UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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UNITED STATES OF AMERICA,

-against-

WILLIAM SCULLY, also known as "Liam Scully,"

Defendant.
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MEMORANDUM OF DECISION AND ORDER
14-CR-208 (ADS)

APPEARANCES

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SPATT, District Judge:

On November 12, 2015, the Defendant William Scully a/k/a Liam Scully (the "Defendant" or "Scully") was convicted, after a jury trial, of 66 felony counts with which he was charged pursuant to a 75-count superseding indictment filed on July 22, 2015. Scully now moves under Federal Rule of Criminal Procedure ("Fed. R. Crim. P." or the "Rule(s)") 29 for a judgment of acquittal on all counts, and under Rule 33 for a new trial in the interest of justice. For the reasons that follow, the Rule 29 motion is granted in part and denied in part, and the Rule 33 motion is denied in its entirety.

I. Procedural Background

A. The Original Indictment

On April 9, 2014, the Government filed a 73-count indictment against Scully and co-Defendant Shahrad Rodi Lameh. The charges in the indictment stemmed from their ownership and operation of Pharmalogical, Inc. ("Pharmalogical") d/b/a Medical Device King and MDK, and Taranis Medical Corp. ("Taranis"), companies that were engaged in the business of selling prescription drugs and other pharmaceutical products. In general, the indictment alleged that Scully and Lameh, through these companies, knowingly and willfully imported foreign versions of prescription drugs and medical devices, which were not approved by the federal Food and Drug Administration ("FDA") for use in the United States, and, using materially false and fraudulent pretenses, sold them to customers around the country.

In particular, the indictment charged Scully and Lameh with the following felony counts:

(i) Count One: Conspiracy to Commit Wire Fraud in violation of 18 U.S.C. § 1349;

(ii) Counts Two through Eighteen: Wire Fraud in violation of 18 U.S.C. § 1343;

(iii) Count Nineteen: Conspiracy to Commit Mail Fraud in violation of 18 U.S.C. § 1349;

(iv) Counts Twenty through Thirty-Six: Mail Fraud in violation of 18 U.S.C. § 1341;

(v) Count Thirty-Seven: Conspiracy to Distribute Misbranded Drugs in violation of 18 U.S.C. § 371;

(vi) Counts Thirty-Eight through Fifty-Four: Introduction of Misbranded Drugs into Interstate Commerce in violation of 21 U.S.C. §§ 331(a) and 333(a)(2);

(vii) Counts Fifty-Five through Seventy-One: Receipt of Misbranded Drugs in Interstate Commerce and Delivery Thereof for Pay in violation of 21 U.S.C. §§ 331(c) and 333(a)(2);

(viii) Count Seventy-Two: Fraudulent Importation and Transportation of Goods in violation of 18 U.S.C. § 545; and

(ix) Count Seventy-Three: Trafficking in Counterfeit Drugs in violation of 18 U.S.C. § 2320(a)(4).

On April 30, 2014, Scully and Lameh pled not guilty to all counts and were released on bond.

However, Lameh thereafter entered a plea agreement with the Government, pursuant to which he appeared before United States Magistrate Judge Steven I. Locke on October 16, 2014, and pled guilty to Counts 1 and 37 of the indictment. On October 20, 2014, this Court accepted the guilty plea, and Lameh is currently awaiting sentencing.

B. The Superseding Indictment

On July 22, 2015, the Government filed a superseding indictment against Scully, which added two substantive counts:

(i) Count Seventy-Four: Introduction of Unapproved New Drugs into Interstate Commerce in violation of 21 U.S.C. §§ 331(d) and 333(a)(2); and

(ii) Count Seventy-Five: Unlicensed Wholesale Distribution of Prescription Drugs in violation of 21 U.S.C. §§ 331(t) and 333(b)(1)(D).

By agreement of the parties, Scully's arraignment on the superseding indictment was postponed until October 7, 2015, the first day of jury selection. On that date, he appeared before Magistrate Judge Locke and pled not guilty to all counts.

C. The Trial

On October 8, 2015, the trial commenced. Over the course of approximately five weeks, forty witnesses, including the Defendant, testified, and the parties introduced numerous items of documentary and physical evidence. The Court notes that, as a defense

to each of the charged counts, the Defendant asserted that he lacked the requisite culpable mind state because at all times he was relying in good faith upon the advice of his counsel.

On November 10, 2015, the Court submitted 71 of the 75 charged counts to the jury.

On November 12, 2015, the jury returned guilty verdicts on 66 felony counts. As to each guilty count, the jury explicitly indicated on the verdict sheet that the Defendant had not established the defense of advice of counsel.

II. Discussion

For purposes of these motions, familiarity with the underlying trial record, which spans more than 3,500 transcribed pages, is presumed. The Court's discussion of the evidence adduced at the trial will be limited to the specific challenges presently raised by the Defendant. In this regard, references to the trial transcript are denoted as "Tr."

A. The Rule 29 Motion

1. The Applicable Legal Standards

"A defendant bears a heavy burden in seeking to overturn a conviction on grounds that the evidence was insufficient." United States v. Cruz, 363 F.3d 187, 197 (2d Cir. 2004); United States v. Si Lu Tian, 339 F.3d 143, 150 (2d Cir. 2003) (quoting United States v. McCarthy, 271 F.3d 387, 394 (2d Cir. 2001)). In particular, "a conviction will be affirmed if '*any* rational trier of fact could have found the essential elements of the crime[s] beyond a reasonable doubt.' " Id. (quoting Jackson v. Virginia, 443 U.S. 307, 319, 99 S. Ct. 2781, 61 L. Ed. 2d 560 (1979)) (emphasis in original). Stated otherwise, a Rule 29 judgment of acquittal is only appropriate " 'if the evidence that the defendant committed the crime is nonexistent or so meager that no reasonable jury could find guilt beyond a reasonable doubt.' " United States v. Temple, 447 F.3d 130, 136 (2d Cir. 2006), cert. denied, 549 U.S. 997, 127 S. Ct. 495, 166 L. Ed. 2d 373 (2006) (quoting United States v. Guadagna, 183 F.3d 122, 130 (2d Cir. 1999)).

"In assessing the evidence, a court is constrained to bear in mind that Rule 29 'does not provide [it] with an opportunity to substitute its own determination of . . . the weight of the evidence and the reasonable inferences to be drawn for that of the jury.' " Temple, 447 F.3d at 136 (quoting Guadagna, 183 F.3d at 129). Rather, "[w]here a jury has rendered a verdict of guilty, the duty of a court passing on a Rule 29 motion is to 'review all of the evidence presented at trial in the light most favorable to the government, crediting every inference that the jury might have drawn in favor of the government.' " Id. (quoting United States v. Walker, 191 F.3d 326, 333 (2d Cir. 1999)).

Of particular relevance here, " '[t]he proper place for a challenge to a witness's credibility is in cross-examination and in subsequent argument to the jury,' United States v. Roman, 870 F.2d 65, 71 (2d Cir. 1989) (quotation marks omitted), not in a motion for a judgment of acquittal." United States v. Truman, 688 F.3d 129, 139 (2d Cir. 2012); see United States v. Ashburn, 11-cr-303, 2015 U.S. Dist. LEXIS 115629, at *44 (E.D.N.Y. Aug. 31, 2015) (" 'Matters of competing inferences, the credibility of witnesses, and the weight of the evidence are within the province of the jury,' and the court is 'not entitled to second-guess the jury's assessments' " (quoting United States v. Rea, 958 F.2d 1206, 1221-22 (2d Cir. 1992))). "It is the province of the jury and not of the court to determine whether a witness who may have been inaccurate, contradictory and even untruthful in some respects was nonetheless entirely credible in the essentials of his testimony." United States v. O'Connor, 650 F.3d 839, 855 (2d Cir. 2011).

In this regard, relevant circumstances bearing upon a witness's testimony – such as a cooperation agreement with the Government and inconsistencies in his or her testimony – are simply "factors relevant to the weight the jury should accord to the evidence, and do not [necessarily] justify the grant of a judgment of acquittal." Truman, 668 F.3d at 140 (quoting United States v. Coté, 544 F.3d 88, 100 (2d Cir. 2008)). In this Circuit, "even the

testimony of a single accomplice witness is sufficient to sustain a conviction, provided it is not 'incredible on its face,' United States v. Florez, 447 F.3d 145, 155 (2d Cir. 2006), or does not 'def[y] physical realities,' Coté, 544 F.3d at 101 (quotation marks omitted)." Id. at 139.

"In short, '[w]here a court concludes after a full analysis of the evidence in connection with a Rule 29 motion that 'either of the two results, a reasonable doubt or no reasonable doubt, is fairly possible, [the court] must let the jury decide the matter.' " United States v. Martinez, 978 F. Supp. 2d 177, 186-87 (E.D.N.Y. 2013) (quoting Temple, 447 F.3d at 137).

With these principles in mind, the Court will now turn to the Defendant's specific contentions. First, the Court will address several broad arguments that the Defendant raises in an effort to overturn all 66 guilty counts. Second, the Court will address several narrower arguments that challenge the sufficiency of the evidence relating to individual guilty counts.

2. The Arguments Directed at All Guilty Counts

The Defendant asserts three related bases for overturning all of the jury's guilty verdicts, each of which attacks the sufficiency of the evidence that he acted with the requisite criminal intent.

First, Scully contends that he established the advice of counsel defense, thereby negating criminal intent, an essential element required to sustain a conviction on any of the charges against him. Second, Scully contends that the testimony of attorney Geoffrey Kaiser, Esq. was not relevant to this case and confused the jury about the merits of his advice of counsel defense. Third, Scully contends that the totality of the evidence adduced at trial, especially the testimony of Shahrad Rodi Lameh, was otherwise insufficient to establish the criminal intent required to sustain convictions on any of the charges against him. The Court will consider each of these arguments in greater detail below.

a. As to Whether Scully Established an Advice of Counsel Defense

i. The Legal Standards

In order "to benefit from an advice of counsel defense, a party must show that he (1) 'honestly and in good faith' sought the advice of counsel; (2) 'fully and honestly la[id] all the facts before his counsel'; and (3) 'in good faith and honestly follow[ed] counsel's advice, believing it to be correct and intending that his acts be lawful." United States v. Colasuonno, 697 F.3d 164, 181 (2d Cir. 2012) (quoting Williamson v. United States, 207 U.S. 425, 453, 28 S. Ct. 163, 52 L. Ed. 278 (1908)).

Controlling authorities recognize that this rule "presupposes the defendant's solicitation of advice in good faith" and does not offer protection for someone who "willfully and knowingly violate[s] the law and [seeks to] excuse himself from the consequences thereof by pleading that he followed the advice of counsel." United States v. Beech-Nut Nutrition Corp., 871 F.2d 1181, 1194-95 (2d Cir. 1989), cert. denied, 493 U.S. 933, 110 S. Ct. 324, 107 L. Ed. 2d 314 (1989) (quoting Williamson, 207 U.S. at 453). Nor does the defense provide shelter for someone who allegedly relied upon the good faith advice of a professional, but nonetheless acted with "willful blindness" to facts that suggested his conduct was illegal. See id. at 1194 (finding "no logical reason" why a jury could not find that a defendant who relied on his counsel's advice also "studious[ly] avoid[ed] . . . gaining other pertinent information" (citing United States v. Duncan, 850 F.2d 1104, 1118 (6th Cir. 1988))).

Rather, a defendant seeking to invoke the advice of counsel defense is required to show, among other things, that he made "complete disclosure to counsel, sought advice as to the legality of his conduct, received advice that his conduct was legal, and relied on that

advice in good faith." Markowski v. SEC, 34 F.3d 99, 104-05 (2d Cir. 1994) (citation omitted).

To prevail on this defense, the Defendant is required to satisfy each element of the applicable legal standard. See Colasuonno, 697 F.3d at 181 (citing United States v. Evangelista, 122 F.3d 112, 117 (2d Cir. 1997)).

ii. Application to the Facts of this Case

The trial record contains evidence that, throughout the relevant time period, Scully was in consultation with his primary attorney, Richard Gertler, Esq., about significant aspects of his business. In this regard, Scully emphasizes that he retained Gertler in 2008, well before Pharmalogical began selling any prescription drugs – a statement that is corroborated by Gertler's billing records – and immediately began discussing the legality of parallel importing prescription drugs for resale in the United States. (Tr. 2701-02, 2711-12, 2718-19, 2332; see Def. Ex. "B"). He further maintains that he remained in regular contact with Gertler throughout the course of Pharmalogical's expansion into new product markets, and sought advice at every critical juncture. (Tr. 2791-93, 2813). In this regard, he points to the various opinion letters that Gertler prepared for him as evidence that Gertler knew about and approved of the same conduct that forms the basis of the Government's charges. (See Def. Ex. "K", "AI", "AP"). Scully claims that the purpose of seeking counsel's advice was "to make sure all the ideas [he] had were completely legal," and, apparently, Gertler repeatedly confirmed that they were. (Tr. 2719-20, 2306).

However, there was also substantial evidence, which, if believed, would defeat one or more of the essential elements of the advice of counsel defense.

(A) Whether Scully Honestly and in Good Faith Sought Gertler's Advice

At trial, there was considerable evidence adduced to suggest that Scully did not honestly and in good faith seek out Gertler's advice.

For example, Lameh disputed the notion that Gertler had been on retainer since 2008, and that Gertler was advising the company about the legality of their business concept before it began parallel importing misbranded drugs. (Tr. 1915, 2174-75). Instead, he testified that he and Scully knew their Botox was misbranded; that Scully did not suggest retaining an attorney until a potentially large client, namely, Dr. James Avellini, demanded proof of the product's legitimacy; and that Gertler's eventual opinion letter regarding the legality of selling the Botox was merely a sales tool, crafted for the sole purpose of assuaging Dr. Avellini's concerns. (Tr. 1915, 2174-75, 2181-82).

