

UNITED STATES DISTRICT COURT¹
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA,)

Plaintiff,)

vs.)

ROSS A. CAPUTO, et al.)

Defendants.)

No. 03 CR 0126

Judge Ruben Castillo

MEMORANDUM OPINION AND ORDER

This is the seventh and last opinion this Court plans to issue in this criminal case. This opinion seeks to comply with this Court’s post-*Booker* duty to articulate the reasons behind the sentences it imposed on September 13, 2006.¹ On that date this Court sentenced defendant Ross A. Caputo (“Caputo”) to a ten-year sentence and defendant Robert M. Riley (“Riley”) to a six-year sentence. Both defendants were directors of AbTox, Inc. (“AbTox”): Caputo was the President and Chief Executive Officer, and Riley was Vice-President of Regulatory Affairs and Chief Compliance Officer. While Caputo is one of many corporate CEO’s who have recently been tried and convicted, Riley is one of only a few Chief Compliance Officers ever tried and convicted in federal court. After an eight-week jury trial, both defendants were convicted of the following nineteen criminal counts: conspiracy (count one); fraud (count two); mail fraud (counts three through five); wire fraud (counts ten through twelve); and the introduction of an altered or misbranded device into interstate commerce (counts thirteen through nineteen).

RELEVANT FACTS

The trial evidence established the following relevant facts. AbTox, based in Mundelein, Illinois, was a medical device manufacturer with essentially a single product: the AbTox Plazlyte sterilizer, which it marketed to hospitals across the country for use in sterilizing reusable medical devices. As a manufacturer of medical devices, AbTox was subject to regulation by the U.S. Food & Drug Administration (“FDA”), under the Medical Device Amendments to the Federal

¹ The prior opinions of this Court in this case can be found at: *United States v. Caputo*, 288 F. Supp. 2d 912 (N.D. Ill. 2003) (motion to dismiss indictment); *United States v. Caputo*, 288 F. Supp. 2d 923 (N.D. Ill. 2003) (motion for bill of particulars); *United States v. Caputo*, 313 F. Supp. 2d 764 (N.D. Ill. 2004) (motion in limine); *United States v. Caputo*, 382 F. Supp. 2d 1045 (N.D. Ill. 2005) (motion to compel, motion in limine); *United States v. Caputo*, 374 F. Supp. 2d 632 (N.D. Ill. 2005) (motions in limine); *United States v. Caputo*, 373 F. Supp. 2d 789 (N.D. Ill. 2005) (motion to compel, motion for rule to show cause).

Food, Drug, and Cosmetic Act. Federal Food, Drug, and Cosmetic Act, § 521(a), as amended, 21 U.S.C.A. § 360k.

Under the 1976 Medical Device Amendments, any new medical device to be introduced into commerce in the United States after 1976 requires the approval of the FDA. Devices already on the market prior to adoption of the 1976 amendments are not subject to this requirement, but continue to be sold as before, provided they are not significantly modified. Under the 1976 Amendments, prior to approval, the FDA reviews the application for Pre-Market Approval (“PMA”), including the manufacturer’s data, and decides whether the proposed device is safe and effective for its intended use. If the FDA finds in favor of the application, it issues a PMA and the device may then legally be marketed under whatever controls the FDA puts in place.

For some medical devices, there is an alternate route to market. Manufacturers intending to market any new medical device may submit a premarket notification to the FDA, also known as the “§ 510(k) process.” 21 U.S.C. § 360(k). Under the 510(k) process, manufacturers set out data to support a finding that their new device is “substantially equivalent” in safety and effectiveness to a medical device already lawfully in commercial distribution. This notification is reviewed by the FDA’s Office of Device Evaluation, which can either find the device “substantially equivalent” to the legally marketed device, in which case the new device is said to be “cleared” for marketing, or “not substantially equivalent,” in which case it cannot be marketed without Pre-Market Approval. In some situations, the agency may tell the applicant that it needs more information. In that case, the device is not yet cleared and cannot be marketed.

Beginning in about November 1990, AbTox began seeking 510(k) clearance for its sterilizer. The sterilizer submitted to the FDA was a gas-plasma sterilizer, with a one cubic foot

sterilization chamber, and employing a 10% peracetic acid mixture as its principal sterilant.

AbTox interacted with the FDA for four years, providing data intended to show that the described sterilizer was as safe and effective as ethylene oxide (“EtO”), the prevailing means of low-temperature sterilization for medical instruments.

During the pre-market notification process, AbTox engaged in different forms of fraudulent conduct. Adverse test results were, for the most part, withheld from FDA reviewers, while favorable results achieved under the same test protocols were disclosed. FDA reviewers testified at trial that the information withheld was material. Caputo and Riley both played a significant role in withholding test data. Both of them were kept informed of test results on an almost daily basis. Caputo signed the first FDA submission—known jokingly among the scientific staff at AbTox as the “submission of omissions”—while Riley was editor-in-chief of the various submissions and also AbTox’s primary contact with the FDA.

At some point in the process, the defendants decided that instead of selling the small, one cubic foot sterilizer, for which there was no viable market, they would develop and sell a larger sterilizer. The larger sterilizer had different design and engineering characteristics: a six cubic foot chamber; a 5% peracetic acid mixture; different temperature, pressure, and gas flow rate; and a single, as opposed to multiple, use of the sterilant. The defendants began selling the larger sterilizer in Canada and overseas in late 1993. Throughout 1994 Riley and Caputo continued to negotiate with the FDA concerning the small sterilizer, hammering out the details concerning permissible uses and the precise language of the operator’s manual, all the time knowing, but concealing from the FDA, that the defendants had no intention of ever marketing the sterilizer they were asking the FDA to clear.

