UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: GUIDANT CORP. IMPLANTABLE DEFIBRILLATORS PRODUCTS LIABILITY LITIGATION	MDL No. 05-1708 (DWF/AJB)
This Document Relates to: Leopoldo Duron, Jr., Plaintiff, v. Civil No. 06-25 (DWF/AJB) Guidant Corporation, Guidant Sales Corporation, Boston Scientific Corp., and Cardiac Pacemakers, Inc., Defendants.	**ORDER** **ADDRESSING PLAINTIFFS' AND DEFENDANT'S *DAUBERT* MOTIONS**
Eugene Clasby, *an individual on behalf of himself and all others similarly situated*, Plaintiff, v. Civil No. 05-2596 (DWF/AJB) Guidant Corporation, *an Indiana corporation*, Defendant.	

Thomas A. Schultz, Esq., and Kyle E. Lakin, Esq., Lopez Hodes Restaino Milman & Skikos, counsel for Plaintiff Leopoldo Duron, Jr.

Timothy A. Pratt, Esq., and Michael D. Moeller, Esq., Shook, Hardy & Bacon LLP, Thomas J. Stoddard, Esq., Gordon & Rees, counsel for Defendants Guidant Corporation and Guidant Sales Corporation.

Timothy A. Pratt, Esq., Shook, Hardy & Bacon LLP, counsel for Defendant Cardiac Pacemakers, Inc.

Lance A. Harke, Esq., and Sarah Clasby Engel, Esq., Harke & Clasby, LLP, counsel for Plaintiff Eugene Clasby.

Timothy A. Pratt, Esq., Michael D. Moeller, Esq., Deborah A. Moeller, Esq., and Eileen Tilghman Moss, Esq., Shook Hardy & Bacon, LLP, Joseph M. Price, Esq., Faegre & Benson, LLP, and Jennifer C. Webb, Esq., counsel for Defendant Guidant Corporation.

This matter is before the Court pursuant to Plaintiff's Motion to Exclude or Limit Testimony of John E. Moalli, Thomas Ross, and David F. Williams Pursuant to Federal Rules of Evidence 702 and Defendants'[1] Motion to Exclude Selected Testimony of Plaintiff's Experts.[2] Guidant opposes Plaintiff's Motion, and Plaintiff Leopoldo Duron, Jr. and Dr. Eugene Clasby oppose Guidant's Motion.

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[1] For the purposes of this Order, Defendants Guidant Corporation, Guidant Sales Corporation, Boston Scientific Corp., and Cardiac Pacemakers, Inc. shall be referred to collectively as "Guidant."

[2] The parties agree that, to the extent applicable, this Court's *Daubert* rulings in *Duron* will also apply to the *Clasby* case, as the experts disclosed in both cases are the same. Therefore, both Plaintiff and Guidant incorporated their arguments made in the *Duron* case into their *Daubert* submissions made in the *Clasby* case. Thus, this Order addresses all *Daubert* issues in both the *Duron* and *Clasby* cases.

BACKGROUND

In March 2002, Dr. Steven Higgins surgically implanted an implantable cardioverter defibrillator ("ICD"), the VENTAK PRIZM 2 DR, Model 1861 (the "Prizm 2"), in Leopoldo Duron, Jr. after an electrophysiology study showed that he needed an ICD. In December, 2002, Dr. Interian surgically implanted a Prizm 2 in Dr. Eugene Clasby after he collapsed and suffered cardiac arrest. An ICD is a device that is implanted in a patient with certain ventricular arrhythmias or with a risk of having such arrhythmias. It monitors a patient's heart rhythm and, if needed, acts to correct or restore that rhythm. An ICD can function both as a pacemaker and a defibrillator. Guidant manufactured the Prizm 2.

On June 17, 2005, Guidant issued a notice to doctors explaining that the Prizm 2 ICDs manufactured before April 2002 were subject to a recall due to a short-circuiting problem. On June 29, 2005, the Food and Drug Administration classified Guidant's recall as a Class I recall, which is reserved for devices that create a reasonable probability of serious adverse health consequence or death. On August 19, 2005, Dr. Sardul Singh explanted Duron's Prizm 2 and replaced it with a different Guidant-manufactured ICD. On May 4, 2006, Dr. David Galbut explanted Clasby's Prizm 2 and replaced it with a different Guidant-manufactured ICD. Clasby's original device was not part of the 2005 recall.

On October 14, 2005, Duron filed a complaint in the Southern District of California against Guidant related to the recall of the Prizm 2 and Duron's subsequent explant surgery. On January 11, 2006, the Judicial Panel on Multidistrict Litigation

transferred Duron's case to this Court pursuant to 28 U.S.C. § 1407 for coordinated and consolidated pretrial proceedings. On June 3, 2005, Clasby filed a complaint in the Southern District of Florida against Guidant related to alleged defects in the Prizm 2 and Clasby's subsequent explant surgeries. On November 7, 2005, the Judicial Panel on Multidistrict Litigation transferred Clasby's case to this Court pursuant to 28 U.S.C. § 1407 for coordinated and consolidated pretrial proceedings. After agreement by the Plaintiffs Lead Counsel Committee ("PLCC"), acting on behalf of the MDL plaintiffs, and Guidant to try five bellwether cases, *Duron v. Guidant Corp., et al.*—a case classified as involving an explant without complications—was chosen by the Court to be the first bellwether trial, and *Clasby v. Guidant Corp., et al.*—a case classified as involving an explant with complications—was chosen by the Court to be the second bellwether trial.[3] The *Duron* trial is scheduled to begin on July 30, 2007, and the *Clasby* trial is scheduled to begin on August 27, 2007.