Lameh further testified that Gertler's opinion letter regarding the legality of importing and selling intrauterine devices known as Mirenas had similar origins. Critically, he testified that Pharmalogical had already begun importing and distributing misbranded Turkish-language Mirenas before receiving any opinion on the legality of that conduct. (Tr. 2182). He also testified that the sole motivation for obtaining a written opinion on the legality of parallel importing Mirenas was that another potentially lucrative client, namely, Planned Parenthood, demanded assurances as to the legitimacy of the devices and the legality of purchasing them with noncompliant labels. (Tr. 1922-24, 2175). Further, even after Planned Parenthood returned its initial order of Mirenas because they lacked the appropriate labeling; and even though Lameh testified that he and Scully "kn[ew] that there was something wrong with" the devices; the two men nevertheless decided to sell them elsewhere. (Tr. 1926).

The evidence also revealed that, prior to the preparation of the Mirena opinion letter, Scully had been advised by FDA officials that the Mirenas he sought to import were considered unapproved new drugs, the distribution of which constituted a federal crime. (See Govt. Ex. "82"). Despite this admonition, he sought out contrary advice from Gertler. (Tr. 2757-58).

Further, as the Government points out, the jury was entitled to consider certain evidentiary gaps in the trial record, which contradict Scully's version of the events. For example, Pharmalogical expanded into the sale of oncology drugs in late-2010 or early-2011, but Gertler's billing records do not reflect that he provided any legal services to Pharmalogical during this time. Despite the testimony by Scully and Gertler that those records do not necessarily reflect all of the pertinent discussions that occurred during that time period, (Tr. 2290-92), the jury was entitled to – and apparently did – conclude otherwise.

The jury also heard that, although Gertler prepared written opinion letters approving of Pharmalogical's sale of Botox and Mirenas, he was neither asked to prepare, nor did prepare a similar written endorsement of the company's expansion into cancer drugs. In this regard, the jury heard Scully and Gertler repeatedly contend that, despite appearing to relate specifically to Botox and Mirenas; and despite not stating otherwise; the opinion letters were meant to convey advice relating to every other prescription drug that Pharmalogical might potentially import and distribute. (Tr. 2360, 2369, 2452, 2515-16; 2607-10). The jury was entitled to assess the credibility of this explanation, and draw its own conclusions about whether Scully in good faith and honestly sought his counsel's advice about this important aspect of his business.

Finally, the evidence showed that, following the execution of a search warrant on Pharmalogical's offices in May 2012, Gertler was under the impression that Scully would

refrain from selling any oncology products until the Government's investigation into his business was concluded. (Tr. 2004-05, 2008, 2451, 2662-63). In fact, Scully conceded that, although the business continued to operate on a limited scale, a decision had been made to cease selling oncology products. (Tr. 2907, 2913-14, 2916). However, while under federal investigation, and without consulting Gertler, Scully formed a second company, Taranis Medical Corp., and resumed distributing misbranded cancer drugs. (Tr. 2543, 2550, 2628, 2631, 2877, 2889, 2915).

The Court notes that, at the trial, Gertler maintained that the decision to refrain from selling oncology drugs in mid-2012 was not the result of any legal opinion that Scully had committed a crime. (Tr. 2451-52). Nevertheless, the jury was entitled to draw its own inferences from the fact that Scully, unknown to his business partner and his attorney, prepared and executed written agreements creating a "sales component subsidiary" of Pharmalogical; unilaterally authorized Taranis to use Pharmalogical's wholesale license to distribute prescription drugs; acquired and stocked a warehouse space in Suffolk County; and began fulfilling orders for imported oncology drugs. (2015-19, 2030, 2453, 2550, 2628, 2631, 2877-78, 2883-85, 2889, 2915, 3038). In this case, the jury apparently concluded that these facts were not consistent with "honestly and in good faith [seeking] the advice of counsel."

Accordingly, in the Court's view, there was sufficient evidence from which a jury could reasonably conclude that Scully did not sustain his burden as to the first element of the advice of counsel defense, namely, the requirement that he honestly and in good faith sought the advice of his counsel. Therefore, his Rule 29 motion, to the extent that it seeks a judgment of acquittal as to all guilty counts on this basis, is denied.

(B) Whether Scully Fully and Honestly Laid All the Facts Before Gertler

At trial, there was also considerable evidence that Scully withheld material facts from Gertler.

For example, Lameh testified that the Botox opinion letter was based, at least in part, on false information that Scully provided to Gertler specifically in order to obtain written confirmation that could be furnished to customers. (Tr. 2181-82). In particular, by the time the men consulted Gertler regarding the legality of their Botox business, Lameh testified that he and Scully already knew the relevant packages lacked valid National Drug Codes ("NDCs") and believed them to be misbranded. (Tr. 1915, 2174-75, 2181). According to Lameh, they also knew that the deficient labeling on their products had led customers and others in the industry, including manufacturer representatives, to "badmouth" Pharmalogical and encourage prospective customers to demand proof of the authenticity of the foreign drugs. (Tr. 1943, 1946, 2174). However, the Botox opinion letter nevertheless concluded that "Pharmalogical has no reason to believe it is not in full compliance with" the relevant federal laws. (See Def. Ex. "K").

Further, as noted above, Lameh testified that Pharmalogical had already begun importing and distributing misbranded Turkish-language Mirenas before receiving any legal opinion on that subject. (Tr. 2182). In this regard, he plainly testified that he and Scully withheld this fact from Gertler because they "knew it was illegal" and wanted to respond to Planned Parenthood in a way that would secure its patronage. (Tr. 1976). Gertler confirmed that he was unaware of this fact. (Tr. 2488, 2573-74).

There was other evidence to indicate that the Mirena opinion letter was based on inaccurate or incomplete information supplied by Scully. For example, the letter is premised, in part, on the assumption that Pharmalogical purchased Mirenas directly from

the product manufacturer, namely, Bayer, or one of its authorized distributors. (Tr. 2762-63; see Def. Ex. "AI"). However, both Scully and Lameh conceded that this was untrue. (Tr. 2217, 2762). The evidence showed that even Gertler knew this was untrue. (Tr. 2533-34, 2542, 2577). Nevertheless, all three men held the letter out to customers as a reliable legal opinion.

According to Gertler, if Scully had, in fact, told any customers that he purchased products directly from the manufacturer, that statement would be false. (Tr. 2533-34). Yet, Charles Burke, of South Shore Neurologic Associates, and Dr. Faisal Waheed Paracha, of Kingston Oncology Hematology, both testified that Scully specifically told them that the company purchased products directly from the manufacturer. (Tr. 381-83, 386-91, 405, 1259, 1265). Lameh also testified that he observed Scully strongly imply to prospective customers that their products had been obtained directly from the manufacturer. (Tr. 1965).

Scully himself testified that all of the products that Pharmalogical sold "were coming from the original manufacturers," (Tr. 3043), although his testimony indicates that he could not actually verify the relevant chain of custody. In this regard, he conceded that many of the products he purchased from Ozay Pharmaceuticals, a supplier in Turkey, had come from "middlemen," not the actual manufacturer, and that he had not attempted to identify who those middlemen were. (Tr. 2931). He took a similarly misleading approach with Pharmalogical's website, which contained the carefully-crafted statement that Pharmalogical "only offer[ed] brand products from FDA approved and registered facilities." (Tr. 3043-44; see Govt. Ex. "81").

Of particular importance in this portion of the analysis, Gertler's testimony revealed that he knew very little about the authenticity of Pharmalogical's products. Initially, despite testifying that he advised Pharmalogical over the course of several years on

whether the specific labeling on its products complied with federal laws and regulations, he conceded that he never actually inspected any of the company's inventory and admitted that he "had no idea what was sold and when it was sold." (Tr. 2489, 2516, 2674).

Further, despite claiming to know the identities of Pharmalogical's suppliers, Gertler conceded that he was unaware that the company purchased the bulk of its inventory from World Medical in Great Britain and Ozay Pharmaceuticals in Turkey. (Tr. 2488, 2533, 2538, 2615). In fact, he was unaware that Scully was importing Mirenas from Turkey at all. (Tr. 2488). He was unaware that Pharmalogical was selling products without the required "Rx Only" designation on the package, and he was unaware that Pharmalogical was unable to obtain pedigrees or certificates of authenticity from suppliers – this despite the fact that Scully told prospective customers that all of Pharmalogical's products were FDA-approved. (Tr. 696, 1259, 1265, 2617, 2674, 2744, 2926, 2930).

Further, there was substantial evidence at the trial that, in forming his opinions on the legality of Pharmalogical's business, Gertler was not adequately informed about aspects of the company's importation methods, some of which he admitted would be material to his analysis.

In this regard, the Mirena opinion letter indicates that Pharmalogical "follows all laws and regulations governing importing Mirena into the USA," thus obviating the need for Gertler to have considered the federal customs laws. However, Gertler conceded that he never even had a conversation with Scully about the methods that Pharmalogical used to move its products through customs. (Tr. 2483).

The jury heard evidence that Ozkan Semizoglu, the principal of Ozay Pharmaceuticals, advised Lameh that customs officials were being paid cash bribes to release shipments of drugs that had been seized at the border. (Tr. 1979-80). Gertler testified that he was not aware of these bribes. (Tr. 2481-82). The jury also heard evidence

that packages of prescription drugs intended for delivery to Pharmalogical were seized by customs officials, sometimes permanently. (Tr. 1978-79; see Govt. Ex. "179"). Gertler conceded that he was also unaware of this fact, (Tr. 2483, 2511, 2538), and testified that he would consider it "important to know" if this was happening to his client's packages. (Tr. 2675).

Further, Scully testified that he received written notifications when packages were seized, some of which explicitly indicated that the confiscated items were misbranded or unapproved drugs. (Tr. 2945). Gertler said he had never seen these documents, and Scully did not contend otherwise. (Tr. 1957, 2511-12, 2956-57).

Scully and Lameh both testified that they traveled to Dusseldorf, Germany in 2011 to attend a global pharmaceutical exposition at which they discussed importation methods with representatives of Ozay Pharmaceuticals. (Tr. 1976, 1983, 2828-29). In this regard Lameh testified that these discussions focused on ways to avoid having shipments of unapproved drugs seized at the border. (Tr. 1978). For example, they discussed shipping lower quantities of products per package; falsifying the declared value of the packages; and strategically spacing deliveries, all to avoid detection by federal investigators and customs officials. (Tr. 1981-82).

Gertler testified that he was unaware that Scully and Lameh had traveled to Dusseldorf for this purpose. (Tr. 2483-84, 2537). Nor was he aware that Scully was falsely identifying the contents of prescription drug packages as "samples" to avoid detection by customs officials (Tr. 2487-88); that he was deliberately causing his shipments to be sent in small packages (Tr. 2488); that he was falsely declaring that valuable shipments of prescription drugs had "no commercial value" (Tr. 2510); or that he was strategically spacing shipments one day apart (Tr. 2537).

Although Scully denied that the company engaged in such techniques to avoid detection by customs, (Tr. 2829), the jury was not required to credit his testimony, and apparently declined to do so.

Further, the jury heard evidence that, without first seeking advice from Gertler, Pharmalogical entered the market for oncology drugs via a "sales arrangement joint venture" with a Canadian company known as Quantum Solutions. (Tr. 2814-16). Although Scully maintained that he discussed the concept of a proposed joint venture with Gertler and another attorney, (Tr. 2816-17), Gertler denied this, and testified that Scully never consulted with him about Pharmalogical's licensing arrangement with Quantum, and never sought his review of the underlying contract between the two companies. (Tr. 2497-98, 2500-01, 2527).

In this regard, the jury also heard evidence regarding the details of this arrangement, including Lameh's testimony that its purpose and effect was to convince doctors' offices and clinics that they were purchasing products from a licensed and insured American supplier, namely, Pharmalogical, when in reality the products were being supplied by Quantum and shipped from Canada. (Tr. 1962-63). Scully conceded on cross-examination that Pharmalogical "was sending out invoices from a New York address . . . even though the customers were customers of Quantum, a Canadian company." (Tr. 2939-40). Gertler testified that he was not advised of these facts, and that he does not consider it proper for Pharmalogical to have been "pretend[ing]" to sell products to an end user. (Tr. 2499-2500).

There was also considerable evidence at the trial to demonstrate that Scully often effectuated a "bait-and-switch" sales technique, whereby customers of Pharmalogical would order products that were advertised on the company's website as being FDA-approved, and then receive misbranded and unapproved versions of the products. (Tr. 386, 391, 933-35,

964, 1263-65, 1267-69, 1590-94, 1609-10, 1822, 1826-30, 1860). Gertler admitted that he was unaware of this practice. (Tr. 2616-17, 2675-76).

Accordingly, in the Court's view, there was sufficient evidence from which a jury could reasonably conclude that Scully did not sustain his burden as to the second element of the advice of counsel defense, namely, the requirement that he fully and honestly lay all of the facts before his counsel.

In reaching this conclusion, the Court takes special note of an argument set forth by the Defendant in support of a judgment of acquittal. Specifically, the defense relies on a statement of law in the Second Circuit's opinion in United States v. Beech-Nut Nutrition Corp., 871 F.2d 1181, 1194 (2d Cir. 1989), that "a defendant who would rely on an advice of counsel defense is required to have disclosed all *pertinent* information in his possession to his attorney" (emphasis supplied). Focusing on the word "pertinent," the defense argues that any information Scully allegedly withheld from Gertler in seeking his counsel was mere "minutiae," and not material to Gertler's legal analysis. Stated otherwise, the defense contends that, even assuming Scully did not disclose each and every available fact to his attorney, he nevertheless disclosed all "pertinent" facts, which is sufficient to satisfy the second prong of the advice of counsel defense under Beech-Nut. The Court rejects this contention.