On December 22, 1994, the FDA issued a clearance letter finding that when used to sterilize flat stainless steel instruments without lumens (tubes) or hinges, the small sterilizer was “substantially equivalent” to ethylene oxide. This gave AbTox clearance to legally market the small sterilizer in the United States, limited to flat stainless steel instruments without lumens or hinges.

The clearance letter left the defendants with two seemingly insurmountable marketing problems. First, there was no real market for the one cubic foot sterilizer that the FDA had cleared, because it was simply too small to be of practical use in a hospital setting. Second, there was no real market for the unapproved six cubic foot sterilizer if sold within the scope of the clearance; that is, limited to flat stainless steel instruments without lumens or hinges. Hospitals already had a fast, affordable, safe, and effective method of sterilizing stainless steel instruments in steam, and non-stainless steel instruments requiring low-temperature sterilization, such as endoscopes, were not within the scope of AbTox’s marketing clearance. These items were routinely sterilized in ethylene oxide.

Despite these barriers to marketing, under cover of the clearance letter for the small sterilizer, AbTox proceeded to market the large sterilizer throughout the United States. From the start, AbTox’s marketing strategy depended entirely on inducing its customers to purchase the large sterilizer for uses beyond the clearance the FDA had awarded to the small sterilizer.

The first hospitals to buy from AbTox in 1995 were given a variety of printed promotional material boldly proclaiming the ability of the AbTox sterilizer to process instruments with hinges and lumens, and to serve as a complete replacement for ethylene oxide. Indeed, despite having just negotiated with the FDA the section of the operator’s manual defining the sterilizer’s

limitations in painstaking detail, the defendants jettisoned the manual and substituted expansive language tending to obscure the narrow scope of the clearance.

In May 1995, as the FDA investigation of AbTox's promotional practices intensified, and issuance of a warning letter was imminent, the defendants submitted a new 510(k) pre-market notification to the FDA, requesting clearance for expanded claims (lumens, different wraps) and a shorter cycle time. As before, the 510(k) failed to inform the FDA of adverse test results obtained by AbTox. The 510(k) briefly mentioned some of the differences between the cleared sterilizer and the marketed sterilizer, but did not in any way highlight them and did not request clearance for them.

The FDA reviewer found the pre-market notification wholly deficient, and sent AbTox a major deficiency letter, accompanied by a checklist, setting out the kinds of data and materials that should accompany the 510(k) should it be resubmitted. The letter concluded by directing the defendants not to put the device into commercial distribution, and warning AbTox that it would be in violation of the Federal Food, Drug and Cosmetic Act if it did so. That same month, the FDA issued AbTox a warning letter, directing the company to desist from "off-label promotion." The defendants agreed to desist: the most egregious promotional material was discontinued, and the operator's manual was restored to the original language setting out the limitations in the FDA's clearance.

Undeterred, the defendants went on selling their sterilizers to unsuspecting hospitals, which were under the misimpression that they were buying a sterilizer which had been cleared by the FDA. This is the substance of the charges of mail fraud and wire fraud of which Caputo and Riley were convicted. At trial, one after another, representatives of victim hospitals testified that

the defendants' misrepresentations concerning FDA clearance were material, and that they would not have purchased the sterilizer had they known the true facts.

When AbTox's first U.S. customer, St. Joseph Mercy Hospital in Ann Arbor, Michigan (which had bought the uncleared large sterilizer on February 14, 1995), saw the restored language, it advised the defendants that it had been misled about the sterilizer's clearance. In addition, the sterilizer had damaged some endoscopes, an uncleared item, which the hospital had processed in the sterilizer pursuant to AbTox's representations. Defendants Caputo and Riley met with the hospital and its lawyer. They agreed to pay for the damaged endoscopes. Caputo insisted that despite the FDA's limited clearance, or "label copy," of the AbTox sterilizer, the sterilizer was nevertheless capable of processing anything that could be processed in ethylene oxide. Caputo agreed to give St. Joseph Mercy a written guarantee—which was to be kept confidential—that the Plazlyte sterilizer could process a list of non-cleared, or "off-label," medical instruments, even though FDA regulations required AbTox to operate within the scope of the clearance granted by the agency. As a result of AbTox's guarantee, the sale of the large sterilizer did not unravel, and St. Joseph Mercy continued to serve as an important reference hospital for AbTox, including hosting site visits by prospective customers to witness the hospital using the AbTox sterilizer outside its clearance and making a promotional video for AbTox. In addition, a five-page list of off-label instruments processed by the hospital was distributed by AbTox salespeople to prospective customers. Unlike medical device manufacturers such as AbTox, the FDA does not regulate the practice of medicine, and physicians and hospitals are free to use a legally marketed device for any purpose in accordance with their own medical judgment.

The defendants proceeded with their illegal marketing efforts despite the May 1995 FDA

warning letter. The defendants devised a marketing and sales strategy under which AbTox would give lip service to the FDA clearance, while nevertheless vigorously promoting the sterilizer for off-label use. To accomplish this, AbTox adopted various strategies. First, AbTox repeatedly denounced ethylene oxide. Indeed, this predominant method of low-temperature sterilization was believed to be a carcinogen and a danger to the earth's ozone layer, and occasional shortages sometimes made ethylene oxide hard to get. Consequently, many hospitals were eager to discard EtO, and they were receptive to AbTox's claims that its sterilizer was a replacement, or "alternative," to EtO. This anti-EtO campaign was itself a form of off-label promotion, since, if sold within the restrictions of its clearance, the AbTox sterilizer was not a direct replacement for the sterilizer.

