UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

United States of America,

Plaintiff,

v.

Guidant LLC, formerly doing business as Guidant Corporation,

Defendant.

Crim. No. 10-mj-67 (DWF)

MEMORANDUM OPINION AND ORDER

Robert M. Lewis, Assistant United States Attorney, United States Attorney's Office, and Ross S. Goldstein, Esq., United States Department of Justice, Office of Consumer Litigation, counsel for the Government.

Daniel M. Scott, Esq., Kelly & Wolter, P.A., counsel for Guidant.[1]

---

[1] Doug Kelly, Esq., Kelly & Wolter, P.A., and Larry E. Tanenbaum, Esq., Akin, Gump, Strauss, Hauer & Felt, LLP, also appeared at the hearing on behalf of Guidant.

INTRODUCTION

On April 5, 2010, Guidant, LLC[2] ("Guidant") entered pleas of guilty on two misdemeanor counts charged by the Government in the Information. During the plea hearing, the Court also heard argument from counsel representing alleged victims.[3]

Normally, a court accepts or rejects a plea agreement at a plea hearing. At the April 5, 2010 plea hearing, however, the Court took the matter under advisement because of the unique contours of this case, including (1) arguments raised by counsel representing individuals claiming to have been injured by Guidant's criminal conduct; (2) the Government's and Guidant's positions with respect to the Court's authority to order

---

[2] Guidant Corporation, through several subsidiaries and affiliated corporations, engaged in the development and interstate sale of a variety of medical devices, including the devices at issue in this case. Boston Scientific Corporation ("Boston Scientific") acquired Guidant Corporation in April 2006, at which time Guidant Corporation became a wholly-owed subsidiary of Boston Scientific. On or about February 19, 2010—less than two weeks before the Government filed its Information—Guidant Corporation became a limited liability company and was renamed Guidant, LLC. The events at issue in this case occurred before Boston Scientific acquired Guidant Corporation.

[3] Charles S. Zimmerman, Esq., Zimmerman Reed, PLLP; C. Brooks Cutter, Esq., Kershqaw, Cutter & Ratinoff, LLP; and Hunter Shkolnik, Esq., Rheingold, Valet, Rheingold, Shkolnik & McCartney, LLP, spoke on behalf of the alleged victims. Elizabeth A. Peterson, Esq., and Robert R. Hopper, Esq., Zimmerman Reed, PLLP; Elizabeth Cabraser, Esq., Lieff, Cabraser, Heimann & Bernstein, LLP; and Richard J. Arsenault, Esq., Neblett, Beard & Arsenault, also appeared at the plea hearing. Mr. Zimmerman is the Plaintiffs' Liaison Counsel and a member of the Lead Counsel Committee in the Guidant MDL, MDL No. 05-1708 (DWF/AJB), to which the Judicial Panel on Multi-District Litigation assigned the undersigned in November 2005. (MDL No. 05-1708 (DWF/AJB), Doc. No. 1.) Ms. Peterson is the attorney for the Guidant MDL Lead Counsel Committee. Mr. Cutter and Mr. Shkolnik are members of the Guidant MDL Steering Committee. Ms. Cabraser and Mr. Arsenault are members of the Guidant MDL Lead Counsel Committee.

restitution; (3) the absence of a probation provision in the Plea Agreement and Sentencing Stipulations ("Plea Agreement"); and (4) the uncertainty as to where the criminal fine and forfeiture money will go. Therefore, the matters now before the Court are (1) whether it has a right to order restitution and, if so, to what victims, if any; and (2) whether to accept the Plea Agreement submitted jointly by the Government and Guidant. For the reasons set forth below, the Court concludes that it has a right to order restitution under 18 U.S.C. § 3771 but that there are no victims directly and proximately harmed by Guidant's criminal conduct as it relates to the crimes to which Guidant has pled guilty to and to the underlying circumstances related to those crimes as admitted by Guidant. Further, for the reasons set forth below, the Court declines to accept the Plea Agreement as currently drafted.

BACKGROUND

Although Guidant developed, manufactured, and sold numerous medical devices, only two devices are the subject of this criminal proceeding—the Ventak Prizm 2DR ("Prizm) and the Contak Renewal ("Renewal").[4] The Prizm is an implantable cardioverter defibrillator ("ICD"). An ICD is a medical device that is implanted in a patient to detect and treat abnormally fast heart rhythms that could result in sudden

[4] Guidant marketed two Renewal devices, the Contak Renewal 1 and Contak Renewal 2. Both devices shared the same design, but the Contak Renewal 2 was a version of the device marketed in some countries outside the United States. For convenience, the Court will refer to both devices as "Renewal."

cardiac death. The Renewal is a cardiac resynchronization therapy defibrillator ("CRT-D"). A CRT-D is a specialized type of ICD.

The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq*., governs, in part, the manufacture, processing, packing, labeling, and shipping in interstate commerce of medical devices. The Food and Drug Administration ("FDA") is the agency of the Government that is charged with enforcement of the FDCA. The FDCA and its regulations categorize medical devices into three classes, depending on their risk to the health, safety, or welfare of the patient, and require medical manufacturers to comply with certain reporting requirements. The Prizm and Renewal are Class III devices. Subject to the highest level of regulation, Class III devices include devices that are intended for use in supporting or sustaining life, are of substantial importance in preventing impairment of health, or present a potential unreasonable risk of illness or injury. Once the FDA approves a Class III device for use, a manufacturer may not make any modification to the device that affects the device's safety or effectiveness without receiving prior approval from the FDA. Moreover, in certain circumstances such as when a correction is made to a device, a medical manufacturer is required to submit a written report to the FDA within a specific amount of time.

On February 25, 2010, the Government charged Guidant with two misdemeanor counts related to the Prizm and Renewal. (Doc. No. 1.) In Count I, Guidant is charged with submitting a false and misleading report to the FDA on August 19, 2003, that concerned a change made to the Prizm on or about November 13, 2002. In Count II,

Guidant is charged with failing and refusing to report to the FDA a medical device correction to the Renewal on or about March 2, 2005.

As many as 20,146 patients in the United States may have been implanted with Prizm and Renewal devices between late 2002 and June 2005. (Doc. No. 4 at 3.) Of those 20,146 patients, approximately 2,657 are claimants in the Guidant MDL. (*Id*. at 4.) On March 1, 2010, the Government filed a Motion for Order for Alternative Victim Notification Procedures pursuant to 18 U.S.C. § 3771(d)(2). In that motion, the Government sought a "reasonable procedure to give effect to the notification provisions of the Crime Victims Rights Act . . . due to the large number of individuals who might assert that they are victims of the offenses charged." (*Id*. at 1.) Because it had "not concluded that any such persons are in fact victims of the offenses charged," the Government submitted the motion "out of an abundance of caution" and recommended that alleged victims be notified in two ways: (1) through the Guidant MDL Lead Counsel Committee and (2) through the United States Attorney and Department of Justice websites. (*Id*. at 1-2, 4-5.) The Court granted the Government's motion on March 11, 2010, and directed that a notice to alleged victims be posted on the websites of the United States Attorney's Office, the Department of Justice Office of Consumer Litigation, and this Court. (Doc. No. 8 at 2-3.) The Court also directed the Clerk of Court to electronically file a copy of the notice in the Guidant MDL and ordered Mr. Zimmerman to provide a copy of the notice to all Guidant MDL claimants who had been implanted with a Prizm or Renewal device and their counsel. (*Id*. at 3.)