ORDER

Guidant has moved to exclude or limit the testimony of certain of Duron and Clasby's experts, pursuant to Federal Rules of Evidence 403 and 702. Rule 403 permits the exclusion of evidence "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Fed. R. Evid. 403. Rule 702 provides a standard of "helpfulness" that requires that expert

[3] Both Duron and Clasby consented to trial in this Court and waived their right to object to venue.

testimony "assist the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. In addition, Rule 704 provides that "testimony . . . otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact." Fed. R. Evid. 704.

Before accepting the testimony of an expert witness, the trial court is charged with a "gatekeeper" function of determining whether an opinion is based upon sound, reliable theory, or whether it constitutes rank speculation. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589-90 (1993). In *Daubert*, the United States Supreme Court imposed an obligation upon trial court judges to ensure that scientific testimony is not only relevant, but also reliable under the Rules of Evidence. *Id.* at 579. In doing so, the Court can consider: (1) whether the theory or technique can be and has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known rate of potential error; and (4) whether the theory has been generally accepted. *Id.* at 593-94. The purpose of these requirements "is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kuhmo Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999).

In *Kuhmo Tire*, the Supreme Court determined, "the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Id.* In other words, a trial court should consider the specific factors identified in *Daubert* where they are reasonable measures of the

reliability of expert testimony. *Id.* The objective of that requirement is to ensure the reliability and relevancy of expert testimony. *Id.*

The Court's focus should be on whether the testimony is grounded upon scientifically valid reasoning or methodology. *United States v. Dico, Inc.*, 266 F.3d 864, 869 (8th Cir. 2001). "As a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination. Only if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded." *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 929-30 (8th Cir. 2001).

Based upon the parties' submissions, arguments of counsel, together with all pleadings, records, and files herein, the Court grants in part and denies in part Plaintiff's motion, and grants in part and denies in part Guidant's motion.

It is **HEREBY ORDERED** that:

1. Plaintiff Duron's Motion to Exclude or Limit Testimony of John E. Moalli, Thomas Ross, and David F. Williams Pursuant to Federal Rules of Evidence 702 (MDL No. 05-1708 (DWF/AJB), Doc. No. 1792; Civ. No. 06-25 (DWF/AJB), Doc. No. 160), and Plaintiff Clasby's Motion to Exclude or Limit Testimony of John E. Moalli, Thomas Ross, and David F. Williams Pursuant to Federal Rules of Evidence 702 (MDL No. 05-1708 (DWF/AJB), Doc. No. 1819; Civ. No. 05-2596 (DWF/AJB), Doc. No. 12) is **GRANTED IN PART** and **DENIED IN PART** as follows:

a. Plaintiffs' Motion to Exclude Dr. John Moalli's opinion that the Prizm 2 is a reliable device is **DENIED**, pursuant to Rule 702. Pursuant to *Daubert*, the focus must be solely on principles and methodology, not on the conclusions that an expert generates. Here, the record establishes the requisites of Rule 702 and the evidentiary threshold required by *Daubert*, 509 U.S. at 589, and *Kumho Tire Co., Ltd.*, 526 U.S. at 152. The Court finds that Plaintiffs' arguments regarding the accuracy of Guidant's self-published Product Performance Reports ("PPRs") and any alleged "underreporting" of deaths, including any failure to account for certain documents in the record, go to weight rather than admissibility. Therefore, subject to proper foundation being laid at trial, Dr. Moalli's opinion is presumptively admissible. To the extent Dr. Moalli intends to testify as to the underlying statistics supporting Guidant's PPRs, proper foundation will need to be laid prior to such testimony. The Court reserves the right to preclude any testimony regarding statistics under Rule 403 at trial. In addition, in order to meet the Rule 703 balancing test, the Court reserves the right to provide a limiting instruction to the jury regarding the expert's use of statistics. Further, to the extent that such testimony regarding Guidant's PPRs and the underlying statistics supporting Guidant's PPRs is intended to be introduced through more than one expert, the Court reserves the right to exclude certain expert testimony on Rule 403 grounds for being cumulative. Such testimony, provided proper foundation

is laid, should only be presented to the jury once. Finally, Dr. Moalli is not allowed to mention any comparison between Guidant's and its competitors' devices nor any comparison as to Guidant's and its competitors' statistics supporting the reliability of their devices.

b. Plaintiffs' Motion to Exclude Dr. John Moalli's opinion that the header is not defective in design is **GRANTED IN PART AND DENIED IN PART** with respect to Duron, and **DENIED** with respect to Clasby. Having considered the submissions, pleadings, and arguments of the parties, the Court finds that evidence as to whether the Prizm 2's header was defective in design is presumptively admissible pursuant to Rules 402 and 403 in Duron to the extent that such testimony is limited to discussion of Guidant's triple redundancy theory as it relates to the surviving claims or defenses. Because the Court granted summary judgment on Duron's design defect claim, Dr. Moalli's opinion that the header does not constitute a "design defect" is not admissible under Rules 402 and 403. In addition, such testimony does not meet the requisites of Rule 702 and the evidentiary threshold required by *Daubert*, 509 U.S. at 589, and *Kumho Tire Co., Ltd.*, 526 U.S. at 152. As to Clasby, the Court finds that Dr. Moalli's opinion as to whether the Prizm 2's header was defective in design is presumptively admissible pursuant to Rules 402 and 403, including any testimony as to whether or not the header constitutes a "design defect."

