

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK**

-----X

UNITED STATES OF AMERICA

-against-

WILLIAM SCULLY, also known as “Liam Scully”

-----X

**MEMORANDUM OF
DECISION AND ORDER**
14-CR-208 (ADS)(SIL)

APPEARANCES:

The United States Attorney, Eastern District of New York

Attorney for the United States of America

610 Federal Plaza

Central Islip, NY 11722

Charles P. Kelly, Assistant United States Attorney

Brendan G. King, Assistant United States Attorney

Katten Muchin Rosenman LLP

Attorneys for the Defendant

575 Madison Avenue

New York, NY 10022

By: Scott A. Resnik, Esq.

Michael M. Rosensaft, Esq., Of Counsel

SPATT, District Judge.

On April 9, 2014, the Government filed a 73-count criminal indictment against the Defendant William Scully, also known as “Liam Scully” (“Scully” or “the Defendant”), and co-defendant Shahrads Rodi Lamah (“Lamah”)(collectively “the Defendants”).

The Government charged the Defendants, as owners and operators of Pharmalogical, Inc. d/b/a Medical Device King and MDK (“Pharmalogical”) with, among other counts, violating the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (the “FDCA”), by trafficking in prescription drugs unapproved by the federal Food and Drug Administration (“FDA”), “misbranded” drugs, and counterfeit oncology drugs.

While the Indictment sets forth 73 counts, it is only 35 pages long, with a description of the Defendants' alleged scheme only encompassing 5 pages and with the enumeration of the counts encompassing 23 of those pages.

On October 16, 2014, on referral to United States Magistrate Judge Steven I. Locke, Lamah entered a guilty plea to Counts 1 through 37 of the Indictment, including one count of conspiracy to distribute "misbranded" drugs. He did not plead guilty to introduction of "misbranded" drugs into interstate commerce; receipt of "misbranded" drugs in interstate commerce and delivery thereof for pay; fraudulent importation and transportation of goods; or trafficking in counterfeit oncology drugs.

On October 20, 2014, this Court accepted that guilty plea recommendation. Lamah is currently scheduled to be sentenced on September 18, 2015.

On February 5, 2015, Scully moved for an order (1) striking all counts based on the erroneous notion that a violation of FDA regulations can create criminal liability; (2) suppressing all emails and other evidence obtained through search warrants due to the Government's material misstatements and omissions in the search warrant affidavits and the constitutionally impermissible way that the Government executed the warrants; (3) dismissing count 73 of the Indictment; (4) dismissing count 72 of the Indictment; and (5) directing further discovery and a bill of particulars, which are necessary for defense counsel to prepare its case; and for other such other and further relief as the Court deems just and proper.

On May 15, 2015, the Court held oral argument on the motion, after which the Court reserved decision and scheduled jury selection for Tuesday, January 5, 2016. Scully agreed to a waiver of his speedy trial rights from May 15, 2015 through January 5, 2016.

For the reasons set forth, the Defendant's motion is denied except to the extent the Court grants the requests for the discovery enclosed by the Government in its motion papers; the discovery it represents it will provide; any recorded conversations with Courtney Fitt; and a Bill of Particulars as described below. The Court will now address each part of the instant motion.

I. BACKGROUND

The following facts are drawn from the indictment, the record of the proceedings before the magistrate judges that issued the search warrants, and the parties' submissions in connection with this motion. See United States v. Sanchez, No. 08-CR-0017 (CPS), 2008 WL 1926701, at *1 (E.D.N.Y. Apr. 30, 2008).

A. The May 2012 Affidavits in Support of the Office Search Warrants

In May 2012, the Government took steps to procure a search warrant for the offices of Pharmalogical and MDK, located at 425 Northern Boulevard, Suite 27, in Great Neck, New York. In support of an application for a search warrant of Pharmalogical and MDK's offices, the Government filed an affidavit sworn to and signed under oath by FDA Special Agent Thomas S. Nasiatka ("Nasiatka").

In that affidavit, Nasiatka stated that based upon an FDA investigation, Pharmalogical and MDK "have been ordering and receiving foreign drugs including cancer and chemotherapy medications such as aloxi, aredia and altuzan as well as botox and related drugs. It has been further determined that these foreign drugs have been sold and/or administered to, among others, cancer patients without their knowledge." (Doc No. 44, Exh 20., at ¶ 4.).

Nasiatka described the background of the underlying investigation. Nasiatka stated that, on February 18, 2011, he met with representatives of the New York State Department of Education, Office of Professional Discipline ("OPD") in Hauppauge, New York, who referred a

case to the FDA for investigation. As detailed in the affidavit, an unidentified complainant to the New York State Board of Pharmacy advised that he or she had received an unsolicited fax from MDK “offering oncology and rheumatology medications for sale at prices unavailable in the traditional market.” (Id. at ¶ 32.) That fax, which provided MDK’s contact number as (877) 321-5567, was attached to Nasiatka’s affidavit.

Thereafter, according to Nasiatka’s affidavit, a New York State Board of Pharmacy representative, acting in an undercover capacity, phoned MDK at (877) 321-5567 and was advised to call (516) 439-5376. The caller was allegedly told that MDK was affiliated with Pharmalogical, a licensed drug wholesaler in New York State. The undercover caller inquired as to how MDK could sell the advertised drugs at the prices offered. According to Nasiatka, the undercover caller was told, among other things, that MDK could offer these prices as it “had no sales force and shipped the drugs from overseas, as the company itself was located in the United Kingdom.” (Id. at ¶ 33.).

Following this telephone exchange, an OPD representative, also acting in an undercover capacity, phoned MDK at (877) 321-5567, left a message, and was later contacted by an individual who identified himself as Shahradi Rodi Lamah. (Id. at ¶ 34.) When asked about the discount prices, Lamah allegedly responded, among other things, that “these prices could be offered because they purchased drugs from manufacturers all over the world, except Canada.” (Id.).

OPD then attempted to conduct a site inspection of Pharmalogical, which was licensed with OPD, at the Great Neck office. After OPD investigators could not speak to the Defendant because he was unavailable, the Defendant apparently called the investigators and confirmed that Pharmalogical sold “chemo drugs” and that he would provide requested supporting invoice and

shipping documents. (Id.). However, according to Nasiakta, Scully never provided these requested documents. (Id.)

Nasiatka further stated that, on February 23, 2011, he accessed the website for the New York State Division of Corporations and confirmed that, on August 24, 2004, Pharmalogical was registered as a domestic business corporation in Suffolk County, New York. (Id. at ¶ 37.) No information was found regarding MDK. (Id.)

Nasiatka also stated that, on February 23, 2011, he accessed the websites for Pharmalogical, www.pharmalogicalinc.com and for MDK, www.medicaldeviceking.com. (Id. at ¶ 38.) The Pharmalogical website offered for sale the advertised supplement “Fibrosolve” and the dermal fillers “Botox” and “Surgiderm.” (Id.) The MDK website indicated that MDK was “Coming Soon” and offered for sale the advertised dermal fillers “Juviderm,” “Surgiderm,” and “Botox.” However, as indicated by Nasiatka, no cancer or rheumatology drugs were offered for sale on either website. (Id.)

On July 7, 2011, Nasiakta again accessed the MDK website and “learned that the site had been updated so that the products offered for sale included 52 different oncology drugs.” (Id. at ¶ 41.)

Nasiatka also stated that, on September 16, 2011, he learned from an unnamed industry representative that an unnamed private investigator had purchased two 5ml vials of Aloxi, an FDA-approved prescription cancer medication, from MDK’s website. (Id. at ¶ 42.) The price of \$140 per 5ml vial was below the established wholesale price of \$371 per vial in the United States. (Id.)

The Aloxi was apparently received by the private investigator on or about September 13, 2011. (Id. at ¶ 43.) A National Drug Code (“NDC”) number, which Nasiatka claimed that all

FDA-approved drugs have, was not present on any of the drug boxes or vials. (Id.) The return address information printed on the UPS label was that of Lisa Mingelli, 877-321-5567, MDK, 425 Northern Blvd. Ste 27, Great Neck, NY 11021. (Id.)

Nasiatka further stated that, on September 22, 2011, he learned that other FDA (OCI) offices had ongoing investigations of Pharmalogical and MDK, “as they sold unapproved Botox to medical facilities in their districts.” (Id. at ¶ 44.) In this regard, Nasiatka stated that “[s]everal undercover purchases had been made and it was determined, as in this case, that the Botox manufactured by Allergan was for foreign market distribution only.” (Id.)

Thereafter, according to Nasiatka, FDA Special Agent Peter Orlando conducted surveillance of the Great Neck office, including of vehicles parked in spaces reserved for Pharmalogical employees. Based on this surveillance, Nasiatka inquired of the New York State Department of Motor Vehicles (“DMV”) and “learned that one was registered to William J. Scully and another to Lisa M. Mongelli.” (Id. at ¶ 45.)

Nasiatka further stated that, on November 28, 2011, he directed another FDA/OCI Special Agent to access the MDK website to conduct an undercover credit card purchase of 4 vials of Aloxi 0.25mg. (Id.) Nasiatka stated that “[a]n account was set up using an undercover pharmacy name and address in Madison, New Jersey” and that “[t]he total cost of the credit card purchase was \$560.00.” (Id.) An email confirmation was received from the email address, medev1@yahoo.com, which was listed in the Domain Registrant information for MDK. (Id.)

Nasiatka stated that, on December 6, 2011, he received the order of 4 vials of Aloxi. The sender shipping label denoted Lisa Mingelli, 877-321-5567, MDK, 425 Northern Blvd. Ste. 27, Great Neck, NY 11201. (Id. at ¶ 47.)

According to Nasiatka, on February 22, 2012, he directed another FDA/OCI Special Agent to access the MDK website to conduct an undercover purchase of 3 kits of Aredia 30mg (4 vials per kit) for \$175 each.

On February 28, 2012, a message was received in the undercover email account used to place the order, from “Liam Scully.” The email stated: “Currently we can get the 90mg of Brand Aredia for \$525.00, if you are ok with it I will go ahead and order it for you. Let me know what you think, and if you want to call feel free too. Thank you. Best regards, Liam Scully.” (Id. at ¶ 51.)

Nasiatka further stated that, on April 3, 2012, the FDA issued an alert to healthcare professionals. The FDA alert stated in part that “[its] lab tests have confirmed that a counterfeit version of Roche’s Altuzan 400mg/16ml (bevacizumab), an injectable cancer medication, found in the U.S. contains no active ingredient. Even if the identified drugs were not counterfeit, Altuzan is not approved by FDA for use in the United States (it is an approved drug in Turkey). (Id. at ¶ 52.)

Thereafter, according to Nasiatka, the FDA/OCI initiated several cases to identify buyers of Altuzan. (Id. at ¶ 53.) One such investigation related to the Sierra Nevada Cancer Center (“SNCC”), located in Carson City, Nevada. (Id.) The FDA/OCI identified SNCC as possibly purchasing counterfeit Altuzan from Quality Special Products (“QSP”), located in Canada. (Id.) Nasiatka stated that, during interviews conducted at SNCC, it was learned than SNCC had also purchased foreign labeled drugs from MDK. (Id.)

During a visit to SNCC on April 3, 2012, SNCC “surrendered” 9 vials of the cancer medication, Mabthera, which was identified as purchased from MDK. (Id. at ¶ 54.) Some of the vials had foreign language labeling and some had stickers covering the foreign language

labeling. (Id.) SNCC also “surrendered” 7 vials of Altuzan 400mg, which also contained foreign labeling. (Id.) SNCC also provided 30 available invoices of purchases from MDK, dated June 6, 2011 to March 8, 2012. (Id.)

On May 3, 2012, after follow up phone conversations and emails with an MDK representative named “Courtney,” an FDA undercover agent received a package of 1 vial of Aredia 90mg and one bottle of Aloxi. (Id. at ¶¶ 56-58.) Niasatka stated that a NDC number, which all FDA approved drugs have, was not present of any of the drug boxes or vials. (Id.)

Based on this investigation, Nasiatka represented that probable caused existed to believe that evidence in the form of business records, correspondence, computer equipment, computer records, and other business records, as detailed in an attachment to the affidavit, containing information relevant to the crimes set forth in the affidavit were located at the Great Neck office of Pharmalogical. (Id. at ¶ 65.)

Accordingly, Nasiatka requested a search warrant for “permission to search and seize, among other things, all foreign labeled pharmaceuticals and all documents relating to their purchase and sale” at the Great Neck office. (Id. at ¶ 62.) Nasiatka outlined the various facial markers that distinguish foreign-market drugs from FDA-approved products, including foreign language labels; absence of the term “Rx Only”; statements that the drug was “imported by” an entity in a foreign country; and absence of an NDC number. (Id. at ¶ 63.)

Nasiatka also requested that approval of examination of any of the aforementioned records be conducted by a qualified computer evidence recovery specialist. (Id. at ¶ 66.)

Nasiatka also requested than the warrant be sealed, stating that the affidavit was part of a “covert investigation into the sale of, among other things, unapproved cancer drugs.”

(Id. at ¶ 72.) Nasiatka represented that “[r]evealing the affidavit at this time could possibly jeopardize the government’s ongoing investigation” and caused the destruction of evidence. (Id.)

B. The May 18, 2012 and May 22, 2012 Office Search Warrants and the Subsequent Execution of Those Warrants

On May 18, 2012, United States Magistrate Judge William D. Wall issued a search warrant under seal for “THE PREMISES KNOWN AND DESCRIBED AS A COMMERCIAL BUILDING, LOCATED AT 425 NORTHERN BOULEVARD, SUITE 27, GREAT NECK, NEW YORK 11201.” Judge Wall expressly relied on Nasiatka’s affidavit and noted that Nasiatka had reason to believe that certain items at the office “constitute[d] contraband, evidence, fruits and instrumentalities of violations of Title 21, United States Code, §§ 331(a) and §§ 333(a)(2).” (Doc No. 44, Exh 3.) Judge Wall directed, among other things, that the search be conducted on or before June 1, 2012; a copy of the warrant be left at the premises; and that a written inventory be prepared.

On May 22, 2012, Judge Wall issued an additional search warrant for the abovementioned premises, noting that Nasiatka had reason to believe that certain computers and hard drives “constitute[d] contraband, evidence, fruits and instrumentalities of violations of Title 21, United States Code, §§ 331(a) and §§ 333(a)(2).” (Id.) Judge Wall authorized “[a]ny computers, computer hard drives, or other electronic device to be searched on-site or off-site for records as detailed on Attachment 1 hereto.” (Id.) Judge Wall directed, among other things, that the search be conducted on or before June 1, 2012; a copy of the warrant be left at the premises; and that a written inventory be prepared.

On May 24, 2012, FDA agents executed the Office Search Warrants. The search, led by Nasiatka, resulted in the seizure of more than 32,000 documents, including financial records. The FDA agents also imaged the hard drives of three computers.

The FDA Agents left a copy of the search warrant and a computer-printed inventory of all items seized. One computer which was seized was returned to Scully on May 29, 2012.

C. The September 21, 2012 Affidavit in Support of the Email Account Search Warrants

In September 21, 2012, Nasiatka submitted another affidavit, sworn to by him, seeking a search warrant related to two email addresses, medev1@yahoo.com and tarnismmed@yahoo.com.

The September 21, 2012 affidavit largely mirrored Nasiatka's May 2012 affidavit in support of the Office Search Warrants. In particular, Nasiatka documented the underlying investigations after February 2011. In addition to the details previously recounted in the May 2012 affidavit, Nasiatka stated that, on or about June 13, 2012, he spoke with a John Doe, a customer of MDK. (Doc No. 44, Exh 1, at ¶ 62.). Doe apparently advised Nasiatka that he had recent phone and email communications with MDK. John Doe stated that on or about June 12, 2012, Scully, who he knew to be a representative of MDK, emailed him and advised him that he could place an order for prescription drugs through Scully, who was listed at the bottom of the email as the President of a company known as Taranis Medical Corp. John Doe was emailed by Scully from the email address tarnismmed@yahoo.com. Previously, John Doe had dealt with Scully and MDK for purchase of drugs through the email address, medev1@yahoo.com.

