

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA**

IN RE: GUIDANT  
DEFIBRILLATORS PRODUCTS  
LIABILITY LITIGATION

MDL No. 05-1708 (DWF/AJB)

This Document Relates to All Actions

**MEMORANDUM, OPINION, AND  
PRETRIAL ORDER NO. 7**

**I. INTRODUCTION**

This matter is before the Court on Plaintiffs’ Motion to Compel Defendants’ Production of Documents Relating to the Independent Panel. The motion is opposed in substantial part by Defendants. Plaintiffs’ Lead Counsel Committee has submitted a memorandum in support of their motion. Counsel for Defendants have submitted a memorandum in opposition to Plaintiffs’ motion.

**II. BACKGROUND**

Plaintiffs have requested that the Court order Defendants to produce documents they have provided to the Independent Panel (the “Independent Panel” or “Panel”) of experts that Guidant Corporation (“Guidant”) established in June 2005 to review issues relating to what has been described as the same problems giving rise to the MDL Plaintiffs’ claims, along with any related documents or communications. Plaintiffs assert, in part, that Defendants’ only objection to the production of these materials is that they are subject to a “self-critical analysis privilege.” Plaintiffs have further asserted that no

such privilege is recognized in the Eighth Circuit; nor is any such privilege applicable to the Independent Panel documents in question.

Defendants acknowledge that they established the Independent Panel to recommend guidelines about the communication of information regarding life-sustaining implantable devices to physicians and patients. Presently, counsel for Defendants have identified approximately 70 documents, consisting of 2,853 pages, that Defendants provided to the Independent Panel. These documents, according to the Defendants, consist of many of the same documents that Defendants are producing as responsive to Plaintiffs' other document requests. In addition, Defendants assert that there are many other documents that they have provided to the Independent Panel that have not been reviewed by counsel and are not ready to be produced.

Plaintiffs' Request No. 24 seeks: "Any and all documents and communications that refer, relate or pertain to the Independent Panel that was convened to consider information relating to the Devices, including, but not limited to, all documents provided to the Independent Panel and any minutes of meeting of the Independent Panel." In addition to the self-critical analysis privilege, Defendants assert that Plaintiffs' request is overly broad, unduly burdensome, and that it seeks information that is neither relevant nor calculated to lead to the discovery of admissible evidence because it is not limited to the recall of failed mechanisms and relevant devices at issue in the litigation before the Court.

Plaintiffs assert that on June 22, 2005, shortly after Guidant's first recall of a Cardiac device, Guidant established an independent panel of experts "to recommend

guidelines for when to disseminate information to physicians and patients about life-sustaining implantable devices. Plaintiffs supplied a press release to the Court entitled *Guidant Requests Independent Panel to Recommend Physician and Patient Communication Guidelines* (June 22, 2005), available at [http://www.guidant.com/news/500/web\\_release/nr\\_000553.shtml](http://www.guidant.com/news/500/web_release/nr_000553.shtml). Guidant asserts that it started the Panel to ensure “the industry and the public have the opportunity to learn from the experience that Guidant and its patients have been through.” According to the press release, the Panel’s mission was to assess the surveillance of device problems and patient/physician education with the goal of establishing industry-wide guidelines and processes for patient notification systems.

On October 7, 2005, Plaintiffs served document requests, on Defendants, including a request for “any and all documents and communications that refer, relate or pertain to the Independent Panel that was convened to consider information relating to the devices, including, but not limited to, all documents provided to the Independent Panel and any minutes of meetings of the Independent Panel.” According to the Plaintiffs, Defendants responded to this request by stating that they would not produce the requested documents on the ground of “self-critical analysis privilege.”

**A. Self-critical Analysis Privilege**

The Court does not have to reach the issue of whether the Eighth Circuit or the District of Minnesota have recognized, to date, any self-critical analysis privilege. There is clearly a disinclination of the courts toward such evidentiary privileges. *In re Baycol*

*Products Litigation*, No. MDL 1431 (MJD/JGL 203 WL 22023449 (D. Minn. Mar. 21, 2003).

