

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	
	:	
Plaintiff,	:	
	:	
v.	:	Case No. 2:09-CR-403-03
	:	
MICHAEL D. HUGGINS	:	
	:	
Defendant.	:	

SENTENCING MEMORANDUM OF DEFENDANT MICHAEL D. HUGGINS

Defendant Michael D. Huggins, through counsel, respectfully submits this sentencing memorandum to assist the Court in determining an appropriate sentence. Mr. Huggins’s sentencing hearing is scheduled for 8:00 a.m. on Monday, November 21, 2011.

INTRODUCTION

As the chief operating officer of Synthes, Mike Huggins accepted an enormous responsibility for the company’s medical devices used by surgeons in treating their patients. With respect to Norian, Mr. Huggins failed in carrying out that responsibility. He failed to heed warning signs concerning Norian’s use in the spine and he failed to get to the bottom of compliance issues and the complexities associated with biologic materials. Mr. Huggins is painfully aware that three patients died during operations involving Norian. He recognizes the seriousness of his offense and blames only himself for his conduct. He feels anguish, regret, and remorse that will stay with him for the rest of his life. Mr. Huggins respects the efforts of the Department of Justice and the Food and Drug Administration (FDA) to investigate and prosecute this matter. And he recognizes that the extensive resources invested in this case, including the

Court's resources, may not have been necessary if he had carried out his responsibilities properly.

For the reasons discussed below, we respectfully submit that a sentence of probation is sufficient but not greater than necessary to meet the purposes of sentencing set forth in 18 U.S.C. § 3553(a)(2). The government's substantial efforts since its criminal investigation became public more than five and one-half years ago, and since Mr. Huggins pleaded guilty 28 months ago, have been well-publicized and very successful. We respectfully submit that a sentence involving any form of incarceration or related restriction on liberty is not necessary to act as a general deterrent. As Mr. Huggins's letter to the Court reflects (Exhibit A hereto), and as the Court will hear directly from Mr. Huggins on November 21, Mr. Huggins accepts responsibility for his conduct. Moreover, he has agreed to pay the \$100,000 maximum fine allowable by statute (which is 20 times higher than the maximum fine recommended by the sentencing guidelines and at least 200 times higher than the recommended minimum fine). He is devastated both personally and professionally. Mr. Huggins's marriage is ending. The prospect of exclusion proceedings by the Department of Health and Human Services (HHS) to end his career in the medical device industry is virtually certain. Mr. Huggins's ability to pursue other opportunities, including teaching, has been limited. Mr. Huggins respectfully asks that the Court consider all of these circumstances, along with the entire record in this matter, in determining an appropriate sentence.

FACTUAL BACKGROUND

The offense conduct for which Mr. Huggins will be sentenced looms large as a grave misstep in an otherwise remarkable life. As the attached letters reflect (Exhibit B, Tabs 1-85), Mr. Huggins had built a seamless life both personally and professionally. Mr. Huggins's family,

friends, and professional colleagues use the same kinds of words when they describe him: integrity, fairness, ethics, hard work, honesty, and compassion. Mr. Huggins treats all persons as individuals who deserve respect regardless of their stations in life. That proposition holds equally true for Mr. Huggins in the personal and work environments. It is a constant theme that runs from his childhood to the present. In a similar vein, Mr. Huggins's family devotion, community and church involvement, and commitment to decency are profound. Indeed, Mr. Huggins's work since he pleaded guilty attests to the life-changing impact this case has had on him. He now devotes himself to improving the lives of others through nonprofit and community group projects.

A. The Nature and Circumstances of the Offense (18 U.S.C. § 3553(a)(1)).

At the hearing on June 6-7, 2011, the Court considered evidence and heard extensive argument concerning the offense conduct. Although Mr. Huggins himself did not speak at the last hearing, he looks forward to the opportunity to address the Court on November 21. His letter to the Court (Exhibit A hereto), provides insight into how and why Mr. Huggins committed his offense. Mr. Huggins understands that the Court may wish to engage in a more specific colloquy with him at the sentencing hearing with respect to the offense conduct. Ultimately, we submit that the evidence before the Court shows that Mr. Huggins committed a serious offense but does not show the sort of intentional misconduct that the government has alleged in this case.

