**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MINNESOTA**
**Criminal No. 10-mj-00067 (DWF)**

UNITED STATES OF AMERICA,

Plaintiff,

v.

GUIDANT LLC, FORMERLY d/b/a GUIDANT CORPORATION,

Defendant.



**Victims' Memorandum in Opposition to the Proposed Guidant Plea Agreement**

The undersigned, on behalf of victims of the criminal misconduct of Guidant LLC ("Guidant"), respectfully submit this memorandum in opposition to the proposed Guidant Plea Agreement. This memorandum also squarely addresses the questions raised in the Court's March 24, 2010 letter regarding the identity of the victims of Guidant's admitted illegal conduct and the appropriateness of including an order of restitution.

## I. Overview

A "crime victim" is any individual who purchased a medical device or drug that did not comply with Food and Drug Administration ("FDA") Regulations. As set forth in detail below, consumers of the Guidant products at issue in this case are "crime victims," both as that term is statutorily defined and as interpreted by controlling jurisprudence. Patients and their healthcare providers justifiably relied

upon the admitted material misstatements and omissions that Guidant made to the FDA. As a direct and proximate result, these patients have suffered severe physical and emotional harm from having non-compliant medical devices surgically implanted into their chests. In addition, these patients have suffered economic harm based on their reasonable assumption that Guidant had complied with all relevant FDA regulations with respect to the subject devices.

It is well established that this Court has discretion to order restitution for violations of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, under its broad equitable powers. Restitution, which exists to deter criminal conduct and to make criminal victims whole, is especially appropriate in this case given the harm suffered by patients, Guidant's disregard for patient safety in its quest for corporate profits, and its extensive history of flouting FDA regulations. This Court is well positioned to implement restitution since it has both civil and criminal jurisdiction over Guidant, jurisdiction over the victims of Guidant's crimes, and civil jurisdiction over the claimants in the MDL. The elements of restitution could include, for example, ratable adjustments and reimbursement to the claimants of those substantial portions of the settlement fund which were consumed by administration, as well as establishing a claims fund for additional victims, and funding independent medical research.

The victims of Guidant's criminal conduct have standing to be heard and hereby oppose the proposed Plea Agreement inasmuch as: 1) it contains no express provisions for restitution; 2) it may be inappropriately interpreted to

circumscribe the number of potential victims; and 3) neither Guidant nor the U.S. Government ("Government") has provided any meaningful disclosure regarding the appropriateness of the fine, forfeiture amount and other agreement terms.

## II. The Plea Agreement

On March 11, 2010, Guidant and the U.S Government ("Government") entered into a proposed Plea Agreement regarding criminal violations of FDCA in connection with the Ventak Prizm 2 DR Model 1861 implantable cardioverter-defibrillator ("Ventak Prizm") and the Contak Renewal 1 Model H135 cardiac resynchronization therapy-defibrillator ("Contak Renewal 1"), which were developed, manufactured, processed, packaged, sold, marketed, and distributed by Guidant. In that proposed agreement, Guidant pleaded guilty to two Counts of violating 21 U.S.C. § 333 by: a) "making materially false and misleading statements on report(s) required to be filed" with the FDA regarding modifications Guidant made to the design of the Ventak Prizm, which affected the "safety, efficacy and performance" of the device; and b) "failing to promptly notify" the FDA of a "correction" made to the Contak Renewal 1, which "reduce[d] a risk to health posed by the device." *See* Plea Agreement and Sentencing Stipulations at 3-7 (DN 9) ("Plea Agreement"). As part of the proposed Plea Agreement, Guidant has agreed to pay a fine of $253,962,251.00 to the Government. *Id.* at 8. In addition, Guidant has agreed to pay a criminal forfeiture to the Government of $42,079,675.00. *Id.* at 9.