To induce prospective customers to buy the unit as an EtO replacement, the defendants instructed and equipped AbTox salespeople to use "validation" as a key tool in selling the large sterilizer. Validation describes the process whereby a hospital will test specific instruments to determine whether they can be adequately processed in a sterilizer under the conditions existing at that particular hospital. A manufacturer may not, however, use validation as a substitute for FDA clearance, or as a way to evade the restrictions the FDA had placed on promotion of the sterilizer. In fact, in the wake of its warning letter, the FDA explicitly instructed defendant Riley that AbTox could "neither promote nor support" validation of instruments not cleared by the FDA. Nevertheless, AbTox either assisted hospitals in performing validations themselves, or referred them to AbTox's sister company, Pharmaceutical Systems, Incorporated ("PSI"), to perform validations for uncleared uses of the sterilizer. Caputo, as President of AbTox, authorized price discounts to offset the cost of validation, and in some cases authorized AbTox to

pay PSI for the validation directly. In most cases, however, AbTox's customers were not aware that Caputo effectively controlled PSI, and thus that PSI was not an independent validation source.

Another program meant to promote use of the AbTox sterilizer as an EtO replacement was the EtO trade-in offer. Through this offer—approved by Caputo and Riley—AbTox offered hospitals \$20,000 worth of free sterilant if they would trade in their ethylene oxide sterilizer to AbTox during the first year after buying the AbTox unit. This would leave the hospitals dependent on the AbTox unit to process off-label instruments, and would enable AbTox to tout the hospital to prospective customers as “EtO free.”

Reference hospitals also formed a crucial tool in the defendants' off-label promotional campaign. The closing of every sale was merely the first step in the next sale to another hospital. Either before or after the sale, as circumstances dictated, AbTox sent clinical specialists to offer hospital personnel training on the operation of the Plazlyte sterilizer. These specialists would also conduct an “instrument audit” to evaluate the suitability of the hospital's reusable instruments to be processed in the AbTox sterilizer, without regard to the limitations of the FDA clearance. Once the hospital had been induced to sterilize instruments outside clearance, it could serve as a valuable reference for other hospitals.

The defendants' off-label promotion had important consequences. As stated above, the small sterilizer had been cleared only for processing stainless steel without hinges or lumens. Instruments containing brass were not within the scope of the FDA clearance. At least as early as late 1990 or early 1991, AbTox personnel became aware that use of the sterilizer to process brass would produce a “blue-green residue” on the instruments, which AbTox scientists identified early

on as copper acetate and zinc acetate. This was produced by interaction of the brass with the peroxidants (peracetic acid and hydrogen peroxide) which served as AbTox's principal sterilant. Despite the recommendation by an AbTox scientist in 1994 that ocular testing be done on the blue-green residue, the defendants never had such testing performed. This testing, which cost between \$500 and \$600, would have shown that copper was damaging to the human eye. Moreover, this fact was already well-documented in existing scientific and medical literature, and could have been discovered by a literature search the defendants never conducted.

Throughout the conspiracy, hospitals in both Canada and the United States notified AbTox of a blue-green residue problem on certain sterilized instruments. Some of these complaints went to defendant Riley, who as AbTox's Chief Compliance Officer was in charge of customer complaints. In 1995, AbTox convened a sort of working group on the blue-green residue issue which was directed by Riley. In early 1996, Riley obtained an opinion from a toxicologist, based on selective, minimal information provided by Riley, that copper acetate presented no danger to patients if introduced intraperitoneally. The fruit of the blue-green working group's labor was AbTox's Technical Note 13, specifically approved by the defendants, in which AbTox informed its customers that blue-green residue could be produced if brass instruments were not completely dry when sterilized, that it was a "natural nutrient for the human body," and that in the opinion of an unnamed toxicologist, it was harmless. Technical Note 13 omitted the toxicologist's limitation of his opinion to intraperitoneal exposure, and was not shown to the toxicologist for comment before being distributed to existing and potential customers nationwide. The purpose of Technical Note 13 was to reassure customers about blue-green residue and lull them into complacency, rather than to warn them of danger or discourage them

from using the AbTox sterilizer to process brass.

Unfortunately, serious eye injuries followed the issuance of Technical Note 13. Within the space of one week in January 1996, three patients undergoing routine eye surgery at Ravenswood Hospital in Chicago suffered corneal decompensation, a rare and devastating eye injury, which involved destruction of the endothelial cell wall separating the cornea from the vitreous matter behind it. As a result, the cornea becomes clouded and significantly blurs vision. Jim Sarns, the AbTox salesperson on the account, testified at trial that the day he learned of the eye injuries, he also saw a sterilization technician washing blue-green residue out of an eye cannula at Ravenswood. He testified that he went immediately to a pay telephone and called defendant Riley to tell him about the eye injuries and blue-green residue. Riley, however, did nothing. He failed to conduct an investigation on behalf of AbTox. He also did not open a complaint file as required by FDA regulations. Victoria Galliani, then an AbTox scientist, testified that she asked Riley whether AbTox should file a Medical Device Report (“MDR”), which the law requires a device manufacturer to file with the FDA when it acquires information from any source that its product may have contributed to a serious injury. Riley told her that he was handling it, that the injuries were caused by “soap,” and that no MDR would be filed.

In almost each instance, the cases of corneal decompensation occurred a little over a month after the hospitals began sterilizing eye instruments in Plazlyte, and the injuries ceased immediately when the use of AbTox for eye instruments was discontinued. Although the hospitals identified as another possible cause Miochol E, an eye wash whose manufacturer had recalled some batches, AbTox was never eliminated as a suspect.

Amidst these eye injuries, in March 1996, the defendants filed their much-delayed,

renewed 510(k) application with the FDA, shortly after a brief FDA inspection to determine compliance with label restriction. This submission set out in more detail the differences (which the defendants called “changes”) between the two sterilizers. FDA reviewer Susanna Barrett had told Riley to include this information. Still, the 510(k) described the “changes” as “minor,” and still did not ask the FDA to clear the larger sterilizer, which AbTox had now been marketing illegally in the United States for over a year.