B. Mr. Huggins's History and Characteristics (18 U.S.C. § 3553(a)(1)).

The presentence investigation report contains a thorough and detailed discussion of Mr. Huggins's personal background, employment history, financial condition, and extensive charitable and community activities since his guilty plea hearing. PSR ¶¶ 76-97, 121. Attached hereto as Exhibit B are 85 letters in support of Mr. Huggins that provide further insight into Mr.

Huggins's character and identity. Many of the letters also provide insight into how Mr. Huggins, as a person who exercised substantial authority within Synthes, could have allowed himself to fail in his responsibilities concerning Norian.¹

The letters are preceded by an index. The first set (Tabs 1-8) is from Mr. Huggins's family. The second set (Tabs 9-17) is from close friends and church officials. The third set (Tabs 18-22) is from people Mr. Huggins has met and worked with as a result of his community and nonprofit activities since he pleaded guilty. The fourth set (Tabs 23-64) is from former co-workers at Synthes at all levels of the organization. The fifth set (Tabs 65-73) is from former co-workers at Scient'x. The sixth set (Tabs 74-85) is from other friends and business acquaintances.²

The letters depict a man whose character traits have been consistent in all respects since early childhood: honest, fair, reliable, hard-working, and compassionate. According to his father, Mr. Huggins "has always been a thoughtful and helpful person to people." Exhibit B, Tab 2. That trait is perhaps best exemplified by Mr. Huggins's extraordinary care of his oldest brother, Robert, over the past last two years. Exhibit B, Tabs 1, 3, 5. Another recent example is Mr. Huggins's befriending of a Kenyan woman, Anne Okelo, and his friendship and assistance in helping Ms. Okelo bring clean water to her village. Exhibit B, Tab 18 ("It is people like Mike who make this world a better place to live in by their dedication and generous acts"). Yet another example of Mr. Huggins's character lies in his efforts to help Scient'x employees find jobs after they were displaced as a result of Mr. Huggins's voluntary departure from the

¹ The original exhibits have been delivered to chambers. Copies of the exhibits have been delivered to counsel for the government and the Probation Officer.

² Counsel for Mr. Huggins began receiving letters on his behalf shortly after the guilty plea hearing in July 2009. Many of the letters are addressed to Judge Stengel. We understand from Mr. Huggins that two of the writers (Father Francis X. Meehan and Rhonda Dunkelberger) are now deceased.

company due to his then-impending guilty plea in this case. Exhibits B, Tabs 1, 69. Kevin Stone, who followed Mr. Huggins from the jewelry business and is now Vice President of North American Logistics at Synthes, describes similar efforts by Mr. Huggins concerning displaced employees at the jewelry company where they worked in the early 1990s. Exhibit B, Tab 23. Mr. Stone also describes Mr. Huggins's thoughtfulness in a much different context: After happening to meet a veteran during a company outing who was having difficulty with his wheelchair, Mr. Huggins "became his chauffeur for the night." *Id.*

Mr. Huggins's compassion and desire to help others was fully on display after the September 2011 terrorist attacks. Paul Strahlendorf describes the efforts that Mr. Huggins made to have two tractor trailers of emergency products sent from Colorado to New York and to obtain passes for Synthes personnel to be allowed to enter the city to deliver medical devices. Exhibit B, Tab 28. Mr. Stone describes how Mr. Huggins "worked personally" with the NYPD to help identify the body of an officer through Synthes records and adds: "In Mike's usual manner, he thanked the team of employees but never asked for any recognition[.]" Exhibit B, Tab 23.