Based on the foregoing, Nasiatka represented that probable cause existed to believe that the aforementioned email addresses contained "contraband, evidence, fruits and instrumentalities of violation of Title 21, United States Code, Sections 331(a) and 333(a)(2)." (Id. at ¶ 64.) Accordingly, Nasiatka requested the issuance of a search warrant under seal as to the aforementioned email addresses for all information that "constitute[d] fruits, evidence and

instrumentalities of violations of Title 21, United States Code, Sections 331(a) and 333(a)(2), involving William Scully and/or Shahrad Rodi Lameh since January 2010.” (Id. at ¶ 63.)

D. The September 21, 2012 Yahoo Search Warrant and Subsequent Execution

On September 21, 2012, Judge Wall issued a search warrant under seal for “THE PREMISES KNOWN AND DESCRIBED AS EMAIL ADDRESSES medev1@yahoo.com and taranised@yahoo.com . . .” (Gov’s Exh 2.) Again, Judge Wall expressly relied on Nasiatka’s affidavit and noted that Nasiatka had reason to believe that the abovementioned email addresses, “in” the Eastern District of New York, “constitute[d] contraband, evidence, fruits and instrumentalities of violations of Title 21, United States Code, §§ 331(a) and §§ 333(a)(2).” (Id.) Judge Wall directed, among other things, that the search be conducted on or before September 28, 2012; a copy of the warrant be left at the premises; and that a written inventory be prepared.

It appears that FDA Agents executed the September 21, 2012 Yahoo search warrant within the prescribed time period.

E. The November 16, 2012 Search Warrant and Its Subsequent Execution

On November 16, 2012, United States Magistrate Judge Arlene R. Lindsay issued a search warrant, apparently under seal, for “THE PREMISES KNOWN AND DESCRIBED AS FENCES INVENTORY AREA OF 3G WAREHOUSE, INC., 565 BROADHOLLOW ROAD, SUITE 1, FARMINGDALE, NEW YORK 11735 (‘SUBJECT PREMISES’).”(Doc No. 44, Exh. 6.) Judge Lindsay expressly relied on an affidavit from Nasiatka and noted that Nasiatka had reason to believe that the aforementioned property concealed “a box containing approximately 105 Mirena intrauterine devices and any other prescription drugs or medical devices received by 3G Warehouse, Inc. at the SUBJECT PREMISES on behalf of Taranis Medical Corp.” (Id.)

Judge Lindsay directed, among other things, that the search be conducted on or before November 23, 2012; a copy of the warrant be left at the premises; and that a written inventory be prepared.

It appears that FDA Agents executed the November 16, 2012 search warrant within the prescribed time period.

F. The November 22, 2013 Affidavits in Support of an Additional Email Search Warrant

On November 22, 2013, Nasiatka submitted another affidavit, sworn to and signed under oath, as part of an application for another search warrant, this time limited to the medev1@yahoo.com email address. The November 22, 2013 affidavit was virtually identical to the September 21, 2012 affidavit except, in part, as to Nasiatka's representation in Paragraph 63 that Scully continued to use the aforementioned email address after September 21, 2012 in connection with Pharmalogical. (Id., Exh. 2).

In particular, Nasiatka quoted an email dated October 9, 2013 from this address which stated: "Hello, I have sent the discontinuance form for Pharmalogical Inc license #029518. I would like to open a new wholesale business under a different corp in a new location. I don't want to send in the application to quickly if the discontinuance hasn't been processed yet. Please let me know your advice on this matter. Thank you. Best regards, Liam Scully." (Id.)

In paragraph 64, Nasiatka referenced the September 21, 2012 search warrant and attached a copy.

G. The November 22, 2013 Search Warrant and Subsequent Execution

On November 22, 2013, Judge Wall issued another search warrant under seal of "THE PREMISES KNOWN AND DESCRIBED AS EMAIL ADDRESS "[EMAIL ADDRESS]", AS SET FORTH IN ATTACHMENT A." Attachment A stated that "[the] warrant applies to

information associated with medev1@yahoo.com that is stored at premises own, maintained, controlled, or operated by Yahoo! Inc., a company headquartered in Sunnyvale, California.”

Judge Wall expressly relied on an affidavit from Nasiatka and noted that Nasiatka had reason to believe that the aforementioned property concealed “[e]vidence, fruits and instrumentalities of violations of 21 U.S.C. Sections 331(a) and 333(a)(2), as set forth in Attachment B and is subject to disclosure without notice to the subscriber or customer, inter alia, under 18 U.S.C. Section 2703(b).” Judge Wall directed, among other things, that the search be conducted on or before December 2, 2013; a copy of the warrant be left at the premises; and that a written inventory be prepared.

H. The Affidavit in Support of an Order of Non-Disclosure of the November 22, 2013 Yahoo Search Warrants and the Order of Non-Disclosure

On December 4, 2013, Nasiatka submitted an affidavit to Judge Wall in support of an application for a non-disclosure order for the November 22, 2013 Yahoo Search Warrant. In that affidavit, Nasiatka averred that “[s]ince the issuance of the warrant, Yahoo! Inc. has advised me that, without an Order under 18 U.S.C. § 2705(b), notice will be sent to the subscriber of the existence of the search warrant.” Nasiatka’s represented that such disclosure would “seriously jeopardize the investigation, including by giving targets an opportunity to flee or continue flight from prosecution, destroy or tamper with evidence, change patterns of behavior, and notify confederates.” (Doc No. 44, Exh 17.)

Judge Wall issued the Order of Non-Disclosure pursuant to Section 2705(b). It appears that FDA Agents executed the November 22, 2013 Search Warrant within the prescribed time period.

I. The Indictment and Pre-Trial Proceedings

On April 9, 2014, the Government filed the instant Indictment, under seal, as against Scully and Lameh. The Indictment contains (1) 18 counts of wire fraud in violation of 18 U.S.C.

§§ 1343, 1349 and 3551 *et seq.*; (2) one count of conspiracy to commit mail fraud in violation of 18 U.S.C. §§ 1349 and 3551 *et seq.*; (3) 17 counts of mail fraud in violation of 18 U.S.C. §§ 1341, 1349 and 3551 *et seq.*; (3) one count of conspiracy to distribute “[m]isbranded” drugs in violation of 21 U.S.C. §§ 331(a) and (a)(2); (4) 17 counts of introduction of “[m]isbranded” drugs into interstate commerce in violation of 21 U.S.C. §§ 331(a) and (a)(2) and 18 U.S.C. §§ 2, 3551 *et seq.*; (5) 17 counts of receipt of misbranded drugs in interstate commerce and delivery thereof for pay in violation of 21 U.S.C. §§ 331(c) and (a)(2) and 18 U.S.C. §§ 2, 3551 *et seq.*; (6) one count of fraudulent importation and transportation of goods in violation of 18 U.S.C. §§ 545, 2, and 3551 *et seq.*; and (7) one count of trafficking in counterfeit drugs in violation of 18 U.S.C. §§ 2320(a)(4), 2, and 3551 *et seq.*

According to the Indictment, the Defendants at all relevant times owned and operated Pharmalogical, a company based in Great Neck, New York that imported and sold prescription drugs to health care providers. (Indictment, at ¶ 23.) Scully was also the owner and operator of Taranis Medical Corp., which allegedly purchased “misbranded” drugs ordered by Pharmalogical and resold them to customers. (*Id.*)

Scully, also known as “Liam Scully,” resided in Commack, New York and used the websites and email addresses, www.pharmalogicalinc.com; www.medicaldeviceking.com; www.taranismedical.com; taranismed@yahoo.com; and medev1@yahoo.com in connection with the sale of prescription drugs. (*Id.* at ¶ 24.)

Lameh resided in Manhasset, New York and used the websites and email addresses www.pharmalogicalinc.com; www.medicaldeviceking.com; and rodilameh@gmail.com in connection with the sale of prescription drugs. (*Id.* at ¶ 25.)

The websites www.pharmalogicalinc.com; www.medicaldeviceking.com; and

www.taranismedical.com were used to make sales to customers. (Id. at ¶ 26.)

The Government alleges that between about February 10, 2009 and July 2013, Scully and Lameh, together with unidentified “others,” “engaged in a scheme designed to fraudulently induce customers to purchase prescription drugs that were misbranded in that they were not approved by the FDA for use in the United States.” (Id. at ¶ 27.) The Government further alleges that, in furtherance of this scheme, Scully and Lameh “placed photographs of certain prescription Medications, which were approved by the FDA for introduction and delivery for introduction into interstate commerce in the United States, on MDK websites in order to mislead customers to believe that the drugs were approved when in truth and in fact, as SCULLY and LAMEH then and there well knew and believed the drugs that they sold were not approved by the FDA for use and introduction and delivery into interstate commerce in the United States.” (Id.)

The Government also contends that Scully and Lameh “obtained misbranded drugs from foreign suppliers using the email addresses of medev1@yahoo.com and rodilameh@gmail.com and/ on behalf of MDK, received payment from customers by credit card, wire transfer, and business check from purchasers of misbranded drugs.” (Id. at ¶ 28.) Further, according to the Government, Scully and Lameh “received, and caused to be received, on behalf of Pharmalogical, Inc., shipments of misbranded drugs through United States Mail Priority and Express Mail” and “also sent, and caused to be sent, on behalf of Pharmalogical, Medical Device King and MDK, shipments of misbranded drugs using commercial interstate carriers, to wit: United Parcel Service of America, Inc. (‘UPS’) and FedEx Corporation (‘FedEx’).” (Id.)

The Government asserts that Scully and Lameh conspired with others to electronically order “prescription drugs from, among other places, the countries of Scotland, Turkey, United

Kingdom, Cayman Islands, Canada, United Arab Emirates, Switzerland and India for sale in the United States, knowing that such prescription drugs were not FDA approved and therefore were not permitted to be distributed and used in the United States.” (Id. at ¶ 29.) It is also alleged that Scully and Lameh, knowing that the prescription drugs obtained from these countries “were not approved for sale in the United States, shipped such drugs using commercial interstate carriers to customers who had ordered them either by telephone or from the MDK websites that falsely advertised such drugs as genuine, safe and approved for sale in the United States.” (Id. at ¶ 30.)

Similarly, the Government contends that Scully and Lameh “falsely represented to prospective customers during telephone calls that the prescription drugs the customers purchased were approved for sale and use in the United States when SCULLY and LAMEH knew that this was not true.” (Id. at ¶ 31.)

Some of these drugs included Altuzan and Mabthera. (Id. at ¶ 32.) Altuzan is the foreign version of Avastin, the trademark name for a drug used to treat certain cancers. The Government claims that Avastin is a prescription drug within the meaning of 21 U.S.C. §§ 353(b)(1)(A) and (B). The FDA initially approved Avastin for use in the United States in 2004. (Id. at ¶ 9.)

Mabthera is the foreign version of Rituxan, the trademark name for a drug that was used, among other purposes, to treat certain cancers and rheumatoid arthritis. (Id. at ¶ 13.) The Government claims that Rituxan is a prescription drug within the meaning of 21 U.S.C. §§ 353(b)(1)(A) and (B). The FDA initially approved Rituxan for use in the United States in 1997.

While the aforementioned drugs were approved by the FDA, the Government claims that they were “not approved for introduction and delivery for introduction into interstate commerce in the United States.” (Id. at ¶ 13.)

The Government maintains that, on or about May 24, 2014, Scully and Lameh “possessed numerous misbranded drugs having imported them with the intention of selling them”

(Id. at ¶ 33.) In this regard, Paragraph 33 of the Indictment contains a corresponding table of such alleged “misbranded” drugs in Scully and Lameh’s possession, delineated by “Drug Quantity and Type” and “Method of Misbranding.” (Id.)

As set forth in this table, the various alleged methods of misbranding are “Lacked English label”; “phrase ‘Rx only’ on label”; and “Not FDA approved for distribution in the United States.” (Id.).

On April 9, 2014, Judge Lindsay issued separate arrest warrants for the Defendants.

On April 30, 2014, the Defendants were arraigned before Judge Wall, at which time they plead not guilty to all 73 counts. The Defendants were released on separate \$500,000 unsecured bonds, with certain conditions. Judge Wall also unsealed the Indictment in its entirety as to the Defendants.

On May 30, 2014, upon an application of the Government, United States Magistrate Judge Gary R. Brown unsealed all documents in this case.

That same day, this Court held a status conference and marked the case as complex.

As noted above, on October 16, 2014, on referral to Judge Locke, Lameh entered a guilty plea to Counts 1 through 37 of the Indictment. Lameh plead guilty to conspiracy to commit wire fraud; wire fraud; conspiracy to commit mail fraud; mail fraud; and one count of conspiracy to distribute misbranded drugs. He did not plead guilty to trafficking in counterfeit oncology drugs.

On October 20, 2014, this Court accepted that guilty plea recommendation. Lameh is currently set to be sentenced on September 18, 2015.

On February 5, 2015, Scully filed the present motion, the various branches of which are discussed later. Following oral argument on the motion on May 15, 2015, the Court reserved decision. At the time, at Scully's request, the Court scheduled a date for jury selection for January 5, 2016 to be conducted, with the parties' consent, before a Magistrate Judge.

II. DISCUSSION

There are several branches to the Defendant's motion to, among other things, dismiss certain counts of the Indictment, to suppress certain evidence, and for an order directing certain discovery and the filing of a bill of particulars. The Court first addresses that part of the motion to suppress, namely, "all emails and other evidence obtained through search warrants due to the Government's material misstatements and omissions in the search warrant affidavits and the constitutionally impermissible way that the Government executed the warrants." (Doc No. 43, at 1.) The Court then addresses the remaining items of the relief requested.

A. The Motion To Suppress

The Fourth Amendment protects the rights of individuals "to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures." U.S. Const. Amend. IV.

A search occurs when the Government acquires information by either "physically intruding' on persons, houses, papers, or effects," "or otherwise invading an area in which the individual has a reasonable expectation of privacy." See Florida v. Jardines, — U.S. —, 133 S. Ct. 1409, 1414, 185 L. Ed. 2d 495 (2013)(internal quotation mark omitted) and United States v. Ganius, 755 F.3d 125, 133 (2d Cir. 2014). "A seizure occurs when the Government interferes in some meaningful way with the individual's possession of property." Ganius, 755 F.3d at 133 (citing United States v. Jones, — U.S. —, 132 S. Ct. 945, 951 n. 5, 181 L. Ed. 2d 911 (2012)).

Further, the Fourth Amendment's Warrants Clause provides that "no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized."

1. Whether the Email Search Warrants were Technically Deficient

The Defendant argues that the Yahoo Search Warrants, signed by Judge Wall in the Eastern District of New York, violated Federal Rule of Criminal Procedure ("Fed. R. Crim. P.") 41 and 18 U.S.C. § 2703 of the federal Stored Communications Act (the "SCA") because they purported to authorize seizure of emails that were conducted in California.

In response, the Government notes that Attachment A to Nasiatka's affidavits in support of the Yahoo Search Warrants, referenced in the Yahoo Search Warrants, states that "[t]his warrant applies to information associated with medev1@yahoo.com that is stored at premises own, maintained, controlled, or operated by Yahoo! Inc., a company headquartered in Sunnyvale, California." (Gov's Exh. 2.) (bolding omitted).

The Defendant counters that, under Rule 41 and 18 U.S.C. § 2703, a judge in one district cannot issue a search warrant for property located in another district.

A review of the relevant rules and statutes is in order. Relevant here, Rule 41(b)(1) provides that at the request of a federal law enforcement officer or an attorney for the federal government: "[A] magistrate judge with authority in the district – or if none is reasonably available, a judge of a state court of record in the district – has authority to issue a warrant to search for and seize a person or *property located within the district.*" (emphasis added).

The SCA was passed as part of the Electronic Communications Privacy Act of 1986 (the "ECPA") and codified at 18 U.S.C. §§ 2701–2712.

Prior to 2001, § 2703(a) provided that:

A governmental entity may require the disclosure by a provider of electronic communication service of the contents of a wire or electronic communication, that is in electronic storage in an electronic communications system for one hundred and eighty days or less, *only pursuant to a warrant issued under the Rules of Criminal Procedure or equivalent State warrant.*

18 U.S.C. § 2703(a)(1998)(emphasis added).

The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (the “Patriot Act”) amended § 2703(a) to permit a government entity to require such disclosures “*only pursuant to a warrant issued using the procedures described in the Federal Rules of Criminal Procedure by a court with jurisdiction over the offense under investigation or equivalent State warrant.*” *Id.* § 2703(a)(2006)(emphasis added). Indeed, “Section 220 of the Patriot Act amended § 2703 by ‘striking ‘under the Federal Rules of Criminal Procedure’ every place it appears and inserting ‘using the procedures described in the Federal Rules of Criminal Procedure by a court with jurisdiction over the offense under investigation.’” *In re U.S.*, 665 F. Supp. 2d 1210, 1216 n. 5 (D. Or. 2009) (describing the statutory amendments); *see* USA PATRIOT Act of 2001, Pub. L. No. 107–56, 115 Stat. 272.

