

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA)
)
v.)
)
SCOTT REUBEN,)
)
 Defendant.)

Criminal No. 10-CR-30002-MAP

GOVERNMENT’S SENTENCING MEMORANDUM

The United States hereby submits its sentencing memorandum in connection with the June 24, 2010 sentencing of the defendant, Scott Reuben (“Defendant” or “Reuben”). Reuben, an anesthesiologist, has been convicted of health care fraud in violation of 18 U.S.C. §1347 for falsifying clinical research about pain management. As set forth in more detail below, the crime took place over a multi-year period, involved multiple victims, from the pharmaceutical companies from whom Reuben obtained the research grants, to the medical journals that published the false articles, to patients who received a treatment regimen that had not actually been studied by Reuben and had not actually achieved the safety and efficacy results reported by him in the false articles. The government’s sentencing recommendation is as follows:

- imprisonment for a term of 14 months;
- fine of \$5,000;
- forfeiture of \$50,000;
- restitution of \$361,932 (\$296,557 payable to Pfizer Inc.; \$49,375 payable to Merck & Co., Inc.; and \$8,000 payable to Wyeth and \$8,000 payable to Rays of Hope;
- supervised release of 2 years; and
- mandatory special assessment of \$100.

As set forth below, the government's recommendation for a sentence of incarceration of 14 months is below the applicable guideline range (18-24 months) and is consonant with the factors of 18 U.S.C. §3553.

I. Introduction

A. The Information/Offense Conduct

The Information, which was filed on January 14, 2010, charged Reuben with one count of health care fraud in violation of 18 U.S.C. §1347.

Reuben was an anesthesiologist who was the chief of acute pain at Bay State Hospital in Springfield, Massachusetts. At all relevant times, he treated patients both pre- and post-operatively, and he conducted research in the area of pain management. PSR ¶8. Reuben's particular research focus was multimodal analgesia therapy, meaning a combination of analgesia therapy instead of the use of opioids. Reuben's theory was that multimodal analgesia therapy would be as effective for pain, promote long term healing and avoid some of the side effects associated with opioid therapy. PSR ¶9.

Reuben made a number of proposals for research funding to pharmaceutical companies which manufactured drugs that he used or proposed to use in multimodal analgesia therapy. Id. Those drugs included Vioxx, manufactured by Merck, and Celebrex, manufactured by Pfizer. Id. In proposals to Merck and Pfizer and others, Reuben represented that he, as the principal investigator, would be performing clinical studies with actual patients. Id. These research grant proposals and the subsequent contracts also contemplated that Reuben would prepare an article for publication in a medical journal based on the results of the research study. Id.

Beginning in approximately 2000, Reuben entered into contracts to perform research as

funded by pharmaceutical companies, purported to perform the research called for by the contracts, and published articles in various medical journals based on the purported results of his research, when in fact those studies had not been performed, and therefore the research results were false and the published articles were false. PSR¶10. The following is a listing of the false articles:

<u>Dr. Reuben False Articles</u>	<u>Grantor</u>	<u>Grant Amount</u>
“The Effect of Cyclooxygenase-2 Inhibition on Analgesia and Spinal Fusion,” <u>Journal of Bone and Joint Surgery</u> ; 2005, 87:536; and “The Effect of Cyclooxygenase-2 Inhibition on Acute and Chronic Donor-Site Pain After Spinal Fusion Surgery,” <u>Register of Anesthesia and Pain Medicine</u> , 2006; 31:6	Pfizer	\$63,425
“Evaluating the Analgesic Efficacy of Administering Celecoxib as a Component of Multimodal Analgesia For Outpatient Anterior Cruciate Ligament Reconstruction Surgery,” <u>Anesthesia & Analgesia</u> ; 2007; 105:222; and “The Effect of Initiating a Preventive Multimodal Analgesic Regimen on Long-Term Patient Outcomes For Outpatient Anterior Cruciate Ligament Reconstruction Surgery,” <u>Anesthesia & Analgesia</u> ; 2007; 105:228.	Pfizer	\$73,512
“A Prospective Randomized Trial on the Role of Perioperative Celecoxib Administration for Total Knee Arthroplasty: Improving Clinical Outcomes,” <u>Anesthesia & Analgesia</u> ; 2008; 106:1258	Pfizer	\$118,200
“The Effect of Intraoperative Valdecoxib Administration on PGE2 levels in the CSF,” <u>Journal of Pain</u> , Supplement; 1:S21 (Abstract 649)	Pfizer	\$41,420