As a child, Mr. Huggins displayed the same qualities that he has displayed in his adult life. Mr. Huggins's younger brother, Brendan, states that Mr. Huggins "is an ethical guy who never had to cheat or cut a corner to get ahead." Exhibit B, Tab 4. His sister, Mary Wright, describes how she "marveled at his humility and kindness towards others" even when they were children. Exhibit B, Tab 6. His older brother, Larry, describes Mr. Huggins as the "calming influence" in the family. Exhibit B, Tab 3.

Mr. Huggins's devotion to his family is palpable. Although their marriage is ending, his wife of more than 27 years, Lisa, describes Mr. Huggins as "the most honorable and compassionate person I have met" and states that their children "both love and admire the

example he set for them.” Exhibit B, Tab 1. After having a biological daughter, Mr. Huggins and his wife became foster parents and then adopted their second daughter. *Id.* Mr. Huggins’s wife describes how he “set up a charitable foundation to show the girls the value of giving.” *Id.* A business colleague, Michael Bradshaw, describes how Mr. Huggins took one of his daughters with him on a business trip to Asia, adding that “it was clear that it gave him much more pleasure to be with her as a devoted father, than to receive respect and attention from his business colleagues.” Exhibit B, Tab 32. Kevin Stone states that Mr. Huggins repeatedly reminded him: “Family should always be #1.” Exhibit B, Tab 23. Another employee, Nancy Wagner, states that Mr. Huggins would “agonize over being away from his family” during business trips. Exhibit B, Tab 30. Joseph Dare, a close friend and neighbor, stated in a letter dated August 11, 2009: “One thing I have in common with [Mr. Huggins] is that we both have an eighteen year old child with special needs. I am keenly aware of how proud Michael is of both his children[.]” Exhibit B, Tab 11. Mr. Huggins’s open-heartedness extends well beyond his immediate family. Over the years, Mr. Huggins has invited family members to live with him when they have been in need – sometimes for months at a time. Exhibit B, Tabs 6, 7.

Mr. Huggins has been dedicated to church activities since early childhood. His sister, Mary Wright, describes Mr. Huggins playing the organ “at Mass when it wasn’t a ‘cool’ thing to do.” Exhibit B, Tab 6. Lisa Huggins describes their activities as Eucharistic Ministers for their parish, where they would “go to the local nursing home to administer the Eucharist” and would be joined by their young daughters. Exhibit B, Tab 1. The late Father Meehan, who was Pastor Emeritus, SS. Simon and Jude, and who knew Mr. Huggins for 20 years, stated that Mr. Huggins is “more than a parishioner” with a “very active community consciousness.” Exhibit B, Tab 9. Sister Margaret Rose, the Principal of SS. Simon and Jude School, describes Mr. Huggins as

“overly generous to our school.” Exhibit B, Tab 10. Joseph Dare adds that Mr. Huggins and his wife “have also been more involved with their church clergy on a personal level than anyone else I know[.]” Exhibit B, Tab 11.

Mr. Huggins’s other friends and neighbors are no less emphatic in their support. Sergeant Joseph Burt, with the West Goshen Police Department, states that Mr. Huggins is “one of the most down to earth people I have ever met” and adds that Mr. Huggins “has the love and respect of all who know him.” Exhibit B, Tab 12. Margaret Hanson, a teacher at SS. Simon and Jude School, states: “Honestly Your Honor, I could give you pages of wonderful things about this man.” Exhibit B, Tab 10. Mark Grella describes moving into the neighborhood in 2004 and how Mr. Huggins “and his family welcomed us into their family and home.” Exhibit B, Tab 16. Joseph Dare describes Mr. Huggins as the “voice of reason when dealing with our community home owners association issues.” Exhibit B, Tab 11. Kathryn Hayes describes her witnessing of Mr. Huggins’s “devotion and love for his family” and how Mr. Huggins has helped “friends and family in need, offering support and assistance.” Exhibit B, Tab 15. Bruce Risler, Mr. Huggins’s friend and advisor for 15 years, describes Mr. Huggins as “the epitome of a Good Samaritan.” Exhibit B, Tab 13. Kevin Wood, a friend who met Mr. Huggins in the early 1980s when they worked at Arthur Andersen, and who asked Mr. Huggins to be the godfather of Mr. Woods’s first child, describes Mr. Huggins as the “epitome of a dedicated hard working employee always looking to do a competent and complete audit with integrity and honesty.” Exhibit B, Tab 17.