Initially, the Court has reservations about whether the word "pertinent" was intended to alter the scope of the advice of counsel defense as suggested by the defense. In fact, more recent Second Circuit authority omits this word from the applicable standard. See, e.g., Colasuonno, 697 F.3d at 181. However, even assuming that this argument is viable, and only the disclosure of "pertinent" facts is required for a defendant to benefit from the advice of counsel defense, Rule 29 relief is nevertheless unwarranted because the question of which facts were "pertinent" to Gertler's analysis is a factual one within the

exclusive province of the jury. In this regard, after considering the totality of the evidence adduced at the trial, the jury was free to determine for itself whether the omissions outlined above constituted mere "minutiae," as the defense contends, or whether they were relevant and material to an informed legal opinion on the legality of Pharmalogical's business. The jury apparently concluded that the latter was true, and at this juncture the Court can discern no substantial basis for disturbing that finding.

(C) Whether Scully Honestly Followed Gertler's Advice, Believing it to be True and Intending that his Actions be Lawful

As to the final element, there was evidence at trial that Scully did not honestly follow the advice provided by Gertler, believing it to be true, and intending that his actions be lawful.

In this regard, Gertler testified that he advised Scully not to actively solicit customers to purchase prescription drugs from Pharmalogical. (Tr. 2527). In fact, the Mirena opinion letter is based partly on this premise. (Tr. 2576; see Def. Ex. "AI"). However, the jury was shown fliers that Pharmalogical circulated widely to potential customers around the country, which contained a list of products the company offered for sale, and corresponding prices, some of which were accompanied by the word "Wow." Although Scully and Gertler testified that they did not consider these fliers to constitute marketing material, or advertisements, or inducements to purchase from Pharmalogical, (Tr. 2501-02, 2504, 2527, 2575, 2763-65), the jury was entitled to reach a different conclusion.

Further, Lameh testified that, following the execution of the search warrant in May 2012, he and Scully arranged for a meeting with Gertler, in order to discuss the viability of continuing to sell misbranded Botox while the FDA's investigation was pending. (Tr. 2008-09). According to Lameh, Gertler advised them that continuing to sell the unapproved

Botox was a crime, but that "the worse [*sic*] case scenario would be a misdemeanor and a slap on the wrist." (Tr. 2009).

Thus, the jury heard evidence that, notwithstanding Gertler's advice that his actions were illegal, Scully continued to conduct business as usual. (Tr. 2010-11). In this regard, Lameh testified that they "were informed" about the risks, and "knew it was wrong," but did so anyway. (Tr. 2005).

The Court further notes that this element of the advice of counsel defense contemplates more than simply whether Scully followed Gertler's advice – it also requires that he believed the advice to be true and intended that his acts be lawful. In the Court's view, there was sufficient evidence at trial to lead a rational jury to conclude that neither of these requirements was met.

In this regard, the jury was entitled to consider whether Scully unjustifiably ignored indications that Gertler's advice was not accurate. This necessarily includes Scully's own background in the pharmaceutical and medical sales industries, which allowed him to give knowledgeable and specialized testimony about a range of relevant subjects. The jury was entitled to consider Scully's superior knowledge base, together with the selective information he shared with Gertler, in determining whether he honestly believed that the advice he solicited from Gertler was true.

In addition, the trial record is replete with instances of objective bases for questioning the validity of Gertler's conclusions. For example, as noted above, Lameh testified that prospective customers and others in the industry openly questioned the legitimacy of Pharmalogical's Botox products and the legality of purchasing them in this country since they lacked valid NDCs. (Tr. 2174). In this regard, representatives of the manufacturer, Allergan, "badmouthed" Pharmalogical to prospective customers and urged them to demand proof of authenticity. (Tr. 1943, 1946, 2174). The jury was entitled to

assess the credibility of, and reject, Gertler's testimony that his conclusions regarding the legality of selling foreign Botox were not altered when attorneys for Allergan threatened to refer Pharmalogical for criminal prosecution. (Tr. 2316-19, 2338-39).

Further, there was evidence that, in 2010, the FDA's Division of Drug Information advised Scully that federal law prohibited the interstate shipment and importation of unapproved new drugs, including "a foreign-made version of a U.S. approved drug that has not been manufactured in accordance with FDA approval." (See Govt. Ex. "82"). The FDA explicitly advised him that the Mirenas he sought to import came within this prohibition. Nevertheless, on this and other occasions, Scully concluded that the FDA officials "weren't understanding what [he] was trying to speak to them about," (Tr. 2754), and sought advice from Gertler, who reached a conclusion which was contrary to the conclusion of the FDA and omitted any reference to the FDA's warning in his nine-page opinion letter on this subject. (Tr. 2582-83, 2757-58).

Although Scully offered a legitimate explanation for consulting with Gertler in this regard – namely, that the FDA had given him inconsistent responses to the same question – a rational jury could have concluded that these circumstances presented a reasonable basis for believing that Gertler's advice was not true. This is especially so in light of the fact that, even after reviewing Gertler's opinion letter on the subject, Planned Parenthood returned its initial order of Mirenas, citing deficient labeling as the reason. (Tr. 1924, 2773-74). Other customers, including Advanced Women's Healthcare, also demanded refunds for Mirenas that they purchased from Pharmalogical on account of foreign-language labeling. (Tr. 1479). Gertler was apparently unaware of this fact. (Tr. 2489, 2621, 2676).

Further, the jury was entitled to consider the evidence that packages of prescription drugs intended for delivery to Pharmalogical were, on occasion, falsely declared as "samples" having "no commercial value"; that e-mail correspondence demonstrated

questionable efforts by Ozay Pharmaceuticals to successfully ship products into the country; and that some of these shipments were permanently seized at the border. In this regard, the jury was entitled to assess whether Scully reasonably believed Gertler's advice to be true, when he admittedly received written notifications from FDA investigators that certain confiscated packages contained misbranded or unapproved drugs, and yet failed to share this information with Gertler. (Tr. 1957, 2511-12, 2945, 2956-57).

Further, there was evidence at the trial that, in April 2010, the FDA issued a bulletin, warning doctors and pharmacies in this country about the presence on the market of a counterfeit version of the cancer drug Altuzan. (Tr. 1985-86). Despite this alert, Gertler concluded that it was "fine" to continue selling Altuzan, even though the relevant FDA bulletin was shown to the jury and states unequivocally that Altuzan "is not approved by the FDA." (Tr. 1987; see Govt. Ex. "73").

Perhaps the most obvious basis for Scully to doubt the truth of Gertler's opinions is the fact that his warehouses were raided by federal agents on two separate occasions, (Tr. 1996, 2890-92, 2919), but he nevertheless received consistent advice from Gertler that his actions were not illegal. This was so, even after Gertler's law firm prepared a legal memorandum plainly concluding that, because Pharmalogical's products lacked the required "Rx Only" designations, "they are considered 'misbranded' and subject to seizure if they were to be offered for sale in the U.S," and that "even where a drug has the identical formula, if it is not manufactured and packaged in a facility listed on the drug's NDA [new drug application], then the drug is no[t] FDA approved and is considered an 'unapproved new drug.' " (Tr. 2003-04; see Govt. Ex. "221").

Based on the foregoing, in the Court's view, there was sufficient evidence to lead a rational jury to conclude not only that Scully failed to honestly follow the advice of his counsel, but also that he selectively chose which portions of that advice to follow in the face

of objective indications that, on the whole, it was materially flawed. The jury was within its authority to rely on both of these circumstances in concluding that Scully failed to sustain his burden as to the third element of the advice of counsel defense.

Based on the foregoing, to the extent that Scully seeks a judgment of acquittal as to all guilty counts on the ground that he established an advice of counsel defense, his Rule 29 motion is denied.

b. As to Whether the Testimony of Geoffrey Kaiser, Esq. was Relevant or Confused the Jury

The Defendant further contends that the testimony of attorney Geoffrey Kaiser was not relevant to this case and sufficiently confused the jury so as to warrant Rule 29 relief. In particular, the defense argues that Kaiser's testimony gave the jury the wrongful impression that he was Scully's attorney, and therefore misled the jury into believing that his advice regarding the illegality of some of Pharmalogical's business practices was sufficient to defeat Scully's advice of counsel defense. The Court finds that this argument lacks merit.

By way of relevant background, on November 5, 2015, following the conclusion of the defense case-in-chief, the Government called Kaiser as a rebuttal witness. (Tr. 3079). Kaiser appeared in court pursuant to a Government subpoena. (Tr. 3080, 3105).

Kaiser is a former federal prosecutor in the Eastern District of New York, where he served as the deputy chief in the public integrity section and chief of healthcare fraud prosecutions. (Tr. 3080-81). In this capacity, he handled matters involving the federal Food, Drug and Cosmetic Act, and led related investigations against corporate entities. (Tr. 3085-86).

After the execution of the search warrant on Pharmalogical's offices in May 2012, Lameh retained Kaiser to represent him in connection with the FDA's ongoing

investigation. (Tr. 2896). In particular, a joint defense agreement was entered into by Richard Gertler, as counsel for the corporation, namely, Pharmalogical; Peter Tomao, Esq., as counsel for Scully; and Kaiser, as counsel for Lameh. (Tr. 2000, 3081-82). Kaiser testified that the agreement "provided that the parties, although separately represented, could consult with one another, share information, exchange views and advise [*sic*] without losing the protection of the attorney/client privilege which each of the parties would otherwise enjoy." (Tr. 3082). Thus, according to Kaiser, all three attorneys participating in this arrangement attended in-person meetings with Scully and Lameh, and were copied on all relevant e-mail correspondence. (Tr. 3082-84).

However, Kaiser acknowledged that the joint defense agreement did not establish an attorney-client relationship between himself and Scully. (Tr. 3106-08). He also conceded that, because he was not retained until mid-2012, he had no knowledge of the legal advice that was given to Scully prior to that time. (Tr. 3111-12).

Relevant here, Scully testified that, immediately after the execution of the search warrant, Pharmalogical continued selling prescription drugs that contained foreign-language labeling and lacked the required "Rx Only" designation. (Tr. 2906-07, 3034). In this regard, he testified that Gertler had advised him that it was lawful to continue operating in this way until further notice. (Tr. 2911).

However, over the defense's objection, Kaiser testified that, to the extent Pharmalogical's products lacked the required "Rx Only" designation or otherwise contained labeling that was not intended for the United States market, he believed they were misbranded. (Tr. 3090, 3096). He further testified that he had an "ongoing concern" about Pharmalogical's sale of these products, and that he had "multiple communications" with Scully and Lameh about the fact that distributing unapproved or misbranded drugs was a crime. (Tr. 3090-93, 3096-98, 3100).

According to Kaiser, he was unaware that Scully and Lameh were continuing to sell misbranded products after the execution of the search warrant. (Tr. 3102, 3117). In fact, during his involvement in the case, he testified that "the conversations [among the joint defense participants] were always . . . that you couldn't [sell products without the "Rx Only" designation]. So the assumption was, from my perspective, was that that advice was being executed. I never received information that it was being ignored." (Tr. 3117).

This is consistent with relevant correspondence between Kaiser and the other members of the joint defense agreement, which was submitted in evidence. In particular, in a June 19, 2012 e-mail, Kaiser cautions that, to the extent Pharmalogical was selling oncology drugs without the "Rx Only" designation on the packaging, they "w[ould] not be able to challenge the [FDA] agent's claim that [the drugs] are misbranded . . ." (Tr. 2006-07, 3088-89; see Govt. Ex. "222" & "230-A").

Further in response to an August 3, 2012 cease-and-desist letter from Medicis, the company that owned the exclusive distribution rights for a medical product known as Restylane in the United States, Kaiser advised the group that: "Insofar as you are in possession of a version of Restylane . . . that is not FDA-approved for sale in the U.S., you clearly cannot sell it. We've talked about that issue previously." (Tr. 2339-41, 3095-96; see Govt. Ex. "231"). Kaiser's August 6, 2012 e-mail also stated, in relevant part, that "Medicis's claims [ ] highlight something we have discussed *many times before*, and that is the importance of ensuring that the products you sell are FDA-compliant in all respects . . ." (Tr. 3097-98) (emphasis supplied).

Turning to the instant motion, the Court finds that Kaiser's testimony was relevant to the issues in this case, including, but not limited to, whether Scully honestly believed Gertler's advice regarding the legality of his business to be correct – an essential component of the advice of counsel defense. As noted above, the jury was entitled to consider evidence

that Scully acted with "willful blindness" to indications that his attorney's advice was not accurate, which necessarily includes the proof that Kaiser repeatedly voiced concerns to Scully that his actions were illegal.

Further the trial record is abundantly clear that Kaiser was never Scully's attorney, and that the joint defense agreement did not establish an attorney-client relationship between them. (Tr. 2896, 3108). In this regard, Kaiser testified unequivocally that he was not retained until mid-2012, and thus has no personal knowledge of the legal advice that was given to Scully prior to that time. (Tr. 3111-12).

Under these circumstances, the Court can discern no substantial risk of jury confusion resulting from Kaiser's testimony, and the defense does not identify any. Of note, the defense does not raise any issue with the substance or clarity of the instructions to the jury regarding the advice of counsel defense. Nor do they point to evidence in the record that the jury was, in actuality, confused. Rather, in a legal memorandum, the defense surmises that "[t]he only rational explanation" for the jury's rejection of Scully's advice of counsel defense "is that they failed to understand it or were confused by Kaiser's irrelevant testimony." Def. Br. at 14.

In the Court's view, this reasoning, lacking in evidentiary support, falls far short of the defense's burden under Rule 29. This is particularly true in light of the discussion above, which makes clear that there was more than enough evidence adduced at trial to lead a rational jury to reject the advice of counsel defense, even without Kaiser's testimony.

