

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
THIRD DIVISION**

Civil No. 05md1726 JMR/AJB

In re: Medtronic, Inc. Implantable
Defibrillator Product Liability Litigation

**ORDER ON MOTION TO
COMPEL DISCOVERY**

This matter is before the Court, Magistrate Arthur J. Boylan, on Motion to Compel Responses to Plaintiffs' First Set of Discovery Requests Focused on Matters Pertaining to Federal Preemption [Docket No. 43]. Plaintiff seeks an order compelling responses to particular interrogatories and document production requests. Hearing on the motion was held on March 9, 2006, at the U.S. Courthouse, 300 South Fourth Street, Minneapolis, Minnesota. Mitchell M. Breit, Esq., argued on behalf of the plaintiffs. Lori G. Cohen, Esq., argued on behalf of the defendant.

Based upon the file, memorandums, affidavits, and arguments of counsel, **IT IS HEREBY ORDERED** that:

1. Plaintiffs' Motion to Compel Responses to Plaintiffs' First Set of Discovery Requests is **granted in part and denied in part** [Docket No. 43] as further provided herein.

Interrogatories

2. Plaintiffs' motion for response to **Interrogatory No. 4**, seeking identification of all companies, operating divisions, departments, and offices which are owned, maintained, or retained by the defendant and which have had responsibilities relating to design, testing,

approval, marketing, promotion, manufacturing, and labeling of defibrillator devices,¹ is **denied**. Plaintiffs' motion for response to **Interrogatory No. 5**, seeking the identity of persons at the FDA or foreign regulatory agency with whom defendant had contact, is **granted in part and denied in part**. Plaintiffs contend that the discovery seeks information about individuals at Medtronic who had contact with regulatory agencies to determine whether truthful and accurate information was provided to regulators. Defendant objects to the interrogatories and argues that they seek information outside the scope of preemption discovery because claims of fraud on the agency cannot be advanced in this action. See *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). At present, discovery in this matter is expressly limited to discovery relating to preemption. Plaintiffs naturally take a broad view of discovery pertinent to preemption while defendant takes a narrow view, arguing that preemption is strictly a question of law, necessitating little or no discovery. Nonetheless, defendant asserts that substantial and sufficient document disclosures have been made with respect to the pre-market approval (PMA) process. Plaintiffs' primary justification for these interrogatories and document requests is the search for information that could be used to challenge the integrity of the PMA, thereby establishing a defense to preemption. Defendant shall provide identification of individuals within Medtronic that had contact with the FDA regarding premarket approval of the recalled cardiac devices described in plaintiffs' master consolidated complaints. To the extent that interrogatory No. 5 seeks information beyond said identification, it is the court's determination that said discovery is outside the parameters of permissible preemption discovery.

¹ Devices are generally referred to as ICDs (implantable cardioverter-defibrillators) and CRT-Ds (cardiac resynchronization therapy defibrillators).

3. Plaintiffs' motion for response to **Interrogatory No. 6**, requesting all warranties, representations, and promotional statements regarding defibrillator devices made by defendant and its sales agents from 1996 to the present, is **denied**. Plaintiffs state that the information is relevant to whether defendant concealed known defects from the FDA and the public. It appears to the court that providing a complete response to this interrogatory would be burdensome. The discovery is not within court ordered parameters limiting discovery to preemption issues.

4. Plaintiffs' motion for response to **Interrogatory No. 7**, seeking names and contact information of all defendant employees who made or received reports regarding device defects and problems, is **denied**. Plaintiffs again assert that the discovery is pertinent to determining whether defendant's submissions to the FDA were timely, truthful, and complete. It is the court's determination that this discovery is outside the parameters of permissible preemption discovery.

5. Plaintiffs' motion for response to **Interrogatory No. 8**, seeking a detailed description of the development process of each device, with diagrams and related memoranda and documents, is **denied**. Again, plaintiffs contend that the discovery relates to whether defendant's submissions to the FDA were timely, truthful, and complete. In the court's view, the discovery sought goes beyond issues of preemption.

6. Plaintiffs' motions for responses to **Interrogatory No. 9** and **Interrogatory No. 10** are denied. Both interrogatories seek details relating to voluntary advisory statements. Such discovery is merits discovery and is broader than the discovery being allowed at this time.

7. Plaintiffs' motion for response to **Interrogatory No. 11**, seeking detailed

information relating to defendant's awareness of battery and capacitor problems in its Gem, Micro Jewel, and Marquis devices is **granted**.

8. Plaintiffs' motion for response to **Interrogatory No. 12**, seeking information regarding sales and marketing of devices containing defects, is **denied**. Plaintiffs state that discovery is directed at determining whether defendant violated FDA regulations relating to distribution and adverse event reporting on Gem, Micro Jewel, and Marquis devices. Plaintiffs do not clearly justify this discovery in the context of preemption and the court does not conclude that the interrogatory relates to preemption. The request is therefore denied.