On October 19, 2009, Congress amended Section 2703(a) again to read that warrant may issue “only pursuant to a warrant issued using the procedures described in the Federal Rules of Criminal Procedure (or, in the case of a State court, issued using State warrant procedures) by a court of competent jurisdiction.” *Hubbard v. MySpace, Inc.*, 788 F. Supp. 2d 319, 321 n. 9 (S.D.N.Y. 2011)(describing the statutory amendment).

In the same legislative session, Congress amended Section 2711(3) to define a “court of competent jurisdiction” as:

(A) any district court of the United States (including a magistrate judge of such a court) or any United States courts of appeals that–

(i) has jurisdiction over the offense being investigated;

(ii) is in or for a district in which the provider of a wire or electronic communication services is located or in which the wire or electronic communications, records, or other information are stored; or

(iii) is acting on a request for foreign assistance pursuant to section 3512 of this title; or

(B) a court of general criminal jurisdiction of a State authorized by the law of that State to issue search warrants.

In Hubbard, a website user brought a civil putative class action against MySpace, Inc., a social networking website, alleging violations of the SCA arising out of website's disclosure of member account information to law enforcement.

As part of the underlying criminal investigation, a Georgia State Magistrate Court had issued a search warrant to a custodian of records in Beverly Hills, California. The search warrant was issued on January 29, 2008, after the 2001 amendments but prior to the 2009 amendments. The search warrants led in part to an arrest, guilty plea, and conviction for contributing to the delinquency of a minor and "enticing a child for indecent purposes" under Georgia law.

In the subsequent federal civil action under the SCA, United States District Judge Lewis A. Kaplan described Section 2703(a) as "ambiguous as to whether a state or federal warrant authorizing a search beyond the ordinary territorial authority of the issuing magistrate or judge is acceptable." However, Judge Kaplan concluded that "even though federal magistrate judges typically may issue warrants only for searches within their districts, extraterritorial warrants are permissible for purposes of Section 2703(a)." Id.

Judge Kaplan based this conclusion in part on certain legislative history to the Patriot Act, which, as noted above, amended Section 2703 of the SCA. In particular, the House Committee on the Judiciary released a report, dated October 11, 2001, which states, in part:

Title 18 U.S.C. § 2703(a) requires a search warrant to compel service providers to disclose unopened e-mails. This section does not affect the requirement for a search warrant, but rather attempts to address the investigative delays caused by the cross-jurisdictional nature of the Internet. Currently, Federal Rules of Criminal Procedure 41 requires that the “warrant” be obtained “within the district” where the property is located. An investigator, for example, located in Boston who is investigating a suspected terrorist in that city, might have to seek a suspect’s electronic e-mail from an Internet service provider (ISP) account located in California. The investigator would then need to coordinate with agents, prosecutors and judges in the district in California where the ISP is located to obtain the warrant to search. These time delays could be devastating to an investigation, especially where additional criminal or terrorist acts are planned.

Section 108 amends § 2703 to authorize the court with jurisdiction over the investigation to issue the warrant directly, without requiring the intervention of its counterpart in the district where the ISP is located.

H.R. Rep. 107–236 (Title 1), at 57 (2001).

Judge Kaplan concluded that, based on this language, “Congress made clear that, in adopting the relevant statutory language, it specifically intended to allow federal courts to authorize searches beyond their normal territorial jurisdictions.” 788 F. Supp. 2d at 325.

A similar conclusion was reached in In re Warrant to Search a Certain E-Mail Account Controlled & Maintained by Microsoft Corp., 15 F. Supp. 3d 466, 470 (S.D.N.Y. 2014). There, a search warrant was issued under the SCA authorizing search and seizure of information associated with a specific web-based e-mail account. Microsoft, an operator of a web-based e-mail service, moved to quash the search warrant to the extent it directed the operator to produce content stored on a server located in Ireland.

United States Magistrate Judge James C. Francis IV denied the motion, holding in part that the warrant did not violate the presumption against extraterritorial application of the law of the United States.

With regard to the apparent tension between Rule 41 and Section 2703(A), Judge Francis acknowledged that the argument that federal courts are without authority to issue

warrants for the search and seizure of property outside the territorial limits of the United States was “not inconsistent with the statutory language” in those provisions. Id.

Indeed, with regard to Section 2703(a), Judge Francis found:

This language is ambiguous in at least one critical respect. The words “using the procedures described in the Federal Rules of Criminal Procedure” could be construed to mean, as Microsoft argues, that all aspects of Rule 41 are incorporated by reference in section 2703(a), including limitations on the territorial reach of a warrant issued under that rule. But, equally plausibly, the statutory language could be read to mean that while procedural aspects of the application process are to be drawn from Rule 41 (for example, the presentation of the application based on sworn testimony to a magistrate judge), more substantive rules are derived from other sources.

Id. Thus, Judge Francis did not hold that Section 2703, considered in conjunction with Rule 41, yielded a clear result.

Rather, relying on the Supreme Court decisions in Florida Power & Light Co. v. Lorion, 470 U.S. 729, 737, 105 S. Ct. 1598, 84 L. Ed. 2d 643 (1985) and Board of Education v. Harris, 444 U.S. 130, 140, 100 S.Ct. 363, 62 L. Ed. 2d 275 (1979) and the Second Circuit’s decision in Hall v. EarthLink Network, Inc., 396 F.3d 500, 504 (2d Cir. 2005), Judge Francis noted that “[i]n light of this ambiguity, it is appropriate to look for guidance in the “statutory structure, relevant legislative history, [and] congressional purposes.” 15 F. Supp. 3d at 471 (quotation marks omitted). Judge Francis then surveyed the SCA’s statutory structure; certain legislative history, including the October 11, 2001 Report of the House Committee on the Judiciary; and certain practical considerations specific to searches outside the United States.

Judge Francis characterized the above-mentioned language contained in the Report of the House Committee on the Judiciary as “significant, because it equates ‘where the property is located’ with the location of the ISP, not the location of any server.” Id. at 474.

“Commentators have suggested that one reason for the amendments effected by Section 220 of the Patriot Act was to alleviate the burden placed on federal district courts in the Eastern District of Virginia and the Northern District of California where major internet service providers [] AOL and Yahoo, respectively, are located.” In re Search of Yahoo, Inc., No. 07-3194 (LAO), 2007 WL 1539971, at *4 (D. Ariz. May 21, 2007); see Paul K. Ohm, Parallel Effect Statutes and E-mail “Warrants”: Reframing the Internet Surveillance Debate, 72 Geo. Wash. L. Rev. 1599, 1613–15 (Aug.2004); Patricia L. Bellia, Surveillance Law Through Cyberlaw’s Lens, 72 Geo. Wash. L. Rev. 1375, 1454 (Aug. 2004)(stating that the “effect of the change was to shift the responsibility for issuance of the order from the court where the service provider is located to the court with jurisdiction over the offense being investigated; prior to passage of the USA Patriot Act, a disproportionate number of such orders were issued in the Eastern District of Virginia, where AOL is located.”); Franklin E. Fink, The Name Behind the Screenshot: Handling Information Requests Relating to Electronic Communications, 19 No. 11 Computer & Internet Law 1, 6–7 (Nov. 2002)(stating that “[t]his provision was intended to relieve the burden on district courts in which major communications providers are located, such as the Northern District of California and Eastern District of Virginia.”). Further, one court has stated that “[t]his is most likely the reason for the special provision for out-of-district warrants for certain electronic communications, such as emails, under Section 220 in all criminal cases, when Section 219 seems to limit (via Rule 41(b)(3)) out-of-district warrants to terrorism cases.” In re Search Warrant, No. 6:05MC168ORL31 (JGG), 2005 WL 3844032, at *5 n. 13 (M.D. Fla. Feb. 13, 2006).

As noted above, the House Judiciary Committee’s Report accompanying the Patriot Act explains that § 2703(a) “attempts to address the investigative delays caused by the cross-

jurisdictional nature of the Internet.” Ohm, Parallel Effect Statutes and E-mail “Warrants”: Reframing the Internet Surveillance Debate, 72 Geo. Wash. L. Rev. at 1614–15 (citing H. R. Rep. No. 107–236, pt. 1 at 57 (2001)). The Committee’s Report further explains that requiring an investigator to coordinate with agents, prosecutors, and judges in the district where the ISP is located would cause time delays that “could be devastating to an investigation, especially where additional criminal or terrorists acts are planned.” Id.

In the Microsoft case, Judge Francis concluded that, based on the language contained the October 11, 2001 Report and other legislative history, Congress “appear[ed] to have anticipated that an ISP located in the United States would be obligated to respond to a warrant issued pursuant to section 2703(a) by producing information within its control, regardless of where that information was stored.” 15 F. Supp. 3d at 474. For these and other reasons, Judge Francis denied the motion to quash in part.

However, execution of the search warrant was stayed on consent pending review of Judge Francis’s decision by a district judge. Thereafter, Chief Judge Loretta A. Preska affirmed Judge Francis’s ruling on the record. Microsoft immediately moved to stay execution of the Warrant pending review by the Second Circuit. The Government sought time to consider whether it would consent to such a stay. Judge Preska granted Microsoft’s motion on the record.

By order dated August 1, 2014, based on the Government’s consent to stay enforcement of the July 31 Order pending appeal, Judge Preska extended the stay “only for such period as will permit Microsoft to file its notice of appeal, request for a stay and request for an expedited appeal.” On August 11, 2014, Judge Preska entered a written order confirming the July 31 Order. That same day, Microsoft filed a notice of appeal. That appeal is pending before the Second Circuit.

While the Second Circuit's resolution of that appeal may affect this area of law, it is not clear that a ruling in favor of Microsoft would necessarily mandate a ruling in favor of the Defendant on this issue. This is because, as noted above, Microsoft challenged a search warrant related to electronic data stored outside the United States. Here, by contrast, the Defendant challenges a search warrant related to electronic data outside the issuing judge's district, but within the United States.

In any event, the Court notes that the Defendant does not cite nor does the Court's independent research reveal any controlling cases to support his argument. To the contrary, almost all the cases appear to support the Government's position, namely, that a federal magistrate may issue a search warrant for electronic evidence outside his or her district under Section 2703(a).

The case, United States v. Vilar, No. S305CR621 (KMK), 2007 WL 1075041 (S.D.N.Y. Apr. 4, 2007), relied upon by the Defendant, involved a foreign search and did not reference the SCA, though it did find that a magistrate judge in one district did not have statutory authority in a non-terrorism case to issue a search warrant targeting property in another district. Id. at *52.

Nor do cases relating to the lack of power to authorize intrusion into a foreign computer support the Defendant's position. For instance, in In re Warrant to Search a Target Computer at Premises Unknown, 958 F. Supp. 2d 753 (S.D. Tex. 2013), the court rejected the Government's argument that data surreptitiously seized from a computer at an unknown location would be "located" within the district where the agents would first view it for purposes of conforming to the territorial limitations of Rule 41. Id. at 756–57. However, there, the Government was not seeking an SCA Warrant.

The Government [did] not seek a garden-variety search warrant. Its application request[ed] authorization to surreptitiously install data extraction software on the

Target Computer. Once installed, the software [would have] the capacity to search the computer's hard drive, random access memory, and other storage media; to activate the computer's built-in camera; to generate latitude and longitude coordinates for the computer's location; and to transmit the extracted data to FBI agents within this district.

Id. at 755. "In other words, the Government [sought] a warrant to hack a computer suspected of criminal use." Id. "Though not 'garden-variety,' the warrant requested there was conventional: it called for agents to intrude upon the target's property in order to obtain information; it did not call for disclosure of information in the possession of a third party." In re Warrant to Search a Certain E-Mail Account Controlled & Maintained by Microsoft Corp., 15 F. Supp. 3d at 477 (distinguishing In re Warrant to Search a Target Computer at Premises Unknown).

The one decision uncovered supporting the Defendant's argument, In re Search Warrant, 362 F. Supp. 2d 1298, 1304–05 (M.D. Fla. 2003), was later reversed on appeal to a District Judge. In re Search Warrant, 2005 WL 3844032, at *6.

As to the case law outside this circuit, some of the cases, like Hubbard and Microsoft, have concluded that the apparent tension between Section 2703(a) and Rule 41 with regard to the permissibility of search warrants outside a judge's district creates an ambiguity. In re United States, 665 F. Supp. 2d at 1219 (finding ambiguity in that "[i]ssued' may be read to limit the procedures that are applicable under § 2703(a), or it might merely have been used as a shorthand for the process of obtaining, issuing, executing, and returning a warrant, as described in Rule 41"); In re Search of Yahoo, Inc., 2007 WL 1539971, at *5 (finding that "the phrase 'using the procedures described in' the Federal Rules remains ambiguous").

Accordingly, some of these courts have, as in Hubbard and Microsoft, turned to legislative history for guidance. See In re U.S., 665 F. Supp. 2d at 1219 (citing 147 Cong. Rec. H7197–98 (2001), which stated that Section 220 "[p]ermits a single court having jurisdiction

over the offense to issue a search warrant for e-mail that would be valid in [sic] anywhere in the United States.”) and In re Search of Yahoo, Inc., 2007 WL 1539971, at *4 and In re Search Warrant, 2005 WL 3844032, at *5.

Some of these courts have also focused on the practical considerations related to out-of-district electronics search warrants. For example, as noted in In re Search of Yahoo, Inc., “[j]udicial and prosecutorial efficiency is better served by permitting the federal district court for the district where the crime allegedly occurred to preside over both the investigation and prosecution of that crime.” 2007 WL 1539971, at *4.

Similarly, in In Re Search Warrant, the Court noted that “it makes little sense to require the government, once it has opened an investigation into an alleged federal crime in the district where that crime allegedly occurred, to have to look to the courts, prosecutors and agents in another district where certain evidence may be found in order to procure a warrant for a search in that other district.” 2005 WL 3844032, at *5. Rather, the Court noted, “as a matter of judicial and prosecutorial efficiency it is practical to permit the federal district court for the district where the federal crime allegedly occurred to oversee both the prosecution and the investigation (including the issuance of warrants) thereof.” Id. (footnotes omitted).

The In Re Search Warrant court further determined, in a footnote, as follows:

Permitting the district court where the crime allegedly occurred to issue an out-of-district warrant for evidence located in another district results in no prejudice to the rights of the defendant, particularly where that defendant is unaware of the investigation. The only person conceivably being inconvenienced is the third party that owns the out-of-district property subject to the search warrant, but as a practical matter, such inconvenience is *de minimis* and, as the United States suggested, such third parties rarely, if ever, seek to contest such warrants.

Id. at n. 14.

The Court also takes note of United States v. Berkos, 543 F.3d 392 (7th Cir. 2008), cited by neither party and which appears to be the only circuit court decision on this issue. There, the Defendant entered a conditional guilty plea to willfully failing to pay more than \$145,000 in child support for his only son, reserving his right to appeal the denial of motions to suppress evidence by the United States District Court for the Northern District of Illinois. The Defendant appealed, arguing in part that the magistrate judge in the Northern District of Illinois lacked authority to issue a search warrant ordering the search and production of electronic evidence pursuant to 18 U.S.C. § 2703(a), where the warrant was directed to an out-of-district internet service provider located in the Southern District of Texas.

The Seventh Circuit disagreed. However, the circuit court “[did] not rely on the extensive legislative history of the 2001 amendment” to Section 2703(a). Id. at 397 n.4. Rather, the Seventh Circuit looked to the “plain language” of Section 2703(a) and Rule 41 and found as follows:

Rule 41(b) is a substantive provision, not a procedural one. Section 2703(a) refers only to the specific provisions of the Rules of Criminal Procedure, namely, Rule 41, that detail the procedures for obtaining and issuing warrants. The word “procedure” is defined as “a specific method or course of action,” Black’s Law Dictionary, 1241 (8th ed. 2004), or “a particular way of accomplishing something or acting.” Merriam Webster’s Collegiate Dictionary, 990 (11th ed. 2003). The common definition of “procedure” supports the conclusion that § 2703(a) incorporates only those provisions of Rule 41 that address the “specific method” or “particular way” to issue a warrant.