c. Plaintiffs' Motion to Exclude Dr. John Moalli's opinion that polyimide was an appropriate insulator is **DENIED**, pursuant to Rule 702. The record establishes the requisites of Rule 702 and the evidentiary threshold required by *Daubert*, 509 U.S. at 589, and *Kumho Tire Co., Ltd.*, 526 U.S. at 152. Further, having considered the submissions, pleadings, and arguments of the parties, the Court finds that Dr. Moalli's opinion regarding the use of polyimide as an insulator is presumptively admissible pursuant to Rules 402 and 403, subject to proper foundation being laid at trial. The Court finds that Plaintiffs' argument that Dr. Moalli's patent search methodology is fundamentally flawed goes to weight rather than admissibility.

d. Plaintiffs' Motion to Exclude Dr. John Moalli's opinion that the Duron and Clasby devices had no manufacturing defect is **DENIED**, pursuant to Rule 702. The record establishes the requisites of Rule 702 and the evidentiary threshold required by *Daubert*, 509 U.S. at 589, and *Kumho Tire Co., Ltd.*, 526 U.S. at 152. Subject to proper foundation being laid at trial, Dr. Moalli's opinion is presumptively admissible.

e. Plaintiffs' Motion to Exclude Dr. Thomas Ross's opinion that the Prizm 2 is a reliable defibrillator is **DENIED**. Pursuant to *Daubert*, the focus must be solely on principles and methodology, not on the conclusions that an expert generates. Here, the record establishes the requisites of Rule 702 and the evidentiary threshold required by *Daubert*, 509 U.S. at

589, and *Kumho Tire Co., Ltd.*, 526 U.S. at 152. Also, given his years of experience as an electrophysiologist, cardiologist, and treating physician, the Court finds that Dr. Ross is a qualified witness to lay the requisite foundation for his opinion. In addition, the Court finds that Plaintiffs' arguments regarding the accuracy of Guidant's PPRs and any alleged "underreporting" of deaths, including any failure to account for certain documents in the record goes to weight rather than admissibility. Therefore, subject to proper foundation being laid at trial, Dr. Ross's opinion is presumptively admissible, however, his opinion must be based on and limited to his own personal experience. In addition, absent an offer of proof made to the Court outside the presence of the jury, Dr. Ross shall not mention his reliance on the FDA's failure to order or recommend explants. Further, to the extent Dr. Ross intends to testify as to the underlying statistics supporting Guidant's PPRs, proper foundation will need to be laid prior to such testimony. The Court reserves the right to preclude any testimony regarding statistics under Rule 403 at trial. In addition, in order to meet the Rule 703 balancing test, the Court reserves the right to provide a limiting instruction to the jury regarding the expert's use of statistics. Further, to the extent that such testimony regarding Guidant's PPRs and the underlying statistics supporting Guidant's PPRs is intended to be introduced through more than one expert, the Court reserves the right to exclude certain expert testimony on Rule 403 grounds for being

cumulative. Such testimony, provided proper foundation is laid, should only be presented to the jury once. Finally, Dr. Ross is not allowed to mention any comparison between Guidant's and its competitors' devices nor any comparison as to Guidant's and its competitors' statistics supporting the reliability of their devices.

f. Plaintiffs' Motion to Exclude Dr. Thomas Ross's opinion that risks from replacing either Duron's or Clasby's device exceeded the benefit of replacement is **GRANTED**. Such an opinion by Dr. Ross does not meet the requisites of Rules 403 and 702 or the evidentiary threshold required by *Daubert*, 509 U.S. at 589, and *Kumho Tire Co., Ltd.*, 526 U.S. at 152. Dr. Ross shall not be permitted to (1) reference the fact that the FDA failed to order explants of the Prizm 2s; (2) reference the Canadian Report or its applicability to a risk analysis; (3) testify that in his opinion, he would not have recommended that Duron or Clasby be implanted with a Prizm 2; and (4) testify that even had he known of the Prizm 2 defects, he would have preferred to implant the defective pre-mitigation devices in his patients, rather than devices that had been manufactured after mitigation of the defects. The proper persons that could testify as to the risks from replacing either Duron's or Clasby's device or the benefits of replacement for Duron or Clasby would be their treating or implanting physicians.

g. Plaintiffs' Motion to Exclude Dr. Thomas Ross's opinion that Duron's emotional symptoms are similar to many patients with

defibrillators and cardiovascular disease is **DENIED**, pursuant to Rule 702. The record establishes the requisites of Rule 702 and the evidentiary threshold required by *Daubert*, 509 U.S. at 589, and *Kumho Tire Co., Ltd.*, 526 U.S. at 152. Subject to proper foundation being laid at trial, Dr. Ross's opinion is presumptively admissible. Given his years of experience as an electrophysiologist, cardiologist, and treating physician, the Court finds that Dr. Ross is a qualified witness to lay the requisite foundation for his opinion. However, his opinion shall be limited to his general opinion as a treating physician, not as an expert in psychology or psychiatry, and his opinion shall be limited to his review of Duron and Clasby's medical reports.

h. Plaintiffs' Motion to Exclude Dr. Thomas Ross's opinion that Guidant acted responsibly is **GRANTED IN PART**. The Court finds that Dr. Ross is qualified to give his opinion on the relationship between ICD manufacturers and physicians, a physician's access to information regarding ICD's, a physician's duty to advise patients, his expectation as a physician of manufacturers, and his understanding of medical norms regarding disclosures from ICD manufacturers to physicians. Therefore, subject to proper foundation being laid at trial, Dr. Ross's opinion will be allowed as to whether Guidant's actions were reasonable and appropriate. However, Dr. Ross's opinion on whether Guidant acted "responsibly" is not admissible under Rule 403. The probative value of such evidence is

substantially outweighed by the danger of unfair prejudice. In addition, such testimony does not meet the requisites of Rule 702 and the evidentiary threshold required by *Daubert*, 509 U.S. at 589, and *Kumho Tire Co., Ltd.*, 526 U.S. at 152.