Accordingly, Scully's Rule 29 motion, to the extent that it seeks a judgment of acquittal as to all guilty counts on the basis that Geoffrey Kaiser's testimony was irrelevant and improperly confused the jury, is denied.

c. As to the Sufficiency of the Evidence Relating to Criminal Intent

The Defendant also contends that the totality of the evidence adduced at trial was insufficient to establish that he acted with the intent to defraud anyone. For this proposition, the defense relies primarily upon the following exchanges that occurred during the cross-examination of Lameh:

> Q: . . . [Y]ou and Pharmalogical never had intentions to ever selling [*sic*] a fake drug, correct?
> A: Correct.
> Q: You only were in business to sell authentic drugs. Fair enough?
> A: Yes.
> Q: You never wanted to hurt anybody. Fair?
> A: Correct.
>
> * * *
>
> Q: It was Pharmalogical's policy and MDK's general policy, that if a doctor was not satisfied with a product, and they didn't open it, they could return it and get their money back, correct?
> A: Yes.
> Q: So you guys were not looking to rip off anyone, were you?
> A: Of course not.
> Q: You weren't looking to defraud, give them something they didn't want and then not let the mget their money back?
> A: Of course not.

(Tr. 2071, 2076).

In the Court's view, these isolated portions of an otherwise expansive trial record cannot suffice to sustain Scully's heavy burden of overturning the jury's verdict. In this regard, the Court notes that the twelve lines of trial transcript reproduced above are extracted from a larger record that exceeds 3,500 pages in length, 240 of which reflect Lameh's testimony over the course of two days. (Tr. 1876-2010, 2112-2220). Thus, to the extent that the defense suggests that this limited portion of favorable testimony is representative of the totality of the evidence – or even of Lameh's broader trial testimony – its contention is unavailing.

In any event, this portion of Lameh's testimony is substantially contradicted by the other testimony that he gave at the trial, which generally conceded that he and Scully knowingly engaged in illegal conduct designed to defraud customers, customs officials, and the FDA, all in the pursuit of financial gain. (Tr. 1915, 1926, 1931, 1965-69, 1970-72, 1984-85, 2174-75, 2177-78, 2005, 2010-11, 2014, 2181-82, 2211). In fact, it cannot be overlooked that Lameh pled guilty to charges arising from his involvement in the very same conduct that forms the basis of the current charges against Scully. (Tr. 1878-79).

In the Court's view, the apparent inconsistencies in Lameh's trial testimony created a factual question for the jury to resolve in the first instance, and which this Court is prevented from second-guessing on a Rule 29 motion. See O'Connor, 650 F.3d at 855 ("It is the province of the jury and not of the court to determine whether a witness who may have been inaccurate, contradictory and even untruthful in some respects was nonetheless entirely credible in the essentials of his testimony"); Truman, 668 F.3d at 140 (holding that the existence of inconsistencies in a witness's testimony is simply one "factor[ ] relevant to the weight the jury should accord to the evidence, and do[es] not justify the grant of a judgment of acquittal"). Therefore, the Court finds that the Defendant's reliance upon these isolated portions of Lameh's testimony is insufficient to sustain his burden on this motion.

Further, in challenging the verdict, the defense relies upon Scully's testimony that, on several occasions, he attempted to contact the FDA directly for guidance as to the legality of his business. In this regard, the defense urges the conclusion that "individuals who intend to defraud their customers and the government [ ] do not reach out time and again to the FDA for guidance." Def. Br. at 15.

However, the Court is not persuaded that this evidence requires a judgment of acquittal. Initially, this theory was repeatedly argued to the jury at the trial, but was

ultimately rejected. For example, in his opening statement, defense counsel told the jury that "Liam himself, and Liam's lawyers, reached out on multiple occasions to the FDA to find out if their business ideas were lawful. Ladies and gentlemen, I submit to you that the evidence will show that criminals do not reach out to the FDA to run their business ideas past them." (Tr. 82). Again, in his closing argument, defense counsel contended that "we know that Liam Scully reached out to the FDA multiple times. This is not what criminals do, ladies and gentlemen." (Tr. 3372). The jury apparently did not accept this premise.

Rather, the jury was entitled to, and apparently did, credit the evidence indicating that Scully was knowingly engaged in the importation and distribution of misbranded drugs well before he attempted to seek guidance from the FDA. In this regard, as noted above, the jury heard evidence that the FDA responded to Scully's inquiries with indications that his conduct was, in fact, not legal, but that he nevertheless sought a more favorable opinion on the same subject matter from his attorney, who prepared a nine-page opinion letter omitting any reference to the FDA's feedback.

In reaching this conclusion, the Court reiterates that Scully offered a seemingly legitimate explanation for these events, namely, that he received apparently conflicting responses from the FDA, and therefore sought legal advice to obtain a definitive opinion as to the legality of his actions. However, as noted in this opinion, assessments of witness credibility are fundamentally and exclusively within the province of the jury. In this regard, the jury was entitled to evaluate the credibility of Scully's testimony in the context of the broader trial record, and determine whether it created a reasonable doubt as to criminal intent.

Viewing this evidence in the light most favorable to the Government, and drawing all inferences in the prosecution's favor, see Temple, 447 F.3d at 136, the Court finds that, despite his apparent efforts to contact the FDA directly, the trial record as a whole could

have led a rational jury to find that Scully acted with the requisite culpable mind state to sustain the challenged convictions. Accordingly, to the extent that Scully seeks a judgment of acquittal as to all guilty counts on this basis, his Rule 29 motion is denied.

3. The Arguments Directed at Individual Guilty Counts

As noted above, the Defendant also challenges the sufficiency of the evidence used to convict him on certain individual counts of mail fraud; wire fraud; introducing misbranded drugs into interstate commerce; and receiving misbranded drugs in interstate commerce and delivering them for pay (collectively, the "Fraud Statutes"). After outlining the applicable legal standards, the Court will proceed to address the merits of each individual contention in greater detail.

a. The Legal Standards

i. The Mail and Wire Fraud Statutes

The essential elements to be proven in order to procure a conviction under the federal mail and wire fraud statutes are the same, namely: (i) a scheme to defraud victims, (ii) of money or property, (iii) through the use of the mails or wires. See Fountain v. United States, 357 F.3d 250, 255 (2d Cir. 2004), cert. denied, 544 U.S. 1017, 125 S. Ct. 1968, 161 L. Ed. 2d 856 (2004) (wire fraud); United States v, Walker, 191 F.3d 326, 334 (2d Cir. 1999), cert. denied, 529 U.S. 1080, 120 S. Ct. 1702, 146 L. Ed. 2d 506 (2000) (mail fraud).

" 'Proof of fraudulent intent, or the specific intent to harm or defraud the victims of the scheme, is an essential component of the 'scheme to defraud' element' of the mail [and wire] fraud statute[s]." United States v. Karro, 257 F.3d 112, 117 (2d Cir. 2001) (quoting Walker, 191 F.3d at 334).

However, it is well-settled that these statutes do not require proof that the harm contemplated by the Defendant actually materialized. See United States v. Binday, 804 F.3d 558, 574 (2d Cir. 2015) (citing United States v. Novak, 443 F.3d 150, 156 (2d Cir.

2006)). Stated otherwise, "[t]he government does not need to prove that 'the scheme successfully defrauded the intended victim,' " only that "some actual harm or injury was *contemplated* by the schemer." United States v. Abdallah, 840 F. Supp. 2d 584, 608 (E.D.N.Y. 2012), aff'd, 528 F. App'x 79 (2d Cir. 2013) (quoting United States v. Dinome, 86 F.3d 277, 283 (2d Cir. 1996)) (emphasis in original).

ii. The Federal Food, Drug and Cosmetic Act

Relevant here, the following actions constitute violations of the federal Food, Drug and Cosmetic Act ("FDCA"):

> The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded [and]
>
> The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

21 U.S.C. § 331(a) & (c).

A defendant is guilty of a felony violation of these provisions "if he has acted with 'intent to defraud or mislead.' " Beech-Nut, 871 F.2d at 1195 (quoting 21 U.S.C. § 333(b)); see United States v. Milstein, 401 F.3d 53, 69 (2d Cir. 2005) (noting that "[t]he 'intent to defraud' element converts conduct that would otherwise be a misdemeanor into a felony").

Similar to the mail and wire fraud statutes, the intent required to sustain a felony conviction under the FDCA does not require proof that anyone was actually misled or defrauded. See, e.g., United States v. McConnell, 14-cr-0001, 2015 U.S. Dist. LEXIS 100779, at *19-*20 (W.D. Va. Aug. 3, 2015) (rejecting the defendant's argument that his conviction under the statute was improper because his product's purchasers were aware that the substances in question were prohibited) (citing United States v. Ellis, 326 F.3d 550, 556-57 (4th Cir. 2003)).

b. Application to the Facts of this Case

Scully contends that the evidence used to sustain convictions against him on certain, but not all, of the counts of the superseding indictment which arose under the Fraud Statutes was legally insufficient. In this regard, he asserts a series of individualized arguments, each relating to the trial evidence pertaining to a specific customer of Pharmalogical. The Court will address these arguments in kind.

i. As to the Sufficiency of the Evidence Relating to Metropolitan Pharmacy (Counts 7, 13, 24, 30, 42, 48, 59 & 65)

First, the Defendant challenges the jury's verdict as to the counts that relate to Metropolitan Pharmacy ("Metro Pharmacy"), a fictional entity created by the FDA for the purpose of making undercover online purchases of prescription drugs from MDK. (Tr. 1818-19).

Relevant here, FDA Special Agent Matthew Comerford testified that, at the time of the purchases, he was conducting an investigation into Pharmalogical's business practices; that he believed the company was selling misbranded drugs; and that he was affirmatively seeking to obtain evidence of this fact. (Tr. 1857-58). Thus, as to these transactions, the Defendant contends that Agent Comerford was not actually misled, and the evidence was therefore insufficient to sustain convictions under the Fraud Statutes. See Def. Br. at 16 (arguing that Agent Comerford "had clear expectations when placing the orders" and did so "for the sole purpose of receiving misbranded goods to obtain evidence [that the FDA] could use to charge Mr. Scully"). This contention is without merit.

In United States v. Abdallah, 840 F. Supp. 2d 584 (E.D.N.Y. 2012), following a jury trial, the defendant was convicted of securities fraud, wire fraud, and conspiracy to commit both offenses. In a subsequent Rule 29 motion, the defendant argued that the evidence at trial had been insufficient to support a conviction under the wire fraud statute. In

particular, the evidence had shown that a telephone conversation occurred between the defendant and a co-conspirator, in which the defendant gave the co-conspirator specific directions about how to manipulate certain stock prices and confirmed that, in exchange, he would provide a kickback. However, unknown to the defendant, at the time of the call, the co-conspirator had been apprehended by the FBI and the telephone call was being recorded. This recording supplied the basis for the wire fraud count.

In his Rule 29 motion, the defendant in Abdallah argued that this phone call could not support a conviction under the wire fraud statute because it "was not made 'for the purpose of executing [the charged] scheme or artifice,' but was rather made to 'gain incriminating information' about the defendant, since [the co-conspirator] was cooperating with the FBI at the time he made the phone call." 840 F. Supp. 2d at 608. The Court notes that this is substantially the same argument that Scully asserts in this case, namely, that Agent Comerford's online purchases cannot support a conviction under the Fraud Statutes because he was making them specifically in order to gain incriminating information.

The district court in Abdallah rejected this argument, noting that, in order to satisfy the elements of wire fraud, "it is the *defendant's* intent that is relevant, not [the co-conspirator]'s intent." Id. (emphasis in original). The court stated that that the defendant's argument "had no merit" because he "intended to continue the scheme to defraud, and believed he was using the wires to further that scheme." Id.

Further, the district court noted that other courts have "flatly rejected" the argument "that the use of a government agent in a telephone call with the defendant makes the offense of wire fraud legally impossible." Id. (citing, among others, United States v. Hammond, 598 F.2d 1008, 1010 (5th Cir. 1979) (upholding a wire fraud conviction where the defendant discussed a fraudulent scheme on the telephone with an undercover FBI agent) and United States v. Sanders, 893 F.2d 133, 138 (7th Cir. 1990) (finding it

"untenable" to interpret the wire fraud statute as "requir[ing] proof that someone actually lost money or property as a result of the scheme" and observing that "[t]he aim of the mail and wire fraud statutes is to punish the scheme to defraud rather than the end result").

Applying these principles, the Court finds that Scully's position with regard to Metro Pharmacy is legally untenable. In this regard, it is well-settled that convictions for mail and wire fraud do not require proof that the Defendant's scheme successfully defrauded anyone – only that he intended for some harm or injury to occur. Therefore, it is of no moment whether Agent Comerford was actually misled by the MDK website, or whether he was successfully defrauded when he received the same products he ordered. What matters is whether the Defendant effectuated the subject transactions intending that the other party be defrauded.

In the Court's view, this reasoning applies with equal force to the charges arising under the FDCA. As noted above, in order for felony liability to attach, the plain language of the statute requires only proof of an "intent to defraud or mislead." The Court can discern no basis for interpreting this language as also requiring proof that the intended victim was, in actuality, defrauded or misled.

In reaching this conclusion, the Court notes that Scully's reliance on the case of Neder v. United States, 527 U.S. 1, 119 S. Ct. 1827, 144 L. Ed. 2d 35 (1999), is misplaced. Relevant here, the Neder case recognized the element of "materiality" in cases arising under the federal mail and wire fraud statutes – that is, in order to sustain a conviction for mail or wire fraud, the underlying "scheme or artifice to defraud" must involve a "material falsehood." Scully argues that any representations he made to Metro Pharmacy were not material, as a matter of law, because Agent Comerford did not actually rely on them. In this regard, Scully reiterates his earlier contention that convictions for mail and wire fraud cannot stand where the alleged victim was not actually misled. See Def. Br. at 17

(asserting that Agent Comerford "never believed anything other than the fact that Pharmalogical was selling misbranded drugs"). For substantially the same reasons as outlined above, this argument lacks merit.

As the Court has noted, in order to uphold Scully's convictions in this regard, there simply is no legal basis for requiring proof that Agent Comerford actually relied to his detriment on Scully's or MDK's misrepresentations. All that is required is Scully's intention that his conduct cause his customers to be misled – a condition apparently proven to the satisfaction of the jury.