Id. at 397-98 n. 4.

The Seventh Circuit also noted that

Rule 41(b) is titled “Authority to Issue a Warrant” and discusses the circumstances as to when a court may issue a warrant, not the procedures to be used for issuing the warrant. In fact, the procedures for issuing a warrant are enumerated at Rule 41I, which of course, would apply to § 2703(a). See Fed. R. Crim. P. 41(e).

Id. at 398.

Berkos also noted that, as part of the 2001 amendments,

Congress amended the relevant language of § 2703(a), striking “under the Federal Rules of Criminal Procedure” everywhere it appeared and replacing that language with “using the procedures described in the Federal Rules of Criminal Procedure.” See PL 107–56, § 220(a)(1). The word “procedures” was also modified by “described in,” which further expressed Congress’s intent that only the procedural aspects of Rule 41 apply to § 2703(a). See id. If all provisions of Rule 41 (or the Federal Rules of Criminal Procedure, for that matter) were strictly procedural, the phrase “described in” would be meaningless. See Gustafson, 513 U.S. at 574–75, 115 S. Ct. 1061 (federal courts should avoid interpreting statutes in a way that renders words or phrases meaningless or redundant).

543 F.3d at 398 n. 5.

Finally, the Seventh Circuit noted that “§ 2703(a) has its own jurisdictional provision authorizing district courts to issue warrants only where it has ‘jurisdiction over the offense.’” Id. at 398. The Seventh Circuit agreed with the Government that “Congress provided such a ‘special circumstance’ through § 2703(a) since warrants pursuant to § 2703(a) do not directly infringe upon the personal privacy of an individual, but instead compel a service provider to divulge records maintained by the provider for the subscriber.” Id. at 398 n. 6.

Similarly, in United States v. Kernell, No. 3:08-CR-142 (CCS), 2010 WL 1408437 (E.D. Tenn. Apr. 2, 2010) report and recommendation adopted, No. 3:08-CR-142 (TWP), 2010 WL 1491861 (E.D. Tenn. Apr. 13, 2010), the court found as follows:

[T]he plain language of 18 U.S.C. § 2703(a) expresses the intent that only the “procedures,” (i.e., the procedural portions) as “described” in Rule 41 are to be “used.” This Court further finds that Rule 41(b) is not a “procedural” provision, but is a “substantive” provision, and thus, it is not incorporated under 18 U.S.C. § 2703(a). It is clear that Rule 41(b) describes no procedure but only substantive authority. It’s very title “Authority to Issue-Warrant” states as much. Indeed, Defendant’s motion is predicated on the claim that this court lacked substantive authority to issue these warrants.

Furthermore, to the extent the Defendant argues subsection (b) of Rule 41 modifies the authority provided in 18 U.S.C. § 2703(a), such an interpretation is prohibited by subsection (a) of Rule 41 which provides that Rule 41 does not “modify any statute regulating searches or seizures or the issuance and execution of a search warrant in special circumstances.”

The Court finds that 18 U.S.C. § 2703(a) is a statute that regulates search and seizure of electronic evidence and the issuance and execution of search warrants in special circumstances – to wit, only by courts with “jurisdiction over the offense under investigation” and only for electronic evidence located out of district. The Court finds this Court and these search warrants, met and complied with the provisions and clear statutory language of 18 U.S.C. § 2703(a).

2010 WL 1408437, at *4 (footnotes omitted); see United States v. Noyes, No. 1:08-CR-55 (SJM), 2010 WL 5139859, at *9 n. 8 (W.D. Pa. Dec. 8, 2010)(Section 2703(a)

“authorizes courts to issue search warrants for electronic communications and evidence located in other judicial districts in cases where the issuing court has jurisdiction over the offense under investigation.”); United States v. Freeman, No. CRIM. 10-68 (JRT)(RLE), 2010 WL 4386897, at *12 n. 6 (D. Minn. May 13, 2010)(“the ECPA authorizes Courts to issue Search Warrants for electronic communications, and evidence, that are located in other Districts, where that Court has jurisdiction over the offense under investigation.”), report and recommendation adopted, No. CRIM. 10-68 (JRT)(LIB), 2010 WL 4386894 (D. Minn. Oct. 28, 2010).

The Kernell Court discussed some of the above-mentioned legislative history to the Patriot Act, but explicitly deemed it “not necessary for th[e] Court’s analysis or ruling.” 2010 WL 1408437, at *4.

In this case, the Court agrees with the comprehensive textual analysis set forth in Berkos and Kernell and finds that 2703(a) authorizes electronic search warrants by a federal magistrate judge that extend outside his or her district. Because the plain terms of Section 2703, considered with Rule 41, dictate this result, the Court need not rely on any

legislative history or practical considerations.

Indeed, as Berkos noted, that search warrants could issue only exclusively by a court with geographical jurisdiction of the electronic property was true prior to the 2001 amendments. 543 F.3d at 397 n. 4. Following that amendment, electronic search warrants could be issued “by a court with jurisdiction over the offense under investigation.” “[W]hen Congress alters the words of a statute – as it did in this case – [the Court must] presume that it intended to change the statute’s meaning.” Id. at 397 n. 4 (citing United States v. Wilson, 503 U.S. 329, 336, 112 S. Ct. 1351, 117 L. Ed. 2d 593 (1992)).

Indeed, “[i]f there was any doubt about the intent of the 2001 Amendment in issue, i.e., § 220, one need only look to its title, ‘Nationwide Service of Search Warrants for Electronic Evidence.’ As such, it is hard to find merit in an argument, as made by the Defendant, that the statute, in fact, precludes the very nationwide service of search warrants for electronic evidence that it was designed and intended to permit.” Kernell, 2010 WL 1408437, at *4.

Further, the fact that the Government could have, as the Defendant suggests, obtained a search warrant from a California federal court, as provided by Section 2711(3)(ii), does not mean that a federal judge of this District, which “has jurisdiction over the offense being investigated,” did not also possess statutory authority to issue the Yahoo Search Warrants.

Based on the foregoing reasons, the Court finds that the Yahoo Search Warrants, both of which specifically referenced Section 2703(b), complied with the requirements of the SCA. The Court further finds that they complied with Rule 41.

2. Whether Proper “Notice” of the Yahoo Search Warrants Was Provided Under Rule 41, the SCA and/or the Fourth Amendment

The Defendant also argues that the Government’s failure to provide “notice” to him of the issuance and execution of the Yahoo Search Warrants violated Rule 41(f)(1)(c). Although Rule 41(f)(1)(c) does not contain the word “notice,” it provides: “The officer executing the warrant must give a copy of the warrant and a receipt for the property taken to the person from whom, or from whose premises, the property was taken or leave a copy of the warrant and receipt at the place where the officer took the property.”

Although the Government took the steps outlined in Rule 41 (f)(1)(c) with regard to Yahoo! Inc. (“Yahoo”), it did not so with regard to the Defendant. The question then becomes whether (1) the Government was required to do so, either under Rule 41 or the SCA and (2) even if it was so required, whether failing to do so should result in the remedy of suppression.

As to the first question, the Court notes that Rule 41 “allows the copy of the warrant and the receipt to be given to the person from whose premises the property at issue was seized, even if that person is not the owner of the property.” In re U.S., 665 F. Supp. 2d at 1221. “There is no separate requirement that the officer provide the warrant, a receipt, or any other form of notice to the owner of the property.” “Thus, when police seize a package from Federal Express (“FedEx”), they may leave a copy of the warrant and receipt at the FedEx facility and do not need to inform the sender or recipient of the package of the seizure.” Id.; United States v. Zacher, 465 F.3d 336, 339 (8th Cir. 2006)(holding that North Dakota Rule of Criminal Procedure 41(d), which the court noted was virtually identical to Rule 41(f)(3), now 41(f)(1)(c) was satisfied by leaving a copy of the warrant at the FedEx facility).

Accordingly, “[w]hen the property to be seized is in the possession of a third party, Rule 41(f)(1)(c) requires no more than what was already accomplished in this case.” In re U.S., 665 F. Supp. 2d at 1221.

Furthermore, the Court notes that, even if Rule 41(f)(1)(c) was violated, it is not clear that a suppression remedy would be appropriate. Indeed, “[t]he Second Circuit has counseled that ‘violations of Rule 41 alone should not lead to exclusion unless (1) there was ‘prejudice’ in the sense that the search might not have occurred or would not have been so abrasive if the Rule had been followed, or (2) there is evidence of intentional and deliberate disregard of a provision in the Rule.’” United States v. Cardona, No. 14-CR-314 (RA), 2015 WL 769577, at *7 (S.D.N.Y. Feb. 24, 2015)(quoting United States v. Burke, 517 F.2d 377, 386–87 (2d Cir. 1975); United States v. Pangburn, 983 F.2d 449, 455 (2d Cir. 1993)(same); Fed. R. Crim. P. 52(a)(“Any error, defect, irregularity, or variance that does not affect substantial rights must be disregarded”).

Indeed, “[s]everal other circuits have also held that minor, or ‘ministerial,’ violations of Rule 41 do not require suppression of evidence.” United States v. Brown, 596 F. Supp. 2d 611, 624 n. 6 (E.D.N.Y. 2009)(citing circuit law from fourth, fifth, sixth, and seventh circuits), aff’d sub nom. United States v. Armstrong, 406 F. App’x 500 (2d Cir. 2010) and aff’d sub nom. United States v. Midyett, 457 F. App’x 7 (2d Cir. 2011).

The Court next considers whether the Government’s failure to provide notice to the Defendant of the issuance and execution of the Yahoo Search Warrants violated any provision of the SCA.

Of relevance here, Section 2703(b)(1)(A) states that a governmental entity may obtain certain electronic communications “without required notice to the subscriber or customer, if the governmental entity obtains a warrant issued using the procedures described in the Federal Rules

of Criminal Procedure . . . by a court of competent jurisdiction.” See also In re U.S. for Historical Cell Site Data, 724 F.3d 600, 606 n. 7 (5th Cir. 2013)(“The Government is not required to provide notice to the subscriber. § 2703(c)(3).”); In re U.S. for an Order Pursuant to 18 U.S.C. Section 2703(D), 707 F.3d 283, 287 (4th Cir. 2013)(“In seeking access to records, the government need not give prior notice to the subscriber or customer. 18 U.S.C. § 2703(c)(3)”); Freeman, 2010 WL 4386897, at *12 n. 6 (“Pursuant to Section 2703, the Government may obtain a Search Warrant requiring third party email service providers, and Internet Service Providers, to disclose the content of stored communications, and other transactional and subscriber data, without notice to the subscriber.”).

However, under § 2703(b)(1)(B), prior notice to the subscriber or customer is required when the governmental entity uses an administrative subpoena, a grand jury or trial subpoena, or court order under Section 2705(d) to obtain the contents of the electronic communications. Further, even for search warrants issued under Section 2703(b)(1)(B), notice to the subscriber or customer may be delayed for a certain period of time pursuant to Section 2705.

Here, the Government obtained access to certain of the Defendant’s email addresses based on warrants which specifically stated that the desired targets of the search were “subject to disclosure without notice to the subscriber or customer, inter alia, under 18 U.S.C. Section 2703(b).” While the search warrant itself did not specify reliance on Section 2703(b)(1)(A), the title of the document as “Search Warrant”; the general citation to Section 2703(b); and the reference to “disclosure without notice”, taken together, made it clear that Judge Wall authorized the electronics searches without notice to the Defendant, consistent with Rule 41(f)(1)(c).

The Defendant cites no authority for its contention that the Government must produce the notice it gave to Yahoo. The Court notes that it is clear, based on the record, that such notice

was given to Yahoo for the simple reason that Yahoo expressed its intention to notify the Defendant of the existence of the search warrant.

Further, even if the underlying Yahoo Search Warrants were defective in not providing for notice to the Defendant, the Government cured any defect when it obtained a non-disclosure court order pursuant to Section 2705(b) after Yahoo raised its objection noted above.

Under Section 2705(b), the government may also apply to the court under specified circumstances for an order commanding a provider “to whom a warrant, subpoena, or court order is directed, for such period as the court deems appropriate, not to notify any other person of the existence of the warrant, subpoena, or court order.” See generally In re U.S. for an Order Pursuant to 18 U.S.C. Section 2703(D), 707 F.3d at 296. Upon such application:

The court shall enter such an order if it determines that there is reason to believe that notification of the existence of the warrant, subpoena, or court order will result in —

- (1) endangering the life or physical safety of an individual;
- (2) flight from prosecution;
- (3) destruction of or tampering with evidence;
- (4) intimidation of potential witnesses; or
- (5) otherwise seriously jeopardizing an investigation or unduly delaying a trial.

Id.; see generally In Matter of Search Warrant for [Redacted]@hotmail.com, No. 14-MJ-71388- (PSG), 2014 WL 7801298, at *1 (N.D. Cal. Nov. 25, 2014).

The Defendant does not argue that the Section 2705(b) order of non-disclosure was procedurally improper, but takes issue with Nasiatka’s representation in the underlying affidavit that such disclosure would “seriously jeopardize the investigation, including by giving targets an opportunity to flee or continue flight from prosecution, destroy or tamper with evidence, change patterns of behavior, and notify confederates.” (Gov’s Exh. 17.).

In this regard, at oral argument, counsel for the Defendant argued as follows:

The Yahoo search warrants were executed in September of 2012 and in November of 2013.

To maintain that this investigation was covert at that time is unsupportable by the obvious facts of what transpired in this case.

Pharmacological, Mr. Scully's business, was searched by the same Special Agent who executed these affidavits in May of 2012; four months before the first search warrant, a year-and-a-half before the second search warrant.

The idea that an investigation remains covert after federal agents storm an individual's place of business and seize evidence and documents from it is unsupportable.

But that's not the only thing that occurred in this case.

As early as June of 2012, three months before the first search warrant, still over a year before the second search warrant, the agent and the United States Attorney's office were in discussion with Mr. Scully's then defense counsel about this case.

As appended to our papers submitted to the Court, there are communications in June of that year and also a representation made by the Special Agent in this case that he was proceeding with or seeking to proceed with a criminal investigation in this matter.

(Trans. at 12-13.)

As an initial matter, the Court notes that the standard for obtaining a Section 2705(b) order of non-disclosure requires less than a probable cause showing. Indeed, "[t]he explicit terms of section 2705(b) make clear that if a courts finds that there is reason to believe that notifying the customer or subscriber of the court order or subpoena may lead to one of the deleterious outcomes listed under § 2705(b), the court must enter an order commanding a service provider to delay notice to a customer for a period of time that the court determines is appropriate. Once the government makes the required showing under § 2705(b), the court is

required to issue the non-disclosure order.” Matter of Application of United States of Am. For an Order of Nondisclosure Pursuant to 18 U.S.C. §2705(B) for Grand Jury Subpoena # GJ2014031422765, 41 F. Supp. 3d 1, 5 (D.D.C. 2014).

Here, it is true that the Defendant knew about the underlying investigation since about May 2012, after which he met with the United States Attorneys’ Office after that time, and he did not flee thereafter. Nor is there any suggestion that he attempted to flee. However, the Court agrees with the Government that the Defendant takes an overly narrow view of the “investigation” in this context. Indeed, while the underlying affidavits in support of the Yahoo Search Warrants largely focused on the alleged criminal behavior of the Defendants, the Yahoo Search Warrants were for business email addresses associated with Pharmalogical and MDK.

Further, the Court notes that those portions of the affidavits seeking a seal of these Search Warrants were general in nature. Indeed, in Paragraph 63 of both the September 21, 2012 and the November 22, 2013 affidavits, Nasiatka averred that the affidavit was “part of a covert investigation into the sale of, among other things, unapproved cancer drugs. Revealing the affidavit at this time could possibly jeopardize the government’s ongoing investigation by causing the destruction of evidence.” (Gov’s Exh 2.) For this reason, Nasiatka requested and obtained a sealing of the Yahoo Search Warrants.

Relatedly, in the affidavit in support of the non-disclosure order pursuant to Section 2705(b), Nasiatka averred:

I believe that sealing these documents is necessary because the items and information to be seized are relevant to an ongoing investigation into a criminal organization trafficking in unlawful drugs. Based upon my training and experience, I have learned that criminals actively search for criminal affidavits and search warrants via the internet, and disseminate them to other criminals as they deem appropriate, e.g., by posting them publicly through online forums. Therefore, premature disclosure of the contents of this affidavit and related documents will seriously jeopardize the investigation, including by giving targets

an opportunity to flee or continue flight from prosecution, destroy or tamper with evidence, change patterns of behavior, and notify confederates.