In order to perpetuate the fiction that the differences between the two sterilizers were merely “minor changes” that did not require new 510(k) clearance, Riley included a material falsehood in the March 1996 510(k). In it, Riley claimed that the “changes” had all been made since the December 22, 1994 clearance, despite the fact that AbTox had been marketing the “changed” sterilizer abroad since late 1993. At trial Riley testified that the misstatement had been merely a mistake, which he blamed on his then-lawyer. However, the government aptly noted that this “mistake” also occurred in a March 1996 civil case deposition and that Caputo made the exact same misstatement in a May 1998 letter to the FDA.

On May 31, 1996, the FDA again rejected AbTox’s filing in a major deficiency letter which set out twenty-three pages of defects in AbTox’s supporting data. The FDA told AbTox that the changes which it had described as “minor” were significant, and that the FDA regarded the “modified” sterilizer as a new sterilizer requiring a new 510(k). Most importantly, the FDA specifically directed the defendants not to put the sterilizer into commercial distribution until it had received a letter from the FDA allowing it to do so. Realizing the significance of the FDA letter, Riley signed each page of the letter and distributed a copy to Caputo. However, the existence of this letter was kept a secret from the rest of the company.

Although the defendants never obtained FDA clearance for expanded uses, they continued their efforts to market the large sterilizer for expanded uses. From May through September 1997 there were more outbreaks of the same rare and devastating corneal decompensation during routine eye surgery at the Truman Veterans Hospital (“VA Columbia”) in Columbia, Missouri, and Missouri Baptist Hospital in St. Louis. There were two cases of corneal decompensation at VA Columbia and seven at Missouri Baptist. At each hospital there had never been any previous outbreak of corneal decompensation before the AbTox sterilizer was put into use, and the incidents of corneal decompensation ceased once the use of the AbTox sterilizer for eye instruments was discontinued. At the time of the 1997 injuries, there is mention of “eye irritations” in two AbTox reports to Caputo, which were also circulated to Riley.

The hospitals sent a set of eye instruments sterilized in Plazlyte to AbTox, where Riley ordered an AbTox scientist to test visible residue. The test found both soap residue and AbTox’s perennial copper acetate, but Riley attributed the injuries to soap, despite the mounting evidence to the contrary. Again AbTox neither opened the required MDR complaint file, ordered ocular testing, or informed the FDA. Six months later AbTox was ordered by the FDA to file the required MDR on the incident. Riley filed a false account, blaming the injuries on soap and omitting any reference to the copper acetate, even though that same day FDA investigators had informed him and Caputo explicitly that copper acetate had been shown by the Center for Disease Control to cause corneal decompensation.

Riley’s inaction ultimately was the last clear chance to have avoided six more corneal decompensation cases at the VA hospital in St. Louis in January 1998. By February 1998, one month after VA St. Louis suffered six more cases of corneal decompensation associated with the

AbTox sterilizer, both defendants definitively knew about the eye injuries. That month, the injuries were mentioned and whitewashed in a report prepared at Riley's direction, which the defendants sent to VA St. Louis.

AbTox's final two 510(k) submissions, made in early July 1996 and February 1998, merely sought clearance for the sterilizer the defendants were already marketing. Both were rejected by the FDA as insufficient. Although after May 31, 1996, no submission for expanded claims was ever again pending with the FDA, both defendants falsely assured employees and customers that applications for expanded claims were always pending, and that FDA clearance was forthcoming.

Thus, defendants Caputo and Riley effectively carried out a bait-and-switch scheme on the FDA and its customers, obtaining clearance on one sterilizer but using the clearance to sell another. The defendants continued to sell the large uncleared sterilizer, in defiance of law and FDA directives, through a pattern of falsehoods and deception, until the company shut down sales operations on April 7, 1998, under pressure from the FDA. In the meantime, AbTox had illegally sold 168 adulterated sterilizers in the United States., causing an intended loss in excess of \$16 million.

ANALYSIS

The sentencing of criminal defendants in the federal system is ultimately governed by 18 U.S.C. § 3553(a). *United States v. Booker*, 543 U.S. 220, 233-34 (2005). That subsection first requires that "[t]he court shall impose a sentence sufficient, but not greater than necessary, to comply with the purposes set forth in" 18 U.S.C. § 3553(a)(2). According to this section, the sentence must:

- (A) reflect the seriousness of the offense, promote respect for the law, and provide just punishment for the offense;
- (B) afford adequate deterrence to criminal conduct;
- (C) protect the public from further crimes of the defendant; and
- (D) provide the defendant with needed education or vocational training, medical care, or other correctional treatment in the most effective manner.

18 U.S.C. § 3553(a)(2). After this general mandate, section 3553(a) lists seven factors for the court to consider “in determining the particular sentence to be imposed.” In addition to the factors set forth at section 3553(a)(2) quoted above, the court is to consider:

- (1) the nature and circumstances of the offense and the history and characteristics of the defendant;
- ...
- (3) the kinds of sentences available;
- (4) the kinds of sentences and the sentencing range established [under the Sentencing Guidelines], subject to any amendments made to such Guidelines by an act of Congress...;
- (5) any pertinent policy statement ... issued by the [United States] Sentencing Commission ... subject to any amendments made to such policy statement by an act of Congress...;
- (6) the need to avoid unwarranted sentence disparities among defendants with similar records who have been found guilty of similar conduct; and
- (7) the need to provide restitution to any victims of the offense.

18 U.S.C. § 3553(a).

Within this general statutory sentencing scheme, the Sentencing Guidelines provide a critical framework because they represent eighteen years’ worth of careful consideration of the proper sentences for federal offenses. *See United States v. Mykytiuk*, 415 F.3d 606, 608 (7th Cir.