Accordingly, to the extent Scully contends that a judgment of acquittal is warranted as to Counts 7, 13, 24, 30, 42, 48, 59 & 65 on the ground that there was insufficient evidence at trial to establish that he succeeded in defrauding or misleading Agent Comerford, his Rule 29 motion is denied.

ii. As to the Sufficiency of the Evidence Relating to Sierra Nevada Cancer Center (Counts 3, 4, 5, 8, 20, 21, 23, 26, 38, 39, 41, 44, 55, 56, 58 & 61)

Scully also challenges the sufficiency of the evidence relating to Sierra Nevada Cancer Center ("SNCC"). Dr. Jorge Perez testified that, after receiving a fax advertisement from MDK in 2011, he and his staff investigated the legitimacy of the company, including by viewing MDK's website, which "appeared [ ] legitimate"; indicated that the company was "fully licensed and insured"; and featured photographs of the products it was offering for sale. (Tr. 261-63). In this regard, Dr. Perez testified that he specifically recalled seeing photographs of English-language oncology drugs on the website, which appeared to be FDA-approved. (Tr. 263).

On June 3, 2011, Dr. Perez placed an initial order for oncology drugs with MDK, which, when they arrived, the staff at SNCC noticed bore foreign-language labeling. (Tr. 265, 268, 281). Dr. Perez testified that the pharmacy technician at SNCC contacted

MDK to inquire about this issue, but received assurances that the labels were not a problem. (Tr. 268). He testified that, based on these assurances, SNCC placed approximately 29 additional orders over the next nine months. (Tr. 268-69, 285).

For purposes of this motion, the Defendant focuses on portions of Dr. Perez's testimony on cross-examination, namely, that, in January and February 2012, SNCC had also been purchasing medications, including Altuzan, from a Canadian company known as Quality Specialty Products, which did not provide proof to SNCC that it was licensed or insured in the United States. (Tr. 290-92). The defense also focuses on the fact that Dr. Perez and SNCC came under federal investigation in Nevada in 2012, which resulted in the FDA confiscating prescription medications from SNCC, including Mabthera. (Tr. 295, 298). He eventually entered into a pretrial diversion agreement with the Government, under which he accepted responsibility for knowingly receiving misbranded drugs in interstate commerce. (Tr. 299-301). The Defendant relies on these facts as proof that Dr. Perez was not defrauded.

However, as noted above, to procure convictions under the Fraud Statutes, the Government was not required to establish that Dr. Perez was actually defrauded. In the Court's view, Dr. Perez's acceptance of responsibility for knowingly receiving misbranded drugs in interstate commerce is not probative of Scully's guilt in this case. There is no evidence that Scully knew that Dr. Perez had come under federal investigation in Nevada. Nor is there evidence that Scully knew SNCC may have also been purchasing misbranded drugs from Quality Specialty Products in Canada. Rather, the evidence that is relevant to the challenged counts is the testimony of Dr. Perez that Scully advertised his products as FDA-approved; fulfilled SNCC's orders with misbranded and unapproved versions of the drugs; and then assured Dr. Perez's staff that the deficient labeling on those products was not problematic, evidencing an intent to defraud. In the Court's view, this evidence was

sufficient to lead a rational jury to conclude that the Government had satisfied the essential elements required to convict Scully under the Fraud Statutes.

Accordingly, to the extent Scully contends that a judgment of acquittal is warranted as to Counts 3, 4, 5, 8, 20, 21, 23, 26, 38, 39, 41, 44, 55, 56, 58 & 61 on the ground that there was insufficient evidence at trial to establish that he succeeded in defrauding or misleading SNCC, his Rule 29 motion is denied.

iii. As to the Sufficiency of the Evidence Relating to Hematology Oncology Center of Iowa (Counts 10, 11, 14, 27, 28, 31, 45, 46, 49, 62, 63 & 66)

The Court reaches the same conclusion with regard to Scully's challenge to the evidence relating to the Hematology Oncology Center of Iowa ("HOCI"). Mitchell Harris, the director of clinical operations at HOCI, testified that he also received a fax advertisement from MDK in February 2012, and after speaking with Scully on the telephone about various administrative matters, placed an initial order for chemotherapy drugs. (Tr. 927-28, 930, 932). Harris testified that he viewed MDK's website, and specifically recalled that it featured photographs of prescription drugs bearing English-language labeling, which appeared to be FDA-approved. (Tr. 930-31).

After placing several orders between February and April 2012, Harris observed that he had received Altuzan from MDK, despite ordering Avastin. (Tr. 935). This led him to contact the product manufacturer and send photographs of what he had received. (Tr. 936). Eventually, federal agents confiscated the drugs from his medical office. (Tr. 937).

As the defense points out, Harris continued ordering products from MDK after this incident. (Tr. 938). He stated that, other than the confiscated Altuzan, the other products he received from MDK "appeared to be fine." (Tr. 980). However, in June 2012, after Scully directed Harris to the website for Taranis Medical Corp, and supplied him with pricing information for that entity, Harris referred him to the FDA. (Tr. 939-40, 944-45).

With regard to Harris and HOCI, Scully again argues that the evidence was insufficient to sustain convictions under the Fraud Statutes because Harris continued purchasing products from MDK after the FDA confiscated the Altuzan in April 2012, and therefore, he could not have been defrauded. According to the Defendant, this evidence proved that Harris "knew exactly what he was purchasing and did not care that the FDA told him it was illegal." Def. Br. at 20. The Defendant also contends that HOCI was purchasing unapproved prescription drugs from a supplier known as Med Solutions, which Scully contends is located in Canada.

However, these facts relate solely to Harris's intent – not Scully's – and are therefore an insufficient basis to overturn the challenged convictions. See Abdallah, 840 F. Supp. 2d at 608. As discussed above, the sufficiency of the Government's case does not hinge on whether Scully succeeded in defrauding Harris. Rather, the critical question is whether Scully "intended to continue the scheme to defraud, and believed he was using the wires to further that scheme." Id. Thus, in the Court's view, Harris's testimony that Scully advertised his products as FDA-approved, and then fulfilled certain orders with misbranded and unapproved versions of the drugs, is sufficient to support the jury's convictions in this regard.

Accordingly, to the extent Scully contends that a judgment of acquittal is warranted as to Counts 10, 11, 14, 27, 28, 31, 45, 46, 49, 62, 63 & 66 on the ground that there was insufficient evidence at trial to establish he succeeded in defrauding HOCI, his Rule 29 motion is denied.

The Defendant also asserts a separate, narrower challenge to Counts 10, 27, 45, and 62 of the superseding indictment, which arise from MDK's alleged April 23, 2012 sale of Altuzan, an unapproved chemotherapy drug, to HOCI.

In this regard, the Government alleged that on April 23, 2012, MDK sold Altuzan to HOCI. However, Harris testified unequivocally that this was not true – that on the date in question, he received Avastin, not Altuzan. Thus, Scully contends that there is no evidence of a crime.

The Government counters by pointing to an invoice reflecting the April 23, 2012 sale, on which the product is described as "Altuzan (Avastin)." The Government also points out that the very next day, April 24, 2012, HOCI placed another order, which was also invoiced as "Altuzan (Avastin)." As to this second order, Harris testified that he received unapproved Altuzan, prompting him to contact the product manufacturer. (Tr. 961-63). Thus, the Government argues that these two invoices, which contain identical product descriptions, support the inference that the same drug, namely, Altuzan, was sold to HOCI on both occasions.

The Government further contends that this evidence is sufficient to sustain convictions under the Fraud Statutes because the jury was entitled to assess the credibility of, and ultimately reject, Harris's testimony. The Government maintains that the Court must defer to the jury's resolution of possible competing inferences to be drawn from the evidence.

As to the mail and wire fraud counts, the Court is of the view that the jury's verdict should stand. As discussed above, these statutes do not require proof that the intended fraud actually materialized. For that reason, the fact that Harris denied actually receiving Altuzan on the date in question is not determinative of this issue. See Sanders, 893 F.2d at 138 ("The aim of the mail and wire fraud statutes is to punish the scheme to defraud rather than the end result"). Rather, the mail and wire fraud statutes only require proof of an intent to defraud, together with the use of interstate mail or wires in furtherance of the scheme.

Applied here, the inclusion of Altuzan – an unapproved European trade name – on MDK's invoices from April 23 and 24, 2012, taken in the context of the broader trial record, could lead a rational jury to conclude that Scully intended to defraud Harris, who testified that he never ordered that product. Thus, viewing the evidence in the light most favorable to the Government, the Court finds that the evidence was sufficient to permit a rational jury to convict Scully of mail and wire fraud. Therefore, his Rule 29 motion, to the extent he seeks a judgment of acquittal on Counts 10 and 27 on this basis, is denied.

However, the Court reaches a different conclusion with regard to Counts 45 and 62, arising under the FDCA. As noted above, the Government charged the Defendant with violating the statute's prohibitions against: (i) introducing misbranded products into interstate commerce; and (ii) receiving misbranded drugs in interstate commerce and delivering them for pay. However, there is no evidence in the record that the April 23, 2012 transaction actually involved misbranded drugs. In fact, Harris's uncontroverted testimony suggests that the opposite is true. Thus, the Court is of the view that, even viewing the evidence in the light most favorable to the prosecution, the jury's verdict to convict on these counts is unsupported by substantial evidence in the record.

In this regard, even though the inclusion of an unapproved trade name on the relevant invoice suggests that Scully intended to defraud his customer, fraudulent intent alone is insufficient to establish a felony violation of the FDCA. Rather, the plain language of the statute indicates that, in order to convict, the jury must find, beyond a reasonable doubt, that Scully actually introduced and/or received misbranded or unapproved drugs in interstate commerce *and* that he completed these acts with the intent to defraud or mislead.

Consistent with this interpretation, the Court instructed the jury, in part, that "in order for the defendant William Scully to be guilty of introducing or delivering for

introduction into interstate commerce a drug that is misbranded, the Government must prove . . . first, that the Defendant participated in introducing into interstate commerce *one or more misbranded drugs*." It further instructed the jury that "in order for the defendant William Scully to be guilty of [receiving misbranded drugs in interstate commerce and delivering them for pay], the Government must prove . . . first, that the Defendant received in interstate commerce from locations outside the United States, *one or more drugs that were misbranded*." Thus, in order to convict, the jury was required to find, beyond a reasonable doubt, that HOCI received Altuzan from MDK on April 23, 2012 – a fact of which there was no proof.

The Second Circuit has explained that, "while [courts] defer to a jury's assessments with respect to credibility and conflicting testimony, and its choice between the competing inferences that can be drawn from the evidence, the jury's inferences must be reasonably based on evidence presented at trial, not on speculation; specious inferences are not indulged." United States v. Torres, 604 F.3d 58, 67 (2d Cir. 2010) (internal quotation marks and citations omitted).

In this case, although the jury was given wide latitude to assess Harris's credibility as a witness and resolve competing inferences from the invoices and other evidence, it was not permitted to draw a factual inference which was unsupported by, or contrary to, the evidence in the record. Therefore, in the Court's view, dismissal of Counts 45 and 62 is warranted.

Accordingly, to the extent Scully seeks a judgment of acquittal as to Counts 45 and 62 on this alternative basis, his Rule 29 motion is granted.

iv. As to the Sufficiency of the Evidence Relating to South Shore Neurology Associates (Counts 15, 18, 32, 35, 50, 53, 67 & 70), Advanced Women's Healthcare (Counts 2, 25, 43 & 60), Kingston Oncology Hematology (Counts 12, 29, 47 & 64), and Jersey Hematology and Oncology (Counts 16, 33, 51 & 68)

The Defendant next sets forth an omnibus argument that simultaneously attacks the sufficiency of the evidence as it relates to several customers, namely, South Shore Neurology Associates ("SSNA"), Advanced Women's Healthcare, Kingston Oncology Hematology ("Kingston"), and Jersey Hematology and Oncology ("Jersey HemeOnc"). The Court will summarize the testimony that is relevant to this contention.

Charles Burke testified that in late-2011, SSNA received facsimiles from MDK containing advertisements for medical supplies. (Tr. 378). According to Burke, he contacted Scully and was told that MDK purchased Botox and Rituxan, a chemotherapy drug, directly from the manufacturers, and that he was able to offer lower prices because he had a small "boutique" operation, with less overhead than larger medical supply companies. (Tr. 381-83, 391). In this regard, Scully provided SSNA with Gertler's Botox opinion letter, which further impressed upon Burke that "the product was coming from Allergan['s manufacturing facility] in Ireland directly." (Tr. 402-05).

In January 2012, SSNA began purchasing products from MDK. (Tr. 384). In particular, on May 22, 2012, SSNA ordered Rituxan, based partly on Scully's statement to Burke that the company acquires that product directly from the manufacturer. (Tr. 386-87). However, Burke testified that, despite ordering Rituxan, SSNA received Mabthera, an unapproved version of the drug. (Tr. 386, 391). Burke testified that he contacted Scully, who told him "that it was the generic version of Rituxan and it'd be fine." (Tr. 391). Following this conversation, SSNA placed one more small order for Rituxan and then ceased ordering that drug from MDK. (Tr. 392).

However, SSNA continued ordering Botox. (Tr. 392). In this regard, Burke testified that he believed he was ordering FDA-approved Botox – again, a belief that was based in part on Scully's representation that MDK purchased the product directly from the manufacturer. (Tr. 388-89). In December 2012, federal agents confiscated the Botox that SSNA had purchased from MDK. (Tr. 392-93).

Burke testified that he believed the drugs the Defendant was selling were FDA-approved; that he would not have made these purchases if he knew that the drugs were not approved; and that he also would not have made these purchases if he knew that MDK did not, in fact, purchase its products directly from the manufacturers. (Tr. 387).

Dr. Olaf Bernhard Franzon testified that, in January 2011, Advanced Women's Healthcare also received a facsimile from MDK containing an advertisement for medical supplies, including Mirena intrauterine devices. (Tr. 1745-46). The advertisement featured two different versions of the product, namely, English-language Mirenas costing $400 each, and Finnish-language Mirenas costing $350 each. (Tr. 1747).