i. Plaintiffs' Motion to Exclude Professor David Williams's opinion that Prizm 2 met reliability performance standards is **DENIED**, pursuant to Rule 702. Pursuant to *Daubert*, the focus must be solely on principles and methodology, not on the conclusions that an expert generates. Here, the record establishes the requisites of Rule 702 and the evidentiary threshold required by *Daubert*, 509 U.S. at 589, and *Kumho Tire Co., Ltd.*, 526 U.S. at 152. Given his many years of experience in biomedical and materials science, including his experience dealing with implantable medical devices and interpretation of reliability rates and survival rates, the Court finds that Professor Williams is a qualified witness to lay the requisite foundation for his opinion. Professor Williams is allowed to rely on information and documents in the record, including Guidant's PPRs. Therefore, subject to proper foundation being laid at trial, Professor Williams's opinion is presumptively admissible. However, to the extent Professor Williams intends to testify as to the underlying statistics supporting Guidant's PPRs, proper foundation will need to be laid prior to such testimony. The Court reserves the right to preclude any testimony regarding statistics under Rule 403 at trial. In addition, in order to meet the

Rule 703 balancing test, the Court reserves the right to provide a limiting instruction to the jury regarding the expert's use of statistics. Further, to the extent that such testimony regarding Guidant's PPRs and the underlying statistics supporting Guidant's PPRs is intended to be introduced through more than one expert, the Court reserves the right to exclude certain expert testimony on Rule 403 grounds for being cumulative. Such testimony, provided proper foundation is laid, should only be presented to the jury once. Finally, Professor Williams is not allowed to mention any comparison between Guidant's and its competitors' devices nor any comparison as to Guidant's and its competitors' statistics supporting the reliability of their devices.

j. Plaintiffs' Motion to Exclude Professor David Williams's opinion that both Duron and Clasby's Prizm 2s are free from manufacturing defects is **DENIED**, pursuant to Rule 702. Pursuant to *Daubert*, the focus must be solely on principles and methodology, not on the conclusions that an expert generates. Here, the record establishes the requisites of Rule 702 and the evidentiary threshold required by *Daubert*, 509 U.S. at 589, and *Kumho Tire Co., Ltd.*, 526 U.S. at 152. The Court finds that Plaintiffs' arguments regarding the fact that Professor Williams has not examined Duron's device goes to weight rather than admissibility. Therefore, subject to proper foundation being laid at trial, Professor Williams's opinion is presumptively admissible. Plaintiffs are allowed to use Professor

Williams's deposition testimony stating that he is not in a position to comment on whether or not there is a manufacturing defect, and that he would not offer such an opinion unless he had actually physically seen the device, during cross-examination.

2. Defendants' Motion to Exclude Selected Testimony of Plaintiff's Experts (MDL No. 05-1708 (DWF/AJB), Doc. No. 1806; Civ. No. 06-25 (DWF/AJB), Doc. No. 155; Civ. No. 05-2596 (DWF/AJB), Doc. No. 7) is **GRANTED IN PART** and **DENIED IN PART** as follows:

a. Guidant's Motion to Exclude Dr. Parisian's opinion that the FDA did not approve the use of polyimide in the header of the Prizm 2 device is **GRANTED IN PART**. Dr. Parisian shall not be permitted to render an opinion on whether the FDA "approved" the use of polyimide in the header of the Prizm 2 device. Such an opinion by Dr. Parisian, regardless of whether it is an impermissible legal conclusion, does not meet the requisites of Rule 702 and the evidentiary threshold required by *Daubert*, 509 U.S. at 589, and *Kumho Tire Co., Ltd.*, 526 U.S. at 152. In addition, Dr. Parisian's opinion on what the FDA did and did not approve does not meet Rule 104 foundation requirements because she lacks personal knowledge on that subject. The proper person that could testify as to what the FDA did and did not approve as to the use of polyimide in the header of the Prizm 2 based on Guidant's submissions to the FDA would be the person responsible for approving the Prizm 2 for distribution in 2000.

Because of this, and given the nature of the opinion, it fails on Rule 403 grounds as well. However, Dr. Parisian is allowed to testify as to the general nature of the approval and regulatory process including compliance with FDA regulations and guidelines, the FDA's general expectations with respect to testing and marketing of new products, Guidant's actions in that respect, and her opinion as to whether Guidant's actions were reasonable and appropriate.

b. Guidant's Motion to Exclude Dr. Parisian's opinion that Guidant violated its obligations as a manufacturer and seller of an FDA-approved medical device by its failure to notify doctors and patients of a product defect (post-sale duty to warn) is **GRANTED IN PART**, pursuant to Rules 702 and 403. Dr. Parisian shall not be permitted to render an opinion on whether Guidant "violated" its obligations as a manufacturer and seller of an FDA-approved medical device by its failure to notify doctors and patients of a product defect. Dr. Parisian is allowed to testify as to the general nature of the regulatory process including compliance with FDA regulations and guidelines, Guidant's actions in that respect, and her opinion as to whether Guidant's actions were reasonable and appropriate. The Court finds that such testimony would assist the trier of fact to understand the evidence or to determine fact issues given the allegations by the Plaintiffs, the purported defenses of the Defendants, and the overall factual record in the case. Dr. Parisian's testimony, however,

shall be limited to her opinion on Guidant's failing to report to the FDA. Dr. Parisian is not allowed to testify as to Guidant's failing to report to doctors and patients. This decision of the Court is made pursuant to Rules 702 and 104 of the Federal Rules of Evidence.