Mr. Huggins’s behavior at work mirrors his conduct at home, church, and in the community. Current and former Synthes employees uniformly describe Mr. Huggins as an evenhanded and principled person who treated everyone with the same consideration regardless

of position. Wilson Reason, who works in the shipping department, describes the “presents and support” that Mr. Huggins provided when Mr. Reason tragically lost his son. As Mr. Reason puts it: “[H]ere is a guy who didn’t know me but treated me with the utmost respect. This is the kind of person who talked to me like I was somebody in the company.” Exhibit B, Tab 25. James Campbell, a machinist, describes how Mr. Huggins checked on Mr. Campbell’s medical condition. Exhibit B, Tab 31. Susan Tipton states that Mr. Huggins “took a personal interest in each of us.” Exhibit B, Tab 33. Edward Hayes states that Mr. Huggins “has earned the respect of everyone, high or low on the totem pole.” Exhibit B, Tab 27. Kevin Stone describes Mr. Huggins’s response to a series of bomb scares and adds: “Who was always concerned about employee safety, first, most, and last? Mike Huggins.” Exhibit B, Tab 23.

Forty-two of the attached letters are from current and former Synthes employees. Every one of them radiates respect for Mr. Huggins regardless of context. Michael Will, who started working with Mr. Huggins after the global reorganization of the Spine division, states: “I am now doing consulting work with several spine companies where this case and Mike Huggins, specifically, is being widely discussed. The constant refrain I hear is ‘How could this happen to Mike Huggins – the most straight-shooting, salt-of-the-earth guy in the spine industry?’” Exhibit B, Tab 24. Mr. Will adds that he “often witnessed Mike standing up to powerful market pressures, as well as, bare-knuckled internal politics to do what he believed was right.” *Id.* Bob Rauker, the former chief patent counsel for Synthes, describes Mr. Huggins’s “honesty, integrity, and complex work environment[.]” Exhibit B, Tab 29. The late Rhonda Dunkelberger stated: “In my memory, Mike Huggins always held to the vision and mission of Synthes by thinking of what would be best for our patients.” Exhibit B, Tab 26. Michael Bradshaw states: “[I]t has

been commented by some colleagues that Mike is truthful to a fault, that he should not be a leader in the ruthless business wars because he was too honest.” Exhibit B, Tab 32.

Employees at Scient’x echo the views of Mr. Huggins expressed by Synthes personnel. Wilmer Johnson states that Mr. Huggins “always put principles before personalities.” Exhibit B, Tab 67. Ann Custin, the Global COO and CFO of Scient’x, states that “doing right versus wrong, was never compromised” by Mr. Huggins at Scient’x. Exhibit B, Tab 65. Mohammad Merzagui, the CFO of Scient’x, S.A., states that Mr. Huggins “was unanimously respected by all.” Exhibit B, Tab 66. Robert Brosnahan, the Vice President of Product Development at Scient’x, states: “Mike is certainly among the most giving and ethical people that I have encountered in my professional and private life.” Exhibit B, Tab 68.