## III. All Individuals Implanted With a Pre-Corrective Device are Victims of Guidant's Criminal Actions

A "crime victim" is defined by the Crime Victims Rights Act ("CVRA"), 18 U.S.C. § 3771 *et seq.*, as "a person directly and proximately harmed as a result of the commission of a Federal offense." 18 U.S.C. § 3771(e). Crime victims are given numerous rights, including "[t]he right to be reasonably heard at any public proceeding in the district court involving release, plea, sentencing, or any parole proceeding," and "the right to full and timely restitution as provided in law." *Id.* § 3771(a)(4), (6).[1]

In cases charging violations of the FDCA, numerous courts have held that a "crime victim" is any individual who purchased a medical device or drug that did not comply with FDA regulations. *See United States v. Universal Mgmt. Servs., Inc.*, 191 F.3d 750 (6th Cir. 1999); *United States v. Kaminski*, 501 F.3d 655 (6th Cir. 2007); *United States v. Lane Labs-USA Inc.*, 427 F.3d 219 (3d Cir. 2005) (holding that district court had the power to order restitution to consumers of misbranded products).

For instance, in *Universal Management Services*, the Sixth Circuit found that all consumers who purchased an unapproved product were victims of defendants' violation of the FDCA, notwithstanding defendants' argument that their device was completely effective. In so holding, the Court reasoned that:

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[1] The CVRA, by its terms, applies to all federal criminal prosecutions. *See, e.g.*, Committee on the Judiciary, Amendments to the Federal Rules of Criminal Procedure, H.R. Doc. No. 110-118, at 51 ("The act defines the term 'crime victim' without limiting it to certain crimes.").

> The approval process exists to protect consumers' health and their pocketbooks. One of the primary goals of the FDCA is to protect consumers from economic harm. . . . It is not the government's burden to prove that a product is not safe and effective. FDCA regulations exist to allow the public to assume that marketed devices have received the imprimatur of FDA approval. To circumvent the law by marketing illegally without approval is to deceive the public both as purchasers and users of the device. In such cases, restitution exist to make the consumer whole.

191 F.3d at 763.

Likewise, in *Kaminski*, the Court held that "society at large" were the victims of defendants' crime of introducing into interstate commerce unapproved new drugs. The Court explained that "[c]onsumers purchase such products upon the mistaken assumption that the products are produced in compliance with federal regulations; the economic harm to consumers contemplated by the FDCA is, thus, that consumers who are deceived in this manner do not get what they pay for." 501 F.3d at 670 (internal quotation marks omitted).

Here, although the Ventak Prizm and Contak Renewal 1 were approved for sale by the FDA at one time, Guidant altered the devices thereafter without properly informing the FDA or the public of these changes, and despite a legal requirement that it do so. *See* Plea Agreement at 3-6. Guidant has admitted that it lied to the FDA in August 2003 about engineering changes made to the Ventak Prizm related to the safety and efficacy of those devices and that it did not notify the FDA about similar issues with the Contak Renewal 1 in 2005. *See id.* at 7; *see also id.* at 3-6. Moreover, after making engineering changes to remedy the life-threatening defects in those devices, Guidant continued to sell its existing

inventory of devices that contained those defects. Accordingly, the victims of Guidant's admitted crimes include individuals implanted with uncorrected Ventak Prizm and Contak Renewal 1 devices, particularly those who received those flawed devices after Guidant was or should have been aware of the issues that affected the safety of those devices. Among these victims are numerous claimants in the civil MDL proceeding, *In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, MDL 1708 (D. Minn.) (the "Guidant MDL"), which commenced after the death of Joshua Oukrop, a young Minnesota resident implanted with a defective Ventak Prizm.

As an initial matter, there can be no dispute that the individuals who received pre-corrective devices from Guidant suffered economic harm as a result of their mistaken assumption that the devices they purchased were in compliance with federal regulations. *See Universal Mgmt. Servs.*, 191 F.3d at 763. Moreover, these device recipients suffered severe physical and emotional harm as a direct result of having a non-compliant medical device surgically implanted into their bodies. Had Guidant not committed the offenses subject to the Plea Agreement, the FDA would not have allowed Guidant to sell its unsafe pre-corrective devices. Indeed, immediately after Guidant disclosed the defects in the Ventak Prizm and Contak Renewal 1 devices in June 2005, all pre-corrective devices were subject to a Class I recall and removed from the market entirely. *See* FDA recall notices for the Guidant Ventak Prizm 2 DR 1861 and Contak Renewal H135 dated June 17, 2005.

