

**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 FOR
PROTECTIVE ORDER**

This matter is before the Court, Magistrate Arthur J. Boylan, on defendant Medtronic, Inc.'s Motion for Protective Order [Docket No. 59]. Defendant seeks a protective order limiting the topic areas for which defendant would be required to produce a corporate witness pursuant to Fed. R. Civ. P. 30(b)(6). Hearing on the motion was held on March 9, 2006, at the U.S. Courthouse, 300 South Fourth Street, Minneapolis, Minnesota, along with plaintiffs' motion to compel discovery. An Order on the motion to compel was issued by the Magistrate Judge on March 24, 2006. 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 defendant Medtronic, Inc.'s Motion for Protective Order is **granted in part and denied in part** [Docket No. 59] as further provided herein. Defendant shall produce Rule 30(b)(6) witness(es) to testify with respect to noticed deposition topics to the extent such deposition discovery is consistent with the discovery allowed pursuant to the court's Order on Motion to Compel Discovery dated March 24, 2006. Defendant shall not be required to produce a corporate witness to testify with respect to matters or topics on which discovery was not permitted in the March 24, 2006, Order.

Defendant objects to deposition topics to the extent that they relate to defibrillators and device components not encompassed within the February 2005 field action involving particular Marquis model devices; that the topics address the merits of plaintiffs' claims rather than preemption; that the topics are repetitive and overlapping; that the topic areas seek information regarding contacts with MHRA and other foreign regulatory agencies; and that the topics seek disclosures that are attorney work product or protected by attorney-client privilege.

With respect to particular topics which will be permissible subject area for inquiry in Rule 30(b)(6) deposition, the magistrate judge makes the following **ORDER**:

Defendant Medtronic shall produce a corporate representative or representatives to testify concerning these topics:

1. PMA submissions and supplementations for each of the devices subject to the February 2005 field action;
2. how information pertaining to FDA regulatory affairs for the devices subject to the February 2005 field action is recorded and organized;
3. the identity of persons with responsibility for FDA regulatory affairs pertaining to the devices subject to the February 2005 field action;
4. the identity of persons with responsibility for PMA submissions and supplements pertaining to the devices subject to the February 2005 field action;
5. the identity of persons with responsibility for the following PMA submissions and supplements: PMA 980016; PMA Supplements S023, S029, S032 and S038 pertaining to PMA 980016; PMA 010031; and PMA Supplements S003 and S005 pertaining to PMA 010031;

6. Medtronic's PMA submissions and supplemental submissions to the FDA as they pertain to the devices subject to the February 2005 field action;

7. the identity of persons with responsibility for or knowledge of the PMA submissions and supplements that involved changes to the design of the devices that were subject to the February 2005 field action;

8. the identity of individuals with knowledge concerning the creation and maintenance of the traceability reports for each of the individually named plaintiffs' devices;

9. the creation and maintenance of the traceability reports for each of the individually named plaintiffs' devices;

10. the submission of the PMA Supplement for the October 2003 redesign of the battery in the subject devices; and

11. the identity of individuals with responsibility for or knowledge of labeling of the devices that were the subject of the February 2005 field action.

Each of the above listed topics on Rule 30(b)(6) depositions shall not be construed as an implicit limitation on the scope of inquiry as to the particular topic, but rather, the scope of inquiry on a particular topic may encompass discovery otherwise permitted pursuant to the court's Order on Motion to Compel Discovery dated March 24, 2006, as follows:

12. the identity of individuals within Medtronic that had contact with the FCA regarding premarket approval of any recalled devices described in plaintiffs' master consolidated complaints, including devices not subject to the February 2005 field action;

13. defendant's awareness of battery and capacitor problems in its Gem, Micro Jewel, and Marquis devices;

14. standard operating procedures for handling and investigating complaints regarding defibrillator devices;
15. procedures for statistical analysis of complaints and adverse events;
16. standard operating procedures and revisions for medical device reporting from 1996 to the present;
17. “Alternative Summary Reporting” for adverse events involving defibrillator devices;
18. defendant’s recall policy from 1996 to the present; and
19. defendant’s first knowledge of device defects or risks, including battery depletion, with respect to any recalled cardiac devices referenced in master consolidated complaints.

Dated: April 3, 2006

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