Other friendships that Mr. Huggins has developed through his business activities over the years describe the same person. Dr. Alex Vaccaro, a respected Philadelphia surgeon, states that he was “always astounded by [Mr. Huggins’s] integrity in terms of his business practices as well as his commitment to patient care.” Exhibit B, Tab 74. James Martin, of Credit Suisse, states: “Over my 26 years working with hundreds of corporate executives, I believe that Mike is the least likely person to compromise his professional ethics and personal integrity for any monetary or professional gain.” Exhibit B, Tab 78. Scott Schorer, President, Americas, of Systagenix Wound Management, states that he “can’t fathom how someone of such high moral fiber as Mr. Huggins could be implicated in a case such as this.” Exhibit B, Tab 75. Alistair Clemow, the President and CEO of Nexgen Spine, describes Mr. Huggins’s unusual effort to meet with employees of Mr. Clemow’s former company to discuss payroll and accounting problems after an acquisition by Synthes, and states that he has “always regarded Mr. Huggins as one of the most decent and ethical executives I have encountered during my thirty years of working in the

medical device industry.” Exhibit B, Tab 76. Michael Simpson, the President and CEO of Knee Creations, LLC, states that “Mr. Huggins has consistently displayed the highest professional and personal standards.” Exhibit B, Tab 77. Dr. Scott Kitchel, an orthopedic surgeon, states that he has “consistently found Mr. Huggins to be of the highest moral fiber.” Exhibit B, Tab 79.

Since the guilty plea hearing in July 2009, and the upending of Mr. Huggins’s career in the medical device industry, Mr. Huggins has invested himself intensely in contributing to nonprofits and community activities. Mary Anne Feeley, with United Way of Chester County, describes Mr. Huggins’s “genuine commitment to learning and applying his business skills to the challenges faced by nonprofits.” Exhibit B, Tab 21. Eric Forsythe, the executive director of Open Hearth, a nonprofit affordable housing organization, has described in detail the contributions that Mr. Huggins has made to his organization. Exhibit B, Tab 19. Mr. Forsythe states that Mr. Huggins “consistently offers dynamic service to our board, which was recently confirmed through his election to the office of Treasurer.” *Id.* Mr. Huggins also conducts employment workshops for Open Hearth and participates in one-on-one counseling sessions. *Id.* Mr. Forsythe adds that Mr. Huggins’s service “ranks with the best” that he has seen in 20 years. *Id.* Colleen DeVirgiliis, the owner of Seva Power Yoga, describes Mr. Huggins’s creation of a “Street Yoga” program for homeless youth and others in at-risk situations and states that Mr. Huggins “has had a positive impact on numerous children in the area.” Exhibit B, Tab 22. Viktor Ohnjec, who is involved in a CEO Roundtable group, similarly describes Mr. Huggins’s community work with Y/PAL youth: “I fully expect stories from the kids that Mike works with to say, ‘In every person’s life, there is one individual who helped turn the person’s life around. For me, that person was Mike Huggins.’” Exhibit B, Tab 20.

* * *

As the attached letters and the PSR show, the same threads weave all aspects of Mr. Huggins's life together. His wife, Lisa, states: "His approach to life, whether personal or professional, has been the same . . . to be honest, ethical, hardworking, and respectful." Exhibit B, Tab 1 (ellipsis in original). Such qualities, of course, do not excuse criminal misconduct of any sort. They do, however, shed considerable light on mitigating factors relevant to the Court's sentencing determination. And in this particular case, we respectfully submit, they permit inferences that the Court may or may not choose to draw with respect to Mr. Huggins's offense conduct, including his motivations, his state of mind, and his ultimate degree of culpability.

DISCUSSION

After *United States v. Booker*, 543 U.S. 220 (2005), the overarching legislative command is that a sentence must be *sufficient, but not greater than necessary*, to comply with the sentencing goals mandated by Congress: just punishment; respect for the law; deterrence, incapacitation; and treatment and correction. See 18 U.S.C. § 3553(a); *United States v. Friedman*, 2011 WL 4470674, *14 (3d Cir., Sept. 28, 2011); *United States v. Fumo*, 655 F.3d 288, 308 (3d Cir. 2011). Before imposing sentence, the Court must first calculate the applicable guideline range. *Id.* In this case, the total adjusted offense level will be 4 if the Court determines that Mr. Huggins has accepted responsibility; it will be 6 if the Court determines that he has not accepted responsibility. PSR ¶¶ 66, 69. The undisputed guideline range is 0-6 months in either event. PSR ¶ 106. The Court must next consider any motions for departure under the guidelines. *Fumo*, 655 F.3d at 308. In this case, a downward departure is not possible, and the government does not claim that a basis for an upward departure exists. PSR ¶ 120 (identifying no grounds for an upward departure); PSR Addendum at 47 (stating that "government has no objections" to PSR). Finally, the court must "consider[] the recommended Guidelines range