After asking for and receiving the Court's permission, a memorandum and supplemental memorandum were submitted on behalf of the "victims."[5] (Doc. Nos. 13

[5] For convenience, any persons represented in the "victims'" memoranda or at the plea hearing by the attorneys noted above will be referred to as "alleged victims." The alleged victims' memoranda do not name individual victims. Instead, the alleged victims explain that "the victims of Guidant's admitted crimes include individuals implanted with uncorrected [Prizm and Renewal] 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." (Doc. No. 13 at 6.) Both memoranda note that many of the alleged victims are also Guidant MDL claimants, and counsel for the alleged victims offer their services to the Court so that they can assist it in the distribution of restitution funds. Ms. Peterson signed the alleged victims' memorandum, and it also lists the following attorneys as counsel of record: Mr. Zimmerman; Mr. Arsenault; Ms. Cabraser; Mr. Cutter; Mr. Shkolnik; Seth R. Lesser, Esq., Klafter, Olsen, and Lesser; Nicholas Drakulich, Esq., The Drakulich Law Firm; Silvija A. Strikis, Esq., Kellogg, Huber, Hansen, Todd, Evans, & Figel, P.L.L.C.; Robert K. Shelquist, Esq., Lockridge, Grindal, and Nauen; Paul G. Cassell, Esq., Hatch, James & Dodge; and F.A. Little, Jr., Stanley, Rueter, Ross, Thornton & Alford, L.L.C. Mr. Lesser is a member of the Guidant MDL Lead Counsel Committee. Mr. Drakulich and Ms. Strikis are members of the Guidant MDL Steering Committee.

The Court also received documents from James F. Allen of Lancaster, New York. Mr. Allen described himself as a "criminal victim," marked his document as "Confidential Document Not for the Public Copy," and submitted a timeline related to certain events involving Guidant and the FDA. The Court received a letter dated April 12, 2010, from Robert G. Hauser, M.D., and Barry J. Maron, M.D. Dr. Hauser and Dr. Maron treated Joshua Okrup, a 21-year-old college student who died in 2005 when his Prizm short-circuited. In the 1980s, Dr. Hauser was the president of Cardiac Pacemakers, Inc., which was once a part of Eli Lilly & Company. After Dr. Hauser left Cardiac Pacemakers, Inc., Eli Lilly & Company spun off that company and four other subsidiaries to form the company that became Guidant Corporation. Dr. Hauser and Dr. Maron urge the Court not to accept the guilty plea because it "does not hold the guilty parties fully accountable and inevitably undermines patient safety." (Doc. No. 21.) Heather S. Sorensen, an MDL claimant who had a Prizm explanted and other related surgeries, submitted a letter urging the Court to reject the Plea Agreement because it does not provide restitution to victims. (Doc. No. 22.) Lisa Salberg, Chief Executive Officer for Hypertrophic Cardiomyopathy Association, submitted an e-mail to the Court, urging it to hold corporations accountable for their actions. (Doc. No. 25.) Finally, Robert O.

(Footnote Continued on Next Page)

and 18.) Guidant and the Government submitted responses to the alleged victims' memorandum and supplemental memorandum. (Doc. Nos. 14, 15 and 20.) On April 5, 2010, Lawrence J. Knopf, Vice President and Secretary of Guidant LLC, entered pleas of guilty on behalf of Guidant to two misdemeanor counts charged in the Information. At the plea hearing, the Court took under advisement whether it had a right to order restitution and if so, to what victims, if any, and whether to accept the Plea Agreement.

DISCUSSION

The Plea Agreement provides that Guidant will waive indictment and plead guilty to an Information alleging:

> a. Count One of the Information will charge Guidant with violating the Federal Food, Drug, and Cosmetic Act by making materially false and misleading statements on reports required to be filed with the United States Food and Drug Administration in violation of 21 U.S.C. § 331(q)(2), a misdemeanor pursuant to 21 U.S.C. § 333(a)(1).
>
> b. Count Two of the Information will charge Guidant with violating the Federal Food, Drug, and Cosmetic Act by failing to promptly notify the United States Food and Drug Administration of a correction it made to a medical device to reduce a risk to health posed by the device, in violation of 21 U.S.C. §§ 331(q)(1) and 360i(g), a misdemeanor pursuant to 21 U.S.C. 333(a)(1).

(Footnote Continued From Previous Page)

Harker, Esq., wrote a letter to the Court, expressing his agreement with the views expressed in Drs. Hauser and Maron's letter. (Doc. No. 26.)

(Doc. No. 9 at 7.) The Plea Agreement further provides that the parties "recommend jointly that the Court impose a sentence requiring Guidant to pay the United States a criminal fine of $253,962,251 pursuant to 18 U.S.C. § 3571(d).[6]" (*Id*. at 8-9.) The Plea Agreement also provides that Guidant will agree to a "criminal forfeiture to the United States in the amount of $42,079,675" and a special assessment of $250 pursuant to 18 U.S.C. § 3013.[7] (*Id*. at 9-10.) In the Plea Agreement, the parties jointly agreed not to include a provision that ordered restitution or probation. The agreement also specifically states that a presentence investigation report is not necessary because the plea and sentencing hearings, together with the record and the Plea Agreement, "will provide the Court with sufficient information concerning Guidant, the crime charged in this case, and Guidant's role in the crime to enable the meaningful exercise of sentencing authority by the Court under 18 U.S.C. § 3553." (*Id*. at 10.)

I. Restitution

The alleged victims urge the Court to reject the Plea Agreement because it does not contain a provision for restitution. The alleged victims assert that "Guidant device

---

[6] Entitled "Alternative fine based on gain or loss," § 3571(d) provides, "[i]f any person derives pecuniary gain from the offense, or if the offense results in pecuniary loss to a person other than the defendant, the defendant may be fined not more than the greater of twice the gross gain or twice the gross loss, unless imposition of a fine under this subsection would unduly complicate or prolong the sentencing process."

[7] Section 3013 requires the Court to assess a corporation $125 if it is convicted of a Class A misdemeanor. 18 U.S.C. § 3013(a)(B)(iii). Guidant pled guilty to two Class A misdemeanors.