(Doc No. 44, Exh. 17, 1-2.)

Notably, this affidavit does not define the breadth of the suspected “criminal organization” or the “targets” of the “ongoing investigation.” The Court does not focus on this language to suggest that the non-disclosure order was based on an overly broad affidavit, but to underscore the legitimate basis of the government’s professed need for the seal and order of non-disclosure. In addition, the Court notes that, as documented in the November 22, 2013 affidavit, the Defendant was engaging in suspicious conduct under the medev1@yahoo.com email address even after execution of the prior Yahoo Search Warrant in September 2012 (*Id.*, Exh. 2, at ¶ 63.)

According to the Government, the basis for the seal and non-disclosure order was borne out by the fact that, as a result of the ongoing investigation, officers from Ozay Pharma, a large supplier of counterfeit prescription drugs to Scully were arrested and charged with trafficking in counterfeit cancer drugs. (Gov’s Br., at 15.) These officers apparently pled guilty in federal court to conspiracy to smuggle unapproved, misbranded, and counterfeit prescription drugs into the United States, as well as fraudulent importation in violation of 18 U.S.C. § 545. (*Id.*) In addition, according to the Government, those officers “had numerous business connections to Scully” and “upon arrest on January 16, 2014 in Puerto Rico, one of the targets had [] Scully’s contact name and phone number on a piece of paper in his pocket.” (*Id.*)(citing Gov’s Exh. 8.)

Further, according to the Government, its “investigation disclosed that Scully was one of the largest customers of the imported oncology drugs and counterfeit cancer drugs from this company, Ozay Pharma, in Turkey and the trip to Puerto Rico was, in part, to replace Scully thereby reflecting his importance to these admitted traffickers in unapproved drugs. Notably, the Yahoo! Emails sought in the search warrants, in fact, contained communications between Scully

and Ozay Pharma in connection with Scully's purchase and illegal importation of unapproved new oncology drugs." (Id.) The Government represents that these emails were produced to Scully as part of discovery.

To be sure, the activities of Ozay Pharma do not appear to have been basis for Nasiatka's affidavits in support of the Yahoo Search Warrants. However, the foregoing evidence may have resulted from the investigation itself and may not have been obtained had the underlying search warrants and order of non-disclosure not been issued.

Accordingly, the Court finds that the Yahoo Search Warrants were properly issued and executed without notice to the Defendant under Section 2703(b) and, even if they were not so issued and executed, the order of non-disclosure under Section 2705(b) cured any defect.

Furthermore, the Court notes that, even if the Yahoo Search Warrants were defective under these provisions of the SCA, the SCA is a statute, not a constitutional rule requiring heightened protection. See United States v. Donovan, 429 U.S. 413, 432 n. 22, 97 S. Ct. 658, 50 L. Ed. 2d 652 (1977)("The availability of a suppression remedy for . . . statutory, as opposed to constitutional violations . . . turns on the provisions of [the statute] rather than the judicially fashioned exclusionary rule aimed at deterring violations of Fourth Amendment rights."); United States v. Guzman, 879 F. Supp. 2d 312, 322 (E.D.N.Y. 2012)(finding that violations of the Juvenile Delinquency Act's (JDA) statutory parental notification requirement did not require a *per se* suppression remedy); United States v. Clenney, 631 F.3d 658, 667 (4th Cir. 2011)("[i]n the statutory context, suppression is a creature of the statute, and its availability depends on the statutory text"); United States v. Abdi, 463 F.3d 547, 556 (6th Cir. 2006)("Although exclusion is the proper remedy for some violations of the Fourth Amendment, there is no exclusionary rule generally applicable to statutory violations."); but see United States v. Pulliam, 748 F.3d 967,

973 (10th Cir. 2014)(“some violations of Rule 41 can lead to the suppression of evidence regardless of whether the search was reasonable under the Fourth Amendment.”).

The Court also notes that the Second Circuit has not yet addressed the question of the constitutionality of the SCA. United States v. Pierce, No. 13-3687-CR, 2015 WL 2166141, at *7 (2d Cir. May 11, 2015). However, the Defendant does not challenge the SCA as unconstitutional, either on its face or as applied to him.

Of relevance here, Section 2708 of the SCA provides that “[t]he remedies and sanctions described in this chapter are the only judicial remedies and sanctions for nonconstitutional violations of this chapter.” The SCA “allows for civil damages, see 18 U.S.C. § 2707, and criminal punishment, see 18 U.S.C. § 2701(b), but nothing more.” United States v. Smith, 155 F.3d 1051, 1056 (9th Cir. 1998); United States v. Reyes, 922 F. Supp. 818, 838 (S.D.N.Y. 1996)(“The remedy for violation of Title II of the ECPA, set forth in 18 U.S.C. § 2707, lies in a civil action against the person or entity who violated the statute.”)(footnote omitted). If the Defendant wishes to sue Yahoo under this provision, he must commence an action no “later than two years after the date upon which [he] first discovered or had a reasonable opportunity to discover the violation.” 18 U.S.C. § 2707(f).

Accordingly, “[t]he SCA ‘affords no suppression remedy for non-constitutional violations [and, therefore,] even if [the Defendant could show] a violation of the statute, exclusion would not be the appropriate remedy.’” United States v. Stegemann, 40 F. Supp. 3d 249, 270 (N.D.N.Y. 2014)(quoting United States v. Powell, 444 Fed. Appx. 517, 520 (3d Cir. 2011)(citation omitted)); see also Smith, 155 F.3d at 1056.

Indeed, the SCA “expressly rules out exclusion as a remedy” by making its remedial provisions exclusive. Smith, 155 F.3d at 1056 (citing 18 U.S.C. 2708); see United States v.

Corbitt, 588 F. App'x 594 (9th Cir. 2014)(“Suppression of the evidence seized is not available as a remedy for a statutory violation of the [Stored Communications] Act.”); United States v. Guerrero, 768 F.3d 351, 358 (5th Cir. 2014)(“[S]uppression is not a remedy for a violation of the Stored Communications Act.”); United States v. Rigmaldeen, No. CR 08–814 (PHX)(DGC), 2013 WL 1932800, at *10 (D. Ariz. May 8, 2013)(“[E]ven if the SCA had been violated in some respect, Defendant’s motion to suppress would be denied. Suppression is not an available remedy for violations of the SCA.”); United States v. Dorsey, No. CR 14-328 (CAS), 2015 WL 847395, at *9 (C.D. Cal. Feb. 23, 2015)(same).

The Court next addresses whether the Government’s failure to provide notice to the Defendant of the issuance and execution of the Yahoo Search Warrants constituted an independent violation of his Fourth Amendment rights despite the absence of a Rule 41 or SCA violation.

The Second Circuit has declined to engraft a notice requirement onto the Fourth Amendment separate and apart from Rule 41. United States v. Pangburn, 983 F.2d 449, 455 (2d Cir. 1993)(“We prefer to root our notice requirement in the provisions of Rule 41 rather than in the somewhat amorphous Fourth Amendment “interests” concept developed by [United States v. Freitas, 800 F.2d 1451 (9th Cir. 1986).] The Fourth Amendment does not deal with notice of any kind, but Rule 41 does.”); see United States v. DiNapoli, No. 01 CR. 51 (LMM), 2001 WL 913935, at *1 (S.D.N.Y. Aug. 14, 2001)(finding “that there is no ‘constitutional requirement that the warrant be exhibited at the outset of a search, or indeed until the search has ended.’”)(citation omitted); see generally Dalia v. United States, 441 U.S. 238, 247, 99 S. Ct. 1682, 60 L. Ed. 2d 177 (1979)(“no basis for a constitutional rule proscribing all covert entries”); Katz v. United States, 389 U.S. 347, 355 n. 16, 88 S. Ct. 507, 19 L. Ed. 2d 576 (1967)(“[O]fficers need not

announce their purpose before conducting an otherwise authorized search if such an announcement would provoke the escape of the suspect or the destruction of critical evidence.”)(citation omitted).

Further, “[t]he prevailing view among federal courts is that the Fourth Amendment does not invalidate the delayed notice aspect of such warrants.” In the Matter of the Application of the U.S. for a Warrant Authorizing, No. 14-MJ-8116 (TJJ), 2015 WL 667923, at *8 (D. Kan. Feb. 13, 2015)(citing Pangburn); see In re Search Warrants Issued Aug. 29, 1994, 889 F. Supp. 296, 301 (S.D. Ohio 1995)(“Although Rule 41 of the Federal Rules of Criminal Procedure does require notice of the execution of a search warrant, no such requirement is found in the Fourth Amendment.”); but see In re U.S., 665 F. Supp. 2d at 1223 (“It is clear that notice is an essential part of the reasonableness calculus in judging searches and seizures under the Fourth Amendment.”).

Accordingly, the Court finds that the Government’s failure to provide notice before or after the issuance and execution of the Yahoo Search Warrants did not violate the Defendant’s Fourth Amendment rights.

3. The Challenges to the Substance of the Yahoo Search Warrants

The Court now considers the Defendant’s more particularized arguments with respect to the Yahoo Search Warrants. The Defendant first challenges the Yahoo Search Warrants as overbroad and lacking in particularity, thereby violating his Fourth Amendment rights. The Defendant also challenges the issuance of the search warrants as based on certain misrepresentations and omissions made in Nasiatka’s underlying affidavits.

Regarding the background underlying the Fourth Amendment, the Second Circuit noted last year that “[t]he British Crown had long used these questionable instruments to enter a

political opponent's home and seize all his books and papers, hoping to find among them evidence of criminal activity.” Ganias, 755 F.3d at 134 (citing Stanford v. Texas, 379 U.S. 476, 482–83, 85 S. Ct. 506, 13 L. Ed. 2d 431 (1965)); United States v. Galpin, 720 F.3d 436, 445 (2d Cir. 2013)(“The chief evil that prompted the framing and adoption of the Fourth Amendment was the ‘indiscriminate searches and seizures’ conducted by the British ‘under the authority of ‘general warrants.’”)(quoting Payton v. New York, 445 U.S. 573, 583, 100 S. Ct. 1371, 63 L. Ed. 2d 639 (1980)).

“The Framers abhorred this practice, believing that ‘papers are often the dearest property a man can have’ and that permitting the Government to ‘sweep away all papers whatsoever,’ without any legal justification, ‘would destroy all the comforts of society.’” Ganias, 755 F.3d at 134 (quoting Entick v. Carrington, 95 Eng. Rep. 807, 817–18 (C.P. 1765).

As the Supreme Court has explained, the English case, Entick, was “undoubtedly familiar to every American statesman at the time the Constitution was adopted, and considered to be the true and ultimate expression of constitutional law with regard to search and seizure.” Jones, 132 S. Ct. at 949 (internal quotation marks omitted).

Accordingly, “the [Warrants C]lause was intended as a bulwark against the ‘general warrant’ abhorred by the colonists and protects against ‘a general, exploratory rummaging in a person’s belongings.’” United States v. Cioffi, 668 F. Supp. 2d 385, 390 (E.D.N.Y. 2009) (quoting Coolidge v. New Hampshire, 403 U.S. 443, 467, 91 S. Ct. 2022, 29 L. Ed. 2d 564 (1971)). “Its overarching purpose is to ensure that ‘those searches deemed necessary should be as limited as possible.’” Cioffi, 668 F. Supp. 2d at 390 (quoting Coolidge, 403 U.S. at 467, 91 S. Ct. 2022). “To achieve its goal, the Warrants Clause requires particularity and forbids overbreadth.” Cioffi, 668 F. Supp. 2d at 390.

Of these two standards, “[b]readth deals with the requirement that the scope of the warrant be limited to the probable cause on which the warrant is based.” Id. (citation and quotation marks omitted). Thus, “the issue is whether there exists probable cause to support the breadth of the search that was authorized.” United States v. Dinero Express, Inc., No. 99 Cr. 975 (SWK), 2000 WL 254012, at *9 (S.D.N.Y. Mar. 6, 2000)(quotation marks omitted); see United States v. Dupree, 781 F. Supp. 2d 115, 154 (E.D.N.Y. 2011).

“Particularity is the requirement that the warrant must clearly state what is sought.” Cioffi, 668 F. Supp. 2d at 390 (citation and quotation marks omitted). “Particularity” concerns arise when a warrant’s description of the place to be searched or the items to be seized “is so vague that it fails reasonably to alert executing officers to the limits of their search and seizure authority.” United States v. Clark, 638 F.3d 89, 94 (2d Cir. 2011). To satisfy the “particularity” requirement, “[a] warrant must be sufficiently specific to permit the rational exercise of judgment [by the executing officers] in selecting what items to seize.” United States v. Liu, 239 F.3d 138, 140 (2d Cir. 2000)(quotation marks, citation, and alterations omitted).

However, “[t]he Fourth Amendment does not require that every item or document to be seized be specifically identified in the warrant; generic terms may be used to describe the materials to be seized.” United States v. Levy, No. S5 11 CR. 62 (PAC), 2013 WL 664712, at *5 (S.D.N.Y. Feb. 25, 2013)(citing United States v. D’Amico, 734 F. Supp. 2d 321, 361 (S.D.N.Y. 2010)). “The level of specificity required by the Fourth Amendment depends on many factors,” including the nature of the crime, and “[w]here . . . complex financial crimes are alleged, a warrant properly provides more flexibility to the searching agents.” Dupree, 781 F. Supp. 2d at 149 (citations omitted); see United States v. Cohan, 628 F. Supp. 2d 355, 362 (E.D.N.Y. 2009) (“[T]he degree to which a warrant must state its terms with particularity varies inversely with

the complexity of the criminal activity investigated.” (quotation marks and citation omitted)); see also United States v. Regan, 706 F. Supp. 1102, 1113 (S.D.N.Y. 1989)(“The degree to which a warrant must state its terms with particularity varies inversely with the complexity of the criminal activity investigated.”).

Furthermore, “the type of evidence sought is also relevant; in particular, courts have recognized that documentary evidence may be difficult to describe *ex ante* with the same particularity as a murder weapon or stolen property.” Dupree, 781 F. Supp. 2d at 149 (quoting Cioffi, 668 F. Supp. 2d at 391); see e.g. United States v. Riley, 906 F.2d 841, 845 (2d Cir. 1990) (“It is true that a warrant authorizing seizure of records of criminal activity permits officers to examine many papers in a suspect’s possession to determine if they are within the described category. But allowing some latitude in this regard simply recognizes the reality that few people keep documents of their criminal transactions in a folder marked ‘drug records.’”); United States v. Zanche, 541 F. Supp. 207, 210 (W.D.N.Y. 1982)(“Unlike other forms of property, business records are often incapable of being itemized one by one, particularly when their existence, but not their precise names or quantity, is all that is known.”).

“Courts tend to tolerate a greater degree of ambiguity where law enforcement agents have done the best that could reasonably be expected under the circumstances, have acquired all the descriptive facts which a reasonable investigation could be expected to cover, and have insured that all those facts were included in the warrant.” United States v. Buck, 813 F.2d 588, 590 (2d Cir. 1987)(quoting United States v. Young, 745 F.2d 733, 759 (2d Cir. 1984), cert. denied, 470 U.S. 1084, 105 S. Ct. 1842, 85 L. Ed. 2d 142 (1985)); see also United States v. Spilotro, 800 F.2d 959, 963 (9th Cir. 1986)(“Warrants which describe generic categories of items are not necessarily invalid if a more precise description of the items subject to seizure is not possible.”).

Nevertheless, “[a] failure to describe the items to be seized with as much particularity as the circumstances reasonably allow offends the Fourth Amendment because there is no assurance that the permitted invasion of a suspect’s privacy and property are no more than absolutely necessary.” United States v. George, 975 F.2d 72, 76 (2d Cir. 1992)(citing Coolidge).