together with the statutory factors listed in 18 U.S.C. § 3553(a) and determine the appropriate sentence, which may vary upward or downward from the range suggested by the Guidelines.” *Fumo*, 655 F.3d at 308. Again, no downward variance is possible in this case, and the government does not claim that a basis for an upward variance exists. PSR ¶ 121 (identifying no grounds for an upward variance); PSR Addendum at 47 (stating that “government has no objections” to PSR).

I. Mr. Huggins Has Accepted Responsibility For His Offense Conduct.

Paragraph 66 of the PSR does not credit Mr. Huggins with having accepted responsibility under U.S.S.G. § 3E1.1. Mr. Huggins has objected to that position. At the hearing on June 6, 2011, the government ultimately agreed with Mr. Huggins’s objection as of that time. 6/6/11 Tr. at 39. The law requires, and the parties agree, that a defendant is entitled to a two-level reduction in his adjusted offense level if he “clearly demonstrates acceptance of responsibility for his offense[.]” U.S.S.G. § 3E1.1. Application Note 1(a) to §3E1.1 states that “a defendant who falsely denies, or frivolously contests, relevant conduct that the court determines to be true has acted in a manner inconsistent with acceptance of responsibility[.]”

The Court will determine before it imposes sentence, of course, whether Mr. Huggins has accepted responsibility for the offense conduct. Mr. Huggins agrees with the Court’s observation at the June 6 hearing that the issue of acceptance of responsibility is in flux until “the moment at which sentence is imposed.” 6/6/11 Tr. at 38. Mr. Huggins plans to speak at sentencing. We anticipate that the colloquy will bear on the Court’s determination concerning the issue of acceptance of responsibility (as well as on the broader question of an appropriate sentence). Mr. Huggins’s letter to the Court describes and admits the failures that underlie his conduct in this case. His letter is entirely consistent with the evidence presented to the Court on

June 6-7, 2011, and the argument of undersigned counsel at that hearing. With all respect to the government's tireless efforts in this case, we respectfully submit that Mr. Huggins's degree of culpability and role in this case is better explained by the mismanagement and related problems that we have described, and that Mr. Huggins regrets and fully acknowledges, than the government's theory that Mr. Huggins intentionally participated in misconduct. Accordingly, recognizing that the issue is not final until the imposition of sentence, we request that Mr. Huggins ultimately be credited with having accepted responsibility and that he be sentenced at a total adjusted offense level of 4.

II. A Sentence of Probation Is Sufficient But Not Greater Than Necessary to Serve the Sentencing Goals Set Forth in 18 U.S.C. § 3553 (a).

The Court is required to “impose a sentence sufficient, but not greater than necessary, to comply with the purposes set forth in paragraph (2)” of Section 3553(a). That subsection requires the Court to consider “the need for the sentence imposed – (A) to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense; (B) to afford adequate deterrence to criminal conduct; (C) to protect the public from further crimes of the defendant; and (D) to provide the defendant with needed educational or vocational training, medical care, or other correctional treatment in the most effective manner[.]” 18 U.S.C. § 3553(a)(2). The Court is also required to consider “the nature and circumstances of the offense and the history and characteristics of the defendant” (Section 3553(a)(1)); “the kinds of sentences available” (Section 3553(a)(3)); “the kinds of sentence and the sentencing range established” under the sentencing guidelines (Section 3553(a)(4)); “any pertinent policy statement” issued by the Sentencing Commission pursuant to 28 U.S.C. § 994 (a)(2) (Section 3553(a)(5)); “the need to avoid unwarranted sentence disparities among defendants with similar

records who have been found guilty of similar conduct” (Section 3553(a)(6)); and “the need to provide restitution to any victims of the offense” (Section 3553(a)(7)).