In the present case, the Court declines to extend the self-critical analysis privilege to the discovery sought. It must be observed by the Court that in the situations where the privilege has been narrowly recognized, it is only where there is a self-evaluation process involved that would be curtailed to the detriment of the public interest. Any fair scrutiny of the press release by the Defendants in this case and the asserted purpose for the Independent Panel establishes that the purpose of the Panel was not evaluative for the Defendants. Rather, the Defendants' press release itself stated, "the industry and the public have the opportunity to learn from the experience that Guidant and its patients have been through." Thus, even if the Court were to conclude that there was some type of self-critical analysis privilege alive and well in the Eighth Circuit or this District, it would decline to apply such a privilege to the facts and circumstances of the case before the Court. Such a privilege would be clearly inapplicable, for the reasons stated.

**B. Defendants' Objection that Plaintiffs' Request is Overbroad**

Defendants' primary objection here is that Plaintiffs seek information that is not relevant or calculated to lead to the discovery of admissible evidence, and that it is not limited to the recalled failure mechanisms and relevant devices at issue in the litigation before the Court. The Court has reviewed the briefs of both parties, and the press releases of June 22, 2005, July 27, 2005, and August 29, 2005. The Court is not suggesting that there are not others, but these are the ones the Court has reviewed.

The press releases stress that the Independent Panel will first review and analyze, and then provide the specific recommendations, to Guidant regarding four core issues defined in the formal charter of the Independent Panel as follows:

- Surveillance and interpretation of low-frequency trends among life-sustaining implantable devices that may affect patient safety and physician decisions for device management.
- Reassessment of benefit and risk to patients in light of new information about marketed devices.
- Device component failure analysis and estimation of its frequency.
- Development of more transparent, understandable and clinically useful communication processes to physicians and patients, including triggers for communication, timing, and novel methods of transferring information.

Given the nature of the allegations in the MDL before this Court and the purpose for which the Independent Panel was created, the Court concludes that Plaintiffs' requests are not overbroad because they are likely to lead to the discovery of admissible evidence. The fact that some of the materials submitted to the Independent Panel may not relate to each of the specific devices is not determinative of the Court's decision because it is clearly the case that the policy, approach, and attitude of the Defendants towards patients and physicians with respect to life-sustaining implantable devices are not only probative, but may well lead to the discovery of admissible evidence as to how the Defendants approached patients and physicians and the general public on all devices precisely as stated by the press release. Thus, at a minimum, the evidence is circumstantially relevant to the issues in the case. For these reasons, the Court will overrule the objections of Defendants as overbroad.

### **C. Unreasonably Cumulative or Duplicative**

The Court will expect the parties to create a reasonable time line to produce this information. However, to the extent the Plaintiffs are clearly entitled to see the substance of all of the information and the contents of all documents that were being submitted to the Panel, given the purpose of the creation of the Panel, the information is clearly not cumulative, even if it is being provided in some other context. The Plaintiffs are entitled to see what the breadth and scope of the information was, based upon individual documents submitted and what the package of information was that was being submitted to the Panel and the purpose of the Panel. The fact that the information may be provided elsewhere does not detract from the probative value of what the Defendants chose to present to the Independent Panel, given the purpose for the creation of the Independent Panel.

### **D. Unduly Burdensome**

It is the Court's view that it may well be burdensome, but not unduly burdensome, as contemplated by the rules, as long both parties are reasonable in approach, given the demands on Plaintiffs and the demands on Defendants in the discovery context. In other words, the Court will first expect the parties to work out a reasonable time line for this discovery, since the Defendants have asserted that many of the documents have not been reviewed as of yet. The Court expects both parties to be reasonable, as the Federal Rules of Civil Procedure and the ABA Civil Discovery Standards contemplate. In the absence of such an agreement, the Court will set the schedule.

Given the fact that these documents may be provided in conjunction with some other discovery request, the parties will have to decide whether or not they can resolve this issue so long as it is clear to the Plaintiffs what package of information was presented to the Independent Panel. In other words, as noted above, Plaintiffs are entitled to review all of the documents that were presented to the Panel so that the context and substance of the information the Defendants gave to the Panel can be understood by the Plaintiffs. If that can be done in some less burdensome fashion, then the parties should utilize their best efforts to reach an agreement. If not, the Court will make the decision on this issue with respect to timing and the form in which these documents will be provided to Plaintiffs.

### **III. CONCLUSION**

Based upon the presentations and submissions of the parties and the Court being duly advised in the premises, the Court hereby enters the following:

#### **ORDER**

1. Plaintiffs' Motion to Compel Defendants' Production of Documents Relating to the Independent Panel is **GRANTED**, consistent with the opinion of this Court.

Dated: March 16, 2006

s/Donovan W. Frank  
DONOVAN W. FRANK  
Judge of United States District Court