Furthermore, the omissions and misrepresentations were not solely directed to the FDA. Victims and their doctors relied upon the same material misstatements and omissions that Guidant had made to the FDA. These victims and their doctors made decisions based on what Guidant has admitted were material misrepresentations by Guidant and Guidant's sales representatives who were often present in the doctors' offices and operating rooms.[2] Although Guidant invoked the learned intermediary doctrine in defending its actions in the Guidant MDL, Guidant never told the Court that the physicians had themselves been misled and could not have had an informed discussion with their patients. Indeed, until the publication of Guidant's Plea Agreement, the true set of facts was never disclosed to the victims. Thus, the Plea Agreement confirms that Guidant not only defrauded the FDA, but its fraud also directly impacted patients implanted with the subject devices and their healthcare providers.

Moreover, Guidant's representations to victims and their healthcare providers that the risk of removing the uncorrected devices was greater than the risk of living with the devices were knowingly false. These representations were made at the same time that Guidant was actively concealing the defects in its

[2] The civil case started with the publication of information by Mr. Oukrup's doctors, physicians at the Minneapolis Heart Institute, who were concerned that they had been misled by Guidant and who asked pointed and direct questions of Guidant after his death. Guidant, however, steadfastly maintained that it had fully and properly disclosed all issues to the FDA. As the Plea Agreement confirms, Guidant did not accurately or fully inform the FDA about the issues with the devices.

devices. Thus, as made abundantly clear in the Plea Agreement, Guidant's first concern was corporate profit, not patient safety.

Finally, Guidant subjected the recipients of uncorrected devices to unnecessary litigation costs. Guidant's criminal plea calls into question the good faith basis for many of the defenses that Guidant raised in the civil litigation and the veracity of statements that Guidant made to the Court in support of those positions. During that litigation, Guidant repeatedly assured this Court that Plaintiffs' account of the events, including Plaintiffs' assertions that Guidant knowingly made false statements to the FDA, was just plain wrong:

> Guidant Counsel Andrew Carpenter: Guidant never concealed the failure mechanism to the FDA or anyone
>
> . . .
>
> Guidant Lead Counsel Timothy Pratt: . . . you have an extraordinarily rare event where the company brought it to the attention of the FDA right along . . .
>
> The Court: I'm not sure what I expect in response. I will ask the same question of opposing counsel on this; but, you know, listening to the argument and going way back to the opening remarks this morning, . . . you describe the history of the lack of concealment, the lack of being entirely forthright with the FDA. That is quite different than the opening remarks of (Plaintiffs') counsel where everything was said short of a criminal conspiracy, in terms of not being forthright with the FDA. You both can't be correct.
>
> Pratt: "Yeah, but—I'm right."

Dispositive Motions Hearing, *In re Guidant Corp.,* No. 05-MDL-1708, at 108, 141-42 (May 18, 2007) (attached as Attach. A). The Guidant MDL Claimants incurred significant expenses based upon a vigorous defense by Guidant, which

has now been shown to have been based on falsehoods. Guidant was of course entitled to defend itself, but not by employing falsehoods or misrepresentations to the Court. Had Guidant admitted the facts now shown in the Plea Agreement, a substantial portion of the attorneys' fees and costs shouldered by these victims in the MDL would not have been expended.

## IV. Restitution Is Available and Justified

The power of the district courts to order restitution for violations of federal law is well established. The Supreme Court of the United States has mapped out the contours of a district court's equitable powers in expansive terms:

> Unless otherwise provided by statute, all the inherent equitable powers of the District Court are available for the proper and complete exercise of that jurisdiction. . . . Power is thereby resident in the District Court, in exercising this jurisdiction, to do equity and to mould [sic] each decree to the necessities of the particular case. It may act so as . . . to accord full justice to all the real parties in interest . . . . In addition, the court may . . . give whatever other relief may be necessary under the circumstances. Only in that way can equity do complete rather than truncated justices. . . . Moreover, the comprehensiveness of this equitable jurisdiction is not to be denied or limited in the absence of a clear and valid legislative command. Unless a statute in so may words, or by a necessary and inescapable inference, restricts the court's jurisdiction in equity, the full scope of that jurisdiction is to be recognized and applied.