Finally, where a magistrate finds probable cause and issues a search warrant, “the task of a reviewing court is simply to ensure that the ‘totality of the circumstances’ afforded the magistrate ‘a substantial basis’ for making the requisite probable cause determination.” United States v. Rissew, 580 F. App’x 35, 36 (2d Cir. 2014)(citations omitted). “Such deference derives not only from the law’s recognition that probable cause is ‘a fluid concept’ that can vary with the facts of each case, but also from its ‘strong preference’ for searches conducted pursuant to a warrant,” Clark, 638 F.3d at 93 (quoting Illinois v. Gates, 462 U.S. 213, 232, 236, 103 S. Ct. 2317, 76 L.Ed.2d 527 (1983)), “and its related concern that ‘[a] grudging or negative attitude by reviewing courts toward warrants will tend to discourage police officers from submitting their evidence to a judicial officer before acting.’” Clark, 638 F.3d at 93 (quoting United States v. Ventresca, 380 U.S. 102, 108, 85 S. Ct. 741, 13 L. Ed. 2d 684 (1965); see also United States v. Hoey, No. S3 11-CR-337 (PKC), 2014 WL 2998523, at *7 (S.D.N.Y. July 2, 2014)(same).

In this case, the Defendant first argues that the Yahoo Search Warrants, on their face, were overly broad and insufficiently particularized, thereby violating his Fourth Amendment rights. In particular, the Defendant argues that the Yahoo Search Warrants unconstitutionally authorized the seizure of a “broad array of non-relevant material.” (Doc No. 44, at 13.) The Court disagrees.

As noted above, the Yahoo Search Warrants specifically limited the information sought to certain business email accounts and to emails after January 1, 2010. Further, the Court notes

that Attachment B, specifically incorporated by each of the Yahoo Search Warrants, contained a section entitled, “Information to be seized by the government,” which limited the seizure of information to that which constituted “fruits, evidence and instrumentalities of violations of Title 21, United States Code, Sections 331(a) and 333(a)(2) involving William Scully and/or Shahrad Rodi Lameh” and which pertained to “[t]he unlawful importation of unapproved prescription drugs into the United States” and/or “[t]he sale of unapproved prescription drugs in the United States.”

In the Court’s view, “[b]y specifically identifying the statutes and conduct that gave rise to the search and seizure, the Search Warrant sufficiently identified the suspected crimes for which there was probable cause, and which the materials to be seized evidenced.” Levy, 2013 WL 664712, at *9; compare United States v. Barthelman, No. CRIM.A. 13-10016 (MLB), 2013 WL 3946084, at *11 (D. Kan. July 31, 2013)(finding email warrants based on general references to criminal statutes to be overbroad and not sufficiently particularized in violation of the Fourth Amendment) with United States v. Deppish, 994 F. Supp. 2d 1211, 1221 (D. Kan. 2014) (distinguishing Barthelman).

Indeed, “[g]enerally, a warrant that authorizes a search for documents or things that constitute evidence of a particular crime is not overbroad; rather, ‘generic terms may be used to describe the materials to be seized so long as the warrant identifies a specific illegal activity to which the item related.’” United States v. Lebovits, No. 11-CR-134 (SMG)(SJ), 2012 WL 10181099, at *23 (E.D.N.Y. Nov. 30, 2012)(citations omitted), report and recommendation adopted, No. 11 CR 134 (SMG)(SJ), 2014 WL 201495 (E.D.N.Y. Jan. 16, 2014) and report and recommendation adopted sub nom. United States v. Gutwein, No. 11 CR 134 (SJ), 2014 WL 201500 (E.D.N.Y. Jan. 16, 2014); see also United States v. Bazzi, No. 07–CR–212 (A)(M)

(JJM), 2010 WL 4451454, at *23 (W.D.N.Y. Apr. 21, 2010)(denying a motion to suppress in part because “although the search warrant used the language ‘included [sic] but not limited to’ in describing the categories of items that could be seized, it instructed that any item seized ‘must relate to violations of’ 18 U.S.C. Sections 1962 and 2320”)(footnote omitted); compare George, 975 F.2d at 75 (“The instant warrant’s broad authorization to search for ‘any other evidence relating to the commission of a crime’ plainly is not sufficiently particular with respect to the things to be seized because it effectively granted the executing officers’ ‘virtually unfettered discretion to seize anything they [saw].’”).

Even if the references to criminality here were “in truly vague terms, “any issue in that regard here is overcome by the reference in the warrants to crimes committed by specifically identified individuals,” namely, Scully and Lameh. Lebovits, 2012 WL 10181099, at *23 (citation omitted).

The Court further notes that, as noted above, this case was formally designated “complex” and involves complex financial crimes, such as wire fraud and mail fraud. Cohan, 628 F. Supp. 2d at 362 (“[T]he degree to which a warrant must state its terms with particularity varies inversely with the complexity of the criminal activity investigated.”)(citation omitted).

The Defendant’s reliance on Cioffi is misplaced. There, the court suppressed email evidence seized under a warrant issued pursuant to § 2703. However, it did so because the “[t]he Warrant did not, on its face, limit the items to be seized from [the defendant’s] personal email account to emails containing evidence of the crimes charged in the indictment or, indeed, any crime at all. Nor did it attach and incorporate the Affidavit.”); see In the Matter of a Warrant for All Content & Other Info. Associated with the Email Account xxxxxxxx gmail.com Maintained at Premises Controlled By Google, Inc., 33 F. Supp. 3d 386, 394 n. 3 (S.D.N.Y. 2014), as amended

(Aug. 7, 2014)(distinguishing Cioffi)(the “Google” case); Levy, 2013 WL 664712, at *9 (same); Lebovits, 2012 WL 10181099, at *23 (same); Kernell, 2010 WL 1491873, at *17 (same).

The Defendant also argues that the Yahoo Search Warrants were overly broad and insufficiently particularized in violation of the Fourth Amendment because they mandated disclosure of the entire contents of email accounts and seizure of those email. Again, the Court disagrees.

In In the Matter of the Search of Information Associated with [redacted]@mac.com that is Stored at Premises Controlled by Apple, Inc., 13 F. Supp. 3d 145 (D.D.C. April 7, 2014), vacated sub nom. Matter of Search of Info. Associated with [redacted]@mac.com that is Stored at Premises Controlled by Apple, Inc., No. 14–228 (RWR), 2014 WL 4094565 (D.D.C. Aug. 8, 2014)(the “D.C. Opinion ”), the court refused to issue a warrant requiring disclosure of the entire contents of an email account on the ground that the Government will “*actually* seize large quantities of e-mails for which it has not established probable cause” 13 F. Supp. 3d at 152. As the D.C. Opinion put it:

Here, the warrant describes only certain emails that are to be seized—and the government has only established probable cause for those emails. Yet it seeks to seize all e-mails by having them “disclosed” by [the email host]. This is unconstitutional because “[t]he government simply has not shown probable cause to search the contents of all emails ever sent to or from the account.”

Id. (quoting In re Applications for Search Warrants for Info. Associated with Target Email Address, No. 12-MJ-8119 (DJW), 2012 WL 4383917, at *9 (D. Kan. Sept. 21, 2012)).

The D.C. Opinion’s characterization of the Government’s application as an improper “seizure” of documents for which it had not shown probable cause cited to Coolidge v. New Hampshire, 403 U.S. 443, 91 S. Ct. 2022, 29 L. Ed. 2d 564 (1971). In Coolidge, in a discussion of the “plain view” exception to the search warrant requirement, the Supreme Court noted that

the warrant requirement serves to ensure that “those searches deemed necessary should be as limited as possible,” *id.* at 467, 91 S. Ct. 2022. Coolidge referred to the history of “general warrants” in colonial times, and stated that “the problem is not that of intrusion *per se*, but of a general, exploratory rummaging in a person’s belongings.” *Id.* As the Supreme Court later explained:

The general warrant specified only an offense — typically seditious libel — and left to the discretion of the executing officials the decision as to which persons should be arrested and which places should be searched. Similarly, the writs of assistance used in the Colonies noted only the object of the search — any uncustomed goods — and thus left customs officials completely free to search any place where they believed such goods might be. The central objectionable feature of both warrants was that they provided no judicial check on the determination of the executing officials that the evidence available justified an intrusion into any particular home.

Steagald v. United States, 451 U.S. 204, 220, 101 S. Ct. 1642, 68 L. Ed. 2d 38 (1981).

In the D.C. Opinion’s view, “any e-mails that are turned over to the government are unquestionably ‘seized’ within the meaning of the Fourth Amendment.” 13 F. Supp. 3d at 150. Thus, by making an application to “seize an entire e-mail account even though it had only established probable cause for some of the e-mails,” the Government was viewed in the D.C. Opinion as having asked the court “to issue a general warrant that would allow a general, exploratory rummaging in a person’s belongings’— in this case an individual’s email account.” *Id.* (citing Coolidge, 403 U.S. at 467, 91 S. Ct. 2022)(additional citation omitted).

The Government filed a challenged seeking review of the denial of its application for a search warrant. The District Court vacated the Magistrate Judge’s order, reasoning that the Government’s affidavit and application under the SCA for the search warrant comported with Fourth Amendment because the warrant appropriately restricted law enforcement officers’ discretion to determine the location to be searched and items to be seized, identified the precise

location to be searched, and specified the particular e-mails to be seized. Matter of Search of Info. Associated with [redacted]@mac.com that is Stored at Premises Controlled by Apple, Inc., 13 F. Supp. 3d at 164. Further, the District Court noted that the supporting affidavit provided probable cause to believe that electronic communications and records relating to alleged kickback conspiracy involving defense contractor would be found in particular e-mail account to be searched. Id.

In In re Applications for Search Warrants for Info. Associated with Target Email Accounts/Skype Accounts, No. 13-MJ-8163 (JPO), 2013 WL 4647554, at *1 (D. Kan. Aug. 27, 2013(the “Kansas Opinion”), the court criticized the warrant sought in that case on the ground that it required an email host to disclose “all email communications in their entirety” and “fail[ed] to limit the universe of electronic communications and information to be turned over to the government to the specific crimes being investigated.” 2013 WL 4647554, at *8.

However, as in the Google case, the Court respectfully disagrees with these aspects of the D.C. Opinion, which was vacated on appeal to the District Judge, and the Kansas opinion because they “too narrowly construe[] the Fourth Amendment’s particularity requirement and [are] contrary to copious precedent.” Id. at 391.

In this regard, the Court agrees with the comprehensive analysis of United States Magistrate Judge Gabriel W. Gorenstein in the Google case set forth in part, as follows:

“[a]mple case authority sanctions some perusal, generally fairly brief, of . . . documents (seized during an otherwise valid search) . . . in order for the police to perceive the relevance of the documents to crime.” United States v. Mannino, 635 F.2d 110, 115 (2d Cir. 1980)(quoting United States v. Ochs, 595 F.2d 1247, 1257 n. 8 (2d Cir. 1979)); accord Andresen v. Maryland, 427 U.S. 463, 482 n. 11, 96 S. Ct. 2737, 49 L. Ed. 2d 627 (1976)(“In searches for papers, it is certain that some innocuous documents will be examined, at least cursorily, in order to determine whether they are, in fact, among those papers authorized to be seized.”). As the Second Circuit has noted, “allowing some latitude in this regard simply recognizes the reality that few people keep documents of their criminal

transactions in a folder marked ‘drug records.’” United States v. Riley, 906 F.2d 841, 845 (2d Cir. 1990). With respect to the execution of search warrants seeking physical evidence, courts “permit[] the government to examine paper documents that might otherwise fall outside the scope of a search warrant to make that determination, recognizing that different types of evidence present different tactical issues.” Metter, 860 F. Supp. 2d at 213. In other words, courts have long recognized the practical need for law enforcement to exercise dominion over documents not within the scope of the warrant in order to determine whether they fall within the warrant. Such exercise of dominion essentially amounts to a “seizure” even if the seizure takes place at the premises searched and is only temporary. See, e.g., United States v. Jones, — U.S. —, 132 S. Ct. 945, 958, 181 L. Ed. 2d 911 (2012)(“A seizure of property occurs when there is some meaningful interference with an individual’s possessory interests in that property.”)(quoting United States v. Jacobsen, 466 U.S. 109, 113, 104 S. Ct. 1652, 80 L. Ed. 2d 85 (1984)(internal quotation marks omitted)).

In the case of electronic evidence, which typically consists of enormous amounts of undifferentiated information and documents, courts have recognized that a search for documents or files responsive to a warrant cannot possibly be accomplished during an on-site search. Thus, “courts developed a more flexible approach to the execution of search warrants for electronic evidence, holding the government to a standard of reasonableness.” Metter, 860 F. Supp. 2d at 214; accord United States v. Graziano, 558 F. Supp. 2d 304, 317 (E.D.N.Y. 2008) (courts have afforded law enforcement “leeway in searching computers for incriminating evidence within the scope of materials specified in the warrant”) (citations omitted); United States v. Scarfo, 180 F. Supp. 2d 572, 578 (D.N.J. 2001)(“Where proof of wrongdoing depends upon documents . . . whose precise nature cannot be known in advance, law enforcement officers must be afforded the leeway to wade through a potential morass of information in the target location to find the particular evidence which is properly specified in the warrant.”); see also United States v. Ganius, 755 F.3d 125, 134–36 (2d Cir. 2014)(“[T]he ability of computers to store massive volumes of information presents logistical problems in the execution of search warrants.”).

...

Notably, every case of which we are aware that has entertained a suppression motion relating to the search of an email account has upheld the Government’s ability to obtain the entire contents of the email account to determine which particular emails come within the search warrant. See United States v. Bach, 310 F.3d 1063, 1065 (8th Cir. 2002)(upholding as constitutionally reasonable the seizure of “all of the information” from defendant’s email account where the service provider did not “selectively choose or review the contents of the named account”); United States v. Ayache, 2014 WL 923340, at *2–3 (M.D. Tenn. March 10, 2014)(denying motion to suppress “seizure of all emails in a defendant’s account [] where there was probable cause to believe that the email

account contained evidence of a crime”); United States v. Deppish, 994 F. Supp. 2d 1211, 1219–21 & n. 37 (D. Kan. 2014)(noting that “nothing in § 2703 precludes the Government from requesting the full content of a specified email account,” and concluding that such a search is not a “general search”); United States v. Taylor, 764 F. Supp. 2d 230, 232, 237 (D. Me. 2011)(upholding search of “all information associated with an identified Microsoft hotmail account”); United States v. Bowen, 689 F. Supp. 2d 675, 682 (S.D.N.Y. 2010)(Fourth Amendment does not require authorities to “ascertain which e-mails are relevant before copies are obtained from the internet service provider for subsequent searching”); United States v. McDarrah, 2006 WL 1997638, at *9–10 (S.D.N.Y. July 17, 2006)(denying motion to suppress seizure of “[a]ll stored electronic mail and other stored content information presently contained in” a specified email account), aff’d, 351 Fed. Appx. 558 (2d Cir. 2009).

Google, Inc., 33 F. Supp. 3d at 390-94.

In sum, the Court concludes that the Yahoo Search Warrants were not overly broad or insufficiently particular in violation of the Fourth Amendment. Further, even if the Yahoo Search Warrants, on their face, violated the Defendant’s Fourth Amendment rights, for reasons explained later, the Court would not grant the desired remedy of suppression.

The Court now turns to the Defendant’s specific claims that Nasiatka made material misrepresentations and omitted material information in his affidavits in support of those warrants.

As to any alleged misrepresentations, the Court notes that the Defendant does not request a hearing pursuant to Franks v. Delaware, 438 U.S. 154, 98 S. Ct. 2674, 57 L. Ed. 2d 667 (1978). By that decision, “where the defendant makes a substantial preliminary showing that a false statement knowingly and intentionally, or with reckless disregard for the truth, was included by the affiant in the warrant affidavit, and if the allegedly false statement is necessary to the finding of probable cause, the Fourth Amendment requires that a hearing be held at the defendant’s request.” 438 U.S. at 155–56, 98 S. Ct. 2674. To

be entitled to a Franks hearing, the defendant's attack on material contained in the search warrant:

must be more than conclusory and must be supported by more than a mere desire to cross-examine. There must be allegations of deliberate falsehood or of reckless disregard for the truth, and those allegations must be accompanied by an offer of proof. They should point out specifically the portion of the warrant affidavit that is claimed to be false; and they should be accompanied by a statement of supporting reasons. Affidavits or sworn or otherwise reliable statements of witnesses should be furnished, or their absence satisfactory explained. Allegations of negligence or innocent mistake are insufficient.