c. Guidant's Motion to Exclude Dr. Parisian's opinion that Guidant acted in violation of the Prizm 2 Premarket Approval ("PMA") letter and the federal Food, Drug, and Cosmetic Act by knowingly selling defective devices after April 2002, is **GRANTED IN PART AND DENIED IN PART**. Pursuant to Rule 702, Dr. Parisian is allowed to testify as to compliance with FDA regulations, Guidant's actions in that respect, and her opinion as to whether Guidant's actions were reasonable and appropriate. In addition, Dr. Parisian is allowed to defer to other experts as to their opinion on whether the PRIZM 2 was "defective" to the extent that those opinions are otherwise admissible. Pursuant to Rules 104 and 403, Dr. Parisian is not allowed to testify as to Guidant's knowledge. There is no foundation for such opinion testimony on what Guidant knowingly did or did not do. Further, such testimony from Dr. Parisian does not meet the requisites of Rule 702 and the evidentiary threshold required by *Daubert*, 509 U.S. at 589, and *Kumho Tire Co., Ltd.*, 526 U.S. at 152, because such testimony is not based upon sufficient facts or data. To the extent any expert intends to testify as to what Guidant knowingly did, the Court notes that the ultimate issue is a fact issue for the jury.

Therefore, such testimony shall not be allowed pursuant to Rules 104 and 403. Dr. Parisian also shall not be permitted to render an opinion on whether Guidant "violated" the Prizm 2 PMA approval letter and the federal Food, Drug, and Cosmetic Act, pursuant to Rules 702 and 403.

d. Guidant's Motion to Exclude Dr. Parisian's opinion that Guidant failed to comply with and violated the conditions of approval for the PRIZM 2 PMA is **GRANTED IN PART AND DENIED IN PART**. The Court finds that this opinion is presumptively admissible pursuant to Rule 702, subject to proper foundation being laid. The Court rejects Guidant's assertion the Dr. Parisian's opinion in this respect is irrelevant and/or an impermissible legal opinion. Although manufacturing changes were made after Duron's Prizm 2 was implanted, the changes were made before Duron incurred his ultimate injury in the explant. Therefore, Dr. Parisian's opinion is relevant to Duron and Clasby's claims for punitive damages. Dr. Parisian, however, shall not be permitted to render an opinion on whether Guidant "violated" the conditions of approval for the PRIZM 2 PMA, pursuant to Rules 702 and 403.

e. Guidant's Motion to Exclude Dr. Parisian's opinion that Guidant failed to comply with regulations governing Class III medical devices, including those related to their manufacture and sale is **GRANTED IN PART AND DENIED IN PART**. Dr. Parisian is allowed to testify as to the general nature of the approval and regulatory process

including compliance with FDA regulations and guidelines, the FDA's general expectations with respect to testing and marketing of new products, Guidant's actions in that respect, and her opinion as to whether Guidant's actions were reasonable and appropriate. Such testimony meets the requisites of Rule 702 and the evidentiary threshold required by *Daubert*, 509 U.S. at 589, and *Kumho Tire Co., Ltd.*, 526 U.S. at 152. Dr. Parisian is not allowed to testify as to whether Guidant's conduct was ethical or not because such testimony lacks sufficient foundation, does not meet the requisites of Rule 702, and under Rule 403, the probative value of testimony as to Guidant's "ethical or unethical conduct" is substantially outweighed by the danger of unfair prejudice.

f. Guidant's Motion to Exclude Mr. Armstrong's opinion that Mr. Duron's or Mr. Clasby's Prizm 2 was not built per design specifications is **DENIED.** Having considered the submissions, pleadings, and arguments of the parties, the Court finds that evidence as to whether Mr. Duron's or Mr. Clasby's Prizm 2 was built per design specifications is presumptively admissible pursuant to Rules 402 and 403.

g. Guidant's Motion to Exclude Mr. Armstrong's opinion that Mr. Duron's or Mr. Clasby's Prizm 2 might have malfunctioned had it remained implanted or that the presence of the manufacturing defect in the Prizm 2 increased the risk to people implanted of it failing to function appropriately is **DENIED**. Given Mr. Armstrong's considerable

experience with the medical device industry and implantable defibrillators and pacemakers, the Court finds that Mr. Armstrong is a qualified witness to lay the requisite foundation for these opinions. Subject to foundation being laid at trial, such testimony will be presumptively admissible pursuant to Rule 702. The Court rejects Guidant's assertion that Mr. Armstrong cannot reliably opine about polyimide generally or about factors that he believes degrade polyimide when used in ICDs. Mr. Armstrong is allowed to testify as to his knowledge of industry standards as to the use of polyimide in ICDs. To the extent Guidant's request for exclusion includes any opinion from Mr. Armstrong regarding a statistical analysis of the likelihood of either Duron or Clasby's specific devices failing, Guidant's request is **GRANTED** subject to Plaintiff's right to make an offer of proof to the Court, outside the presence of the jury, pursuant to Rule 104. Until further order of the Court, Mr. Armstrong is not allowed to testify as to any statistical analysis of the likelihood of any specific devices failing.