The Court has received extensive evidence and heard argument concerning the circumstances of the offense. Mr. Huggins’s letter to the Court and the colloquy with the Court that we anticipate at the sentencing hearing, of course, bear directly on the circumstances of the offense as well. The PSR addresses Mr. Huggins’s history and characteristics in detail and we also have addressed that factor above in detail. We address the remaining sentencing factors in reverse order.

A. Restitution (§ 3553(a)(7)).

The PSR correctly states that restitution is not an issue in this case. PSR ¶ 119.

B. Avoidance of Unwarranted Sentence Disparities (§ 3553(a)(6)).

As the court of appeals has stated, “Congress’s primary goal in enacting § 3553(a)(6) was to promote national uniformity in sentencing rather than uniformity among co-defendants in the same case.” *United States v. Parker*, 462 F.3d 273, 277 (3d Cir. 2006). At the same time, “although § 3553(a) does not require district courts to consider sentencing disparity among co-defendants, it also does not prohibit them from doing so.” *Id.* Section 3553(a)(6) “by its terms plainly applies only where co-defendants are similarly situated.” *Id.* at 278. For the reasons stated herein, Mr. Huggins respectfully submits that a sentence of probation is appropriate, and that Section 3553(a)(6) should not be a material factor in his sentencing.

C. Pertinent U.S.S.C. Policy Statements (§ 3553(a)(5)).

The sentencing guidelines provide that “commentary is to be treated as the legal equivalent of a policy statement; both may be helpful in interpreting a section and determining how it was intended to be applied. U.S.S.G. § 1B1.7.” *United States v. Craddock*, 993 F.2d 338,

341 n.3 (3d Cir. 1993). The applicable guideline is Section 2N2.1. Application Note 1 to that guideline states: “This guideline assumes a regulatory offense that involved knowing or reckless conduct. Where only negligence was involved, a downward departure may be warranted.” The plea agreement in this case, drafted by the government, goes even further and characterizes the crime as a strict liability offense. The Court may choose to take those distinctions into account in determining an appropriate sentence for Mr. Huggins.

D. Sentencing Guidelines (§ 3553(a)(4)).

As discussed above, the Court must determine whether Mr. Huggins has accepted responsibility and whether the total adjusted offense level is 4 or 6. The undisputed guideline range in either event is 0-6 months.

E. Training, Medical Care, and Treatment (§ 3553(a)(2)(D)).

A sentencing court is required to consider the need “to provide the defendant with needed educational or vocational training, medical care, or other correctional treatment in the most effective manner.” 18 U.S.C. § 3553(a)(2)(D). See *United States v. Hankerson*, 496 F.3d 303, 309 (3d Cir. 2007). As the information in the PSR reflects, Mr. Huggins does not require educational or vocational training, medical care, or other correctional treatment. While the Court must consider this factor, it need not assign it weight under the circumstances of this case.

F. Incapacitation (§ 3553(a)(2)(C)).

Section 3553(a)(2)(C) requires the Court to consider the need to “protect the public from further crimes of the defendant[.]” Mr. Huggins has no criminal history. The evidence before the Court shows that Mr. Huggins does not pose a risk of recidivism. We respectfully submit that this factor, although it must be considered by the Court, should not be assigned any weight.

G. Deterrence (§ 3553(a)(2)(B)). Section 3553(a)(2)(B) states that the Court must consider the need for a sentence “to afford adequate deterrence to criminal conduct[.]” This factor encompasses the concepts of specific deterrence and general deterrence. See, e.g., *United States v. Serafini*, 233 F.3d 758, 776 (3d Cir. 2000).