2005). In *Mykytiuk*, a thoughtful opinion authored by Judge Wood, the U.S. Court of Appeals for the Seventh Circuit indicated that the Guidelines remain an essential tool in creating a fair and uniform sentencing regime across the country and, therefore, held that a sentence properly calculated under the Guidelines is entitled to a rebuttable presumption of reasonableness. *Id.* See also *United States v. Blue*, 453 F.3d 948, 952 (7th Cir. 2006) (reiterating holding in *Mykytiuk* that sentences falling within the properly calculated Guidelines range is presumed reasonable and defendant bears the burden of rebutting the presumption by showing that the sentence is inconsistent with the section 3553(a) sentencing factors). The majority of the Courts of Appeals throughout the country have adopted the Seventh Circuit's holding that sentences properly calculated under the Guidelines are presumptively reasonable. See, e.g., *United States v. Clark*, 434 F.3d 684, 685-86 (4th Cir. 2006) (a sentencing court shall first calculate the range prescribed by the Guidelines and then consider that range as well as other relevant factors set forth in the Guidelines and § 3553(a) before imposing the sentence); *United States v. Smith*, 440 F.3d 704, 707 (5th Cir. 2006) (sentences properly calculated under the Guidelines are presumptively reasonable); *United States v. Williams*, 436 F.3d 706, 708 (6th Cir. 2006) (same); *United States v. Whitrock*, 454 F.3d 866, 868 (8th Cir. 2006) (same); *United States v. Cage*, 451 F.3d 585, 593-94 (10th Cir. 2006) (same); *United States v. Dorcely*, 454 F.3d 366, 376 (D.C. Cir. 2006) (same).

Where Courts of Appeals decline to hold that a sentence within the Guidelines range is entitled to a rebuttable presumption of reasonableness, they continue to reiterate the central importance of the initial Sentencing Guideline range in the post-*Booker* determination of what constitutes a reasonable sentence. See, e.g., *United States v. Pho*, 433 F.3d 53, 61-64 (1st Cir. 2006) (district court does not have authority to impose sentence outside advisory Sentencing

Guideline range based solely on categorical policy-based rejection of Guidelines, as Congress and Sentencing Commission have authority over sentencing policy and seek to promote uniformity in federal sentences; judicial discretion over sentencing must be limited to case-specific circumstances); *United States v. Rattoballi*, 452 F.3d 127, 132-33 (2d Cir. 2006) (stating that “[i]n calibrating our review for reasonableness, we will continue to seek guidance from the considered judgment of the Sentencing Commission as expressed in the Sentencing Guidelines and authorized by Congress;” and holding that “[w]hile district courts enjoy discretion following *Booker*, that discretion must be informed by the § 3553(a) factors; a district court cannot import its own philosophy of sentencing if it is inconsistent with the § 3553(a) factors”); *United States v. Cooper*, 437 F.3d 324, 332 (3d Cir. 2006) (holding that a sentence falling within the Guidelines range is more likely to be reasonable than one outside the Guidelines range); *United States v. Guerrero-Velasquez*, 434 F.3d 1193, 1195 n.1 (9th Cir. 2006) (stating that the Guidelines are still an important aid for district judges seeking to determine the appropriate sentence for a defendant and help to maintain uniformity in sentencing throughout the country); *United States v. Hunt*, 459 F.3d 1180, 1185 (11th Cir. 2006) (holding that the Guidelines are to serve as a starting point for consideration as to whether a given sentence is “reasonable” in view of the entirety of section 3553(a)).

The duty of a district judge to articulate the reasons for his or her sentence has been subject to varying standards of review. This Court, like its colleagues, carefully studies all of this Circuit’s decisions—especially in the area of post-*Booker* sentencing law. In a prior opinion by this Court, we noted certain initial inconsistencies in our Circuit’s post-*Booker* precedent. *See United States v. Spano*, 411 F. Supp. 2d 923 (N.D. Ill. 2006), *aff’d* 447 F.3d 517 (7th Cir. 2006).

Specifically, we noted that despite the rebuttable presumption of reasonableness for a within-Guideline sentence, it seemed that our Circuit was moving toward a somewhat subjective standard of reasonableness review which did not give proper deference to the front line views of sentencing judges at the district court level. *Spano*, 411 F. Supp. 2d at 923.

We are pleased to report that the Seventh Circuit appears to have averted this Court's dire prediction of post-*Booker* sentencing law. Since this Court's *Spano* opinion, our Circuit has shown considerable deference to this Court's district colleagues. In fact, Judge Posner has expressly noted that a district judge's choice of sentence, whether inside or outside the Guideline range, is discretionary and subject therefore to only light appellate review. *United States v. DeMaree*, 459 F.3d 791 (7th Cir. 2006). This Court's review of recent opinions by our Circuit discloses that district judges remain free to use their post-*Booker* discretion as long as they do not countermand the clear dictates of Congress or the Sentencing Commission. *See, e.g., United States v. Miller*, 450 F.3d 270 (7th Cir. 2006) (district court needed to abide by the policy choices made by Congress and Sentencing Commission with respect to crack cocaine penalties); *United States v. Galicia-Cardenos*, 443 F.3d 553 (7th Cir. 2006) (only Congress can authorize fast-track discounted sentencing program).

The one glaring disagreement this Court still has with the Seventh Circuit's case law development is its determination that the concept of "departures" under the Sentencing Guidelines is obsolete after *Booker*. *United States v. Arnaout*, 431 F.3d 994, 1003 (7th Cir. 2005). This holding, which started as *dicta*, has been subsequently repeated in more express terms in recent opinions in this Circuit. *See United States v. Johnson*, 427 F.3d 423, 426 (7th Cir. 2005).