“Evaluation of the Safety and Efficacy of the Perioperative Administration of Rofecoxib for Total Knee Arthroplasty,” 2002; <u>Journal of Arthroplasty</u> , 17:26	Merck	\$49,375
“Evaluation of Efficacy of the Perioperative Administration of Venlafaxine XR in the Prevention of Post-Mastectomy Pain Syndrome, <u>Journal of Pain and Symptom Management</u> , 2004; 27:133	Wyeth/Rays of Hope	\$16,000

The grant amounts associated with the articles referenced above total \$361,932 and form the basis both for the restitution order that the Government seeks (and which the parties agree to in the plea agreement). This amount also forms the basis for the sentencing guideline loss calculation. See U.S.S.G. §2B1.1(b)(1)(G). The five journals and the four grantors fall one shy of the 10 victims needed to trigger the multiple victim enhancement in U.S.S.G. §2B1.1(b)(2)(A).

By way of specific example, in July 2005, Reuben proposed to Pfizer that he would perform research on the topic of “Perioperative Administration of Celecoxib [Celebrex] as a Component of Multimodal Analgesia for Outpatient Anterior Cruciate Ligament Reconstruction Surgery.” In his proposal, Dr. Reuben informed Pfizer that the “goal of this study is to assess the analgesic efficacy of utilizing celecoxib in a preemptive multimodal analgesic technique for patients undergoing outpatient ACL surgery,” and that he intended to include 100 patients in the study, with 50 of them randomized to receive Celebrex and 50 of them to receive a placebo. PSR ¶12.

On or about September 1, 2005, Dr. Reuben entered into an Independent Research Grant Agreement (the “Agreement”) with Pfizer to conduct a clinical research study entitled “Perioperative Administration of Celecoxib [Celebrex] as a Component of Multimodal

Analgesia for Outpatient Anterior Cruciate Ligament Reconstruction Surgery.” As part of that Agreement, Pfizer agreed to provide (and indeed paid) a research grant in the amount of \$73,512.00 and sufficient supplies of Celebrex and placebo to conduct the study. As such, for the purpose of the Agreement, Pfizer was a health care benefit program as defined by 18 U.S.C. §24(b). PSR ¶13

Dr. Reuben’s protocol for the study was to treat 100 patients, with 50 receiving placebo and 50 receiving Celebrex as part of the multimodal analgesia therapy. In the articles by Dr. Reuben about this study (“Evaluating the Analgesic Efficacy of Administering Celecoxib as a Component of Multimodal Analgesia for Outpatient Anterior Cruciate Ligament Reconstruction Surgery,” Vol. 105: 222-227, 2007 Anesthesia & Analgesia; and “The Effect of Initiating a Preventive Multimodal Analgesic Regimen on Long-Term Patient Outcomes for Outpatient Anterior Cruciate Ligament Reconstruction Surgery,” Vol. 105: 228-232, 2007 Anesthesia & Analgesia), he claimed to have treated 200 patients, 100 with placebo and 100 with Celebrex. Dr. Reuben also claimed in these articles that patients had achieved success with multimodal analgesia therapy. PSR ¶14.

Dr. Reuben knew those claims were materially false because he knew he had not enrolled any patients into that study and the results reported both to Pfizer and to Anesthesia & Analgesia Journal and in turn to the public were wholly made up by him. PSR ¶15.

B. The Plea Agreement

The plea agreement contains a sentencing guideline analysis, which is set forth below in Section II. The plea agreement also provides in paragraph 4 that the government agrees to recommend the following sentence to the Court:

- incarceration at the low end of the Guideline range of (which appears to be 18-24 months);
- fine of \$5,000;
- restitution of \$361,932 (\$296,557 payable to Pfizer Inc.; \$49,375 payable to Merck & Co., Inc.; and \$8,000 payable to Wyeth and \$8,000 payable to Rays of Hope;
- forfeiture of \$50,000;
- supervised release of 2 years; and
- mandatory special assessment of \$100.

Defendant also agrees to recommend the same sentence, with the exception of the term of incarceration and period of supervisory release. Thus, the dispute about sentencing is between the government's recommendation of a below guideline incarcerative sentence of 14 months and Reuben's recommendation of home confinement.