Id. at 171, 98 S. Ct. 2674. Therefore, “[t]o invoke the Franks rule, a defendant is required to show: (1) ‘that there were intentional and material misrepresentations or omissions’ in the warrant affidavit, and (2) that the ‘alleged falsehoods or omissions were necessary to the . . . probable cause finding.’” United States v. Mandell, 752 F.3d 544, 552 (2d Cir. 2014)(quoting United States v. Awadallah, 349 F.3d 42, 64-65 (2d Cir. 2003)).

Notably, “there is . . . a presumption of validity with respect to the affidavit supporting the search warrant.” Franks, 438 U.S. at 171, 98 S. Ct. 2674. The standard for entitlement to a Franks hearing is high, see Rivera v. United States, 928 F.2d 592, 604 (2d Cir. 1991), and requires a “substantial preliminary showing” that a false statement was knowingly and intentionally, or with reckless disregard for the truth, included in the affidavit for the search warrant. Franks, 438 U.S. at 155–56, 98 S. Ct. 2674; see also United States v. Mandell, 710 F. Supp. 2d 368, 372 (S.D.N.Y. 2010)(“Hearings under Franks are not freely granted.”).

However, in the event a defendant is successful in obtaining a Franks hearing, “[i]n order to challenge successfully a search warrant based on an attack on the allegations in a supporting affidavit, a defendant ‘must show by a preponderance of the evidence that the affidavit contained false statements that were material on the issue of

probable cause.” United States v. Wapnick, 60 F.3d 948, 955 (2d Cir. 1995)(citation omitted); see also United States v. Lahey, 967 F. Supp. 2d 698, 709 (S.D.N.Y. 2013) (“To require suppression, a movant must demonstrate, by a preponderance of the evidence, both the affiant’s *intent* to mislead the issuing judge and the materiality of the affiant’s falsehoods or omissions.”); see United States v. Fernandes, 50 F. Supp. 3d 398, 402-03 (W.D.N.Y. 2014)(enunciating the Franks hearing standard).

In this case, in his main memorandum of law, reply brief, and at oral argument, the Defendant cites Franks once and only for the proposition that the “reckless disregard” prong of the Franks inquiry can sometimes be reckless from the omission of critical information.

As to the Defendant’s specific claims in this regard, he first argues that both of Nasiatka’s affidavits in support of the Yahoo Search Warrants lead with highly inflammatory and unsupported language in paragraph 4 that MDK and Pharmalogical “have been ordering and receiving foreign drugs including cancer medication . . . It has been further determined that that these foreign drugs have been sold and/or administered to, among others, cancer patients without their knowledge.” (Gov’s Exh 2.)

However, the Defendant points to nothing specific with regard to this statement, or others like it in those affidavits, that were untrue. According to the Government, it has produced to the Defendant the invoices referenced to certain counts of the indictment evidencing the sale of oncology drugs, including but not limited to Mabthera and Altuzan, that could not be sold legally in the United States. (Id., Exh. 9.)

Further, parsed closely, the words “have been sold,” in the passive voice, do not state that MDK and Pharmalogical sold such drugs “directly” to any cancer patients.

However, even without such parsing, paragraph 4 of the affidavits does not imply or suggest direct sales, nor do the underlying relevant counts of the Indictment rest on any alleged “direct” sales. Indeed, in the Court’s view, the affidavits in support of the Yahoo Search Warrants, considered in the totality, make clear that Pharmalogical and MDK, through which the Defendant allegedly committed the underlying offenses, sold drugs to medical facilities, not directly to individuals.

The Defendant next takes issue with the following language in Paragraph 33 of the affidavits discussing the nature of an undercover phone call made by a New York State Board of Pharmacy representative to an MDK phone number. (Oral Arg Trans., 16-18.) According to Nasiatka, “[t]he undercover caller inquired as to how [MDK] could sell the advertised drugs at the prices offered and was told that they could offer these prices, as [MDK] had no sales force and shipped the drugs from overseas, *as the company itself was located in the United Kingdom.*” (Affids, at ¶ 33.) (emphasis added).

The Defendant contends that the emphasized language falsely suggested that MDK was located outside the United States. However, the Court finds that the immediately preceding language, “shipped the drugs from overseas,” considered in conjunction with the numerous references in the affidavits to Great Neck, New York as the location of Pharmalogical and MDK, render this argument without merit. In other words, considered in its totality, the Court is of the view that the emphasized language, although not entirely artful, could not mislead the issuing judge.

The Defendant next argues that the Yahoo Search Warrants neglected to reference the execution of the prior search warrants in this investigation, including the execution of the May 24, 2012 warrant of Pharmalogical’s office in Great Neck and the execution of

the Warehouse Search Warrant. The Defendant contends that this omission was critical because those searches yielded, among other items, approximately 5,000 emails from medev1@yahoo.com and taranismed@yahoo.com. Relatedly, the Defendant contends that some of these emails include written attorney opinions to him advising him that his business model for purchasing pharmaceutical drugs manufactured in Europe for sale in the United States was legal. (Scully's Exhs. 4-5.)

The Court notes that the affidavit in support of the November 22, 2013 Yahoo Search Warrant specifically referenced the prior Yahoo Search Warrant. Further, while the Government may not properly rely on the fact that Judge Wall was the issuing judge as its reason for neglecting to mention any prior search warrants, the Defendant cites no authority supporting his argument that the fact of this prior execution calls into question the necessity of the Yahoo Search Warrants. In any event, whether or not there were prior search warrants does not impact on the requisite probable cause showing.

Indeed, the Government represents that execution of the Yahoo Search Warrants yielded evidence of the Defendant's ongoing criminality after the execution of the Office Search Warrants and none of which could have been obtained through the execution of the Office Search Warrants.

The Court next considers the Defendant's argument that Nasiatka should have revealed that he received certain legal advice advising him of the legality of his business model.

As background, in the criminal context, 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); accord United States v. Beech–Nut Nutrition Corp., 871 F.2d 1181, 1194 (2d Cir. 1989)(Noting that, the “thrust” of the “advice-of-counsel defense” “is that the defendant, on the basis of counsel’s advice, believed his conduct to be lawful and thus could not be found to have had unlawful intent. . . . [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.”).

Each requirement must be satisfied. Cf. United States v. Evangelista, 122 F.3d 112, 117 (2d Cir. 1997)(affirming the denial of an advice-of-accountant jury charge in a tax fraud case for the defendants’ demonstrated failure to follow accountant’s advice).

Here, the Court notes that, according to the Defendant, the Government did not become aware of the legal opinions the Defendant received regarding the legality of his business model until March 1, 2013. Therefore, the Defendant’s contention that this fact should have not have been omitted in the affidavits is apparently only relevant to the later-issued November 22, 2013 Yahoo Search Warrant.

The Government notes that the above-mentioned legal advice was limited to only two items the Defendant sold. The Government also argues that this legal advice was from 2009 and 2010; had express limitations and disclaimers; and was based on incomplete and inaccurate information and assumptions.

Here, without opining on the merits of the Defendant’s advice and counsel defense, the Court find that there is nothing to suggest that the written advice he received

would have, if disclosed to the issuing judge, defeated a probable cause showing for the Yahoo Search Warrants.

The Defendant separately argues that Nasiatka should have revealed that following the New York State Board of Pharmacy undercover calls, the State of New York renewed Pharmalogical's license. The Government responds that this omission "has no impact on the probable cause presented in the affidavit because New York State advised the case agent that the license had to be renewed absent an arrest." (Doc No. 48, at 10.) The Government does not cite any specifics to substantiate the truth of this assertion by "New York State," or that it was even made. (See Oral Arg Trans., at 19-20.)

Nevertheless, as with the advice and counsel defense, there is nothing to suggest the fact of Pharmalogical's license renewal, if disclosed to the issuing judge, would have defeated probable cause for the Yahoo Search Warrants.

The Court reaches a similar conclusion with respect to the omission that during the time period of the FDA's investigation, the United States Drug Enforcement Agency ("DEA") conducted an onsite review of Pharmalogical and granted it a DEA license. The DEA license concerned controlled substances, which are not at issue in this case. While the Defendant is correct to the extent that the DEA is likely "not in the business of reviewing a drug company and granting them a controlled substance license if [it] think[s] anything about that business is fraudulent or improper," (id. at 20.), there is nothing to suggest the fact of the DEA license grant, if disclosed to the issuing judge, would have defeated probable cause for the Yahoo Search Warrants.

The Court also finds that the fact that the FDA returned certain items to the Defendant, including non-prescription drugs such as Juvederm, Resylane, and Euflexxa,

following execution of the Office Search Warrants, if disclosed to the issuing judge, would have defeated probable cause for the Yahoo Search Warrants. The Court notes that the Government represents that these items were returned because the manufacturers had not provided complete information to the case agent and that, given complete information which was obtained later, the items would not have been returned.

The Defendant also argues that the issuing judge should have been made aware of the fact that, as a result of the execution of the Office Search Warrants in May 2012, Pharmalogical stopped selling all oncology products; that Scully thought he was complying with United States law; and he was prepared to take whatever steps necessary to ensure such compliance. However, it is not clear how a cessation of allegedly unlawful activities obviates the need for further investigation regarding prior alleged unlawful activities.

In any case, the Court credits the Government's response that, in October 2013, the Defendant sought a new wholesaler license in New York and New Jersey using the email address, medev1@yahoo.com and the company name, Zymodyne LLC, to continue his selling of misbranded and counterfeit cancer drugs. The Government notes that the November 22, 2013 Yahoo Search Warrant was sought in response to this continuing investigation and was limited to that email address.

The Defendant also argues that the affidavits improperly suggested that distributing non-English label drugs, a violation of an FDA regulation, 21 C.F.R. 201.15(c)(1), gives rise to criminal liability.

However, as noted later, the Court finds that a violation of this FDA regulation can serve in part as a predicate basis for the relevant counts. The Court further

determines that even if this were not so, references to violations of FDA regulations may, in certain circumstances and for purposes of showing probable cause in support of a search warrant, be relevant to allegations of alleged criminal conduct. This is particularly so where, as here, the alleged violation of the FDA regulation is intertwined with the alleged criminal conduct.

Based on the foregoing reasons, the Court rejects the Defendant's constitutional arguments challenging the breadth and particularity of the Yahoo Search Warrants and his arguments made in connection with certain alleged misrepresentations and omissions in procuring those warrants.

4. The Challenge to the Government's Retention of Material Obtained as a Result of the Execution of the Yahoo Search Warrant

Relying on Ganias, the Defendant separately argues that the Government's unlawful retention of all emails from medev1@yahoo.com and taranised@yahoo.com, regardless of relevance and privilege, justifies suppression of the contents of those emails.

The Government responds that the Defendant was provided a copy of the disks received from Yahoo and that the emails have been properly retained for authentication purposes. The Government appears to argue that it may do this, approximately more than a year and half after executing the second Yahoo Search Warrant, notwithstanding the lack of any relevancy or privilege.

"Like all activities governed by the Fourth Amendment, the execution of a search warrant must be reasonable." United States v. Lustyik, 57 F. Supp. 3d 213, 230 (S.D.N.Y. 2014)(citing United States v. Ramirez, 523 U.S. 65, 71, 118 S. Ct. 992, 140 L. Ed. 2d 191 (1998)). For example, government agents "may not seize and retain items outside the

scope of a warrant.” Lustyik, 57 F. Supp. at 230 (citing United States v. Matias, 836 F.2d 744, 747 (2d Cir. 1988)).

In Ganias, the Government executed a search warrant at the offices of an accountant that permitted it to obtain records of two corporate clients of the accountant. 755 F.3d at 127–28. The agents made forensic images of the hard drives of all three of the accountant’s computers, which included files containing the accountant’s “personal financial records”— records that were beyond the scope of the warrant. Id. An agent executing the warrant on November 19, 2003 “assured” the accountant that any computer files unrelated to the investigation “would be purged once [the Government] completed [its] search” for relevant files. Id. The Government had segregated the accountant’s personal financial records by December 2004 but never kept its promise to purge or delete these non-responsive files. Id. at 129, 136–37.

In late 2004, the Government began to suspect that the accountant was personally involved in criminal activity. Id. at 129. The Government then obtained a second warrant on April 24, 2006, to search the defendant’s personal financial records, images of which had remained in the Government’s possession pursuant to the first warrant. Id. at 129–30. At the time the Government secured the second warrant, however, the images of the personal financial records “had been in the Government’s possession for almost two-and-a-half years” and “would not have existed but for the Government’s retention of those images” because, in the interim, the accountant had altered the original files. Id.

The Second Circuit noted that while “wholesale removal” of “intermingled computer records” may be permissible where off-site sorting is “necessary and reasonable,” “this accommodation does not somehow authorize the Government to retain

all non-responsive documents indefinitely, for possible use in future criminal investigations.” Id. at 140 (citation omitted).

Responding to the Government’s argument that returning or destroying the non-responsive files is “entirely impractical” “because doing so would compromise the remaining data that was responsive to the warrant, making it impossible to authenticate or use it in a criminal prosecution,” the Second Circuit noted that it “[was] not convinced that there [wa]s no other way to preserve the evidentiary chain of custody.” Id. at 139.

However, “[w]hile Ganias expressed skepticism about the need for retaining non-responsive files for this purpose, it was willing to ‘assume’ the need existed and stated that in such an event, the retained material should not be used ‘for any other purpose’—presumably referring to the material’s use in that case as the basis for a second warrant.”

Google, Inc., 33 F. Supp. 3d at 399 n.7.

Further, “although the Second Circuit has emphasized that unreasonable retention of irrelevant data can present a critical problem, there is no defined time period in which the Government must segregate the data responsive to the Warrant from the unresponsive, though some recent case law has outlined the broad contours of what is considered reasonable.” United States v. Romain, No. 13 CR. 724 (RWS), 2014 WL 6765831, at *8 (S.D.N.Y. Dec. 1, 2014); Ganias, 755 F.3d at 136 (Government retention of documents for two and a half years was unreasonable); see also United States v. Metter, 860 F. Supp. 2d 205, 215 (E.D.N.Y. 2012)(“[U]nder current law there is no established upper limit as to when the government must review seized electronic data to determine whether the evidence seized falls within the scope of a warrant Numerous cases hold that a delay of several months between the seizure of electronic evidence and

the *completion* of the government’s review of that evidence as to whether it falls within the scope of the warrant is reasonable.”).

Here, the retention of documents allegedly outside the scope of the Yahoo Search Warrants mirrors the two and half year time-frame deemed unreasonable in Ganias. However, the Government states that any such emails are being retained for authentication purposes only and will not be used in future criminal investigations. Accordingly, consistent with Ganias, suppression is not an appropriate remedy for the alleged improper retention.

The Court further finds that, with respect to the retention of these emails, the Defendant has not shown a lack of good faith on the part of the Government. Compare Metter, 860 F. Supp. 2d at 212-16 (suppressing evidence based on the Government’s lack of good faith in a 15–month delay in reviewing electronic evidence it had seized).

In sum, the Court recognizes that “it may be necessary for the Government to maintain a complete copy of the electronic information to authenticate evidence responsive to the warrant for purposes of trial.” Google, Inc., 33 F. Supp. 3d at 399 (footnote omitted).

The Court notes that while suppression is not an appropriate remedy here, “Rule 41(g) of the Federal Rules of Criminal Procedure authorizes ‘[a] person aggrieved by an unlawful search and seizure of property or by the deprivation of property’ to move for the property’s return ‘in the district where the property was seized.’” See Lugo v. United States, No. 11-CV-3715 (SJF), 2014 WL 2002738, at *2 (E.D.N.Y. May 14, 2014)(quoting Rule 41(g) and outlining the standards for such an action). Although this provision is contained in the Federal Rules of Criminal Procedure, such a motion “is

treated as a claim for civil equitable relief.” United States v. Romano, No. 09 CR 170 (SJ), 2014 WL 5421234, at *2 (E.D.N.Y. Oct. 23, 2014)(citing Boero v. DEA, 111 F.3d 301, 303 (2d Cir. 1997)).

5. The Challenge to the Issuance and Execution of the Office Search Warrants

The Defendant makes largely the same arguments in seeking to suppress the materials derived from the execution of the Office Search Warrants that he does in seeking to suppress the materials derived from the execution of the Yahoo Search Warrants. Of course, many of the arguments related to the SCA and Rule 41 are not applicable to the Office Search Warrants.