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." (Doc. No. 13 at 16.) The Government and Guidant respond that the Court does not have authority to order restitution because restitution is not available for the charged offenses,[8] and they accuse the alleged victims of using this criminal proceeding as a way to improperly seek an equitable remedy. Moreover, according to the Government and Guidant, even if the Court has authority to order restitution, there are no victims that were directly and proximately harmed by Guidant's criminal conduct as it relates to the crimes to which it has pled guilty and to the underlying circumstances of those crimes which Guidant admitted to during its pleas.

The Court has no inherent authority to impose restitution; rather, "[f]ederal courts cannot order restitution in a criminal case without a statutory basis." *United States v. Lachowski*, 405 F.3d 696, 698 (8th Cir. 2005). The foundational inquiry for determining whether restitution is available is to identify the offense charged, in this case violations of 21 U.S.C. §§ 331(q)(1) and (2). Those portions of the FDCA do not contain a specific restitution provision. There are, however, two other possible statutory bases for ordering

[8] The parties agree that the Court can order a defendant to pay restitution as a condition of probation. *See* Doc. No. 20 at 3; Doc. No. 24 at 102; 18 U.S.C. § 3563. Although the Court rejects the Government's position that placing Guidant on probation would be meaningless and a waste of taxpayers' money, for the reasons discussed below with respect to why the alleged victims are not entitled to restitution under 18 U.S.C. § 3771, restitution to any alleged victims will not be a condition of any ordered probation of Guidant.

restitution in this case: (1) 18 U.S.C. §§ 3663, 3663A and (2) 18 U.S.C. § 3771. The Court will consider each in turn.

A. VWPA and MVRA

The Government and Guidant assert that there is no statutory basis for restitution under the discretionary Victim and Witness Protection Act of 1982 ("VWPA"), 18 U.S.C. § 3663, or the Mandatory Victims Restitution Act of 1996 ("MVRA"), 18 U.S.C. § 3663A, because violations of 21 U.S.C. §§ 331(q)(1) and (2) are not enumerated in the statutes. The Court agrees, noting that the alleged victims have offered no authority to support their assertion that restitution is available under either the VWPA or the MVRA. The VWPA provides, in relevant part:

> The court, when sentencing a defendant convicted of an offense under this title, section 401, 408(a), 409, 416, 420, or 422(a) of the Controlled Substances Act (21 U.S.C. 841, 848(a), 849, 856, 861, 863) (but in no case shall a participant in an offense under such sections be considered a victim of such offense under this section), or section 5124, 46312, 46502, or 46504 of title 49, other than an offense described in section 3663A(c), may order, in addition to or, in the case of a misdemeanor, in lieu of any other penalty authorized by law, that the defendant make restitution to any victim of such offense, or if the victim is deceased, to the victim's estate. The court may also order, if agreed to by the parties in a plea agreement, restitution to persons other than the victim of the offense.

18 U.S.C. § 3663(a)(1)(A). The MVRA provides, in relevant part:

> (a)(1) Notwithstanding any other provision of law, when sentencing a defendant convicted of an offense described in subsection (c), the court shall order, in addition to, or in the case of a misdemeanor, in addition to or in lieu of, any other penalty authorized by law, that the defendant make restitution to the victim of the offense or, if the victim is deceased, to the victim's estate.
>
> . . .
>
> (c)(1) This section shall apply in all sentencing proceedings for convictions of, or plea agreements relating to charges for, any offense--

> (A) that is--
>
> (i) a crime of violence, as defined in section 16;
> (ii) an offense against property under this title, or under section 416(a) of the Controlled Substances Act (21 U.S.C. 856(a)), including any offense committed by fraud or deceit; or
> (iii) an offense described in section 1365 (relating to tampering with consumer products) . . .

18 U.S.C. § 3663A(a)(1), (c)(1). Therefore, because neither statute mentions the violations at issue in this case, there is no statutory basis for restitution under either the VWPA or the MVRA.

B. CVRA

The alleged victims cite in passing the Crime Victim's Right Act ("CVRA"), 18 U.S.C. § 3771, as a statutory source for restitution in this case. A "crime victim" is defined under the CVRA as a person "directly and proximately harmed as a result of the commission of a Federal offense." 18 U.S.C. § 3771(e). The CVRA gives crime victims "[t]he right to full and timely restitution as provided in law." 18 U.S.C. § 3771(a)(6). In their memoranda, neither the Government nor Guidant directly address whether the CVRA provides an avenue for restitution. At the plea hearing, however, citing a conclusory footnote in *In re Doe*, 264 Fed. Appx. 260 (4th Cir. 2007), the Government asserted that the CVRA does not provide any substantive rights with regard to restitution but rather simply refers back to the restitution at law provided by the VWPA and MVRA. Guidant agreed at the plea hearing with the Government that the CVRA does not provide the Court with more jurisdiction than is otherwise provided in the VWPA and MVRA.

Because the United States Court of Appeals for the Eighth Circuit has not directly addressed the issue of whether § 3771 provides an independent basis for restitution, the Court looks to other courts for guidance. The Court finds a recent case from the United States Court of Appeals for the Sixth Circuit instructive because, unlike the footnote relied upon by the Government, this case provides an in-depth discussion of the precise issue before the Court.

In *In re McNulty*, 597 F.3d 344 (6th Cir. 2010), an alleged victim of a corporate defendant's antitrust conspiracy sought restitution under the CVRA. The Sixth Circuit affirmed the district court's decision that McNulty was not a victim for the purposes of the CVRA because the harms he complained of did not flow from the defendant's criminal conduct. *Id*. at 352. In so finding, however, the *McNulty* court reviewed the CVRA's legislative history and sister courts' decisions on the CVRA, and it compared the CVRA to the VWPA and MVRA. After doing so, the Court concluded, among other things: (1) "the CVRA definition does not contain the qualifier 'for which restitution may be ordered' and thus applies to all federal criminal prosecutions regardless of whether the offense qualifies for restitution; (2) "because the CVRA does not include the specific language included in the [MVRA and VWPA], which predate the CVRA, we cannot assume that Congress intended the definitions to be identical"; and (3) "we find our case law construing the VWPA and the MVRA persuasive, both for how the CVRA is to be interpreted procedurally and for when an individual qualifies as a victim of a conspiracy." *Id*. at 350, n.5. The Court finds the Sixth Circuit's reasoning persuasive

and concludes that the alleged victims possibly can be "crime victims" under § 3771, despite the fact that the charged offenses are not enumerated in §§ 3663 and 3663A.