The day after receiving this fax, Dr. Franzon testified that he approved an initial order for a product invoiced as "Mirena American." (Tr. 1747). In this regard, Dr. Franzon testified that he believed he was ordering an English-language Mirena – a belief that was confirmed when MDK charged him $400 for the product, namely, the advertised rate for the English-language version. (Tr. 1747). Dr. Franzon further testified that he believed he was approving the purchase of an FDA-approved product. (Tr. 1746, 1750).

Between January 18, 2011 and December 21, 2011, Advanced Women's Healthcare placed numerous additional orders for Mirenas from MDK. (Tr. 1754-55).

However, at an unspecified time in 2011, a discussion with a colleague led Dr. Franzon to inspect his office's inventory, and he noticed that the Mirenas were packaged in boxes containing foreign-language labeling. (Tr. 1748-49). On December 21, 2011, Dr.

Franzon wrote a letter to MDK, requesting a refund for the Mirenas "due to the concern of using non-FDA-approved devices." (Tr. 1479; see Govt. Ex. "2"). He testified that he eventually received a refund from MDK, but that if he had known that the devices were not FDA-approved, he would not have purchased them in the first place. (Tr. 1750-51). He also testified that, to the extent that the Mirenas were unapproved, he was misled into purchasing them. (Tr. 1751).

Dr. Faisal Waheed Paracha testified that he was referred to MDK through word-of-mouth in April 2012, when he formed his own medical practice, namely, Kingston Oncology Hematology. (Tr. 1254-56).

Dr. Paracha testified that, before placing any orders, he visited the website for MDK, which stated that the company was a licensed and authorized distributor of prescription drugs in the United States. (Tr. 1257). He further testified that the website featured a list of the prescription drugs being offered for sale, along with corresponding photographs of the products and their labeling. (Tr. 1257). Dr. Paracha viewed the images corresponding to certain chemotherapy drugs, including Eloxatin and Rituxan, and observed that the labeling on the drugs was written in English. (Tr. 1257-58). He testified that the versions of the drugs on the website appeared to be FDA-approved. (Tr. 1258).

After viewing the website, Dr. Paracha called MDK on the telephone and spoke with Scully. (Tr. 1258). After Dr. Paracha identified himself as a prospective customer, Scully assured him that MDK was a licensed distributor of the medications featured on the website, and that all of the drugs that it offered for sale were FDA-approved. (Tr. 1259).

On May 1, 2012, Dr. Paracha placed an order for Rituxan. (Tr. 1263). However, instead of Rituxan, he received Mabthera. (Tr. 1264). Kingston's oncology nurse noticed the discrepancy and brought it to Dr. Paracha's attention – at that time, neither of them recognized the trade name Mabthera. (Tr. 1264-65). Dr. Paracha called MDK to discuss

this issue and was assured by Scully that Rituxan and Mabthera "are the same drugs," which both contain the same active ingredient, namely Rituximab. (Tr. 1265). According to Dr. Paracha, Scully advised him that Mabthera is "the same thing as Rituxan" and "it's FDA approved." (Tr. 1265). Based on these representations, Dr. Paracha used the drug on his patients. (Tr. 1265).

On May 7, 2012 and May 10, 2012, Dr. Paracha placed two more orders for Rituxan. (Tr. 1266, 1270). On both occasions, he received Mabthera. (Tr. 1267, 1269).

Dr. Paracha testified that, following a discussion with a colleague, he contacted MDK to request the "pedigrees" for the medication that MDK had shipped him. (Tr. 1267-68). According to Dr. Paracha, by making this request, he was seeking information relating to the origins of the drugs, and their distribution history. (Tr. 1268-69). Dr. Paracha described Scully's response to this request: "He said that it's not necessary. We [MDK] don't need them. We deal with the distribution of the main manufacturers, and this is something that's not a standard [*sic*] for us to ship to practices." (Tr. 1269). Dr. Paracha was not satisfied with this response and did not place another order with MDK after May 10, 2012. (Tr. 1269).

In June 2012, Dr. Paracha received a telephone call from federal agents regarding the products he purchased from MDK. (Tr. 1270). The telephone call was followed by a visit, during which investigators advised Dr. Paracha that the drugs in question were not FDA-approved. (Tr. 1270). He testified that he would not have purchased these drugs if he had known that they were unapproved, and that he was misled by Scully's statements. (Tr. 1271-73).

Finally, Rohit Sethi, of Jersey HemeOnc, testified that he discovered MDK through an internet search for the chemotherapy drug Eloxatin. (Tr. 1586-87). Sethi testified that

he viewed the MDK website, which, among other things, stated that the company offered brand-name products which were FDA-approved. (Tr. 1587).

Between August 29, 2011 and May 22, 2012, Sethi placed approximately twenty orders, usually by telephone, for prescription drugs from MDK. (Tr. 1590-94). However, he testified that, on several occasions, the medications that he received were not the same medications he ordered. For example, on seven occasions between September 6, 2011 and February 21, 2012, Sethi ordered Rituxan, but received Mabthera. (Tr. 1590-94, 1609-10).

Similarly, on five occasions between November 28, 2011 and May 22, 2012, Sethi ordered Reclast, but received Aclasta. (Tr. 1591-94). On April 30, 2012, Sethi ordered Avastin, but received Altuzan. (Tr. 1594).

Sethi testified that he "absolutely" believes he was misled by Scully and would not have purchased any prescription drugs if he had known that they were not FDA-approved. (Tr. 1600).

In his current motion, Scully asserts that the evidence of his business dealings with these customers was insufficient to sustain convictions under the Fraud Statutes because each of them placed numerous orders over the course of several months, thereby demonstrating that they "kn[ew] exactly what they were ordering and receiving." Def. Br. at 22. However, in the Court's view, this is merely a reiteration of Scully's arguments relating to Metro Pharmacy, SNCC, and HOCI, which were already discussed and rejected.

In this regard, the Court again notes that the Government was not required to establish that these customers were actually defrauded, only that Scully possessed the intent to defraud them. Therefore, even if the evidence had shown that these witnesses knowingly and repeatedly purchased misbranded drugs from Pharmalogical – a proposition that is belied by their largely consistent accounts of being actively misled – relief under Rule 29 would not necessarily be warranted. As discussed above, in all of these instances,

the evidence, viewed in the light most favorable to the Government, was otherwise sufficient to lead a rational jury to conclude that Scully possessed the requisite fraudulent intent to sustain convictions under the Fraud Statutes.

Accordingly, to the extent Scully contends that a judgment of acquittal is warranted as to Counts 2, 12, 15, 16, 18, 25, 29, 32, 33, 35, 43 47, 50, 51, 53, 60, 64, 67, 68 & 70 on the ground that there was insufficient evidence at trial to establish that he succeeded in defrauding SSNA, Advanced Women's Healthcare, Kingston, and Jersey HemeOnc, his Rule 29 motion is denied.

v. As to the Sufficiency of the Evidence Relating to Dr. Rudolph D. Jacob (Counts 40 & 57)

Finally, Scully challenges the sufficiency of the evidence relating to his November 28, 2011 transaction with Dr. Rudolph D. Jacob. The only remaining counts arising from this transaction charge Scully with violations of the FDCA, namely, introduction of misbranded drugs into interstate commerce, and receipt of misbranded drugs in interstate commerce and delivery of those drugs for pay.

Due to illness, Dr. Jacob did not testify at the trial. Consequently, the Government voluntarily dismissed Count 6 and Count 22, which alleged mail and wire fraud, respectively, arising from the November 28, 2011 transaction. In this regard, the Government conceded that Dr. Jacob's testimony would have been necessary to establish those counts. (Tr. 2236). However, the Government specifically chose to proceed with the remaining counts under the FDCA, contending that Dr. Jacob's testimony was not necessary to sustain its burden as to them. (Tr. 2238-39).

In his Rule 29 motion, Scully now contends that the Government's failure to offer testimonial evidence regarding the November 28, 2011 transaction between the Defendant and Dr. Jacob is also fatal to the two remaining FDCA counts. In particular, Scully argues

that, without proof of any relevant communications or representations upon which Dr. Jacob relied, the documentary evidence alone is insufficient to establish that Scully possessed the specific intent to defraud Dr. Jacob.

In response, the Government contends that the documentary evidence relating to this transaction "definitively establishes" that Scully sold Dr. Jacob misbranded Botox and received money in exchange. Gov. Br. at 15. In this regard, the Government offered documentary evidence demonstrating that, on November 28, 2011, Dr. Jacob's medical office purchased twelve vials of Botox from MDK. (See Govt. Ex. "63"). A related invoice reflects that Dr. Jacob placed this order by telephone; that he paid for the products with a credit card at the time of the order; and that MDK shipped the items via UPS.

The documentary evidence also shows that, on April 19, 2012, Dr. Jacob's office wrote a letter to the Defendant, stating that several of the patients who had received treatments using the Botox purchased from MDK "complained that their Botox 'either did not work at all' or that it 'worked a little and wore off in about a week.' " (See Govt. Ex. "64"). The letter continued: "For us this represents an excessive failure rate . . . Prior to this shipment of Botox we have never had any complaints from patients about the ineffectiveness of the product." Thus, Dr. Jacob's office demanded a full refund. The Government also introduced evidence that Dr. Jacob disputed the relevant credit card charge with his bank, and ultimately obtained a fifty-percent refund from MDK.

The Government further contends that Scully's specific intent to defraud Dr. Jacob may be established through circumstantial evidence of his more general intent to deceive the FDA and the consuming public.

In this regard, the Government relies upon the Second Circuit's opinion in United States v. Milstein, 401 F.3d 53 (2d Cir. 2005). In that case, following a jury trial, the defendant was convicted of various crimes, including introducing misbranded drugs into

interstate commerce, and distributing prescription drugs without the required product pedigrees, both in violation of the FDCA. The charges arose from a scheme whereby the defendant purchased, repackaged, and sold foreign prescription drugs to doctors, pharmacists, and pharmaceutical wholesalers in the United States, all while taking substantial measures to hide his unlawful conduct from the government.

Of note, at the defendant's trial, the district court charged the jury that, under the FDCA, " 'intent to defraud' includes intent to defraud not only the wholesale distributors who made direct purchases from [the defendant] but also retail consumers and government agencies." Milstein, 401 F.3d at 69. The defendant appealed, asserting that this jury charge had violated his Constitutional rights to due process under the Fifth Amendment and the notice requirements of the Sixth Amendment. Specifically, in Milstein, the defendant argued that he had no notice he could be convicted based on evidence that he intended to defraud the government and the consuming public, rather than simply those who purchased products directly from him.

The Second Circuit rejected this argument, finding ample evidence that the defendant knew that the FDA and the end users of his products "were possible subjects of his 'intent to defraud.' " Id. at 70. Initially, the court noted that the defendant had devised "a scheme that on its face [wa]s designed to deceive all purchasers in the chain of distribution." Id. Indeed, "[t]he very nature of the fraud as alleged in the indictment implie[d] an intent to defraud customers." Id. at 70.

Further, the court found that "[b]y misleading governmental agencies, and 'thereby frustrating their efforts to protect the public,' [the defendant had] 'indirectly misled and defrauded the public,' thus contravening the 'overriding congressional purpose [of] consumer protection' embedded in these provisions." Id. at 69 (quoting United States v. Mitcheltree, 940 F.2d 1329, 1348 (10th Cir. 1991)).

Moreover, the court in Milstein identified several examples of the prosecutors alerting the defendant to the fact that they intended to prove that the FDA and the consuming public were victims of his fraud. These included a statement by the prosecutor that the prescription drugs at issue "were powerful and potentially dangerous drugs distributed with a callous disregard for the health and well being of the end users." Id. at 70. Also, the government had described the scheme as involving "counterfeit prescription drugs that were intended for injection by women having difficulty with conception and that were falsely labeled as sterile and safe for injection when, in fact, they were tainted with microorganisms that could cause infection." Id. As to the FDA, the court noted that "the indictment suggested a fraud that was reasonably understood to have been aimed at deceiving regulators." Id. The government had also indicated in court papers that it planned to prove his efforts to obstruct the FDA's investigation. See id.

The Court notes that the Defendant fails to address the Milstein case in his reply, other than to summarily declare the Government's position "ridiculous." Def. Reply Br. at 7. The Court disagrees with this assessment, and finds the Milstein case to be instructive as to the Government's burden.

Although the Defendant in this case does not assert Constitutional challenges, as did the defendant in Milstein, in the Court's view, the Second Circuit's reasoning in that case nevertheless implies that the Government may satisfy its burden of proving fraudulent intent under the felony provisions of the FDCA through evidence that the Defendant intended to deceive a government agency, such as the FDA, and the consuming public, to whom his misbranded products would ultimately be administered.

Applying these principles, the Court finds that the evidence in this case was sufficient to lead a rational jury to conclude that Scully possessed the requisite intent relative to Dr. Jacob so as to sustain felony convictions under the FDCA.

Similar to the criminal scheme in Milstein, the evidence demonstrates that Scully's scheme to import and distribute unapproved foreign drugs for sale in this country was, on its face, designed to deceive all purchasers in the chain of distribution. Although he attempted to insulate himself from this reality by asserting that Pharmalogical only sold products to doctors, pharmacies, and other healthcare professionals, it strains credulity to suggest that he did not understand that his products would ultimately be administered to patients in need of sometimes life-saving medical treatment. In fact, Scully conceded at the trial that he understood he was selling "cancer drugs" to be "infused in people." (Tr. 2962). Indeed, when asked by AUSA Kelly to assume that this case involved "cancer drugs that you [Scully] were going to send out to have infused in patients in America," Scully responded: "I don't need to assume that, because I did sell those products." (Tr. 2964-65). Further, particularly with respect to Dr. Jacob, the documentary evidence makes clear that Scully was advised by Dr. Jacob's medical office that numerous patients had been injected with Pharmalogical's Botox products, and many had complained that the drug was ineffective.