*Porter v. Warner Holding Co.*, 328 U.S. 395, 398 (1946) (citations and internal quotation marks omitted). In *Mitchell v. Robert DeMario Jewelry, Inc.*, the Supreme Court built upon its ruling in *Porter*, expanding the equitable power of the district court even further:

> When Congress entrusts to an equity court the enforcement of prohibitions contained in a regulatory enactment, it must be taken to

> have acted cognizant of the historic power of equity to provide complete relief in the light of statutory purposes. As this Court has long ago recognized, there is inherent in the Courts of Equity a jurisdiction . . . to give effect to the policy of the legislature.

361 U.S. 288, 291-92 (1960).

Section 332(a) of the FDCA explicitly provides that "[t]he district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown to restrain violations of section 331 of this title." 21 U.S.C. § 332(a). As held by at least two circuit courts, this provision grants a district court the discretion to order restitution for violations of the FDCA under its broad equitable powers. *See, e.g., Lane Labs-USA*, 427 F.3d at 226-27; *Universal Mgmt. Servs.*, 191 F.3d at 762 (holding that grant of equitable power in § 332(a) was so broad that it was within the district court's authority to order restitution); *see also United States v. Rx Depot, Inc.*, 438 F.3d 1052, 1062 (10th Cir. 2006) (holding that § 332(a) grants a district court broad equitable powers, including the power to order disgorgement).

In *Lane Labs-USA*, for instance, the Third Circuit examined relevant Supreme Court precedent, including *Porter* and *Mitchell*, and concluded that the "equitable power of district courts under § 332(a) . . . is broad enough to encompass *all equitable remedies* that would further the purposes of the Act," including restitution. 427 F.3d at 226 (emphasis added). The Court further held that restitution furthers the FDCA's mandate to "protect[] not only the public's health, but also . . . [the] consumers as to the quality or content of products" *Id.* at

227. In so holding, the court expressly rejected the argument that "awarding restitution under the FDCA would rewrite or improperly expand the remedies available under the statute," explaining that "Congress has placed no unambiguous restriction on equity jurisdiction under § 332(a)[; and that] the arguments of amicus and other commentators are little more than entreaties that we ignore or overrule *Porter* and *Mitchell*, neither of which we have the power to do." *Id.* at 235.

Restitution is especially important to consider in cases involving violations of the FDCA. As the Supreme Court noted in *Porter*, a courts' equitable powers "assume an even broader and more flexible character" when the public interest is involved than when "only a private controversy is at stake." 328 U.S. at 398. Restitution provides a critical avenue by which victims of Guidant's offenses can be compensated for the harm they suffered. *See Universal Mgmt. Servs.*, 191 F.3d at 763-64; *Kaminski*, 501 F.3d at 670; *Lane Labs-USA*, 427 F.3d at 231-32.

Independently, this Court also has authority to order restitution as a condition of probation under 18 U.S.C. § 3563(b)(2). *See Kaminski*, 501 F.3d at 669. In the event that this Court accepts the Plea Agreement, victims reserve their rights to assert at sentencing that organizational probation is appropriate in this case. Under U.S. Sentencing Guideline § 8d1.1(a), the court "*shall* order a term of probation . . . if the organization within the five years prior to sentencing engaged in similar misconduct, as determined by a prior criminal adjudication, and any part of the misconduct underlying the instant offense occurred after that adjudication."

(Emphasis added.) U.S. Sentencing Guideline § 8d1.1(a)(6) further provides that probation is appropriate "if such sentence is necessary to ensure that changes are made within the organization to reduce the likelihood of future criminal conduct."