The Court's inquiry, however, does not end here, because a person can only be a "crime victim" under the CVRA if that person is "directly and proximately harmed as a result of the commission of a Federal offense." 18 U.S.C. § 3771(e). The requirement that the victim be "directly and proximately harmed" encompasses the traditional "but for" and proximate cause analyses and is therefore necessarily fact-specific. *In re McNulty*, 597 F.3d at 350. A district court must "look at the offense itself only to determine the harmful effects the offense has on parties. Under the plain language of the statute, a party may qualify as a victim, even though it may not have been the target of the crime, as long as it suffers harm as a result of the crime's commission." *In re Stewart*, 552 F.3d 1285, 1289 (11th Cir. 2008) (court held that mortgage borrowers were CVRA victims of conspiracy to deprive bank of honest services, where defendants were bank officer and co-conspirator whose offense caused borrowers to pay excess fees that defendants pocketed). Therefore, in order to determine whether there are any crime victims, as defined by § 3771(e), that were directly and proximately harmed by Guidant's criminal conduct, the Court must (1) look to the offense of conviction, based solely on facts admitted by Guidant and then (2) determine, based on those facts, whether any person or persons were directly and proximately harmed as a result of the commission of that offense. *In re McNulty*, 597 F.3d at 351 (internal citations omitted).

1. Count One: Submission of False and Misleading Report to FDA

Guidant pled guilty to violating 21 U.S.C. § 331(q)(2), as charged in Count One of the Information. That statute provides, in relevant part, "[t]he following acts and the causing thereof are prohibited: . . . [w]ith respect to any device . . ., the submission of any report that is required by or under this chapter that is false or misleading in any material respect." 21 U.S.C. § 331(q)(2). Under the FDCA, an FDA-approved medical device cannot be lawfully modified in any manner that affects the device's safety and effectiveness, unless and until the manufacturer submits a supplemental premarket approval application regarding the change and receives approval from the FDA to market the modified device. 21 C.F.R. § 814.39(a). Only changes that do not affect a device's safety and efficacy can be made to devices without prior FDA approval; however such changes must be reported to the FDA in post-approval annual reports. 21 C.F.R. § 814.39(b).

At the plea hearing, Guidant admitted that it manufactured the Prizm, which was approved for sale and marketing by the FDA in August 2000. Guidant admitted that it discovered in 2002 that the Prizm had a potential for "arcing" or electrical short-circuiting failures that cause the Prizm to fail to deliver life-saving therapies in

certain circumstances. After that discovery, Guidant admitted that it made changes to the Prizm in April and November of 2002 that affected the device's safety and efficacy.[9]

Specifically, Guidant admitted that on November 13, 2002, it implemented a manufacturing change to the Prizm that applied an insulated sleeve to the backfill tube of the pulse generator in an effort to prevent arcing. Guidant was required by the FDA to submit an annual report related to the Prizm and its family of devices. When it reported the November 2002 change in its August 2003 annual report for June 2002-June 2003, Guidant stated that the November 2002 change was a minor alteration that did not affect safety and efficacy of the Prizm 2: "Device performance is unaffected by this change and the devices continue to meet physical and functional requirements." (Doc. No. 14 at 3.) At the plea hearing, Guidant admitted that the November 2002 change indeed affected the safety and efficacy of the Prizm, and that as a result, its submission in August 2003 concerning the November 2002 change was false and misleading as charged in Count One of the Information.

2. Count Two: Failure and Refusal to Report Medical Device Correction

Guidant pled guilty to violating 21 U.S.C. § 331(q)(1), as charged in Count Two of the Information. That statute provides, in relevant part, "[t]he following acts and the causing thereof are prohibited . . . [t]he failure or refusal to . . . (B) furnish any

[9] There have been no reports of arcing failures on Prizm devices manufactured after the November 2002 was implemented.

notification or other material or information required by or under section 360i . . . of this title." 21 U.S.C. § 331(q)(1). Section 360i, entitled "Records and reports on devices," requires manufacturers to, among other things, submit to the FDA written reports within ten working days for any "corrections" made to medical devices undertaken to reduce a risk to health posed by the device. *See* 21 U.S.C. 360(i)(g); 21 C.F.R. § 806.10. "*Correction* means the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal from its point of use to some other location." 21 C.F.R. § 806.2(d) (emphasis in original). "*Risk to health* means (1) a reasonable probability that use of, or exposure to the product will cause serious adverse health consequences or death; or (2) that use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious health consequences is remote." 21 C.F.R. 806.2(j) (emphasis in original).

At the plea hearing, Guidant admitted that it manufactured and sold the Renewal, which is both an ICD and a pacemaker, after it received FDA approval at the end of 2002 through approximately 2005. Guidant admitted that at some point it learned that the Renewal had a short-circuit flaw because a high-voltage wire was routed along the bottom of the header and therefore in contact with the pulse generator. The flaw could make the device arc, thereby rendering the device nonfunctional. Guidant admitted that the Renewal contained a detector that would beep to alert a patient of a potential problem with the device. If a person's device was beeping, that person would go to his or her doctor, who would perform a test on the device. In certain cases, the test results would

display a yellow "shorted shock lead" warning screen that would advise doctors to conduct a low voltage test to evaluate the device's leads. The warning screen did not, however, advise doctors that the device may short-circuit due to a flaw in the header and therefore, the warning screen did not alert doctors that a patient's problem could be with the device itself.

Guidant further admitted that in July 2004, it learned that a doctor in Spain had tested a patient's Renewal device; received the "shorted shock lead" warning screen; conducted a test to evaluate the device's leads; and upon finding no problem with the leads, sent the patient home. Guidant admitted that the patient died approximately one week later when his Renewal device failed to deliver therapy after the patient suffered a cardiac event. Guidant admitted that the patient's death was its first report of a death from the Renewal's short-circuit flaw and its fourth report of an arcing incident. Guidant admitted that on August 26, 2004, it stopped shipment of all Renewal devices, although it continued to market the Renewal devices already in the field at that time. By March 2005, Guidant admitted that it knew of twelve Renewal arcing incidents.[10] It admitted that it prepared and distributed a product update in March 2005 that provided doctors with instructions as to what to do when they received a yellow "shorted shock lead" warning screen. Guidant admitted, however, that the product update did not discuss

[10] At the plea hearing, Guidant explained that it had informed the FDA of these incidents but in separate documents unrelated to the March 2005 product update.

the short-circuiting flaw in the header, the Spanish patient's death, or the other arcing incidents.

Guidant admitted that the March 2005 product update was designed to reduce a risk to health and that it was a correction to the labeling[11] of the Renewal. Guidant admitted that it is guilty of the crime charged in Count Two of the Information because it did not submit the March 2005 product update to the FDA within 10 days. Instead, in June 17, 2005, it officially informed the public and the FDA about the arcing problems in the Prizm and Renewal devices, including how the yellow warning screen was related to the problem.