h. Guidant's Motion to Exclude Dr. Tyers' opinion that Guidant should have warned the medical community, in February 2002, of the Prizm 2's propensity to fail from electrical arcing in the header is **DENIED**. Such testimony by Dr. Tyers is presumptively admissible pursuant to Rule 702, subject to proper foundation being laid at trial. The Court finds that Dr. Tyers is qualified to give his opinion on the

relationship between ICD manufacturers and physicians, a physician's access to information regarding ICD's, a physician's duty to advise patients, his expectation as a physician of manufacturers, and his understanding of medical norms regarding disclosures from ICD manufacturers to physicians. The Court finds that such testimony will assist the jury. Therefore, subject to proper foundation being laid at trial, Dr. Tyers' opinion will be allowed as to whether Guidant's actions were reasonable and appropriate.

i. Guidant's Motion to Exclude Dr. Tyers' opinion that Guidant failed to notify the medical community of engineering changes to the Prizm 2 is **DENIED**, pursuant to Rule 702. Dr. Tyers' opinion is presumptively admissible subject to proper foundation being laid at trial.

j. Guidant's Motion to Exclude Dr. Tyers' opinion that Duron and Clasby sustained injury from the implantation and explantation of their Prizm 2s is **GRANTED IN PART AND DENIED IN PART**. First, Guidant has shown insufficient prejudice from this opinion being disclosed in an untimely manner; therefore, Guidant's untimeliness argument fails. Second, because of Dr. Tyers' qualifications, he is able to review Duron and Clasby's medical reports and, subject to proper foundation being laid at trial, the Court will allow Dr. Tyers to opine on whether he believes they were injured by their explant surgeries. However, Dr. Tyers will not be allowed to testify that in his opinion, either Duron or Clasby should not

have been implanted with an ICD. Such opinion is inadmissible under Rules 402 and 403.

k. Guidant's Motion to Exclude Dr. Tyers' opinion that Guidant violated ethical norms is **GRANTED**. The Court finds that Dr. Tyers is qualified to give his opinion on the relationship between ICD manufacturers and physicians, a physician's access to information regarding ICD's, a physician's duty to advise patients, his expectation as a physician of manufacturers, and his understanding of medical norms regarding disclosures from ICD manufacturers to physicians. Therefore, subject to proper foundation being laid at trial, Dr. Tyers' opinion will be allowed as to whether Guidant's actions were reasonable and appropriate. However, Dr. Tyers's opinion on Guidant's compliance with ethical norms is not admissible under Rule 403. The probative value of such evidence is substantially outweighed by the danger of unfair prejudice. In addition, such testimony does not meet the requisites of Rule 702 and the evidentiary threshold required by *Daubert*, 509 U.S. at 589, and *Kumho Tire Co., Ltd.*, 526 U.S. at 152.

l. Guidant's Motion to Exclude Dr. Tyers' opinion that the majority of the medical community has specific expectations of ICD manufacturers like Guidant is **DENIED**, pursuant to Rule 702. Such information will assist the jury to determine fact issues in the case given the allegations by the Plaintiffs, the purported defenses of the Defendants, and

the overall factual record in the case. The Court finds that Dr. Tyers is qualified to give his opinion on the relationship between ICD manufacturers and physicians, a physician's access to information regarding ICD's, a physician's duty to advise patients, his expectation as a physician of manufacturers, and his understanding of medical norms regarding disclosures from ICD manufacturers to physicians. Further, in light of the fact that Dr. Tyers is frequently consulted by physicians specializing in the care of patients receiving implantation of pacemakers and ICDs, Dr. Tyers is qualified to opine generally on the expectations of the medical community. Therefore, Dr. Tyers' opinions as to what he believes the medical community's expectations are of ICD manufacturers are presumptively admissible, subject to proper foundation being laid at trial. Guidant's assertion that because Dr. Higgins' opinion conflicts with Dr. Tyers' opinion, Dr. Tyers' opinion is therefore unreliable or unsupported is rejected by the Court. The Court finds that Guidant's argument goes to the weight rather than its admissibility.

m. Guidant's Motion to Exclude Dr. Tyers' opinion that the majority of physicians and patients would have taken certain action(s) had Guidant notified them of the risk of a header short in the Prizm 2 is **GRANTED**. Such an opinion by Dr. Tyers does not meet the requisites of Rule 702 and the evidentiary threshold required by *Daubert*, 509 U.S. at 589, and *Kumho Tire Co., Ltd.*, 526 U.S. at 152. In addition, Dr. Tyers'

opinion does not meet Rule 104 foundation requirements because he lacks personal knowledge as to what specific physicians and patients would have done. Given the nature of the opinion, it fails on Rule 403 grounds as well. To the extent Dr. Tyers intends to opine on what actions *he* would have taken had Guidant notified him of the risk of a header short in the Prizm 2, based on proper foundation being laid at trial, such testimony is presumptively admissible.

n. Guidant's Motion to Exclude Dr. Jewell's opinion that the reliability numbers in Guidant's PPRs are ineffective for assessing a patient's risk of serious device malfunction is **DENIED**. The Court finds that Dr. Jewell's opinion is presumptively admissible pursuant to Rule 702, subject to proper foundation being laid at trial. The Court rejects Guidant's assertion that Dr. Jewell's opinion as to the effectiveness of the reliability numbers in Guidant's PPRs is irrelevant. Although the PPRs were issued after Duron's Prizm 2 was implanted, they were issued before Duron incurred his ultimate injury in the explant. Therefore, Dr. Jewell's opinion may be relevant to some of the parties' claims or defenses and is relevant, at a minimum, to Duron and Clasby's claims for punitive damages. In addition, given Dr. Jewell's experience in biostatistics, the Court finds that Dr. Jewell is a qualified witness to lay the requisite foundation for this opinion. The Court notes that a number of the experts base their opinions on Guidant's PPRs. The Court recommends that the parties consider what

would be agreeable to all parties as to the scope of the use of these PPRs at trial. Any remaining issues as to such scope should be brought to the Court's attention at the Pre-trial.

