

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA,  
  
Plaintiff,

v.

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

Defendant.

Criminal No. 10-mj-67 (DWF)

GOVERNMENT'S MEMORANDUM IN  
RESPONSE TO MDL PLAINTIFFS'  
OBJECTIONS TO PLEA AGREEMENT

The United States of America, by and through its undersigned attorneys, the United States Attorney for the District of Minnesota and the Office of Consumer Litigation of the U.S. Department of Justice, hereby submits this memorandum in response to the objections to the plea agreement filed by the Plaintiffs' Lead Counsel Committee in In re: Guidant Corp. Implantable Defibrillators Prods. Liab. Litig., MDL No. 1708 (D. Minn.) (the "MDL"). For the reasons explained below, we respectfully request that the Court overrule the objections and accept the plea agreement.

The objections should be overruled because: (1) criminal restitution is not authorized for the offenses of conviction under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et. seq., "FDCA") in this case; (2) even if criminal restitution were available for these offenses, the Court would need to determine on an individual basis whether each individual

qualifies as a "crime victim" for purposes of restitution and such a process would unduly complicate and prolong this matter; (3) the MDL plaintiffs have an adequate remedy at law; and (4) individuals who suffered an uncompensated pecuniary loss may petition the Attorney General for compensation from forfeited funds in excess of \$42 million.

BACKGROUND

On February 25, 2010, the United States of America charged Guidant LLC (formerly known as Guidant Corporation and hereinafter referred to as "Guidant") with two misdemeanor violations of the FDCA pursuant to 21 U.S.C. § 333. The filing of the Information was pursuant to a plea agreement that was reached following a lengthy criminal investigation. As described more fully in the plea agreement, Guidant will plead guilty to: (1) making a materially false statement in a required submission to the FDA with regard to the Ventak Prizm 2DR device; and (2) failing to notify the FDA of a "correction" to the Contak Renewal devices, which the company made to reduce a risk to health caused by the devices. As a result of these offenses for which the defendant will be convicted, the plea agreement calls for a combined criminal penalty in excess of \$296 million, the largest criminal penalty ever assessed against a medical device manufacturer, and which is more than twice the pecuniary gain Guidant derived from the charged offenses.

The plea agreement is submitted for the Court's approval pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C). For

the reasons discussed below, the United States recommends acceptance of the plea agreement, the objections of the MDL plaintiffs notwithstanding.

ARGUMENT

I. Restitution Is Not Available For the Charged Offenses

"Federal courts cannot order restitution in a criminal case without a statutory basis." United States v. Lachowski, 405 F.3d 696, 698 (8th Cir. 2005) (quoting United States v. Pawlinski, 374 F.3d 536, 540 (7th Cir. 2004), and citing cases from the Seventh, Eighth, and Eleventh Circuit Courts of Appeal). Restitution is only authorized for offenses covered by a federal restitution statute. The FDCA does not contain a specific restitution provision. Moreover, violations of the FDCA are not among the offenses for which restitution is authorized under Title 18. See 18 U.S.C. §§ 3663-3663A. The defendant has been charged with and will plead guilty to violations of Title 21, United States Code, Sections 331 and 333. There is no basis to order restitution as part of the sentence under those statutes. Cf. United States v. Minneman, 143 F.3d 274, 284 (7th Cir. 1998) (restitution not allowed for Title 26 tax offense, but allowed for Title 18 tax conspiracy); United States v. Stout, 32 F.3d 901, 905 (5th Cir. 1994) (restitution order for Title 26 tax offense improper); United States v. Snider, 957 F.2d 703, 707 (9th Cir. 1992) (restitution for Title 31 structuring offense improper because it is not among offenses listed in 18 U.S.C. § 3663).

The decisions cited in the MDL plaintiffs' objection to the plea are inapposite. In United States v. Kaminski, 501 F.3d 655, 669-70 & n.12 (6th Cir. 2007), the district court imposed restitution as a condition of probation following a jury trial; here, the contemplated sentence does not include probation. The other decisions involved civil enforcement proceedings pursuant to 21 U.S.C. § 332 in which a court is authorized to impose equitable remedies. See United States v. Lane Labs-USA Inc, 427 F.3d 219 (3d Cir. 2005); United States v. Universal Mgt. Svcs., Inc., 191 F.3d 750 (6th Cir. 1999). While courts undoubtedly can order restitution in the circumstances of those cases, that authority does not extend to the criminal sentence in the instant case for the reasons set forth above.