The Guidelines permit departures from the prescribed sentencing range in cases in which the judge “finds that there exists an aggravating or mitigating circumstance of a kind, or to a degree, not adequately taken into consideration by the Sentencing Commission in formulating the guidelines that should result in a sentence different from that described.” 18 U.S.C.A. § 3553(b)(1). This provision was not invalidated by the *Booker* decision, where Justice Breyer surgically severed certain provisions of the sentencing statute but left the above departure section wholly intact. *Booker*, 543 U.S. at 264. Moreover, Justice Breyer expressly acknowledged the “two decades of appellate practice in cases involving departures,” and directed the district courts to consult the Guidelines and take them into account at sentencing. *Id.* at 261.

Every other Circuit, except for the Ninth,² agrees that the appropriate sentencing methodology is the three-level analysis of: (1) applying the Guidelines; (2) considering any downward departures under the Guidelines; and (3) considering whether the resulting sentence range yields a reasonable sentence under the general factors enumerated in 18 U.S.C. § 3553(a). *See, e.g., United States v. McBride*, 434 F.3d 470, 471 (6th Cir. 2006) (because Guideline “departures” are a part of the appropriate Guideline range calculation they are still a relevant consideration for determining the appropriate Guideline sentence); *United States v. Samuelsen*, No. 05-4280, 2006 WL 2826730, at *5 (3d Cir. Oct. 4, 2006) (expressly rejecting the Seventh Circuit’s position that departures are obsolete and clarifying that departures under the Guidelines

² In *United States v. Mohamed*, the Ninth Circuit adopted *Arnaout*’s language that “the concept of ‘departures’ has been rendered obsolete in the post-*Booker* world,” and held that post-*Booker*, the scheme of departures has been replaced by the requirement that judges impose a reasonable sentence. 459 F.3d 979, 986 (9th Cir. 2006). Yet even *Mohamed*, unlike our Circuit, recognized that the pre-*Booker* system of departures should not be ignored because it may carry indicia of the Sentencing Commission’s policy judgments and suggest that a sentencing decision was reasonable. *Id.* at 987.

remain an important cog in the sentencing mechanism separate and apart from the 18 U.S.C. § 3553(a) variances from the Guidelines); *United States v. Calzada-Maravillas*, 443 F. 3d 1301 (10th Cir. 2006) (Guideline departures survive *Booker*); *United States v. Chase*, 451 F. 3d 474, 482 (8th Cir. 2006) (affirming departure after *Booker*). This almost universal approach is consistent with 18 U.S.C. § 3553—which explicitly authorizes departures under the Guidelines—and with the remedial portion of the *Booker* opinion—which did not excise the concept of departures from the Guidelines. *Booker*, 543 U.S. at 246-62.

In this case, consistent with its own sentencing practices, this Court followed the three-level sentencing analysis to arrive at its sentences for Caputo and Riley.

CAPUTO’S AND RILEY’S SENTENCES

I. Application of Advisory Sentencing Guidelines

A. Defendant Caputo

In the case of defendant Caputo, this Court determined that the advisory Guideline range was 108 to 135 months. This range was based on this Court’s specific sentencing findings that the total offense level was 31 and that Caputo had no relevant prior criminal history and therefore was in Criminal History Category I.

The advisory sentencing range was calculated by applying the 1997 edition of the Guidelines manual, which was more favorable to Caputo than the 2005 edition. Caputo’s offense level started at six. A fifteen level enhancement was applied because the Court calculated the intended loss at more than \$10 million but less than \$20 million. U.S. Sentencing Guidelines Manual (“U.S.S.G.”) § 3 B1.1(a).

Caputo also received a two level adjustment for obstruction of justice, pursuant to

U.S.S.G. § 3C1.1, for violating this Court's order directing him not to transfer personal monies over \$10,000 for the payment of non-attorney fee expenses after his conviction; for willfully misleading the Court about the overall worth of his assets; and for attempting to inappropriately transfer title to some of his vehicles after his conviction. (*See* 9/13/06 Tr. at 8-9.) Finally, both defendants received a two level enhancement pursuant to U.S.S.G. § 2 F1.1(b)(4)(A) because their offenses involved the conscious or reckless risk of serious bodily injury.

B. Defendant Riley

Riley's advisory sentencing calculations were the same as Caputo's with one important exception. First, the Court declined to use an obstruction enhancement even though the government strongly asserted that Riley had committed perjury when he testified. The Court specifically found that Riley's trial testimony was misleading but not willful. (9/13/06 Tr. at 8, 59-60). Second, the Court expressly found that Riley had been manipulated by Caputo throughout the fraudulent scheme. (*Id.*) Riley's initial advisory sentencing range was 87 to 108 months based on a total adjusted offense level of 29 and a Criminal History Category of I.

II. Consideration of Applicable Downward Departures

The Court next determined whether the initial advisory sentencing ranges for each defendant should be subject to a discretionary sentencing departure. The Court concluded that Caputo did not merit any departure, although elements of the offense caused the Court to consider, but in the end reject, a potential upward sentencing departure. (9/13/06 Tr. at 39.) The Court, did, however, grant Riley a downward departure of two levels after concluding that the four level enhancement pursuant to U.S.S.G. § 3B1.1(a) for being an organizer or leader of a

criminal activity that involved five or more participants or was otherwise extensive, while technically applicable to Riley, overemphasized the extent of his role in this offense. (9/13/06 Tr. at 60-61.) The Court reached this conclusion because it found repeatedly at the sentencing hearing that Caputo had expertly selected and extensively manipulated Riley throughout the execution of the fraudulent scheme. (*Id.* at 57-60.) Therefore, this Court used a limited departure to adjust Riley's advisory sentencing range downward to 70 to 87 months based on a total offense level of 27 and a Criminal History Category of I. In essence, the Court believed that a two level rather than a four level enhancement was far more appropriate for the unusual role Riley had in this offense.