Probation is plainly appropriate in this case given that in June 2003, Endovascular Technologies, Inc. ("Endovascular Technologies") (a wholly owned subsidiary of Guidant) entered into a plea agreement involving similar criminal acts surrounding nondisclosure of issues relating to the Ancure Endograft system. *See* Attach. B. Guidant has now pleaded to criminal misconduct involving the Ventak Prizm and Contak Renewal 1 devices, based on conduct that occurred within five years of the Endovascular Technologies plea.

## V. Objections to the Plea Agreement

The Supreme Court has held that a defendant has "no absolute right to have a guilty plea accepted." *Santobello v. New York*, 404 U.S. 257, 262 (1971). "A court may reject a plea in exercise of sound judicial discretion." *Id.* "[I]t is not only permitted but expected that the court will take an active role in evaluating the agreement." *United States v. Kraus*, 137 F.3d 447, 452 (7th Cir. 1998); *In re Morgan*, 506 F.3d 705, 712 (9th Cir. 2007) (stating that the court should use its "considerable discretion to assess the wisdom of [the] plea bargain[]"). "The authority to exercise judicial discretion implies the responsibility to consider all relevant factors and rationally construct a decision." *United States v. Moore*, 916 F.2d 1131, 1136 (6th Cir. 1990).

As set forth in the Plea Agreement, and as the Court is well aware from its involvement in the Guidant MDL, the factual basis for Guidant's plea is that in early 2002 Guidant became aware of life-threatening defects in the Ventak Prizm devices and in 2003, became aware of similar life threatening defects in the Contak Renewal 1 devices. In May 2002, Guidant undertook engineering changes to the Ventak Prizm devices and in November 2004, Guidant undertook engineering changes to the Contak Renewal 1 devices, in an effort to correct these defects and mitigate the risk of death and serious injury. Notwithstanding these changes, however, Guidant continued to sell its inventory of pre-corrective devices and allowed these devices to be implanted into unsuspecting patients. In so doing, Guidant violated explicit FDA regulations, including 21 U.S.C. § 360i and 21 C.F.R. § 806.10, which require Guidant to notify the FDA within 10 days of making a medical device correction. As Guidant itself has publically reported, these pre-corrective devices have resulted in several deaths and numerous cases of serious bodily injury. In addition, thousands of patients have had these defective devices surgically explanted from their bodies.

Therefore, the scope of Guidant's criminal conduct extends beyond making false statements to the FDA, to a pattern and practice of misrepresenting risks in order to bolster its corporate profits. As set forth in the criminal information and as discovery revealed in the parallel civil proceeding, Guidant engaged in a broad scheme to sell its inventory of life-threatening devices to unsuspecting patients, notwithstanding Guidant's knowledge of the defects in these devices, and

Guidant's efforts to correct those defects. Guidant's illegal scheme directly resulted in multiple patient deaths and even more cases of serious bodily injury.

In evaluating the appropriateness of the proposed Plea Agreement, the Court should also be cognizant of Guidant's prior felony plea for similar conduct and the recent discovery of continuing reporting violations. As mentioned above, this is not the first time that Guidant has admitted to making false statements to the FDA. On June 12, 2003 a wholly owned subsidiary of Guidant, Endovascular Technologies pleaded guilty to one felony count of making false statements to the FDA, in violation of 18 U.S.C. § 1001, and nine felony counts of shipping misbranded medical devices in interstate commerce, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2), in connection with the Ancure Endograft System device. *See* Plea Agreement, *United States v. Endovascular Techs.*, No. Cr. 03-0179 SI (N.D. Cal. June 12, 2003). As set forth in that plea agreement, Endovascular Technologies knowingly failed to report malfunctions to these devices that "may have caused or contributed to patients' deaths and serious injuries or [] would be likely to cause a death or serious injury if the malfunction were to recur." In connection with the plea agreement, Guidant entered into a Corporate Integrity Agreement with the Government wherein it agreed to institute certain corporate compliance programs.

