at 21 U.S.C. § 360i. Pursuant to the statute, device manufacturers, like the defendants, have different reporting requirements than user facilities, such as hospitals. Specifically, a manufacturer must retain certain records and submit a report to the FDA when it "becomes aware of information that reasonably suggests" that one if its devices has caused death or a serious injury or has malfunctioned. 21 U.S.C. § 360i(a)(1)(A) and (B). When a device user facility becomes aware that a device has contributed to the death of a patient or a serious injury, it must report that information to the FDA and the manufacturer. 21 U.S.C. § 360i(b).

In addition, the statute provides that certain reports may not be "admissible or otherwise used in a civil action" unless the person making the report knew of the falsity of the information contained therein:

> (3) No report made under paragraph (1) by—
> (A) a device user facility,
> (B) an individual who is employed by or otherwise affiliated with such a facility, or
> (C) a physician who was not required to make such a report,

> Shall 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).

It is clear from the statutory language that the reference to paragraph (1) is to the first paragraph of section (b), or 21 U.S.C. § 360i(b)(1). Paragraph 1, in turn, imposes reporting obligations on device user facilities, not manufacturers. Thus, the limitations imposed by paragraph (3) do not apply to manufacturers.

However, manufacturers are not completely out of the woods. Under an FDA regulation, codified at 21 C.F.R. § 20.63, manufacturers are prohibited from disclosing "[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, biologic, or medical device product." 21 C.F.R. § 20.63(f). Thus, while adverse event reports in defendants' possession are discoverable, information contained therein that would disclose the identity of a voluntary reporter can never be disclosed.

Having determined that adverse event reports are not ipso facto inadmissible and non-discoverable, the next question is what discovery should be permitted. To that end, the MAUDE database provides the clear solution. I see no reason why that database cannot provide plaintiffs with the information they seek. Additionally, Medtronic's proposed topics for the 30(b)(6) deposition hit the mark and therefore shall be used with one addition. Plaintiffs will be permitted to also ask whether the deponent is aware of any adverse event reports pertaining to the subject devices that are not reflected in the MAUDE database.

F. Plaintiffs May Not Explore Information Pertaining to the Defendants' Financial Condition

Plaintiffs seek various forms of financial information about defendants, arguing that it bears on their potential entitlement to punitive damages. [#86-1] at 40-43.

In D'Onofrio v. SFX Sports Group, Inc., 247 F.R.D. 43 (D.D.C. 2008), I dealt with this precise issue. In that case, I concluded that, although information about the defendants' financial condition was relevant to the issue of punitive damages, until the court concluded, as a matter of law, that the issue of punitive damages was properly before it, discovery of such information was premature. Id. at 52-53. Instead, I directed defendants to produce, in camera, for the trial judge's consideration at the pretrial conference, a statement of their net worth, certified as accurate by a public accountant. Id. at 53. I will do the same here.

CONCLUSION

For the reasons stated above, Plaintiffs' Motion for Relief [#86] will be **GRANTED** in part and **DENIED** in part, and Defendants Unomedical Devices S.A. de C.V.'s and Unomedical A/S's Motion for Protective Order [#89] will be **GRANTED** in part and **DENIED** in part. An Order accompanies this Memorandum Opinion.

Digitally signed by John M. Facciola
DN: c=US, st=DC, l=Washington, email=John_M._Facciola@dcd.uscourts.gov, o=United States District Court, cn=John M. Facciola
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JOHN M. FACCIOLA
UNITED STATES MAGISTRATE JUDGE