GUIDANT PRODUCTS LITIGATION
MDL NO. 1708

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November 8, 2006

The Honorable Donovan W. Frank
Judge of U.S. District Court
Warren E. Burger Federal Building
316 North Robert Street, Room 738
St. Paul, MN 55101

Re: *In re* Guidant Corp. Implantable Defibrillators Products Liability Litigation, MDL 1708

Dear Judge Frank:

Plaintiffs respectfully submit this letter to bring the Court's attention to a deficiency in the record relevant to Defendants' Motion for Summary Judgment on Plaintiffs' Claims Related to the Ventak Prizm 2 DR Model 1861 Based on Federal Preemption (filed May 8, 2006) ("Motion"), and to highlight several recent cases bearing upon that Motion.

In support of their Motion, Defendants submitted an Affidavit of Brian Novak ("Affidavit"), the Manager of Regulatory Affairs at Cardiac Pacemakers, Inc. Plaintiffs have become aware that Attachment C to the Affidavit (Approval Letter from James E. Dillard III, Director of Division of Cardiovascular and Respiratory Devices, FDA, to Laura L. Shepler, Senior Regulatory Affairs Associate, Guidant Corp. (Aug. 4, 2000) ("Approval Letter"), does not include the FDA's Conditions of Approval for Cardiac Pacemakers and Programmers (issued Mar. 4, 1998), which was originally attached to the FDA's Approval Letter. In order to make the record complete, a copy of the Conditions of Approval should be included in the appendices to the Motion and is attached for the Court's convenience as Exhibit A.

Furthermore, in addition to the authorities selectively cited by Defendants, Plaintiffs respectfully bring to the Court's attention recent pertinent authorities rejecting analogous arguments for preemption of tort claims involving dangerous or defective medical devices and drugs. In *Desiano v. Warner-Lambert & Co.*, Nos. 05-1705, -1743, -1745, 2006 WL 2846454 (2d Cir. Oct. 5, 2006), the Second Circuit definitively held that the Supreme Court's holding in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) does not preclude a consumer plaintiff from asserting common law claims against a defendant manufacturer simply because such claims also allege that the defendant withheld information from or misled the FDA. The *Desiano* court reasoned that in contrast to the "fraud-on-the-FDA claim" in *Buckman*, a consumer plaintiff brings a products liability claim on his own behalf, based on injuries that he or she has suffered. Accordingly, "the presumption against preemption applies, [and] indeed, stands at its strongest." 2006 WL 2846454, at *8. Furthermore, common law products liability claims "are premised on traditional duties between a product manufacturer and . . . consumers. [They do not derive] from . . . a newly-concocted duty between a manufacturer and a federal agency," as was the case in *Buckman*. *Id.* at *9. Finally, the court excerpted portions of the oral argument in *Buckman*, where pharmaceutical industry lawyers themselves conceded that traditional tort remedies would not be implicated by the eventual rule in *Buckman*: "' The *fraud* claim is preempted, but if there is negligent design, negligent manufacturing, failure to warn, common law malpractice, all of those claims are available.' " *Id.*

at *12 n.8 (quoting Oral Argument Transcript, *Buckman*, 531 U.S. 341 (2000) (No. 98-1768), 2000 WL 1801621, at *21). Thus, *Desiano* affirms what this Court has previously held in, *In re St. Jude Medical, Inc.*, that *Buckman* does not apply to plaintiffs' state common law products liability claims. *See In re St. Jude Medical, Inc.*, No. MDL-01-1396, 2004 WL 45503, at *13 (D. Minn. Jan. 5, 2004) ("[consumer claims] based in traditional state tort law [are] in sharp contrast [to] the cause of action asserted in *Buckman*[, which] depended entirely on the regulatory relationship between the federal government and the FDA."); *see also Colacicco v. Apotex, Inc*, 432 F. Supp. 2d 514, 538 (E.D. Pa. 2006) ("[W]hen the Supreme court held that the claims [in Buckman] were impliedly preempted by the FDCA, it limited this holding to the rationale that *policing fraud upon the FDA* is decidedly a federal function.").

Plaintiffs also note a number of recent cases, which hold that the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*. and the FDA regulations interpreting that statute, do not implicitly preempt common law claims of failure to warn against drug manufacturers. *See McNellis v. Pfizer*, No. Civ. 05-1286, 2006 WL 2819046, at *6 (D.N.J. Sept. 29, 2006) ("the FDCA and the FDA's regulations do not conflict with New Jersey's failure-to-warn law because those federal regulations merely set minimum standards with which manufacturers must comply. . . . FDA regulations explicitly allow a manufacturer to add or strengthen warnings without prior FDA approval."); *Levine v. Wyeth*, 2006 Vt. 107, 113 (2006) ("[t]here is [ ] no conflict between federal labeling requirements and state failure-to-warn claims. Section 314.70(c) allows, and arguably encourages, manufacturers to add and strengthen warnings that, despite FDA approval, are insufficient to protect consumers. State tort claims simply give these manufacturers a concrete incentive to take this action as quickly as possible."); *Perry v. Novartis*, No. CIVA 05-5350, 2006 WL 2979388, at *6 (E.D. Pa. Oct. 16, 2006) ("We believe it is more in keeping with the narrow scope of preemption to allow state law to require the addition of warnings so long as there has been no specific FDA determination as to the sufficiency of the scientific evidence to support a particular warning."); *but see Colacicco*, 432 F. Supp. 2d at 527-28 (finding plaintiffs' failure to warn claim against generic drug manufacturer implicitly preempted by the FDCA when the FDA had "specifically and repeatedly rejected claims that adult use of [Selective Serotonin Reuptake Inhibitors] was associated with suicidality" and because the regulations governing generic drug manufacturers do not allow them to unilaterally strengthen their warning label); *Ackerman v. Wyeth Pharmaceuticals*, No. 4:05CV84, 2006 WL 2591078, at *7 (E.D. Tex. Sept. 8, 2006) ("absent some evidence that a drug manufacturer has misled the FDA or failed to disclose crucial information, preemption should apply in a failure to warn case").

Significantly, the regulations governing a drug manufacturer's duty to update product labeling under the FDCA is nearly identical to the regulations governing a medical device manufacturer's duty to update product labeling under the Medical Device Amendments ("MDA"). *Compare* 21 C.F.R. § 314.70(c)(6)(iii) (permitting manufacturers to update a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" without prior FDA approval) *with* 21 C.F.R. § 814.39(d)(1)-(2) (permitting "[l]abeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction" without prior FDA approval). Accordingly, these cases each affirm that Plaintiffs' failure to warn claims are not implicitly preempted by the MDA or its accompanying regulations.

Enclosed as Exhibit B, please find copies of each of the recent cases cited above.

Respectfully submitted,

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