Notwithstanding that Corporate Integrity Agreement (and the present criminal proceedings), Guidant has recently been required to halt all sales of its heart-rhythm devices as a result of further reporting failures. On March 15, 2010,

Boston Scientific (Guidant's parent company) issued a press release stating that it "has stopped shipment and is retrieving field inventory of all its implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds). The Company has determined that some manufacturing process changes were not submitted for approval to the U.S. Food and Drug Administration (FDA). At this time, the company has identified two instances of changes that, while successfully validated, were not submitted to the FDA."[3] Thus, even with the Plea Agreement pending, Guidant has *again* been found to violate FDA regulations regarding the reporting and/or approval of engineering changes to the same sort of devices as the Ventak Prizm and Contak Renewal 1.

Given Guidant's numerous past and present violations, it is hard to imagine a scenario that could demonstrate recidivism more than the facts surrounding Guidant's conduct. Under these circumstances, Guidant, as a serial violator of FDA regulations, should be required to pay restitution to the broad class of victims who have been directly harmed by Guidant's criminal conduct. Accordingly, the victims of Guidant's conduct object to the Plea Agreement on the following grounds.

First, victims object to the Plea Agreement to the extent that the Plea Agreement could be interpreted to circumscribe the number of potential victims of Guidant's crimes. As set forth above, the relevant authority mandates that *all*

[3] News Releases, *Boston Scientific Announces Ship Hold and Inventory Retrieval of ICD and CRT-D Devices* (Mar. 15, 2010), *available at* http://bostonscientific.mediaroom.com/index.php?s=43&item=900.

individuals who have been implanted with pre-correction Ventak Prizm or Contak Renewal 1 device are victims of the criminal offense. However, to the extent that the Court agrees with any suggestion (from Guidant, the Government, or otherwise) that the victims of the admitted criminal conduct is more limited – because Guidant has plead guilty only to submitting a false report regarding the Ventak Prizm device in August 2003 and a failure to report a Product Update on the Contak Renewal 1, which was sent to physicians in March 2005 – the Plea Agreement should be rejected because it improperly restricts the class of victims entitled to restitution.

Second, the victims of Guidant's criminal conduct object to the Plea Agreement because it contains no express provision for restitution. As set forth above, Guidant device recipients are clearly victims of Guidant's criminal offenses and any Plea Agreement and Sentencing Stipulation that does not include a provision for restitution for said victims is neither fair nor appropriate. Accordingly, the Court should reject any Plea Agreement that does not contain a meaningful restitution component including an organized and Court supervised process that allows for timely and orderly compensation to all victims.

Finally, neither Guidant nor the Government has provided any meaningful disclosure regarding the appropriateness of the fine and forfeiture amount. Before any plea agreement should be accepted, the Court and victims should be apprised of how those amounts were calculated, what relation they bear to profits earned by Guidant from the violative devices, and why they are appropriate in light of the

seriousness of Guidant's criminal offenses. Moreover, Guidant and the Government should disclose whether any restitution provision was considered and if so, why such a provision was not included in the Plea Agreement. Only after Guidant and the Government make these disclosures, can the Court (and victims) properly evaluate whether the fine and forfeiture amounts are appropriate under the circumstances.

## VI. Request of the Court

For the reasons set forth above, we respectfully request this Court find that (1) any individual implanted with a pre-correction Ventak Prizm or a Contak Renewal 1 is a victim of Guidant's illegal conduct; (2) that this Court has authority to order restitution for the victims of Guidant's misconduct; (3) that an order of restitution is appropriate; (4) that this Court has the authority to reject the Plea Agreement; (5) that the Court rejects the proposed Plea Agreement subject to the provision of further information to the Court by Guidant and the Government, specifically (a) how the fine and disgorgement amounts in the Plea Agreement were determined and whether the prior settlement in the MDL proceeding factored into those determinations; (b) whether and how the prior guilty plea by a Guidant subsidiary and the related Corporate Integrity Agreement that Guidant was subject to were considered for purposes of the Plea Agreement; and (c ) whether and how the issue of restitution for victims was considered for purposes of the Plea Agreement.