In this regard, as in Milstein, the record is replete with examples of the Government advising Scully that it intended to establish his guilt through proof that the consuming public was a primary victim of his fraud. In fact, well before the trial, the Government filed a motion *in limine* seeking to prevent the Defendant from introducing evidence that no patients were harmed by the products he sold. See DE [75] (noting "the particularly vulnerable patient population, i.e., cancer patients, that was being administered drugs sold by defendant" in support of the Government's request that Scully be precluded from asserting "that no one was harmed by the drugs he sold"). Scully vigorously opposed this motion, arguing that the effect on patients who ultimately received treatment using his products was "directly relevant" to the issues in this case. See DE [79]. Thus, in the

Court's view, it is reasonable to conclude that Scully was on notice that his intent to defraud individual customers, such as Dr. Jacob, could and probably would be established, at least in part, through circumstantial proof extending beyond those specific customers, namely, to the consuming public at large.

Further, the record is clear that the Government repeatedly voiced its intention to establish Scully's fraudulent intent through proof of his efforts to obstruct the FDA's investigation. For example, in pre-trial submissions, the Government explicitly contended that "[i]n the misbranding and other counts, the fraud extends to the FDA." See DE [75]. Also, in his opening statement, AUSA Kelly advised the jury that "[t]he evidence [would] show that defendant Scully was constantly trying to stay one step ahead of being caught" by federal authorities. (Tr. 57). Further, as outlined above, substantial evidence was introduced at the trial demonstrating that Scully and Lameh engaged in elaborate importation techniques to ensure that packages of unapproved and misbranded drugs successfully entered the country without detection by investigators and customs officials.

Accordingly, consistent with the authority of Milstein, the Court agrees with the Government that the evidence – including circumstantial evidence that Scully intended to deceive the relevant government agencies and the consuming public – was sufficient to lead a rational jury to convict Scully of felony violations of the FDCA in connection with his November 28, 2011 sale of Botox to Dr. Jacob. Thus, Scully's Rule 29 motion, to the extent it seeks a judgment of acquittal as to Counts 40 and 57, is denied.

B. The Rule 33 Motion

1. The Applicable Legal Standards

Under Fed. R. Crim. P. 33(a), "the court may vacate any judgment and grant a new trial if the interest of justice so requires." This rule, "by its terms gives the trial court 'broad discretion . . . to set aside a jury verdict and order a new trial to avert a perceived

miscarriage of justice.' " United States v. Ferguson, 246 F.3d 129, 133 (2d Cir. 2001) (quoting United States v. Sanchez, 969 F.2d 1409, 1413 (2d Cir. 1992)); see United States v. Landau, 155 F.3d 93, 104 (2d Cir. 1998) ("A district court should grant a new trial if it is convinced that the jury has reached a seriously erroneous result or that the verdict is a miscarriage of justice" (internal quotation marks and citation omitted)).

In passing on a Rule 33 motion, the Court's role is to "strike a balance between weighing the evidence and credibility of witnesses and not 'wholly usurp[ing]' the role of the jury." Ashburn, 2015 U.S. Dist. LEXIS 115629, at *62-*63 (quoting Ferguson, 246 F.3d at 133). In this regard, "[i]t is only where exceptional circumstances can be demonstrated that the trial judge may intrude upon the jury function of credibility assessment." Sanchez, 969 F.2d at 1414. For example, "[w]here testimony is patently incredible or defies physical realities, it may be rejected by the court, despite the jury's evaluation." Id.

Thus, in order to warrant Rule 33 relief, "[t]here must be a real concern that an innocent person may have been convicted," id., and that "letting [the] guilty verdict stand would be a manifest injustice," Ferguson, 246 F.3d at 134. By comparison, Rule 33 relief is not warranted where the Court is "satisfied that 'competent, satisfactory and sufficient evidence' in the record supports the guilty verdict.' " Id. (quoting Sanchez, 969 F.2d at 1414).

With these principles in mind, the Court will now turn to the Defendant's specific contentions. First, Scully challenges the Court's evidentiary ruling that precluded him from testifying about the advice he received from attorney Peter Tomao, Esq. In this regard, in its discretion, the Court held, pursuant to Federal Rule of Evidence ("Fed. R. Evid.") 403, that the danger of unfair prejudice from Scully singularly testifying to these communications – without Tomao also appearing in Court to give testimony – substantially outweighed its probative value. In his present motion, Scully contends that

this determination deprived him of his Constitutional right to fully present his advice of counsel defense, requiring a new trial.

Second, Scully contends that a new trial is warranted because the Government introduced evidence in support of certain charged offenses which were dismissed at the conclusion of the trial. According to the Defendant, this evidence was not relevant to any of the counts that were ultimately submitted to the jury, and was therefore prejudicial to the defense because it tainted the jury's verdict.

The Court will consider each of these arguments in greater detail below.

2. As to Whether the Defendant was Denied his Constitutional Right to Present a Defense

a. The Applicable Law

A criminal defendant has a fundamental Due Process right to present a defense. See Washington v. Texas, 388 U.S. 14, 19, 87 S. Ct. 1920, 18 L. Ed. 2d 1019 (1967); Washington v. Schriver, 255 F.3d 45, 56 (2d Cir. 2001) ("The right to call witnesses in order to present a meaningful defense at a criminal trial is a fundamental constitutional right secured by both the Compulsory Process Clause of the Sixth Amendment and the Due Process Clause of the Fourteenth Amendment" (internal citations omitted)).

However, the Second Circuit has observed that this right "of course, is not absolute," and a defendant " 'must comply with established rules of procedure and evidence designed to assure both fairness and reliability.' " United States v. Mi Sun Cho, 713 F.3d 716, 721 (2d Cir. 2013) (quoting Schriver, 255 F.3d at 56). "Thus, a defendant does not have an unfettered right to offer testimony that is inadmissible under the rules of evidence." Id. (citing Taylor v. Illinois, 484 U.S. 400, 410, 108 S. Ct. 646, 98 L. Ed. 2d 798 (1988)).

Under Rule 403, "[t]he court may exclude evidence if its probative value is substantially outweighed by a danger of . . . unfair prejudice." The district court is

"afforded great deference" in striking a balance between the probative value of evidence and the associated danger of unfair prejudice because "it sees the witnesses, the parties, the jurors, and the attorneys, and is thus in a superior position to evaluate the likely impact of the evidence." United States v. Quinones, 511 F.3d 289, 310 (2d Cir. 2007) (quoting United States v. Paulino, 445 F.3d 211, 217 (2d Cir. 2006)).

Relevant here, out-of-court statements may be excluded under Rule 403 even if they are deemed not to be hearsay, or fall within an established exception to the general rule against hearsay. See United States v. Kaiser, 609 F.3d 556, 572 (2d Cir. 2010). For example, "[s]uch evidence is not admissible if 'the probative value of [the] evidence for its non-hearsay purpose is outweighed by the danger of unfair prejudice resulting from the impermissible hearsay use of the declarant's statements.' " Id. at 573 (quoting United States v. Reyes, 18 F.3d 65, 70 (2d Cir. 1994)). As the Second Circuit has noted:

> [T]he fact that a statement falls within an exception to the hearsay rule does not mean that the statement is not to be classified as hearsay; nor does it mean that the statement is automatically admissible. It means simply that the statement – assuming that the criteria specified in the exception are met – is not excluded by the rule against hearsay. The court retains its normal discretion to exclude the evidence on other grounds, such as lack of relevance, improper purpose, or undue prejudice.

United States v. Gupta, 747 F.3d 111, 131 (2d Cir. 2014), cert. denied, __ U.S. __, 135 S. Ct. 1841, 191 L. Ed. 2d 722 (2015) (internal citations omitted) (emphasis in original).

In other words, an out-of-court statement does not lose its essential character as hearsay – as well as the concomitant concerns over trustworthiness and reliability – simply because it falls within an exception to the hearsay rule. Rather, "after the district court finds by a preponderance of the evidence that the hearsay statement is admissible under [an exception to the rule against hearsay], it must still perform the balancing test required under Fed. R. Evid. 403 'in order to avoid the admission of facially unreliable hearsay.' " United States v. Dhinsa, 243 F.3d 635, 655 (2d Cir. 2001), cert. denied, 534 U.S. 897, 122

S. Ct. 219, 151 L. Ed. 2d 156 (2001) (quoting United States v. Thai, 29 F.3d 785, 814 (2d Cir. 1994), cert. denied, 513 U.S. 977, 115 S. Ct. 456, 130 L. Ed. 2d 364 (1994)).

"A District Court has 'broad discretion' to admit or exclude evidence under Rule 403," United States v. Yousef, 327 F.3d 56, 121 (2d Cir. 2003), cert. denied, 540 U.S. 933, 124 S. Ct. 353, 157 L. Ed. 2d 241 (2003) (quoting United States v. Birney, 686 F.2d 102, 106 (2d Cir. 1982)), and "[e]ven erroneous evidentiary rulings rarely result in depriving a defendant of the fundamental constitutional right to present a meaningful defense," Mi Sun Cho, 713 F.3d at 721 (citing Schriver. 255 F.3d at 56); see United States v. Thomas, 581 F. App'x 100, 102 (2d Cir. 2014) (noting that the trial court maintains "a superior position to assess relevancy and to weigh probative value of evidence against its potential for unfair prejudice" (quoting United States v. Abu-Jihaad, 630 F.3d 102, 131 (2d Cir. 2010)).

b. Application to the Facts of this Case

Applying these principles, the Court finds that Scully's contention that he was prevented from asserting a meaningful defense at trial is without merit.

By way of relevant background, on November 3, 2015, during the defense case-in-chief, counsel sought to elicit testimony from Scully regarding opinions that attorney Peter Tomao gave to him about the legality of his business. (Tr. 2722). Although Scully initially attempted to answer counsel's question, the Court granted a motion by the Government to strike his response on hearsay grounds, namely, that it contained a statement of what Tomao told him. (Tr. 2722).

The following day, on November 4, 2015, defense counsel filed a letter motion seeking reconsideration of this ruling, contending that Scully did not intend to offer the out-of-court statements for their truth, but rather to establish their effect on Scully's state of mind at the time he was operating his business.

Following oral arguments, and after consideration of the applicable caselaw, the Court modified its prior ruling. (Tr. 2809-10). In particular, the Court relied upon Fed. R. Evid. 403 to hold that, even if, as the Defendant contended, the proposed testimony concerning communications between him and Tomao fell within an exception to the rule against hearsay – for example, to demonstrate Scully's then-existing state of mind – any probative value that this evidence may have had for a non-hearsay purpose was outweighed by the unfair prejudice that would result to the Government from its inability to cross-examine the declarant. In so holding, the Court noted that Tomao was not unavailable, and that defense counsel had not offered any rational basis for neither calling him as a fact witness nor subpoenaing him to testify.

Turning to the present motion, the Court now adheres to its evidentiary ruling that permitting Scully to give a one-sided and self-serving account of his communications with Peter Tomao posed an outsized risk of unfairly prejudicing the Government's cause at trial, even if those statements were offered for the non-hearsay purpose of demonstrating Scully's then-existing state of mind.

In this regard, the Court takes special note of the Second Circuit's observation that an out-of-court statement does not shed its fundamental character as hearsay simply because it falls within an exception to the hearsay rule. Applied here, although the hearsay rule itself may not have mandated the exclusion of Scully's proposed testimony; and notwithstanding the arguable tendency of this testimony to serve a non-hearsay purpose, namely, to demonstrate Scully's then-existing state of mind; the Court nonetheless was not satisfied that this evidence bore sufficient indicia of reliability to justify admission without the imposition of reasonable safeguards, namely, corroborating testimony by the declarant that could be subjected to cross-examination.

Thus, the Court disagrees with the Defendant's current contentions that "the issue is not one of hearsay" and that "it makes no difference if the government can or cannot cross-examine Mr. Tomao." Def. Br. at 30. On the contrary, despite the stated purpose for which Scully's testimony was offered, in the Court's view, it nevertheless bore the trappings of unreliable hearsay. This assessment is supported by the trial record as it relates to Richard Gertler. For example, throughout this case, Scully steadfastly maintained that he honestly and in good faith sought Gertler's advice at every critical juncture; that he consistently received approval from Gertler that his conduct was legal; and that he followed Gertler's advice at all times with the intent that his actions be lawful. He testified unequivocally to these facts at trial and, judging from his current motion papers, was prepared to testify similarly regarding his experiences with Peter Tomao.

However, at the time Scully sought to testify about his communications with Tomao, the Court and the jury had already witnessed the Government's thorough cross-examination of Gertler, which, as outlined above, raised serious questions as to Scully's version of the relevant events, and whether the elements of the advice of counsel defense had been satisfied. In this respect, Gertler's testimony was vital to a balanced evaluation of the evidence.

Therefore, in the Court's view, it was reasonable to require that Scully's testimony about Tomao also be accompanied by live testimony from the declarant – an adversarial safeguard intended to ensure its reliability. In this regard, the Government would have been unfairly disadvantaged if it were denied this opportunity, and, in the Court's view, the danger of such prejudice substantially outweighed the probative value to be derived from Scully's unilateral testimony as to his state of mind. This is particularly true in light of the fact that the proposed evidence relating to Peter Tomao is largely cumulative of the

evidence relating to Gertler, which is already in the record and apparently failed to raise a reasonable doubt in the minds of the jurors.

In any event, there is no basis for concluding that the Court somehow prevented Scully from asserting his chosen defense theory at the trial, or otherwise curtailed his Constitutional rights in this regard.