With respect to Mr. Huggins specifically, the evidence shows that punishment apart from probation and imposition of the statutory maximum fine that Mr. Huggins has agreed to pay is not necessary to deter Mr. Huggins from committing an offense in the future. The \$100,000 fine is 20 times greater than the maximum fine recommended in U.S.S.G. § 5E1.2(c)(3) and either 400 or 200 times greater than the minimum recommended fine under that guideline (depending on whether the Court determines that the total adjusted offense level is 4 or 6). Mr. Huggins has not committed an offense in the past. There is no evidence suggesting that he may commit an offense in the future. Moreover, the offense of conviction occurred in a highly complex regulatory environment. Given the collateral consequences associated with the offense, it is unlikely that Mr. Huggins will even have the opportunity to act as a senior executive again in such an environment. And if he does, the evidence before the Court shows the unlikelihood that Mr. Huggins would risk inviting even a tiny fraction of what this case has entailed.

With respect to the general public, and the medical device industry in particular, a sentence of incarceration, or some lesser restriction on liberty other than probation, is not necessary to deter others from committing offenses in the future. This case has been extremely well-publicized in the industry, on blogs, and in the mainstream press. As Michael Will put it: “I am now doing consulting work with several spine companies where this case and Mike Huggins, specifically, is being widely discussed. The constant refrain I hear is ‘How could this happen to Mike Huggins – the most straight-shooting, salt-of-the-earth guy in the spine industry?’” Exhibit

B, Tab 24. The attached letters to the Court show that Mr. Huggins was one of the most widely respected executives in the device industry. Persons in the broader public, and in the medical device industry in particular, are fully on notice that serious consequences will flow from misconduct and mismanagement with respect to matters within the jurisdiction of the FDA and HHS.

H. Seriousness of the Offense, Just Punishment, and Respect for the Law (§ 3553(a)(2)(A)).

Finally, the Court is required to consider the need for the sentence imposed “to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense[.]” 18 U.S.C. § 3553(a)(2)(A). Mr. Huggins certainly regards the offense as serious. If the Court credits Mr. Huggins with having accepted responsibility, the total adjusted offense level will be 4. We submit that the \$100,000 statutory maximum fine that he has agreed to pay, should the Court choose to impose it, is itself sufficient to reflect the seriousness of the offense. Nor is a sentence other than probation with appropriate conditions and the imposition of a fine necessary to promote respect for the law and ensure just punishment. As Mr. Huggins’s letter to the Court shows, he is remorseful and chastened. His life has been upended as a result of his offense and the ensuing five and one-half year investigation. The collateral consequences of his conviction have been severe already and are likely to become worse. And not least significant for Mr. Huggins, given the profound importance that he has always placed on his reputation, the damage that he has inflicted on himself will never go away.

CONCLUSION

For the reasons stated above, and for any other reason that the Court may deem just and proper, defendant Michael D. Huggins respectfully requests that the Court impose a sentence of probation with conditions that the Court may deem appropriate.

Dated: November 14, 2011

Respectfully submitted,

/s/ Gregory L. Poe
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Counsel for Michael D. Huggins

CERTIFICATE OF SERVICE

I, Catherine M. Recker, hereby certify that I caused a true and correct copy of the foregoing Sentencing Memorandum of Defendant Michael D. Huggins (including exhibits) to be served via hand delivery on this 14th day of November, 2011, on the following:

Mary E. Crawley
Gerald B. Sullivan
Assistant United States Attorneys
United States Attorney's Office
615 Chestnut Street, Suite 1250
Philadelphia, PA 19106

I also caused a true and correct copy of the foregoing Sentencing Memorandum of Defendant Michael D. Huggins (including exhibits) to be served via United States mail, first class postage prepaid, via hand delivery on this 14th day of November, 2011, on the following:

Alexander T. Posey
Senior United States Probation Officer
The Madison Building
400 Washington Street
Suite 101
Reading, PA 19601

/s/ Catherine M. Recker

Catherine M. Recker