In the alternative – and given the short time frame between the announcement of the Plea Agreement and the April 5, 2010 hearing – the undersigned request that they be given the opportunity to more fully brief and/or demonstrate by evidence at an evidentiary hearing, the important and complex issues discussed above. This request includes but is not limited to providing the Court with additional support for its position that device recipients are victims of Guidant's criminal conduct, providing the Court with formal briefing on the issue of restitution, and informing the Court on the victims' position on the adequacy of the fine and forfeiture amounts set forth in the Plea Agreement and Sentencing Stipulation.

Undersigned further request that the Court authorize or encourage the Government, Guidant, and/or the probation officer assigned this case to confer with undersigned counsel about these matters and provide additional information so that undersigned counsel may take a more formal position with respect to the appropriateness of the current fine and forfeiture amounts, and on sentencing issues.

Finally, undersigned counsel respectfully requests the Court appoint the undersigned to act on behalf of the eligible victims regarding this matter. Especially regarding any restitution related claims process, undersigned counsel believe they can create a fair, simple, and streamlined process. In fact, undersigned counsel have demonstrated to this court the ability to do so in the MDL proceeding. The Government should not require an entirely new and

different claims process that requires victims to, after years of civil litigation, begin a new and foreign process filled with uncertainty, confusion, and governmental red tape and administered by an entity that lacks the familiarity with the many subtle nuances associated with the methodical claims process employed in the MDL.

Date: 3/30/2010

s/ Elizabeth Peterson

Charles S. Zimmerman - #120054
Co-Lead Counsel, Guidant MDL
Elizabeth Peterson - #34347X
ZIMMERMAN REED
651 Nicollet Mall, Suite 501
Minneapolis, MN 55402
(612) 341-0400
(612) 341-0844

Richard Arsenault
Co-Lead Counsel, Guidant MDL
NEBLETT, BEARD & ARSENAULT
2220 Bonaventure Court
Alexandria, LA 71301
(800) 256-1050
(318) 561-2591

Elizabeth Cabraser
Co-Lead Counsel, Guidant MDL
LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP
275 Battery Street, 30th Floor
San Francisco, CA 94111-3339
(415) 956-1000
(415) 956-1008

Seth R. Lesser
Co-Lead Counsel, Guidant MDL
KLAFTER OLSEN & LESSER
Two International Drive
Suite 350
Rye Brook, NY 10573
(914) 934-9200
(914) 934-9220

C. Brooks Cutter
KERSHAW, CUTTER & RATINOFF, LLP
401 Watt Avenue
Sacramento, CA 95864
(916) 448-9800
(916) 669-4499

Nicholas Drakulich
THE DRAKULICH LAW FIRM
2727 Camino del Rio South
Suite 322
San Diego, CA 55402
(858) 922-8187

Hunter J. Shkolnik
RHEINGOLD, VALET, RHEINGOLD,
SHKOLNIK & MCCARTNEY LLP
113 East 37th Street
New York, NY 10016
(212) 684-1880
(212) 689-8156

Silvija A. Strikis
KELLOGG, HUBER, HANSEN,
TODD, EVANS & FIGEL, P.L.L.C.
Sumner Square
1615 M Street, N.W., Suite 400
Washington, DC 20036
(202) 326-7939
(202) 326-7999

Robert K. Shelquist
LOCKRIDGE GRINDAL NAUEN
100 Washington Avenue South
Suite 2200
Minneapolis, MN 55401
(612) 339-6900
(612) 339-0981

Paul G. Cassell
Special Counsel
HATCH, JAMES & DODGE
10 West Broadway, Suite 400
Salt Lake City, UT 84101-2065
(801) 585-5202
(801) 581-6897

F.A. Little, Jr.
Special Counsel
STANLEY, REUTER, ROSS, THORNTON
& ALFORD, L.L.C.
Capital One Bank Building
934 3rd Street, Suite 1003
Alexandria, Louisiana 71301
(318) 445-0002
(318) 445-0052