III. Consideration of Reasonableness of Sentences Under 18 U.S.C. § 3553(a) Factors

A. Nature and Circumstances of the Offense

The nature and circumstances of this offense are outlined in the Relevant Facts section of this opinion. At sentencing, it was apparent that both defendants still somehow believed they had merely been convicted of technical, regulatory violations. Yet, the Court and the jury both saw overwhelming evidence that the defendants had engaged in a prolonged, massive fraud upon the FDA and relevant hospitals by marketing an illegal sterilizer that ultimately put the general public at risk. Despite repeated admonitions and warning letters from the FDA, the defendants placed themselves above the law, believing that they had better scientific and industry knowledge than the FDA. Essentially, both defendants viewed the FDA as a regulatory nuisance that could be neutralized through various misleading and false submissions. Both defendants were motivated by individual economic greed and the desire to capture market share, and they placed these goals over and above our nation's complex regulatory scheme which protects the health of our country.

The FDA regulates roughly a quarter of the U.S. economy, including food, drugs, cosmetics and medical devices. The FDA depends on the timely receipt of all material and true information to complete its mission of protecting the public health. The FDA simply could not function if corporate executives could choose when to provide information or whether they will provide incomplete, misleading or false information. Thus, the defendants willfully interfered with an important governmental function. This case involved a scheme which went beyond economic harm to the marketplace and involved direct physical harm to consumers. It is hard to imagine a more egregious corporate crime, yet the egregiousness of the harm caused by the defendants' conduct is difficult, but not impossible, to measure.

B. Impact of the Defendants' Crime Upon Victims

Twenty-five patients at five hospitals are known to have suffered corneal decompensation in one eye after ocular surgeries performed with instruments sterilized in the illegal AbTox sterilizer. To this date, some of these twenty-five individuals are still suffering the lingering effects of the ineffective and illegal AbTox sterilizer marketed by the defendants.

The AbTox company sold to U.S. customers approximately 172 units of the AbTox Plazlyte sterilizer Model ABT 1.0, under the false pretense that it had been cleared for sale by the FDA. At trial, a sample of hospital representatives testified that their hospital would not have purchased the AbTox unit had it known that the unit had not been cleared, or that the FDA had directed AbTox not to market the unit. Based on AbTox's own records, Special Agent Stich of the FDA has identified 144 U.S. hospitals which purchased and paid for 167 uncleared units. The total amount of their purchases was \$17,209,074.50. (Government Trial Ex. 55).

C. The On-Going National Problem Of Corporate Crime & Recent Actions of Congress and the Sentencing Commission

1. Recent Increases In White Collar Sentences

Both Congress and the Sentencing Commission have targeted our nation's ongoing corporate crime rate. The average federal sentence faced by corporate executives has more than tripled in most instances as a direct result of the U.S. Sentencing Commission's 2002 Economic Crime Amendment and the Sarbanes-Oxley Legislative Initiative. It is noteworthy that the Second Circuit recently held that a twenty-five year sentence was reasonable for a massive securities fraud conducted by a corporate CEO. *United States v. Ebbers*, 458 F.3d 110, 129 (2d Cir. 2006). The Court expressly stated that the twenty-five year (below Guidelines) sentence was a long sentence for a white collar crime, yet noted that the harsh sentence was not unreasonable in light of the new fraud sentencing Guidelines authorized by Congress. *Id.* at 129-30. Our own Circuit recently affirmed a sentence of 118 months as reasonable, even though it may have been above the advisory sentencing range, due to the overall severity of a fraud offense which involved over one hundred million dollars and an elaborate corruption scheme. *See United States v. Leahy, et al.*, ___ F.3d ___, 2006 WL 2819947 (7th Cir. Oct. 4, 2006). Similarly, this case involves an elaborate fraud scheme which caused a multi-million dollar loss while corrupting an entire company and its employees. In addition, this case compromised the overall safety of the public.

At sentencing, the government urged this Court to apply, or at least consider, the application of the 2005 Sentencing Guidelines, which potentially would have dramatically increased the initial advisory ranges to 262 to 327 months for each defendant. *See United States v. DeMaree*, 459 F.3d 791 (7th Cir. 2006) (use of newer version of Guidelines did not violate the Ex Post Facto Clause). This Court carefully considered the use of the 2005 Sentencing Guidelines but concluded that a sufficient and necessary sentence under 18 U.S.C. § 3553(a)

could be reached by applying the older version of the Guidelines, which was more favorable to the defendants.

2. The Recently Amended Organizational Sentencing Guidelines

Among the pertinent policy statements issued by the Sentencing Commission are the Amended Organizational Sentencing Guidelines. At the tenth anniversary of the Sentencing Guidelines for Organizations, the U.S. Sentencing Commission announced its intention to form an advisory group to review the effectiveness of the Guidelines. 66 Fed. Reg. 48306, 48306-07 (Sept. 19, 2001). The Sentencing Commission asked the advisory group to focus on the Organizational Guidelines definition of an effective compliance program. U.S. Sentencing Commission, News Release (Feb. 21, 2002). In April 2004, the Sentencing Commission approved revisions to the Sentencing Guidelines for Organizations, pursuant to the recommendations of the advisory group. These revisions, which became effective on November 1, 2004, emphasize that an organization must both promote an organizational culture that encourages ethical conduct and exercise due diligence to prevent and detect criminal conduct. *See* 8B2.1, United States Sentencing Guidelines. The Guidelines set forth the following compliance requirements:

1. Standards and procedures to prevent and detect criminal conduct;
2. Adequate resources and authority for the program;
3. Personal screening related to the goals of compliance;
4. Training in the standards and procedures at all levels;
5. Non-retaliatory internal reporting systems;
6. Periodic auditing, monitoring and evaluation of the program's overall effectiveness;

7. Incentives and discipline to promote compliance and ethical conduct; and
8. Reasonable, responsive and preventive steps upon detection of a violation.

Id.