o. Guidant's Motion to Exclude Dr. Jewell's opinion that Guidant had not clearly delineated "trigger level" for decisions to communicate, report, or take action with regard to device malfunctions is **GRANTED**, pursuant to Rule 702 and the evidentiary threshold required by *Daubert*, 509 U.S. at 589, and *Kumho Tire Co., Ltd.*, 526 U.S. at 152. In addition, based on the record before it, the Court finds such area of testimony to be outside Dr. Jewell's expertise as a biostatistician, and thus, pursuant to Rules 702 and 403, he shall not be permitted to testify as such.

p. Guidant's Motion to Exclude Dr. Jewell's opinion that there is a distinct advantage to change-out for the entire Prizm 2 device population is **GRANTED**. Dr. Jewell's opinion does not meet the requisites of Rule 702 and the evidentiary threshold required by *Daubert*, 509 U.S. at 589, and *Kumho Tire Co., Ltd.*, 526 U.S. at 152. In addition, based on the record before it, the Court finds such area of testimony to be outside Dr. Jewell's expertise as a biostatistician, and thus, pursuant to Rules 702 and 403, he shall not be permitted to testify as to the balancing of explant risks with arcing failure risks.

q. Guidant's Motion to Exclude Dr. Swerdlow's opinion that when an ICD manufacturer determines that a non-random malfunction may

have serious clinical consequences and that future similar failures are likely, physicians expect: (1) that the manufacturer will make a substantive effort to determine the likelihood of future failures, including an active audit and, if appropriate, accelerated laboratory testing; (2) that the manufacturer will notify physicians promptly; and (3) that the manufacturer will act expeditiously to retrieve potentially-affected ICDs that have not been implanted, is **DENIED**, pursuant to Rule 702. Such information will assist the jury to determine fact issues given the allegations by the Plaintiffs, the purported defenses of the Defendants, and the overall factual record in the case. The Court finds that Dr. Swerdlow is qualified to give his opinion on his expectation as a physician of ICD manufacturers when a manufacturer determines that a non-random malfunction may have serious clinical consequences and that future similar failures are likely. Further, in light of the fact that Dr. Swerdlow has not only implanted 800-900 ICDs, but has also worked with another surgeon to implant 250-300 additional ICDs, and has consulted with both Medtronic, Inc. and St. Jude Medical, Inc. regarding ICDs, Dr. Swerdlow is qualified to opine generally on the expectations of the medical community. To the extent that Dr. Swerdlow has not specifically consulted physicians specializing in the care of patients receiving ICDs, such assertions go to weight not admissibility. Therefore, Dr. Swerdlow's opinions as to what he believes the medical community's expectations are of ICD manufacturers are presumptively admissible,

subject to proper foundation being laid at trial. Guidant's arguments as to Dr. Swerdlow's lack of experience in medical device manufacturing, FDA requirements, and polyimide go to weight rather than admissibility.

r. Guidant's Motion to Exclude Dr. Swerdlow's opinion that Guidant withheld information from physicians regarding an electrical arcing problem in the Prizm 2, and in doing so, Guidant: (1) denied physicians the information necessary to provide patients with ongoing informed consent; (2) denied individual ICD patients the information necessary to decide, in consultation with their physicians, whether or not to explant at-risk ICDs; and (3) denied physicians information they might reasonably use in deciding not to select Guidant ICDs for de novo implants, is **GRANTED IN PART AND DENIED IN PART**, pursuant to Rule 702. Such information will assist the jury to determine fact issues given the allegations by the Plaintiffs, the purported defenses of the Defendants, and the overall factual record in the case. The Court finds that Dr. Swerdlow is qualified to give his opinion on the relationship between ICD manufacturers and physicians, a physician's access to information regarding ICD's, a physician's duty to advise patients, his expectation as a physician of manufacturers, and his understanding of what information is necessary to provide physicians and patients to allow for an informed decision regarding implants and explants. Therefore, Dr. Swerdlow's opinions as to what information he believes was necessary for Guidant to

provide to physicians and patients so they could make informed decisions as to implants and explants are presumptively admissible, subject to proper foundation being laid at trial. Guidant's arguments as to Dr. Swerdlow's lack of experience in medical device manufacturing, FDA requirements, and polyimide go to weight rather than admissibility. However, Dr. Swerdlow's opinion on any moral or ethical accountability attributable to Guidant's failure to disclose information to physicians is not admissible under Rule 403. The probative value of such evidence is substantially outweighed by the danger of unfair prejudice. In addition, such testimony does not meet the requisites of Rule 702 and the evidentiary threshold required by *Daubert*, 509 U.S. at 589, and *Kumho Tire Co., Ltd.*, 526 U.S. at 152.