Because these Title 21 offenses are not subject to the restitution provisions, an agreement to plead guilty to them should not be rejected for lack of a restitution provision.

II. Determining Whether Each MDL Claimant Is a Crime Victim Entitled to Restitution Would Unduly Complicate and Prolong the Sentencing Process

The government recognizes that people have suffered harm associated with their use of the medical devices at issue here. However, restitution may only be awarded to victims of the offense of conviction. Because restitution is not authorized for the offenses of conviction here, there is no basis for the Court to reject the plea agreement.

Further, to be entitled to restitution a person must have been directly and proximately harmed as a result of the

commission of an offense for which restitution may be ordered. 18 U.S.C. §§ 3663(a)(2), 3663A(a)(2). See also 18 U.S.C. § 3771(b)(2)(D) (similarly defining "crime victim" under the Crime Victims' Rights Act). "[R]estitution may be awarded only to victims of the offense of conviction, and a victim may not be compensated for conduct unrelated to the offense of conviction, even if that unrelated conduct was the subject of criminal charges dropped by the government in exchange for the defendant's guilty plea." United States v. Chalupnik, 514 F.3d 748, 752 (8th Cir. 2008); United States v. DeRosier, 501 F.3d 888, 896 (8th Cir. 2007) ("Restitution may only be awarded for the loss caused by the specific conduct that is the basis of the offense of the conviction.").

Thus, even if the offenses of conviction were recognized under Sections 3663 or 3663A, identifiable victims must have been "directly and proximately harmed" from the conduct that forms the basis for offenses charged - i.e., Guidant's false statement to FDA in Count 1 of the Information and/or Guidant's failure to report the device correction to FDA as alleged in Count 2. Although MDL plaintiffs were harmed during the course of their treatment with Guidant's devices, it is less certain that those harms were the direct and proximate result of the strict liability offenses charged in the Information. Further, any causation determination must be based on "an individualized inquiry; what constitutes sufficient causation can only be

determined case by case, in a fact-specific probe.” United States v. Vaknin, 112 F.3d 579, 588 (1st Cir. 1997).<sup>1</sup>

“In other words, the mere fact that an injury is related to a crime is insufficient for restitution; there must be a ‘direct and proximate’ connection between the two to support an award.” In re Doe, 264 Fed. Appx. 260, 263 (4th Cir. 2007); see also United States v. Cutter, 313 F.3d 1, 7 (1st Cir. 2002) (“First restitution should not be ordered if the loss would have occurred regardless of the defendant’s misconduct underlying the offense of conviction. Second, restitution is inappropriate if the conduct underlying the conviction is too far removed, either factually or temporally, from the loss.”); United States v. Woods, \_\_\_ F. Supp. 2d \_\_\_, 2010 WL 724194, at \*5 (N.D. Iowa March 3, 2010) (relying on Doe, Cutter, and Vaknin in absence of “precise causation standard for restitution awards”).

A Court also must be able to specifically calculate each victim’s actual provable loss on an individual basis. This is because “restitution is limited to the victim’s provable actual loss.” United States v. Lange, 592 F.3d 902, 907 (8th Cir. 2010). A Court cannot impose restitution to unidentified victims and hold it in reserve in case victims come forward.<sup>2</sup> See United

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<sup>1</sup> This would require identifying and sorting through the facts relating to more than 20,000 device recipients.

<sup>2</sup> Objectors’ suggestions (Mem. at 2) that restitution could include creating a “claims fund” or a requirement that Guidant fund “independent medical research,” are beyond the scope of the restitution statutes.

States v. Catoggio, 326 F.3d 323 (2d Cir. 2003) (reversing restitution order in RICO case with thousands of potential victims where court ordered restitution to unidentified victims and without determining their actual losses). And the restitution order must be finalized within 90 days after sentencing. 18 U.S.C. § 3664(d)(5).<sup>3</sup>

Here, it is not clear that the MDL Plaintiffs' injuries, while not insignificant, flow directly and proximately from the specific criminal conduct charged,<sup>4</sup> and any process necessary to fulfill the request would unduly complicate and prolong the sentencing process. See 18 U.S.C. § 3663(a)(1)(B)(ii). The objection to the plea agreement should be overruled.