II. **Guidelines Analysis**

"[A] district court should begin all sentencing proceedings by correctly calculating the applicable Guidelines range." Gall v. United States, 552 U.S. 38, 49 (2007). Here the parties appear to agree that the applicable Sentencing Guidelines calculation results in a Total Adjusted Offense Level of 15, which when combined with a Criminal History Category of I yields an advisory sentencing guideline range of 18-24 months of incarceration. See PSR ¶29. To be sure, the Guidelines are now advisory. However, the Supreme Court also "recognized that, in the ordinary case, the Commission's recommendation of a sentencing range will 'reflect a rough approximation of sentences that might achieve §3553(a)'s objectives.'" Kimbrough v. United States, 552 U.S. 85, 109 (2007) (internal citation omitted).

The calculations are set forth below:

Health Care Fraud in violation of 18 U.S.C. §1347

base offense level (U.S.S.G. §2B1.1(a)(2))	6
	+
loss enhancement (U.S.S.G. §2B1.1(b)(1)(G))	12
	-
acceptance of responsibility (U.S.S.G. §3E1.1)	<u>3</u>
Total Offense Level =	15
Range for CHC I =	18-24 months

III. Sentencing Factors Under 18 U.S.C. §3553

The United States submits that its recommended sentence of 14 months incarceration is appropriate in light of the §3553 factors, particularly the nature and circumstances of the offense and the history and characteristics of the defendant, §3553(a)(1); and the need for the sentence to reflect the seriousness of the offense and afford adequate deterrence, §§3553(a)(2)(A) and (B).

A. Nature and Circumstances of the Offense/History and Characteristics of the Defendant.

In assessing these factors, it is important to set the context for this crime and this defendant. The criminal conduct here, and the related offense conduct, involved defrauding pharmaceutical companies, falsifying clinical research results, sending false articles based on false clinical research results to a number of scholarly medical journals, which in turn published these false articles, which in turn led members of the pain management medical community to read these false articles and in some instances base their treatment protocols for their patients on the false article they read.

For example, the editors of one of the journals that published a false article by Reuben, The Journal of Bone & Joint Surgery, wrote in an a letter submitted hereto as Exhibit 1, that it published an article by Reuben that “purported to define a new method of pain management following spinal fusion, a procedure which is performed more than 250,000 times a year in the United States alone.” The letter goes on to explain that once the “fraudulent nature of this publication was identified, The Journal had to create a novel, heretofore, unused, procedure to retract it.” The letter concludes that the “reputation of the Journal of Bone and Joint Surgery as an absolutely reliable source of quality patient care information has been permanently damaged, and we will never fully recover. Most importantly, while it is impossible to measure, many patients have been adversely affected by his [Reuben’s] actions.”

In the same vein, as Dr. Jacques Chelly, Director of the Division of Regional Anesthesia and Acute Interventional Pain at the University of Pittsburgh Medical Center said in the wake of learning of Reuben’s fraud, multimodal analgesia was “in shambles concerning many of the drugs we use. The big chunk of what people had based their protocol on is gone.” Chelly noted that he stopped giving celecoxib and pregabalin to many patients upon finding out that Reuben’s research on multimodal analgesia was fraudulent. Exhibit 2 (copy of March 2009 Anesthesiology News, quoting and citing to Dr. Chelly). Thus it is important to recognize that Reuben’s false research did not just defraud pharmaceutical companies, it reached the trade press, the pain management professionals and had an impact on patient care.

Significantly, Reuben’s criminal conduct took place over a wide span of time. The false articles identified herein span dates from 2002 to 2008. This was not a one time aberrant occurrence. Even the specific crime at issue, involved approximately 18 months between

research proposal in 2005 to publication in 2007. Reuben's mental condition is the subject of much discussion in his sentencing brief, and certainly it merits careful and sensitive consideration, but it is important to understand that during the entirety of the period of the criminal conduct, Reuben was going to work day in and day out and anesthetizing patients, treating patients post-operatively, teaching students, and by all outward accounts to colleagues, patients and friends, functioning at a high level. For example, one of his former colleagues at Bay State Medical Center, Dr. Shameema Faruqui wrote to the Court:

I have always found Scott to be a very cordial and helpful colleague. He was well liked by the nursing and office staff. His patients loved him as their pain physician. Scott is an accomplished anesthesiologist and an excellent teacher. The pain fellows and anesthesiology residents always looked forward to working with him.