3. Directly and Proximately Harmed

The alleged victims assert that they were directly and proximately harmed by Guidant's conduct, at least with respect to Guidant's purported overall scheme underlying the actions for which it has admitted guilt. The alleged victims' definition of "victim" has evolved through these proceedings. Their most recent position is that a crime victim is "any individual who purchased a medical device or drug that did not comply with the [FDA] Regulations" (Doc. No. 13 at 1), namely, "all patients implanted with a pre-corrective [Prizm or Renewal device]." (Doc. No. 18 at 3.)

---

[11] Labeling means "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

At the plea hearing, the Government noted that it was mindful of the injuries suffered by Prizm and Renewal device recipients, but it asserted that Congress did not intend for such recipients to be considered victims for the crimes at issue in this case. As discussed above, the Government contends that the Court does not have statutory authority to order restitution and that even if the Court did, the Government argues that the alleged victims' injuries do not "flow directly and proximately from the specific criminal conduct charged, and any process necessary to fulfill the request would unduly complicate and prolong the sentencing process." (Doc. No. 15 at 7.)

Guidant agrees with the Government and summarizes the alleged victims' argument as follows: "They argue that patients made decisions to purchase devices based upon statements made by Guidant well after the purchase relating to different devices, that is, they made a purchase of a pre-change device in 2002 in reliance upon a statement that was later to be made about post-change devices in 2003." (Doc. No. 14 at 5.) Guidant further points out that the alleged victims "have not attempted to identify any Plaintiff that purchased a pre-changed device after the publication of the 2003 Annual Report to the FDA setting forth the November 13, 2002 change to the Prizm 2. Nor have they attempted to identify any plaintiff that purchased a Renewal 1 device that is subject to Count 2." (Doc. No. 20 at 1-2.)

The Court agrees with the Government and Guidant that the alleged victims are not victims for the purposes of restitution in this case. Because Count One relates solely to Guidant's filing of a false and misleading report in August 2003, only persons directly and proximately harmed by Guidant's August 2003 filing would be victims of Count

One. There is nothing in the record to suggest that any person was harmed in any manner as a result of Guidant's statement in August 2003 that the November 2002 change--which, by all accounts, made the device safer—did not affect the safety and efficacy of the Prizm. In this way, the alleged victims' reliance of the chain of events that happened prior to the August 2003 filing is irrelevant for the purposes of defining "victim" as it applies to Count One because this count only involves how Guidant described the November 2002 change in its August 2003 report. Much to the alleged victims' and public's frustration, Guidant's motivation for when and how it described the November 2002 change, and for that matter the April 2002 change, makes no difference in the Court's analysis of Count One, given the elements of the crime as charged in Count One.

Count Two relates to the March 2005 product update that Guidant failed to disclose to the FDA within 10 days of its issuance. The update itself properly went to the doctors for whom it was intended. There is nothing in the record to suggest that any person was harmed in any manner as a result of Guidant's failure to provide the FDA with a copy of that product update. In this way, the alleged victims' reliance on Guidant's failure to include certain facts about the Renewal failures in March 2005 is irrelevant for the purposes of defining "victim" as it applies to Count Two. Given the elements of 21 U.S.C. § 331(q)(1), the crime charged in Count Two relates only to Guidant's failure not to disclose the update to the FDA and not to the contents of the update itself.

In sum, contrary to the Government's and Guidant's position, the Court concludes that it has the authority under the VCRA to order restitution for victims of crimes. It also concludes, however, that there are no persons who were directly and proximately harmed by Guidant's criminal conduct in this case.[12]

II. Plea Agreement

"Whether to approve or reject a plea agreement is a matter confided to the sound discretion of the trial court." *United States v. Nicholson*, 231 F.3d 445, 451 (8th Cir. 2000); *see also In re United States*, 503 F.3d 638, 641 (7th Cir. 2007) (explaining that a court can reject a plea bargain if the agreed sentence would be one the judge deems inappropriate); *Government of the Virgin Islands v. Walker*, 261 F.3d 370, 375 (3rd Cir. 2001) (stating that "[a] sentencing court can, of course, reject the results of a plea negotiation if it concludes that the resulting agreement is not in the best interest of justice"). Therefore, at this stage, the Court must determine whether to accept and be

[12] Even if the Court had concluded that the alleged victims or other individuals were victims in this case, the Court would decline to order restitution because individualized, fact-specific inquiry for each victim (which would necessarily involve offsets of recovery from any civil proceeding including the Guidant MDL) would be unduly burdensome and unmanageable. *See* 18 U.S.C. § 3663(a)(1)(B)(ii) ("[t]o the extent that the court determines that the complication and prolongation of the sentencing process resulting from the fashioning of an order of restitution under this section outweighs the need to provide restitution to any victims, the court may decline to make such an order"); *see also* U.S. Sentencing Guidelines Manual § 8B1.1(b)(2) ("to the extent the court finds, from facts on the record, that (A) the number of identifiable victims is so large as to make restitution impracticable; or (B) determining complex issues of fact related to the cause or amount of the victim's losses would complicate or prolong the sentencing process to a degree that the need to provide restitution to any victim is outweighed by the burden on the sentencing process").

bound to the specific provisions of the Plea Agreement.[13] After careful deliberation, the Court exercises its discretion and declines to accept the Plea Agreement. The Court concludes that two provisions of the Plea Agreement, discussed below, are not in the best interests of justice and do not serve the public's interests because they do not adequately address Guidant's history and the criminal conduct at issue. *See, e.g., United States v. Greener*, 979 F.2d 517, 520 (7th Cir. 1992) (holding the district court did not abuse its discretion by concluding the plea "would not adequately represent the defendant's criminal conduct").

A. Probation

As mentioned previously, the Government and Guidant jointly agreed to a Plea Agreement that contains no provision requiring probation, and the Plea Agreement itself specifically states that a presentence investigation report is not necessary because the plea and sentencing hearings, together with the record, will provide the Court with sufficient information. When asked at the plea hearing why the Government was not seeking probation, Mr. Goldstein on behalf of the Government replied:

> Well, the problem with probation—there is a fundamental problem with probation and it goes to sort of the corporate structure. As the Court is aware, the entity—Boston Scientific is a conglomerate. They have countless subsidiaries and they do business through different countries, through different subsidiaries, for different purposes, they have holding corporations. That is modern business practice. That is the way it is done. I am not faulting the company for that at all, that is just the way it is done. And it is done purposefully to insulate themselves from certain types of liability or tax liability or criminal liability in this case.

[13] *See* II.C below concerning Rule 11(c)(1)(C) plea agreements.

> The problem is, Guidant LLC, as far as the Government knows, is no longer operating. A term of probation for a non-operating subsidiary that doesn't have any assets that is not doing—conducting business is absolutely meaningless. And the Court would be imposing probation merely for the purpose of ordering restitution.