9. Plaintiffs' motion for response to **Interrogatory No. 14**, requesting standard operating procedures for handling and investigating complaints regarding defibrillator devices, is **granted**. Plaintiffs contend that the discovery is aimed at determining when and how defendant became aware of defects and the timing of defect reports to the FDA. The discovery is not burdensome and will be allowed.

10. Plaintiffs' motion for response to **Interrogatory No. 15**, seeking procedures for statistical analysis of complaints and adverse events, is **granted**. Defendant's response shall be limited to the recalled cardiac devices described in Plaintiffs' master consolidated complaints.

11. Plaintiffs' motion for response to **Interrogatory No. 16**, requesting detailed description of communications with component suppliers regarding batteries and capacitors, is **denied**. Plaintiffs assert that the discovery is pertinent to determining whether defendant's submissions to the FDA were truthful and complete. The court is not persuaded that his information is relevant to preemption and the discovery is therefore denied.

12. Plaintiffs' motion for response to **Interrogatory No. 19**, requesting discovery

of standard operation procedures and revisions for medical device reporting from 1996 to the present, is **granted in part and denied in part**. Plaintiff contends the discovery is pertinent to defendant's adverse event reporting policies and deviation from those policies. While the relevance to preemption is not abundantly clear, the discovery is not overly burdensome and will be allowed.

Document Production Requests

13. Plaintiffs' motion for production pursuant to **Document Request No. 1**, therein requesting policies on procedures on various subjects with respect to Micro Jewel and Gem device models, as well as several Marquis device models, is **denied**. Plaintiff argue that the documents are relevant to a determination of whether defendant submitted truthful and accurate information to FDA in connection with its PMA application. The motion is not clearly pertinent to preemption and is over broad with respect to subject devices.

14. Plaintiffs' motion for production pursuant to **Document Request No. 2**, seeking documents relating to customer, patient and physician complaints, as well as materials relating to component rejections and returned devices or components, is **denied**. Plaintiffs content that the discovery is designed to determine when defendant became aware of defects and advised the FDA and public of such defects. The request is beyond the scope of preemption discovery that is permitted in this action and has the appearance of a request for a list of potential clients.

15. Plaintiffs' motion for production pursuant to **Document Request No. 4**, seeking discovery of defendant's communications with component suppliers, is **denied**. Plaintiffs assert that the materials are relevant to whether submissions to the FDA were truthful

and complete. The court is not persuaded that the discovery relates to preemption and it is over broad.

16. Plaintiffs' motion for production pursuant to **Document Request No. 5**, seeking standard operating procedures and revisions for device reporting since 1996, is **granted**.

17. Plaintiffs' motion for production pursuant to **Document Request No. 6**, requesting documents depicting defendant's internal organizational structure with regard to communications involving device defects and failures, is **denied**. Plaintiffs state that the information is relevant to a determination as to whether defendant concealed device risks from the FDA. It is the court's determination that this discovery is outside the parameters of permissible preemption discovery.

18. Plaintiffs' motion for production pursuant to **Document Request No. 7**, seeking defendant's "Alternative Summary Reporting" for adverse events involving defibrillator devices, is **granted**. Defendant's response shall be limited to the recalled cardiac devices complained of in plaintiff's master consolidated complaints. To the extent that the request seeks documents which defendant believes are privileged, appropriate privilege logs shall be prepared and served.

19. Plaintiffs' motion for production pursuant to **Document Request No. 8**, therein seeking product complaint forms, field reports, and failure investigation reports for implanted and explanted devices, is **denied**. This is merits discovery.

20. Plaintiffs' motion for production pursuant to **Document Request No. 9**, requesting reports generated from analysis of explanted devices, is **denied**. This is merits discovery.

21. Plaintiffs' motion for production pursuant to **Document Request No. 10**, seeking documents relating to defendant's policy for health hazard evaluation from 1996 to the present, is **denied**. This discovery is outside the parameters of preemption discovery.

22. Plaintiffs' motion for production pursuant to **Document Request No. 11**, seeking documents relating to defendant's recall policy from 1996 to the present, is **granted**. Plaintiffs state that the information may be used to determine whether defendant distributed devices after having obtained knowledge of defects. The discovery is not overly burdensome.

23. Plaintiffs' motion for production pursuant to **Document Request No. 12**, seeking all reports, logs, notes, journals, memoranda, correspondence, and other documents relating to any devices which did not pass quality control inspection, is **denied**.

24. Plaintiffs' motion for production pursuant to **Document Request No. 14**, requesting production of documents relating to instructions to persons responsible for sales inquiries relating to device defects, and motion for production pursuant to **Document Request No. 25**, requesting communications with sales agents regarding device recall and removal, are **denied**. The requested information is not sufficiently relevant to preemption and the production would be burdensome at this stage of the litigation.