Initially, the Court notes that, approximately one month before the trial, the Government filed a motion *in limine* seeking to totally preclude Scully from asserting the advice of counsel defense. On October 1, 2015, over the Defendant's objection, the Court ordered that an evidentiary hearing be held to determine whether sufficient questions of fact existed to warrant permitting the jury to hear evidence in support of this defense. On October 6, 2015, following a hearing at which the Government presented evidence in support its position, the Court issued a written opinion specifically "den[ying] the Government's motion *in limine* to the extent it [sought] to preclude the presentation of any evidence in support of an advice of counsel defense at trial." See DE [103]. In particular, the Court held that it was "unable to conclude on the record before it that the evidence [was] so contrary to Scully's contentions that he should be precluded from presenting his alleged reliance on his counsel's advice to the jury," and that this outcome was warranted even without requiring Scully to present witnesses or testify himself at the *in limine* hearing. See id. at 6.

Thus, even before the trial began, the Court affirmatively granted the Defendant the right to pursue his chosen defense theory at the trial – a fact materially at odds with his current allegations.

Further, even a cursory review of the challenged evidentiary ruling reveals that it did not exclude *all* evidence of the advice of counsel defense. It did not even exclude *all* evidence relating to Peter Tomao. In fact, the record contains numerous references to

Tomao's active involvement in advising Scully with regard to his business. (Tr. 2000, 2002-04, 2006-08, 2018, 2030, 2339-41, 2721-22, 2307, 2314, 2891, 2895-96, 3088-89, 3091, 3109, 3081-82).

Rather, the Court simply conditioned the Defendant's ability to give prejudicial hearsay testimony on the Government's ability to cross-examine the declarant, namely, Peter Tomao – a local attorney, who is well-known to the Court and counsel, and who neither side contends was unavailable or beyond the reach of a subpoena at the time of trial. In the Court's view, this is entirely consistent with the Second Circuit's observation that a defendant's fundamental right to present his defense is not absolute, and must occasionally yield to established rules of procedure and evidence designed to assure both fairness and reliability. See Mi Sun Cho, 713 F.3d at 721.

Under these circumstances, the Court can discern no basis for concluding that, in the absence of Scully's proposed testimony, the jury "reached a seriously erroneous verdict," which constitutes a manifest injustice under Rule 33. Landau, 155 F.3d at 104. On the contrary, as noted above, the Court is of the view that Scully's proposed testimony regarding Tomao is largely cumulative of his testimony regarding Gertler, which the jury repeatedly rejected as insufficient to establish the advice of counsel defense. In this regard, there is no substantial reason to believe that Scully's testimony regarding his communications with Tomao would have altered his narrative in any material way. Even if it did, the verdict sheet makes clear that the jury simply did not believe Scully's testimony regarding his alleged reliance upon the advice of his counsel. Thus, the Court also cannot discern any reason to believe that the jury would have reached a different result, and acquitted Scully, based on additional self-serving testimony that Tomao, in addition to Gertler, approved of his conduct.

In sum, the Court is of the view that this evidence, had it been admitted, would have done little to offset the substantial evidence of guilt embodied in the testimony of Lameh and Pharmalogical's customers, who collectively testified to a pattern of fraudulent conduct that was inconsistent with honest reliance upon the advice of counsel. Stated otherwise, even considering the proposed testimony regarding Tomao, the Court is nonetheless "satisfied that 'competent, satisfactory and sufficient evidence' in the record supports the guilty verdict.' " Ferguson, 246 F.3d at 134 (quoting Sanchez, 969 F.2d at 1414).

Accordingly, to the extent Scully contends that a new trial is warranted because he was deprived of his Constitutional right to fully present his chosen defense, his Rule 33 motion is denied.

3. As to Whether Prejudicial Spillover Occurred

Lastly, Scully contends that a new trial is warranted because the Government introduced evidence relating to certain counts of the superseding indictment that were ultimately dismissed and not submitted to the jury. It is the Defendant's position that this evidence was prejudicial; was not relevant to the remaining counts upon which the jury actually deliberated; and that it therefore tainted the jury's verdict as to the 66 guilty counts.

By way of relevant background, on October 28, 2015, at the close of the Government's case-in-chief, the Defendant moved pursuant to Rule 29 to dismiss each of the then-remaining 73 counts of the superseding indictment. (Tr. 2235). Following extensive arguments by counsel, the Court denied the motion with respect to all but two counts: Count 72 (Fraudulent Importation and Transportation of Goods) and Count 73 (Trafficking in Counterfeit Drugs), and reserved decision as to them. (Tr. 2275).

On November 5, 2015, the defense rested. (Tr. 3078). On that date, defense counsel renewed its motion for dismissal as to Count 72 and Count 73. (Tr. 3141). Following

additional arguments, the Court granted the motion, and dismissed those counts. (Tr. 3158-60). The remaining 71 counts were submitted to the jury, who returned verdicts of guilty as to 66 of them.

As noted above, Scully now contends that two categories of evidence relating to the dismissed counts – namely: (i) evidence that some products sold by Pharmalogical were counterfeit; and (ii) evidence that Scully smuggled unapproved and misbranded drugs into this country – improperly "spilled over" into the jury's deliberations and tainted their eventual verdicts.

a. The Applicable Law

"When fewer than all criminal counts have been dismissed at trial or reversed on appeal, a court must determine whether prejudicial spillover from evidence introduced in support of the dismissed or reversed counts requires the remaining convictions to be upset." Jelinek v. Costello, 247 F. Supp. 2d 212, 276 (E.D.N.Y. 2003) (citing United States v. Rooney, 37 F.3d 847, 855 (2d Cir. 1994)). Stated otherwise, "[t]he concept of prejudicial spillover . . . requires an assessment of the likelihood that the jury, in considering one particular count or defendant, was affected by evidence that was relevant only to a different count or defendant." United States v. Hamilton, 334 F.3d 170, 182 (2d Cir. 2003).

In establishing his entitlement to a new trial on this ground, the Defendant "bears an extremely heavy burden," United States v. Friedman, 854 F.2d 535, 563 (2d Cir. 1988), cert. denied, 40 U.S. 1004, 109 S. Ct. 1637, 104 L. Ed. 2d 153 (1989), and "must show compelling prejudice" resulting from the introduction of certain evidence, Hamilton, 334 F.3d at 181-82 (quoting United States v. Vebeliunas, 76 F.3d 1283, 1293 (2d Cir. 1996)); see United States v. Gambino, 809 F. Supp. 1061, 1074 (S.D.N.Y. 1992) (noting that "claims of 'prejudicial spillover' rarely succeed").

As the parties appropriately note, the Second Circuit has developed a three-part test for determining whether there was likely prejudicial spillover from the evidence submitted in support of counts that were ultimately dismissed:

> (1) whether the evidence introduced in support of the vacated count[s] "was of such an inflammatory nature that it would have tended to incite or arouse the jury into convicting the defendant on the remaining counts," (2) whether the dismissed count[s] and the remaining counts were similar, and (3) whether the government's evidence on the remaining counts was weak or strong.

Hamilton, 334 F.3d at 182 (quoting Vebeliunas, 76 F.3d at 1294).

It has been held that "[t]he first prong of this test is not met where 'the evidence that the government presented on the reversed [or dismissed] counts was, as a general matter, no more inflammatory than the evidence that it presented on the remaining counts.' " Id. (quoting United States v. Morales, 185 F.3d 74, 83 (2d Cir. 1999), cert. denied, 529 U.S. 1010, 120 S. Ct. 1282, 146 L. Ed. 2d 229 (2000)).

As to the second prong, the Second Circuit has noted that, "[i]n cases where the vacated and remaining counts emanate from similar facts, and the evidence introduced would have been admissible as to both, it is difficult for a defendant to make a showing of prejudicial spillover." United States v. Wapnick, 60 F.3d 948, 954 (2d Cir. 1995), cert. denied, 517 U.S. 1187, 116 S. Ct. 1672, 134 L. Ed. 2d 776 (1996) (citations omitted); see United States v. Naiman, 211 F.3d 40, 50 (2d Cir. 2000) ("The trial evidence of bribery does not support a claim of prejudicial spillover because much of the evidence . . . was also admissible for purposes of the misapplication charge").

Further, the Court notes that "where the record indicates that the jury was able to distinguish between counts or between defendants, and to assess separately the evidence pertinent to each, [the Second Circuit has] found no basis for concluding that a new trial is warranted because of prejudicial spillover." Hamilton, 334 F.3d at 183. In this regard,

"[t]he absence of such spillover is most readily inferable where the jury has convicted a defendant on some counts but not on others." Id.

b. Application to the Facts of this Case

Applying these standards, the Court finds that the Defendant has not sustained his "extremely heavy burden" of establishing "compelling prejudice" from the spillover of irrelevant evidence.

As to the first prong, Scully contends that the allegations of counterfeiting and fraudulent importation, which were at the root of the dismissed counts, were of a far more serious nature than the allegations of fraud, conspiracy, and distribution of misbranded drugs, which were ultimately submitted to the jury. Thus, he contends that the evidence introduced in support of those charges necessarily poisoned the jury's verdict as to the remaining 71 counts. The Court disagrees.

Initially, in the Court's view, Scully's position unjustifiably trivializes the conduct for which he was found guilty, and exaggerates the relative severity of the conduct alleged in the dismissed counts. See, e.g., Def. Reply Br. at 13 (arguing that the allegations of fraud and conspiracy "pale in comparison" to the allegations of counterfeiting and fraudulent importation); id. at 12-13 (characterizing the evidence as showing only that he "openly ran a business where he sold authentic drugs that were in nonconforming boxes or had instructions that were in different languages and told doctors these were FDA approved"). In this regard, Scully again surmises that the only plausible explanation for the jury's rejection of his advice of counsel defense is that the jurors were shocked by evidence of "fake cancer drugs" and "smuggling." Id. at 14 ("The extreme prejudice from having the counterfeit and smuggling allegations in the case is apparent from the jury's verdict and apparent disbelief in an advice of counsel defense"). This argument is unavailing.

Although the Defendant attempts to minimize the severity and impact of the Government's case, there is no basis for substituting his subjective assessment of the evidence for that of the jury. In this regard, the record includes substantial incriminating testimony from almost forty Government witnesses, the vast majority of whom provided a largely consistent account of Scully's fraudulent scheme to distribute unapproved and misbranded prescription drugs in the United States. As discussed above, among other things, this presentation included evidence that Scully falsely advertised FDA-approved versions of prescription drugs on his website, and then fulfilled orders with unapproved versions; that he falsely advised customers that his products were FDA-approved and purchased directly from the manufacturers, when, in fact, this was not the case; and that many of the unapproved drugs he sold were ultimately administered to unwitting patients. For example, Dr. Paracha testified that he administered chemotherapy drugs purchased from MDK, based partly on Scully's representation that they were FDA-approved. Also, in the case of Dr. Jacob, the evidence showed that some patients received cosmetology injections of an ineffective product.

As outlined more fully above, the evidence was also sufficient to demonstrate that Scully effectuated his fraud partly through the use of manipulated legal opinions, which were premised on incomplete and inaccurate information, and which reached objectively questionable conclusions.

Under these circumstances, the Court can see no principled basis for concluding that the evidence introduced in support of the two dismissed counts was, as a general matter, any more shocking or inflammatory than the rest of the evidence introduced on the remaining counts. There certainly does not appear to be a basis for concluding that the challenged evidence "was so inflammatory as to make the jury convict on the basis of

prejudice rather than evidence or logic." United States v. Post, 950 F. Supp. 2d 519, 542 (S.D.N.Y. 2013).

As to the second prong, the Court finds that the dismissed counts and the remaining counts stem from the same facts, and that most of the evidence introduced at trial was admissible as to both. For example, as outlined above, there was considerable evidence at trial to suggest that Scully took affirmative measures to import unapproved and misbranded drugs without being detected by federal investigators and customs officials. For purposes of this motion, he contends that this evidence "should never have been heard" by the jury because the Court ultimately dismissed Count 72, which was based on fraudulent importation and transportation of goods.

However, in the Court's view, this evidence does not constitute prejudicial spillover because it would have been admissible at the trial in any event. For example, among other things, this evidence is highly relevant to Scully's advice of counsel defense, and would have been admissible to establish whether he fully and honestly disclosed all aspects of his business to his attorneys, including and especially Pharmalogical's importation methods. The evidence overwhelmingly demonstrated that he did not.

Further, the verdict sheet in this case makes clear that the jury ably distinguished between the various counts, and separately assessed the evidence pertinent to each. For example, of the 71 counts that were ultimately submitted to the jury, judgments of acquittal were rendered as to five unique wire fraud counts. As noted above, in this Circuit, the absence of prejudicial spillover "is most readily inferable where the jury has convicted a defendant on some counts but not on others." Hamilton, 334 F.3d at 183; see also Naiman, 211 F.3d at 50 (finding no prejudicial spillover where "[t]he specificity of the verdict that the jury rendered reveal[ed] a deliberate and measured decision. . . . [T]he jury appear[ed] to have sorted through the voluminous evidence and arrived at a rational decision").

Finally, as to the third prong, this Court is of the view that the Government's presentation was strong, and did not rely upon the emotional appeal of inflammatory, but ultimately improper evidence to secure a conviction. On the contrary, as outlined in detail above, the Court finds that there was more than enough evidence unrelated to the dismissed counts to support the jury's verdicts.

Accordingly, to the extent Scully contends that a new trial is warranted because evidence introduced in support of dismissed Count 72 and Count 73 "spilled over" into the jury's deliberations as to the remaining counts, his Rule 33 motion is denied.

III. Conclusion

Based on the foregoing, the Defendant's motion pursuant to Fed. R. Crim. P. 29 is granted in part and denied in part. In particular, the motion is granted as to Counts 45 and 62 of the superseding indictment. Accordingly, the convictions on those counts are vacated and a judgment of acquittal shall be entered as to them. The Defendant's motion for acquittal is denied in all other respects.

Further, the Defendant's motion pursuant to Fed. R. Civ. P. 33 for a new trial is denied.

SO ORDERED:

Dated: Central Islip, New York
March 16, 2016

/s/ Arthur D. Spatt
ARTHUR D. SPATT
United States District Judge