(Doc. No. 24 at 101-102.) The Court then asked the Government why it would not serve the public interest to, as a condition of probation, require good faith compliance on the part of Guidant or Boston Scientific. The Government responded that it did not believe the Court had jurisdiction over Boston Scientific, although it conceded that the parent company could agree to it. The Government explained that it is already supervising Boston Scientific through a recent unidentified civil settlement, that "there are other vehicles in play," (*id*. at 103), and that the Office of Inspector General of the Department of Health and Human Services[14] ("OIG") has not yet taken a position with regard to this case. For these reasons, the Government asserts that probation is not necessary because "there is adequate supervision through another vehicle. And supervising a company that is really a piece of paper at this point is meaningless and would be a waste of the Court's resources and the taxpayer's money, I think." (*Id*. at 105.)

Interestingly, these statements seem to contradict the tone of the Government's press release on the day of the plea hearing:

---

[14] As mandated by Public Law 95-452, OIG's mission is to protect the integrity of Department of Health and Human Services ("HHS") programs, as well as the health and welfare of the beneficiaries of those programs. http://oig.hhs.gov (last visited April 25, 2010.)

> "Guidant's guilty plea today is about accountability," said Assistant Attorney General Tony West, who heads the Justice Department's Civil Division. "This successful prosecution serves as an important wake up call to all those who seek to withhold vital information about public health and safety. We will continue our efforts to prosecute those who jeopardize public health by evading their reporting obligations to the FDA."
> . . .
>
> "Today's entry of a guilty plea by Guidant LLC and the proposed resolution would represent the largest criminal penalty ever imposed on a device manufacturer for violating the Food Drug and Cosmetic Act," said Commissioner of Food and Drugs Margaret A. Hamburg, M.D. "The FDA will continue to commit enforcement resources to seeking this type of criminal resolution and stiff sanctions when device manufacturers fail to adhere to the statutory and regulatory requirements that exist to ensure the safety and efficacy of their products."

(Press Release, The United States Department of Justice, Medical Device Manufacturer Guidant Pleads Guilty for Not Reporting Defibrillator Safety Problems to FDA (April 5, 2010)).

At the plea hearing, the alleged victims urged the Court to reject the Plea Agreement because it did not require the Court to place Guidant on probation, presumably because the alleged victims recognize that the Court can, as a part of probation, order restitution.[15] The alleged victims characterized Guidant as a repeat offender by pointing to (1) a 2003 guilty plea by a Guidant subsidiary, Endovascular Technologies, Inc., (2) a $22 million civil settlement in December 2009 between Boston Scientific and the U.S. Department of Justice related to post-market surveys and payments made to doctors by Guidant Corporation before it was acquired by Boston

[15] *See* footnote 12 above.

Scientific; and (3) Boston Scientific's March 15, 2010 announcement that it had stopped shipment and was retrieving field inventory of all its ICDs and CRT-Ds.[16] As part of both the Endovascular Technologies, Inc.'s guilty plea and the $ 22 million civil settlement, corporate integrity agreements were entered into with the OIG to promote, among other things, compliance with federal regulations.[17] The alleged victims contend that Guidant, as a company, does not respect the criminal justice system and should be required to do more than simply pay fines as a consequence for its criminal behavior.

In addition to the alleged victims, Drs. Hauser and Maron[18] urge the Court to reject any plea agreement that does not contain a probation provision:

> Also at issue in this case is the safety of future generations of patients who receive medical devices. Manufacturers control the quality of their products. Manufacturers are the first to know when a medical device is dangerous or underperforming. Thus, it is in the best interest of patients, and society in general, for manufacturers to be liable for the safety and effectiveness of their products. To allow a repeat offender, like Guidant, to escape with a fine (that is entirely borne by the shareholders of Boston Scientific) does not hold the guilty parties fully accountable and inevitably undermines patient safety.

(Doc. No. 21 at 2.)

---

[16] On April 15, 2010, Boston Scientific announced that it was resuming shipment of its ICDs and CRT-Ds after receiving FDA clearance for two manufacturing changes for its devices.

[17] The record is not clear as to whether Guidant Corporation itself is bound to either one of those agreements.

[18] *See* footnote 5 above.

There is no dispute concerning the validity, in general, of placing a corporation on probation. *See, e.g., U.S. v. Missouri Valley Const. Co.*, 741 F.2d 1542, 1550 (8th Cir. 1984) (citing cases for the validity of (1) imposing community service as a condition of corporate probation and (2) requiring corporate defendants or their employees (including employees of parent or subsidiary corporations) to conduct activities to educate the public or to receive instruction on compliance with the law). The Court respectfully disagrees with the Government's view that probation would be a waste of the taxpayers' money, especially given that Guidant could be required, as a condition of probation, to reimburse the Government for any costs associated with its probation. The Court also disagrees with the Government's position that Guidant's current corporate structure renders any probation meaningless, especially given the fact that Boston Scientific itself recently entered into a $22 million settlement and corporate integrity agreement based on certain pre-acquisition actions by Guidant. Guidant Corporation became Guidant LLC less than two weeks before the Government filed the Information. The interests of justice are not served by allowing a company to avoid probation simply by changing their corporate form. At a minimum, the public's interest in accountability would be served by Guidant and Boston Scientific being placed on probation, regardless of the fact that Boston Scientific acquired Guidant after the events in question. And, the Court believes that a period of probation would likely benefit, rather than harm, Guidant's and Boston Scientific's public image.

Moreover, the Court is surprised that Chapter Eight of the United States Sentencing Commission Guidelines Manual, which is entitled "Sentencing of

Organizations, is not referenced or made any part of the Plea Agreement. Specifically, § 8D1.1 requires, among other things, a court to order a term of probation:

> (3) if, at the time of sentencing, (A) the organization (i) has 50 or more employees, or (ii) was otherwise required under law to have an effective compliance and ethics program; and (B) the organization does not have such a program;
>
> . . .
>
> (6) if such sentence is necessary to ensure that changes are made within the organization to reduce the likelihood of future criminal conduct;
>
> . . .
>
> or
>
> (8) if necessary to accomplish one or more of the purposes of sentencing set forth in 18 U.S.C. § 3553(a)(2).

U.S. Sentencing Guidelines Manual § 8D1.1(3), (6), (8). As a condition of probation, a court "may impose other conditions that . . . are reasonably related to the nature and circumstances of the offense or the history and characteristics of the organization." *Id.* § 8D1.3(c). A court also may order an organization to establish a program to eliminate the risk that the instant actions would occur in the future; to perform community service if it is designed to repair the harm caused by the offense; and to establish an effective compliance and ethics program, which often includes an outside compliance officer paid by the organization. *Id*. §§ 8B1.2, 1.3, 8B2.1. In so doing, "a court should consider the views of any governmental regulatory body that oversees the conduct of the organization relating to the instant offense." *Id*., Application Note 1 to § 8D1.4.