### III. Objectors Have an Adequate Remedy at Law

The MDL Plaintiffs have taken advantage of their rights to seek compensation from Guidant through the civil judicial process. It is the government's understanding that the majority

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<sup>3</sup> At least one court has interpreted the "directly and proximately" causation criteria to evince Congress' intent that restitution orders be administratively possible and for the victim analysis to be efficiently determinable. United States v. Reifler, 446 F.3d 65, 135 (2d Cir. 2006).

<sup>4</sup> For example, in Doe, the petitioner asserted that she was a victim of Purdue Pharma's criminal FDCA convictions relating to that company's marketing of the prescription painkiller OxyContin. She alleged that she had suffered harm as a result of her use of the drug for chronic pain. The court held that "the chain of causation between Purdue's conduct and her addiction is too attenuated to support [restitution]." Doe, 264 Fed. Appx. at 264. See also United States v. Kones, 77 F.3d 66, 69, 71 (3d Cir. 1996) (holding patient was not victim of defendant doctor's scheme to submit false insurance claims).

of those claims have been settled, and those claimants are presumably receiving compensation for their injuries. Indeed, the law would require any individual's restitution to be offset by any amount he or she recovered as compensatory damages for the same loss. 18 U.S.C. § 3664(j)(2).

As the Court of Appeals has recognized, "restitution is essentially a civil remedy created by Congress and incorporated into criminal proceedings for reasons of economy and practicality. Therefore, restitution, at least in theory, tracks the recovery to which the victim would have been entitled in a civil suit against the criminal." United States v. Chalupnik, 514 F.3d 748, 753 (8th Cir. 2008). The objectors have already utilized an adequate remedy at law to seek compensation for their injuries.

#### IV. Remission of Forfeited Funds Is Available

In addition to a criminal fine, the plea agreement in this case calls for Guidant to criminally forfeit over \$42 million. Under Department of Justice regulations, the Attorney General may return forfeited property (including money) to a victim of the crime underlying the forfeiture, provided that certain eligibility criteria are met. See 28 C.F.R. § 9. A victim seeking remission under this avenue instead of Sections 3663 and 3663A of Title 18 is required to demonstrate in a petition to the Attorney General:

(1) A pecuniary loss of a specific amount has been directly caused by the criminal offense, or related

offense, that was the underlying basis for the forfeiture, and that the loss is supported by documentary evidence including invoices and receipts;

(2) The pecuniary loss is the direct result of the illegal acts and is not the result of otherwise lawful acts that were committed in the course of a criminal offense;

(3) The victim did not knowingly contribute to, participate in, benefit from, or act in a willfully blind manner towards the commission of the offense, or related offense, that was the underlying basis of the forfeiture;

(4) The victim has not in fact been compensated for the wrongful loss of the property by the perpetrator or others; and

(5) The victim does not have recourse reasonably available to other assets from which to obtain compensation for the wrongful loss of the property.

28 C.F.R. § 9.8.

Accordingly, even without an order of restitution from the Court, crime victims who have suffered an uncompensated pecuniary loss will have a vehicle to seek recovery from more than \$42 million in forfeited funds if the plea agreement is accepted. While the government at this stage cannot confirm that any particular petition will succeed because the decisions are made based on individual claims and circumstances, remission is an avenue for compensation of loss caused by crimes, and any person who suffered pecuniary harm as the result of the devices involved in this case may pursue this remedy. In fact, the government 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 sentencing to the offenses of conviction.

CONCLUSION

Thousands of patients were affected to varying degrees by Guidant's recalls during the summer of 2005. However, for all the reasons discussed above, restitution is not available for the crimes to which the defendant stands to be convicted. The United States respectfully asks that the objections be overruled and that the Court accept the plea agreement.

Dated: April 1, 2010

Respectfully submitted,

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Attorney for the United States  
*Acting under authority conferred  
by 28 U.S.C. § 515*

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