25. Plaintiffs' motion for production pursuant to **Document Request No. 15**, seeking all documents regarding testing protocols and remedies for problems and defects, is **denied**. Plaintiffs assert that the discovery is relevant to determination of timely, truthful and complete compliance with FDA reporting requirements. The requested information is not sufficiently relevant to preemption.

26. Plaintiffs' motion for production pursuant to **Document Request No. 16**,

seeking all documents relating to when defendant first learned of device defects or risks, including battery depletion, is **granted**. Defendant's response is limited to the recalled cardiac devices described in plaintiff's master consolidated complaints. To the extent that the document request seeks documents that are privileged, appropriate privilege logs shall be produced.

27. Plaintiffs' motion for production pursuant to **Document Request No. 24**, requesting all communications between defendant and physicians relating to device performance, and motion for production pursuant to **Document Request No. 34**, seeking notes, correspondence and other materials from medical care professionals regarding device problems, are **denied**. Plaintiffs assert that the discovery is relevant to determination of timely, truthful and complete compliance with FDA reporting requirements. This is merits discovery.

28. Plaintiffs' motion for production pursuant to **Document Request No. 28**, seeking presentations, including Powerpoint, intended for medical personnel, patients and the United Kingdom MHRA, and relating to device performance, is **denied**. Plaintiffs contend that the discovery relates to whether false or incomplete information was provided to the FDA. The discovery is not within the scope of permissible preemption discovery.

29. Plaintiffs' motion for production pursuant to **Document Request No. 29**, seeking discovery of defendant's brochures on devices for distribution to patients and physicians, is **denied**; plaintiffs' motion for production pursuant to **Document Request No. 30**, seeking physician training manuals, including drafts and updates, for particular defibrillator models, is **denied**; plaintiffs' motion for production pursuant to **Document Request No. 31**, seeking all market and sales communications to field agents, physicians, and others, relating to device recalls, is **denied**; and plaintiffs' motion for production pursuant to **Document Request**

No. 32, seeking all sales and promotion materials relating to numerous specified defibrillator models, is **denied**. Plaintiffs state that each of these document requests seeks discovery relating to the determination of whether defendant concealed defects from the FDA and the public. These requests seek information which is outside the scope of permissible preemption discovery, is over broad with respect to device models, and is overly burdensome.

30. Plaintiffs' motion for production pursuant to **Document Request No. 33**, requesting documents identifying actions taken to warn patients of device dangers, is **denied**. Plaintiff assert that the discovery is designed to determine whether defendant provided timely notice of device defects. This is merits discovery.

31. Plaintiffs' motion for production pursuant to **Document Request No. 35**, seeking documents identifying third parties involved in device design, approval and marketing, is **denied**. Plaintiff states that the discovery relates to the determination as to whether submissions to the FDA were true and accurate. The request is not designed to lead to production of documents relating to preemption.

32. Plaintiffs' motion for production pursuant to **Document Request No. 36**, asks for documents regarding design, manufacture and quality assurance of batteries and capacitors, is **denied**. Plaintiff request the information to determine whether device components were properly tested for performance and safety. The request is over broad with regard to the present focus on preemption discovery.

33. Plaintiffs' motion for production pursuant to **Document Request No. 37**, requesting documents describing investigation and review finding and documents identifying every device sold, and identifying the patient, addresses, and locations of implantation, is

denied. This is outside the bounds of preemption discovery.

Dated: March 24, 2006

s/ Arthur J. Boylan
Arthur J. Boylan
United States Magistrate Judge

MEMORANDUM

The court limited initial discovery in this matter to discovery relating to the issue of federal preemption. Consequently, plaintiffs has attempted to justify its numerous interrogatories and document production requests in the context of preemption discovery, arguing in many instances that the requested information is pertinent to a determination as to whether actions by defendant in regard to the pre-market approval process should act to invalidate FDA device approval, thereby arguably precluding the application of federal preemption. Defendant on the other hand insists that the discovery at issue in this motion relates to possible fraud on the FDA claims, fraud on the public claims, or non-compliance with FDA requirement claims, none of which, in defendant's view, preclude preemption. Based upon the respective positions of the parties, as reflected in the arguments, as well as in the discovery itself, preemption discovery can therefore be construed to be either very broad or quite narrow.

Upon its examination of plaintiffs' interrogatories and document requests, and plaintiffs' reasons for the particular requests, the court has concluded that in many instances plaintiffs are essentially seeking substantial merits discovery. Consequently, discovery directed at determining whether defendant was untruthful or deceptive with regard to its interactions with the FDA is largely disallowed. With regard to discovery that is being allowed pursuant to this

Order, the court has determined that interrogatory responses and document productions which are not obviously burdensome with regard to the volume of material, the scope of necessary inquiry or search, or mere lack of clarity in the request, should be required in instances where some application to preemption might possibly be argued. Nothing in the court's order shall be deemed to be a denial of claimed privilege. However, any discovery responses being withheld on the basis of privilege should be the subject of an appropriate privilege log.

A.B.