The sentencing guidelines further instruct, among other things, that:

> (a) The court may order the organization, at its expense and in the format and media specified by the court, to publicize the nature of the offense committed, the fact of conviction, the nature of the punishment imposed, *and the steps that will be taken to prevent the recurrence of similar offenses*.
>
> . . . .
>
> (c) If probation is ordered under § 8D1.1(a)(3), (4), (5), or (6), the following conditions may be appropriate:
>
> (1) The organization shall develop and submit to the court an effective compliance and ethics program consistent with § 8B2.1 (Effective Compliance and Ethics Program). The organization shall include in its submission a schedule for implementation of the compliance and ethics program.
>
> . . .
>
> (4) In order to monitor whether the organization is following the program referred to in subdivision (1), the organization shall submit to: (A) a reasonable number of regular or unannounced examinations of its books and records at appropriate business premises by the probation officer or experts engaged by the court; and (B) interrogation of knowledgeable individuals within the organization. *Compensation to and costs of any experts engaged by the court shall be paid by the organization.*

U.S. Sentencing Guidelines Manual § 8D1.4(a), (c) (emphasis added).

The Court believes that a term of probation would be appropriate in this case and could be fashioned in a manner to serve the public's interest and address the accountability concerns raised by Drs. Hauser and Maron and likely shared by many others. For instance, as a condition of probation, Guidant, through Boston Scientific, could be ordered to perform community service designed to repair the harm caused by its offenses, namely to help build the public's confidence in the FDA regulation process, the medical device manufacturers' quality control efforts, and the cardiac healthcare industry

in general. Indeed, Boston Scientific could be ordered, as a condition of probation and *in addition to* a criminal fine, to dedicate a certain amount of its resources to some of its already-established charitable programs. Boston Scientific has at least two programs that would be appropriate in this case, specifically its Close-the-Gap program, which is a program that looks for ways to address disparities in cardiovascular care for the underserved patient populations of women, black Americans, and Hispanic/Latino Americans or its Lead-the-Way program, which is a national educational program that helps give middle and high school students the rigorous ground-level education they need to develop strong backgrounds in science and engineering. *See* http://www.bostonscientific.com/CorporateResponsibility (last visited April 25, 2010).

Guidant, through Boston Scientific, could also be required to establish a compliance and ethics program, or if one is already established, to dedicate *additional* resources to that program to address the specific crimes in this case. Such a program could be overseen by a compliance officer skilled in the regulatory area and who perhaps could work in coordination with either the FDA or the Heart Rhythm Society,[19] or both.

---

[19] The Heart Rhythm Society, formerly known as North American Society of Pacing and Electrophysiology or NASPE, is "the international leader in science, education and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders." As such, it is often "an intermediary between government regulatory agencies and its members . . . [and therefore it] maintains a strong working relationship with officials at the U.S. Food and Drug Administration (FDA) and provides input into medical devices and pharmaceutical health care polices as they are being developed at the FDA." http://www.hrsonline.org (last visited April 25, 2010).

A presentence investigation report would, of course, allow the Court to consider the feasibility of any of these suggestions or of additional conditions of probation.

B. Forfeiture

As part of the plea, Guidant agreed to forfeit $42,079,675 as a result of the crime as charged in Count Two. Because the Renewal devices, which are the subject of the forfeiture, cannot be located or have been sold, the Government is seeking the value of the forfeited property directly from Guidant pursuant to 21 U.S.C. § 853(p) and 28 U.S.C. 2461(c). The record is not entirely clear as to how the forfeited amount was calculated. According to Guidant, it agreed to let the Government decide which portion of the monetary penalty should be directed toward a fine[20] and which should be forfeited. (Doc. No. 14 at 5.)

---

[20] The Administrative Office of the United States Courts is supervised by a Director and a Deputy Director. 28 U.S.C. § 601. One of the Director's duties is to "establish procedures and mechanisms within the judicial branch for processing fines, restitution, forfeitures of bail bonds or collateral, and assessments." 18 U.S.C. § 604(18); *see also* 28 C.F.R. 0.171(c) ("The Director of the Executive Office for United States Attorneys shall be responsible for the establishment of policy and procedures and other appropriate action to accomplish the satisfaction, collection, or recovery of fines, special assessments, penalties, interest, bail bond forfeitures, restitution, and court costs arising from the prosecution of criminal cases by the Department of Justice and the United States Attorneys."). There are three types of criminal debt: special assessments, restitutions, and fines. For most criminal cases excluding certain environmental, railroad, unemployment insurance, and postal service violations, § 820.50.30 of Budget and Finance Section of the Guide to Judiciary Policies and Procedures provides (in generalized terms) that money collected from a criminal fine is first considered to be part of the special assessment and deposited into the Crime Victims' Fund; second the money is applied for restitution, if there is any ordered in a particular case; and third, the remaining fine principal and interest is paid into the Crime Victims' Fund. The Crime Victims' Fund, established by 42 U.S.C. 10601, is a major funding source for victim

(Footnote Continued on Next Page)

Under Department of Justice regulations, the United States Attorney General may return forfeited property (including money) to a victim of the crime underlying the forfeiture, provided that certain eligibility requirements are met. *See* 28 C.F.R. § 9.4 (describing what information an individual should submit in support of a petition for remission, where the information should be submitted, and who reviews the petition). For the purposes of forfeiture, a victim is defined as "a person who has incurred a pecuniary loss as a direct result of the commission of the offense underlying a forfeiture." 28 C.F.R. §9.2(v). The Government states that it "specifically contemplated the crime victim remission provisions in negotiating the forfeiture provisions of the plea agreement in this case notwithstanding the fact that the restitution statutes do not apply at sentences to the offense of conviction." (Doc. No. 15 at 9.) Yet, the Government also argues that there are no victims in this case. By arguing so, the Government places a very high burden on the very individuals it claims it considered when drafting the Plea Agreement.

The forfeiture remission process can be, to say the least, cumbersome, and for this reason, the Court believes that the interests of justice would be served only if clear guidelines were established by the Government that directed individuals as to how they

---

(Footnote Continued From Previous Page)

services throughout the Nation. The fund has an allocation process that includes an annual funding cap based on the prior year's receipts from fines, and it includes payments to the Children's Justice Act, U.S. Attorney's victim-witness coordinator program, the FBI victim-witness specialist program, the Federal Victim Notification System, and state compensation and assistance grants, among others. More information on the Crime Victims' Fund can be found at http://www.ovc.gov (last visited April 25, 2010).

can petition for the remission of any forfeited funds in this case. The Government would also need to have a contact person to answer individuals' questions concerning this process. The Court has no role is the remission of forfeited funds. 28 C.F.R. § 9.1(2) ("[r]emission and mitigation functions in judicial cases are performed by the Criminal Division of the Department of Justice. Within the Criminal Division, authority to grant remission and mitigation is delegated to the Chief, Asset Forfeiture and Money Laundering Section, Criminal Division."). Nevertheless, the Court reminds individuals that forfeited funds are available only to individuals who suffered pecuniary losses *as a direct result* of Guidant's commission of the offense as charged in Count Two relating to Renewal devices. In this way, the remission process necessarily involves an analysis similar to the one the Court performed above when it determined that there were no victims for the purposes of restitution. The Court expects that any remission proceeding would reach the same result.