Another former colleague, Dr. Howard Krasner wrote to the Court:

I have worked closely with Dr. Reuben clinically, and can speak to his excellent clinical skills. . . Dr. Reuben has always provided excellent anesthesia care for thousands of patients over the years. . . His contributions to resident education were substantial, such that he had been voted the best clinical instructor in the Anesthesiology Department by our residents several times over his teaching career.

All the while that Reuben was providing excellent patient care and outstanding teaching, he was also engaging in criminal research fraud. And yet, while he "does not contend that his bi-polar illness prevented him from knowing right from wrong," Defendant's Sentencing Memo at p. 10, nor could he given the extremely high functioning life he was otherwise leading, he seeks a departure for "significantly reduced mental capacity" under U.S.S.G. §5K2.13.

1. No departure/deviation is warranted under U.S.S.G. §5K2.13.

Under this guideline a downward departure is warranted only if (1) the defendant committed the offense while suffering from a significantly reduced mental capacity; and (2) the significantly reduced mental capacity contributed substantially to the commission of the offense. Reuben is not able to meet either of these criteria. First, Application Note 1 of U.S.S.G. §5K2.13 defines significantly reduced mental capacity as meaning that the defendant “has a significantly impaired ability to (A) understand the wrongfulness of the behavior comprising the offense or to exercise the power of reason; or (B) control behavior that the defendant knows is wrongful.” Reuben concedes that he knew right from wrong, and thus cannot meet the first prong of this definition. To the extent he is arguing that he could not control behavior that he knew was wrongful, there is no evidence of that and that assertion defies credulity. This argument requires the Court to accept that in his day to day personal and professional life he was able to make dozens of cogent, coherent and controlled decisions regarding patient care, teaching, personal and familial relationships, yet he could not control his fraudulent research activities.

However, even assuming Reuben suffered from “significantly reduced mental capacity,” he does not and cannot explain how his bipolar disorder “contributed substantially to the commission of the offense.” He argues that “[w]ithout his mental disorder, he simply would not have had the stamina to maintain all of this activity. Stated crudely, his bipolar disorder acted like a drug, giving him an extraordinary amount of energy and drastically lowering his perceived need for sleep and down-time.” Defendant’s Memo at 13. However, the crime he committed stemmed from his failure to do the research, not by doing something illegal that required

“stamina” or “an extraordinary amount of energy.” The link between his disease and his conduct does not make sense, particularly in light of all of the high functioning conduct that he otherwise engaged in during the exact same long period of time. There is no evidence to explain how Reuben could be divining right from wrong in all phases of his life other than his fraudulent research activities.

There are cases in which bipolar disorder (coupled with other diseases and traits) has been found by courts to constitute a “significantly reduced mental capacity” and then “contributed substantially to the commission of the offense,” such that there has been a departure under U.S.S.G. §5K2.13. However, this is not such a case. Reuben cites United States v. Follette, 990 F.Supp. 1172 (D. Neb. 1998) in support of his argument that bipolar can form the basis for a departure to a non-incarcerative sentence. However, that case involved a young woman who had not finished high school, and who suffered from mental impairments beyond bipolar, who was an accessory after the fact to an armed robbery because her boyfriend (by whom she was pregnant at the time) prevailed on her to do so. That case also did not involve the profound general deterrence impact that an incarcerative sentence here would have.

2. Reuben’s bipolar disorder does not exempt him from imprisonment.

Reuben argues that he has “an extraordinary physical impairment,” U.S.S.G. §5H1.4, that renders him an appropriate candidate for home detention. In the main, bipolar is a somewhat common condition which psychiatrists are able to treat. Studies suggest that there is a meaningful percentage of the prison population that suffer from and are treated in prison for mental diseases like bipolar. A United States Department of Justice Special Report from September 2006 entitled “Mental Health Problems of Prison and Jail Inmates” reported that an

“estimated 15% of state prisoners and 24% of jail inmates reported symptoms that met criteria for a psychotic disorder.” (Report attached hereto as Exhibit 3). The Bureau of Prisons (“BOP”) is actually quite used to and adept at dealing with psychiatric disorders. There are a number BOP facilities that specialize in providing care to mentally ill inmates. As BOP explained in its letter attached hereto as Exhibit 4, Reuben will be able to continue on his medication and therapeutic regimen. It would be unfortunate and unfair to consign only poor defendants with bipolar disorder to incarceration, while privileged white collar defendants like Reuben are thought to “have suffered enough” and merely get home detention.