s. Guidant's Motion to Exclude Dr. Swerdlow's opinion that if Guidant had disclosed certain information, physicians would have: (1) discussed therapeutic risks, benefits, and alternatives with patients implanted with pre-mitigation Prizm 2s; (2) implanted no or few pre-mitigation Prizm 2s; (3) explanted many pre-mitigation Prizm 2s; (4) reduced utilization of the Prizm 2; and (5) implanted fewer overall Guidant ICDs and more ICDs manufactured by Guidant's competitors, is **GRANTED IN PART**. Such an opinion by Dr. Swerdlow does not meet the requisites of Rule 702 and the evidentiary threshold required by *Daubert*, 509 U.S. at 589, and *Kumho Tire Co., Ltd.*, 526 U.S. at 152. In

addition, Dr. Swerdlow's opinion does not meet Rule 104 foundation requirements because he lacks personal knowledge as to what specific physicians and patients would have done. Given the nature of the opinion, it also fails on Rule 403 grounds. In addition, Dr. Swerdlow's opinion on any moral or ethical accountability attributable to Guidant's failure to disclose information to physicians is not admissible under Rule 403. The probative value of such evidence is substantially outweighed by the danger of unfair prejudice. In addition, such testimony does not meet the requisites of Rule 702 and the evidentiary threshold required by *Daubert*, 509 U.S. at 589, and *Kumho Tire Co., Ltd.*, 526 U.S. at 152. However, to the extent Dr. Swerdlow intends to opine on what actions *he* would have taken had Guidant disclosed certain information to him, based on proper foundation being laid at trial, such testimony is presumptively admissible. Further, the Court rejects Guidant's assertion that because Dr. Higgins' opinion conflicts with Dr. Swerdlow's opinion as to the timing of Guidant's disclosure Dr. Swerdlow's opinion is therefore unreliable or irrelevant. The Court finds that Guidant's argument goes to weight rather than admissibility.

t. Guidant's Motion to Exclude Dr. Healy's opinion that polyimide was not an appropriate material for use in Guidant's ICDs is **DENIED**, pursuant to Rule 702. The record establishes the requisites of Rule 702 and the evidentiary threshold required by *Daubert*, 509 U.S. at

589, and *Kumho Tire Co., Ltd.*, 526 U.S. at 152. Given Dr. Healy's experience with biomaterials and biodegradability, and specifically his experience with the design of polymers whose function is to degrade in the human body, the Court finds that Dr. Healy is a qualified witness to lay the requisite foundation for his opinion. Further, having considered the submissions, pleadings, and arguments of the parties, the Court finds that Dr. Healy's opinion regarding the use of polyimide in a human body is presumptively admissible pursuant to Rules 402 and 403, subject to proper foundation being laid. The Court finds that Guidant's argument that Dr. Healy is not familiar with using polyimide in a medical device such as an ICD goes to weight rather than admissibility.

u. Guidant's Motion to Exclude Dr. Healy's opinion that Guidant was negligent in failing to test polyimide before incorporating it into its ICDs is **GRANTED IN PART AND DENIED IN PART**. The Court finds that Dr. Healy is qualified to give his opinion as it relates to biomaterials, biodegradability, and specifically the design of polymers whose function is to degrade in the human body. Dr. Healy is also qualified to give his opinion as to his knowledge of recognized standards regarding biocompatibility and accelerated aging testing generally as to products for use in the human body. Therefore, subject to proper foundation being laid at trial, Dr. Healy's opinion will be allowed as to whether Guidant's actions were reasonable and appropriate. However,

Dr. Healy is not allowed to testify as to whether he believes Guidant's conduct in regard to its polyimide testing was "negligent." Such an opinion by Dr. Healy, regardless of whether it is an impermissible legal conclusion, does not meet the requisites of Rule 702 and the evidentiary threshold required by *Daubert*, 509 U.S. at 589, and *Kumho Tire Co., Ltd.*, 526 U.S. at 152. Such an opinion is also not admissible under Rule 403. The probative value of such evidence is substantially outweighed by the danger of unfair prejudice.

v. Guidant's Motion to Exclude Dr. Healy's opinion that Guidant failed to appropriately characterize and ensure the quality of the polyimide used in its ICDs is **DENIED**, pursuant to Rule 702. The record establishes the requisites of Rule 702 and the evidentiary threshold required by *Daubert*, 509 U.S. at 589, and *Kumho Tire Co., Ltd.*, 526 U.S. at 152. Given Dr. Healy's experience with biomaterials and biodegradability, and specifically both his experience with the design of polymers whose function is to degrade in the human body and his experience in developing protocols for quality control and characterization of materials used in manufacturing, the Court finds that Dr. Healy is a qualified witness to lay the requisite foundation for his opinion. Therefore, Dr. Healy's opinion that Guidant failed to appropriately characterize and ensure the quality of the polyimide used in its ICDs is presumptively admissible, subject to proper foundation being laid at trial.

CONCLUSION

In conclusion, the Court notes that it accommodated the parties' request by altering the schedule as to the *Daubert* submissions regarding case-specific issues in the *Clasby* case. The Court received short submissions from the Plaintiff and a Supplemental Statement from Guidant. In Guidant's statement, Guidant complains that it has not been afforded the opportunity to depose a single expert concerning *Clasby*-specific issues, and was not in a position to file any additional briefing. Guidant then stated that it "reserves the right to file such briefing at a later time." The parties made similar reservations in their *Daubert* motions in the *Duron* case, and have now again made similar reservations in their *Braund* filings. The Court reminds the parties that the time for filing their *Daubert* submissions in *Duron* and *Clasby* has now passed, and the deadlines for their *Daubert* submissions in *Braund*, as well as the rest of the bellwether cases, have been set. The Court will not entertain untimely *Daubert* motions. The burden was and is on the parties to bring proper motions to compel in the event they are unable to procure proper discovery and/or depositions from their adversaries.

Further, as the Court mentioned previously, with or without these *Daubert* rulings, it appears highly unlikely that the cases set for trial can be tried in ten days. The Court strongly urges the parties to closely evaluate their witnesses and their theories and

defenses to narrow their cases so that all parties are given appropriate time to present their cases within the 10-day timeframe.

Dated: June 29, 2007

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