By any measure, AbTox's system of corporate compliance was a total failure from top to bottom. Caputo and Riley both bear primary responsibility for this failure. In this case, Caputo selected Riley to serve as AbTox's Chief Compliance Officer for all the wrong reasons. Caputo knew that he could manipulate and dominate Riley based on his prior personal and business experiences with him. Riley did not have any real training as a compliance officer. Riley had received an MBA from Northwestern University, specializing in marketing, before beginning work in the healthcare industry.

Corporate compliance officers are very much today's corporate "fire personnel." They are often the company's "first-responders" and must focus on both proactive and reactive efforts to be effective. Proactive efforts need to emphasize the complimentary goals of crime prevention and corporate ethical behavior. Reactive efforts measure how well a corporation reacts when it learns that questionable and potentially illegal corporate conduct has occurred. The defendants' behavior in this case turns the concept of corporate compliance on its head. Caputo and Riley subverted the standard compliance goals to ensure that AbTox could proceed with its illegal marketing scheme in direct violation of FDA regulations. Measured by any standards, Riley's actions as AbTox's Chief Compliance Officer were woefully and criminally inadequate. The evidence at trial showed that he continually failed to act to prevent the ongoing illegal marketing of AbTox's only commercially viable sterilizer. Instead, the evidence showed that Riley aided and abetted Caputo's illegal marketing plans. Riley chose to use whatever regulatory expertise he

had to further, shield, and cover up the offenses proven at trial. Riley totally failed to self-report any adverse scientific or healthcare results of the sterilizer to the FDA. Riley also willfully participated in the submission of numerous misleading regulatory filings with the FDA. All of Riley's actions were taken at the behest and with the approval of Caputo.

3. The Further Need For Corporate Crime Deterrence While Avoiding Unwarranted Sentencing Disparity

Despite the initiatives of Congress and the Sentencing Commission, corporate crime remains one of our nation's problems. The need for both general and specific deterrence in this area is especially important to buttress our country's regulatory efforts. Too often, as in this case, the corporate officials on trial answer charges with broad assertions of lack of criminal intent in the face of repeated and unheeded factual red flags. Corporate America should be aware that this type of defense will be effectively undercut by the use of a standard "ostrich" jury instruction.

This instruction, which this Court gave to the jury in this case, states:

"Knowledge may be proved by the defendants' conduct and by all the facts and circumstances surrounding the case. You may infer knowledge from a combination of suspicion and indifference to the truth. If you find that a person had a strong suspicion that things were not what they seemed or that someone had withheld some important facts yet shut his eyes for fear of what he would learn, you may conclude that he acted knowingly as I have used that word. You may not conclude that the defendant had knowledge if he was merely negligent in not discovering the truth."

This language is a standard jury instruction which has been repeatedly approved by our nation's courts including the Seventh Circuit Court of Appeals. *See United States v. Carrillo*, 435 F.3d 767, 779 (7th Cir. 2006). This instruction was especially appropriate in this case, where both Caputo and Riley proceeded to trial on the general defense that they did not realize that their actions were illegal. This defense was overwhelmed by the government's evidence, as outlined

herein, which firmly established that both Caputo and Riley participated in a long-term complex set of misrepresentations despite the FDA's repeated warnings and their actual knowledge of adverse test and patient results.

In view of all the factors outlined herein, it is this Court's hope that the readers of this opinion will come to the realization that the ten and six year sentences imposed here are in large measure part of our country's efforts to create an atmosphere of general corporate crime deterrence. Serious corporate crime sentences are needed to reflect the actions of Congress and the Sentencing Commission and to avoid unwarranted sentencing disparities. More importantly, the sentences provide specific deterrence for Caputo and Riley after assessing each of their roles in the offenses proven at trial.

D. History and Characteristics of the Defendants

This Court acknowledges that both Caputo and Riley lived largely exemplary lives until their involvement in the AbTox sterilizer scheme. Neither defendant had a criminal record, and both defendants were the subject of numerous favorable character letters received by the Court. This factor influenced this Court to sentence Caputo at the mid-Guideline range and to depart downward in the case of Riley and then sentence him at the lower end of his adjusted Guideline range.

The Court specifically notes that, similar to public corruption crimes, most corporate crimes will involve defendants with little or no relevant criminal history. It is important for the community to know that this factor will help the Court assess the exact sentence to be imposed, but will not on its own enable a convicted defendant to avoid a serious sentence in light of the recent actions undertaken by Congress and the Sentencing Commission.

IV. Restitution

The Court fully adopted all aspects of the Presentence Report's recommendation and ordered both defendants to jointly and severally pay \$17,209,074.50 in restitution to the hospitals that had been defrauded by the defendants' illegal scheme. In doing so, the Court accepted the report's conclusion that the sterilizers were worthless because they were not cleared by the FDA and were shown to cause eye injuries. Thus, as a result of the defendants' actions, the hospitals were in the end left with worthless and illegal medical equipment with an undisputed purchase price of \$17,209,074.50. The hospitals were entitled to have the full benefit of what they believed they were purchasing—effective and legal sterilizers.

CONCLUSION

This Court concludes that the proven offenses require sentences that will effectively deter and adequately reflect the seriousness of the defendants' egregious conduct, the need for just punishment, and the protection of the public. In this case, for the reasons stated at sentencing on September 13, 2006, and as supplemented herein, the Court concluded that the just and reasonable sentences for each defendant was a total sentence of ten years' imprisonment and three years of supervised release for Caputo and a total sentence of six years' imprisonment and three years of supervised release for Riley. In addition, the Court waived the imposition of any fine in deference to the full award of \$17,209,074.50 in restitution to the victims in this case. These sentences are sufficient, and no greater than necessary, to accomplish all the sentencing objectives of 18 U.S.C. § 3553(a) in this complex and unusual case.

ENTERED: _____
Judge Ruben Castillo

United States District Court

Dated: October 16, 2006

G:\Opinions\Caputo Opinion and Order 03 CR 0126.wpd