Given the unlikelihood of recovery of any forfeited funds by alleged victims, the question of where the forfeited funds are to go if they are not returned to any victims needs to be answered. According to the Government, $42,079,675 gets "paid into a forfeiture fund from which different law enforcement agencies are empowered to draw from it for law enforcement purposes. It is also used for victim programs, in general, the Office of Crime Victims also has access to it, is my understanding, as well as individual victims, as Your Honor is well aware, [can] petition for remission." (Doc. No. 24 at 106.)

Given this, the Court asks the Government to consider the following. In the Guidant MDL, approximately 75% of the claimants were Medicare recipients who had received Guidant devices at issue in the Guidant MDL, including the Prizm and Renewal devices. Through a global lien resolution program ably led by The Garretson Firm Resolution Group, Inc., Medicare reclaimed a portion of the money it paid for Guidant MDL claimants' medical expenses. It is possible that at least 15,000 of the devices at issue in this case went to Medicare recipients and that, as a result, Medicare likely incurred significant expenses related to the Prizm and Renewal devices. As the alleged victims stated at the plea hearing, "one of the major losers in this whole fiasco with the ICD's was the Medicare Program and the Medicaid Program." (Doc. No. 24 at 91.) For this reason, the Court urges the Government to consider directing that a significant portion of the forfeited funds be paid to Medicare. *See* 18 U.S.C. § 981(e)(1) (allowing the Attorney General to transfer property forfeited on terms and conditions as he may determine to any other Federal agency). The Court respectfully encourages the Government and Guidant to work with The Garretson Firm Resolution Group, Inc., which, it assumes, would be able to employ a mathematical model to assist the Government in determining an appropriate sum that should be directed to Medicare.

C. Rule 11(c)(1)(C) Plea Agreement

The Plea Agreement was entered into pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure. Rule 11(c)(1)(C) provides that a "plea agreement may specify that an attorney for the government will . . . (C) agree that a specific sentence or sentencing range is the appropriate disposition of the case." Fed. R. Crim. P. 11(c)(1)(C).

It further declares that "such a recommendation or request binds the court once the court accepts the plea agreement." *Id*. Therefore, "[a] plea agreement under Rule 11(c)(1)(C), like all plea agreements, is binding on both the government and the defendant, but Rule 11(c)(1)(C) plea agreements are unique in that they are also binding on the court *after* the court accepts the agreement." *United States v. Kling*, 516 F.3d 702, 704 (8th Cir. 2008) (emphasis in the original).

As discussed above, the Court has exercised its discretion and declined to accept—and be bound to—the Plea Agreement. Therefore, because the Plea Agreement is a Rule 11(c)(1)(C) agreement, the Court hereby advises Guidant that it now has an opportunity to withdraw its guilty plea but that if it chooses not to withdraw its guilty plea, the Court may then dispose of this case less favorably than the Plea Agreement contemplated.[21] *See* Fed. R. Crim. P. 11(c)(5)(A)-(C); *U.S. v. Gillen*, 449 F.3d 898, 902 (8th Cir. 2006).

The Government and Guidant are, of course, free to submit a modified Plea Agreement to the Court for its consideration. While the Court may not participate in any plea discussions, *see* Fed. R. Civ. P. 11(c)(1), the Court notes that it would likely consider a modified agreement to be in the interests of justice if it addressed the concerns raised in this Order, specifically with respect to probation, community service,

[21] Paragraph 13(a) of the Plea Agreement provides, in relevant part, "[i]f the Court does not accept the recommended sentence, the United States and Guidant agree that this Plea Agreement . . . shall be rendered void." (Doc. No. 9 at 11.)

coordination with the FDA and any other appropriate regulatory agencies, and a discussion of where the fine and forfeiture funds will go. Finally, the Court believes that a presentence investigation report would be useful in determining the appropriate probationary sentence and whether there are any unintended consequences flowing from placing Guidant or other entities within Boston Scientific's corporate structure on probation.

CONCLUSION

As Guidant alluded to at the plea hearing, sophisticated medical devices, such as the ones at issue in this case, generally have a very high rate of reliability and provide life-saving benefits to many people. Advances in medical technology have, unfortunately, inflated the public's expectations so much so that when any device fails, many assume that there must have been a crime committed or that someone is at fault. This is not necessarily always the case.

The Court reminds the parties, Guidant device recipients, and the public that in any criminal case, the prosecution—not a court—determines what crimes are charged against a defendant. The prosecution has wide discretion in determining what charges to bring. It must make such decisions after carefully considering the facts known at the time, the elements of a particular crime, and the uncertainty of results in any criminal proceeding. A court's responsibility is to apply the law, and a court cannot reject a plea agreement simply because the prosecution could have possibly charged a defendant with additional or different crimes. *See United States v. Miller*, 722 F.2d 562, 564 (9th Cir. 1983) ("When a prosecutor selects a charge, he has made an executive choice. When a

judge sentences a defendant, he has made a judicial choice. When a plea bargain is placed before a court, the necessary interplay between charging and sentencing decisions becomes manifest."); *see also* Standards for Criminal Justice § 14-3.3 (commentary discussion concerning difference between discretion afforded to prosecutor and to a court).

The Court recognizes the frustration that device recipients and the public may have for this criminal proceeding, and the Court is well-aware of the physical and emotional trauma caused by the Guidant recalls. But, as the Court repeatedly stated at the plea hearing, the only matter currently before the Court concerns the criminal case against Guidant and the conduct admitted to, specifically, on the Government's charges concerning reports Guidant made to the FDA about the Prizm and Renewal devices. Although the Guidant MDL claimants and the public may be frustrated with the results of the Guidant MDL, this is not the proper forum in which to address those complaints.

Throughout the Guidant MDL, the Court saw how the MDL process sometimes gave claimants unjustifiable expectations of recovery and therefore caused many claimants to experience anxiety throughout the entire litigation process. Nothing in this Order is intended to give any person who considers herself or himself to be a victim of Guidant's criminal conduct any expectation of future recovery through this proceeding. While such recovery is not entirely foreclosed through a possible remission petition, the Court believes that such recovery is highly unlikely. The Court, however, has no role in the forfeiture proceedings.

Based on the files, records, and proceedings herein, and for the reasons set forth above, **IT IS ORDERED** that:

1. The Court declines to accept the Plea Agreement (Doc. No. 9).

Dated: April 27, 2010

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