B. An Incarcerative Sentence is Important to Promote Respect For Law and to Serve the Aim of General Deterrence.

Reuben argues, in the manner of most white collar criminals that he has suffered enough (money, profession, reputation, divorce) and that a prison term is unwarranted. He argues that his “crime and his illness have taken a respected researcher, anesthesiologist, and family man and left him broke and broken with no profession, and under the constant careful watch of his parents.” Defendant’s Memo at p. 19. Of course, these are the arguments made by virtually all white collar defendants who seek to avoid any incarceration. Most white collar defendants, by definition, have much to lose once convicted of a crime. Because of their education, status and wealth, they are in position to lose good jobs, professional licenses, money and reputation.

And for white collar criminals, it is the prison term that offers the most profound general deterrence. See 18 U.S.C. §3553(a)(2)(B)(sentencing goals include the need to afford adequate deterrence to criminal conduct). “As the legislative history of the adoption of §3553 demonstrates, Congress viewed deterrence as particularly important in the area of white collar crime.” United States v. Martin, 455 F.3d 1227, 1240 (11th Cir. 2006)(internal quotations and

citations omitted). “Restitution is desirable but so is the deterrence of white collar crime (of central concern to Congress), the minimization of discrepancies between white-and blue-collar offenses, and limits on the ability of those with money or earning potential to buy their way out of jail.” United States v. Mueffelman, 470 F.3d 33, 40 (1st Cir. 2006). See also United States v. Politano, 522 F.3d 69, 74 (1st Cir. 2008)(recognizing the importance of general deterrence in post-Booker sentencings).

Research fraud, the crime for which Reuben stands convicted, is a growing and pernicious problem. See “Scandalous science: Scientists cheating on data,” by Daniel Peake, February 17, 2010, Medill Reports (attached hereto as Ex. 5) (“Despite increasing science journal retraction rates in recent years, scientific misconduct in research and publishing persists – particularly in pharmacological and medical research.”). An incarcerative sentence would have profound general deterrence impact on the medical community, and the subset of that community that engages in research. A sentence of probation or home confinement would foster a notion in those communities that the punishment which the members of those communities fear the most, imprisonment, can be avoided by paying restitution. Further, the laudable goal of the Sentencing Commission, to reduce disparities in sentencing between white-collar criminals and blue-collar criminals would be undermined by a home confinement sentence here. Allowing white collar criminals to avoid jail because, as Reuben argues, he has suffered enough, would enforce, rather than reject, that there are two systems of justice extant, one for white-collar offenders, and one for blue-collar offenders.

The applicable §3553 factors and recent First Circuit case law in the area of white collar crime demonstrate that an incarcerative sentence, such as the one recommended by the government, as opposed to the home confinement sentence recommended by Defendant, is appropriate.¹

¹As noted, the government's recommendation is 4 months below the low end of the applicable guideline range, and thus is 4 months lower than the term the government agreed to recommend in the plea agreement. This recommendation reflects a number of factors, including Reuben's timely willingness to come forward about his crime, his effort to make full restitution in the face of personal financial uncertainty, and a recognition that such a sentence would be "sufficient, but not greater than necessary, to comply with the purposes" of 18 U.S.C. §3553(a)(2).

IV. Conclusion

In sum, an incarcerative sentence of 14 months would recognize the seriousness of the offenses, promote respect for the law, and act as a meaningful general deterrent to other potential white collar offenders. In contrast, the home confinement sentence sought by the Defendant would run counter to the well established goals of: (1) reducing disparity in sentencing between blue and white collar criminals; (2) preventing white collar criminals from buying their way out of jail; and (3) deterring white collar crime, particularly the burgeoning problem of medical research fraud.

Respectfully submitted,

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Certificate of Service

I hereby certify that the foregoing documents filed through the ECF system will be sent electronically to counsel for each defendant who is a registered participant as identified on the Notice of Electronic Filing (NEF).

/s/Jeremy M. Sternberg
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Dated: June 22, 2010