For substantially the same reasons set forth in its discussion of the various challenges to the Yahoo Search Warrants, the Court denies the Defendant’s suppression motion as to the Office Search Warrants. In particular, the Court finds that probable cause supported the issuance of the Office Search Warrants. Further, the Court finds that the Defendant has not shown that any alleged omissions would have defeated probable cause if disclosed to the issuing judge. The Court further finds that Nasiatka did not make any misrepresentations to the issuing judge, and even if he did, they were not material so as to defeat probable cause. Finally, the Court finds that even if the Defendant had shown a Fourth Amendment violation, he has not made the required showing to avoid application of the “good faith” exception to the exclusionary rule.

The Court does note that, in conjunction with the affidavits for the issuance of the Office Search Warrant, an attachment to the May 18, 2012 warrant authorized retention of computers seized at the Great Neck offices “for the purpose of authentication and any potential discovery obligations in any related prosecution.”

However, consistent with Ganias, the Government will not be permitted to use any materials outside the scope of the warrant for purposes of a future investigation.

6. Challenge to the Issuance and Execution of the Warehouse Search Warrant

At oral argument, counsel for the Defendant requested that evidence derived from the execution of the Warehouse Search Warrant be suppressed. (Trans., at 23.) This particular relief was not specifically sought in the Defendant's notice of motion or accompanying papers. In any event, the analysis of the Court in rejecting the Defendant's challenge to the Yahoo Search Warrants based on the alleged misrepresentations and omissions applies with full force to the issuance and execution of the Warehouse Search Warrant. Further, the Defendant proffers no independent reason why the Warehouse Search Warrant was defective on its face or executed improperly.

7. The Good Faith Exception Applied to the Issuance and Execution of the Yahoo Search Warrants and Office Search Warrants

In any event, the Court notes that, even if the Defendant had shown a Fourth Amendment violation in connection with the issuance or execution of the Yahoo Search Warrants, the Office Search Warrants, or the Warehouse Search Warrant, suppression is a "prudential" remedy, crafted by the Supreme Court "to compel respect for the constitutional guaranty." United States v. Raymonda, 780 F.3d 105, 117 (2d Cir. 2015)(quoting Davis v. United States, — U.S. —, 131 S. Ct. 2419, 2426, 180 L. Ed. 2d 285 (2011)(internal quotation marks omitted). "Neither a 'personal constitutional right' nor a means to 'redress the injury' of an unconstitutional search, the exclusionary rule is designed to deter future Fourth Amendment violations." Raymonda, 70 F.3d at 117 (citing Davis, 131 S. Ct. at 2426 (internal quotation marks omitted)).

“Because the remedy exacts a heavy toll on the justice system, however, the exclusionary rule does not apply whenever suppressing evidence ‘might provide marginal deterrence.’” Raymonda, 780 F.3d at 117 (quoting Herring v. United States, 555 U.S. 135, 141, 129 S. Ct. 695, 172 L. Ed. 2d 496 (2009)(internal quotation marks omitted)). “The rule’s corrective value justifies its cost when a government agent ‘exhibit[s] deliberate, reckless, or grossly negligent disregard for Fourth Amendment rights.’” Raymonda, 70 F.3d at 117-18 (citing United States v. Stokes, 733 F.3d 438, 443 (2d Cir. 2013)(internal quotation marks and citation omitted). In such a situation, “[g]ood faith is not a magic lamp for [government agents] to rub whenever they find themselves in trouble.” United States v. Reilly, 76 F.3d 1271, 1280 (2d Cir. 1996) on reh’g, 91 F.3d 331 (2d Cir. 1996).

However, when a government agent acts with “an objectively reasonable good-faith belief that their conduct is lawful,” or when their conduct involves only “simple, isolated negligence,” exclusion simply “cannot pay its way.” Davis, 131 S. Ct. at 2427–28 (citations and quotation marks omitted).

In light of this principle, courts have recognized that evidence obtained by government agents “in objectively reasonable reliance” on a warrant subsequently invalidated by a reviewing court is not generally subject to exclusion. See United States v. Falso, 544 F.3d 110, 125 (2d Cir. 2008)(citation and quotation marks omitted). When a government agent genuinely believes that he has obtained a valid warrant from a magistrate and executes that warrant in good faith, there is no conscious violation of the Fourth Amendment, “and thus nothing to deter.” United States v. Leon, 468 U.S. 897, 920–21, 104 S. Ct. 3405, 82 L. Ed. 2d 677 (1984).

To claim the benefits of the good faith exception, however, the agent's reliance on the duly issued warrant "must be objectively reasonable." Id. at 922, 104 S. Ct. 3405. Accordingly, the good faith exception cannot shield even an agent who relies on a duly issued warrant in at least four circumstances: "(1) where the issuing magistrate has been knowingly misled; (2) where the issuing magistrate wholly abandoned his or her judicial role; (3) where the application is so lacking in indicia of probable cause as to render reliance upon it unreasonable; and (4) where the warrant is so facially deficient that reliance upon it is unreasonable." Clark, 638 F.3d 100 (citations omitted). "The Supreme Court has since clarified that these limitations apply not merely in cases of deliberate misconduct" by a government agent, Raymonda, 780 F.3d at 118, but, contrary to the Defendant's contention (Oral Arg. Trans., at 23.), also in situations where an agent is "reckless" or "grossly negligent" in seeking or executing a warrant. Herring, 555 U.S. at 144, 129 S. Ct. 695; see also Davis, 131 S. Ct. at 2427

Indeed, the Second Circuit and district courts in this Circuit have, at times, declined to evaluate a probable cause showing altogether and instead decided Fourth Amendment claims based on the good faith exception. United States v. Cancelmo, 64 F.3d 804, 807 (2d Cir. 1995)(acknowledging that the question of whether probable cause existed was a close one and upholding the search based upon the good faith exception); United States v. Moore, 968 F.2d 216, 222 (2d Cir. 1992)(declining to resolve the question of whether probable cause existed based upon application of the good faith exception), cert. denied, 506 U.S. 980, 113 S. Ct. 480, 121 L. Ed. 2d 385 (1992); United States v. Fama, 758 F.2d 834, 835 (2d Cir. 1985)("While we acknowledge that a creditable probable cause question is raised, we do not reach it because we believe that,

under the circumstances, we are compelled by United States v. Leon, 468 U.S. 897, 104 S. Ct. 3405, 82 L. Ed. 2d 677 (1984), to reverse the suppression order.”); United States v. Sykes, 424 F. Supp. 2d 590, 602 (W.D.N.Y. 2006)(“I conclude that the outcome of the probable cause challenge is so close, whether or not probable cause is found, that the agents were entitled to rely reasonably upon the issuing judge’s determination of that very question.”), aff’d, 304 F. App’x 10 (2d Cir. 2008). At least one court has taken this approach with respect to a particularity challenge. See United States v. Nguyen, No. 13-CR-6044L (MWP), 2014 WL 1512030, at *17 (W.D.N.Y. Apr. 7, 2014)(“I decline to reach the issue of whether the warrants are sufficiently particular, finding instead that Leon’s good faith exception applies.”)(citation omitted), report and recommendation adopted, No. 13-CR-6044L (DGL), 2014 WL 1795045 (W.D.N.Y. May 6, 2014).

Here, as noted above, the Court rejects on the merits each aspect of the Defendant’s Fourth Amendment challenges to the Yahoo Search Warrants, the Office Search Warrants, and the Warehouse Search Warrant.

Alternatively, applying the “good faith” exception to the exclusionary rule, the Court finds that the Defendant has not shown that the issuing magistrate on any of these search warrants was knowingly misled, or misled at all. Compare Reilly, 76 F.3d at 1280 (inferring recklessness, where the affiants “fail[ed] to provide *all* potentially adverse information,” including details about the size and nature of physical premises, which details were relevant to the validity of the search)(emphasis added); cf. United States v. Rajaratnam, 719 F.3d 139, 155-56 (2d Cir. 2013)(finding that the record, including Franks hearing testimony, did not support the finding that the omission of the SEC investigation in the wiretap application under Title III of the Omnibus Crime Control and

Safe Streets Act of 1968 was made with “reckless disregard for the truth.”), cert. denied, 134 S. Ct. 2820, 189 L. Ed. 2d 785 (2014)

Nor is there any suggestion that any of the issuing judges wholly abandoned his or her judicial function. Further, the Court find that the affidavits in support of the Yahoo Search Warrants were not so lacking in indicia of probable cause or were facially deficient as to render reliance upon them unreasonable.

Quite the contrary, the Court finds that the Yahoo Search Warrants were properly supported by probable cause. As noted above, the affidavits made allegations against Scully and Lameh stating that they were potentially engaging in criminal conduct, including selling misbranded and unapproved drugs. The affidavits then related in detail the underlying investigation; including the undercover calls; the discount prices offered by Scully and Lameh; the undercover purchases; the seizures of drugs from third-party facilities that conducted business with Pharmalogical and/or MDK; the use of the business email address; and information connecting the foregoing to the Great Neck offices.

Accordingly, the Court finds that even had the Defendant shown a Fourth Amendment violation in connection with the issuance and execution of the Yahoo Search Warrants, it would apply the “good faith” exception to the exclusionary rule and decline to suppress the evidence obtained as a result.

B. The Motion to Strike All Counts Based on Violation of FDA Regulations

The Defendant also seeks to strike all counts of the Indictment based in whole or in part on the violation of FDA regulations and to strike any references to such regulations. In particular, the Defendant argues that any count based 21 C.F.R. 201.15(c)(1), which, with certain

exceptions, requires that drug labels be written in the English language, be stricken because the Government improperly conflates violations of federal criminal law with violations of FDA regulations.

As noted above, the Defendant is charged with, among other counts, violation of 21 U.S.C. Sections 331(c) and 333(a)(2) of the FDCA. Sections 502 and 503 of the FDCA, codified in Sections 352 and 353, sets forth certain ways a drug can be deemed “misbranded” under the FDCA.

Of relevance here, Section 352(c), entitled “Prominence of information on label,” provides that a drug or device will be deemed “misbranded” “[i]f any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.”

However, as the Defendant contends, nothing in the FDCA criminalizes the use of non-English language labels. Indeed, as the Government concedes, “[Congress] did not specify what terms would be likely to be understood by an ordinary individual for Section 352(c).” (Gov’s Brf., at 17.) Indeed, the Government also concedes that “misbranding” is “not a specified crime.” (Id.)

Rather, the Government relies in part on an FDA regulation, 21 C.F.R. 201.15(c)(1), which provides: “All words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language: *Provided, however,* That in the case of articles distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language

may be substituted for English.” The FDA issued this regulation pursuant to, among other provisions, 21 U.S.C. § 371(a), under which Congress vested in the Secretary of Health and Human Services (“HHS”) “[t]he authority to promulgate regulations for the efficient enforcement” of the FDCA, with certain specified exceptions.

Aside from a single district court case outside this circuit, United States v. Shrum, No. 4:09CR00295 (JMM), 2011 WL 1753488, at *4 (E.D. Ark. May 9, 2011), the Government cites no case where it sought, as it does here, a criminal conviction for a violation of 21 U.S.C. § 352(c) that was based, in whole or part, on a violation of 21 C.F.R. 201.15(c)(1). Nor has the Court uncovered any such case, at least one that included a written opinion on the merits.

In Shrum, the Defendant was charged with, among other counts, “misbranding” under the FDCA. At the jury trial, over the government’s objection and in accordance with the Defendant’s argument, the Court did not instruct the jury on the Code of Federal Regulations, “finding that to instruct the jury on the regulations would be confusing as th[ose] regulations do not have the force and effect of criminal statutes.” 2011 WL 1753488, at *4. However, the Court “allowed the parties to argue the regulations in closing arguments to support their theories of the case, permitting the jury to determine based on the evidence at trial, whether ‘any word, statement, or other information required by or under authority of [the Act] to appear on the label or labeling [was] prominently placed thereon . . . in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.’” 21 U.S.C. § 352(c).

Following a conviction of “misbranding” and other counts, the Court denied the Defendant’s motion for a new trial. The Court found that, with respect to the English language regulation, “the jury was properly instructed and taken as a whole, the jury instructions

adequately advised the jury of the offenses charged and the burden of proof required of the government.” Id.

In United States v. 1500 90-Tablet Bottles, 384 F. Supp. 2d 1205 (N.D. Ill. 2005) aff’d sub nom. United States v. Genendo Pharm., N.V., 485 F.3d 958 (7th Cir. 2007), the United States brought an *in rem* action under the FDCA against a pharmaceutical corporation for the seizure and condemnation of certain imported prescription drugs and for permanent injunction. A bench trial was held. The Defendant-corporation admitted that some of the drugs that it caused to be imported to another company were not labeled in English. The Defendant further “admit[ted] that a drug held for sale in interstate commerce that fails to meet the requirements of 21 U.S.C. § 352(c) and 21 C.F.R. § 201.15(c)(1) is deemed to be misbranded as a matter of law unless exempt by the [FDCA].” 384 F. Supp. 2d at 1208.

The Court found that the Defendant violated 21 U.S.C. § 331(d) by introducing into interstate commerce and causing the introduction and delivery for introduction into interstate commerce “new drugs” within the meaning of 21 U.S.C. § 321(p), which did not comply with the specifications of a New Drug Application approved by the FDA that meets the requirements of 21 U.S.C. § 355(b) and (d). However, the Court did not find it necessary to address whether the Defendant was criminally liable, or subject to a seizure and condemnation in a criminal proceeding, based on any violation of Section 352(c) or 21 C.F.R. § 201.150. Id. at 1217 n. 8.

In this case, at oral argument, the Government contended that “no count depends solely on the lack of an English language regulation” and pointed out the fact that none of the captions for the counts in the Indictment reference a C.F.R. regulation. (Trans., at 35-37.)

However, to base a ruling on whether the captions for the counts in the Indictment reference 21 C.F.R. 201.15(c)(1) would be to elevate form over substance.

Indeed, the Government does not deny that it relies in part on the lack of an English language label for some of the counts. According to the Government, “[u]nder FDA regulations, a drug was deemed to be misbranded under section 352(c) unless ‘all words, statements, and other information required by or under authority of the [the FDCA] to appear on the label or labeling [] appear thereon in the English language.’” (Indictment, at ¶ 17.)

Therefore, regardless of whether the counts in the Indictment reference 21 C.F.R. 201.15(c)(1), the Government takes the position that a violation of that FDA regulation serves as a predicate for a violation of Section 352(c) and is punishable as a federal crime.

In this regard, as the Defendant notes, Paragraph 33 of the Indictment contains a table in which the Government outlines what it considers various “method[s] of misbranding.” The table lists the following 15 instances of alleged “misbranding”:

Drug Quantity and Type	Method of Misbranding
62 Mirena IUDs	Lacked English label and phrase “Rx only” on label
53 vials of Aloxi	Lacked English label
24 bottles of Aclasta	Not FDA approved for distribution in the United States
12 bottles of Velcade	Lacked phrase “Rx only”
12 bottles of Vidaza	Lacked English label
18 Implanon subdermal Contraceptive implants	Lacked English label
6 vials of Botox label	Lacked phrase “Rx only” on label

5 bottles of Venofer label	Lacked phrase "Rx only" on label
4 vials of Zometa label	Lacked phrase "Rx only" on label
3 vials of Mabthera	Not FDA approved for distribution in the United States
1 syringe of Avonex	Lacked English label
1 box Plavix label	Lacked phrase "Rx only" on label
1 box Lipitor	Lacked English label
14 Nova T380 IUDS	Not FDA approved for distribution in the United States
20 boxes Euflexxa	Lacked phrase "Rx only" on label

(Indictment, at ¶ 33.)(emphasis added).

Thus, the Government appears to rely in at least six instances on a violation of 21 C.F.R. 201.15(c)(1), as a predicate, in whole or in part, for a violation of Section 352(c), punishable as a federal crime. The question then becomes whether this theory is a correct or permissible reading of Section 352(c).

"The Constitution vests in Congress the legislative power to define criminal conduct." United States v. Dhafir, 461 F.3d 211, 215 (2d Cir. 2006); see Whitman v. United States, 135 S. Ct. 352, 353, 190 L. Ed. 2d 381 (2014)(mem)(Scalia, J., joined by Thomas, J., concurring in denial of certiorari)("legislatures, not executive officers, define crimes."). The Supreme Court has also expressed "the plain principle that the power of punishment is vested in the legislative, not in the judicial department." United States v. Wiltberger, 18 U.S. 76, 95, 5 L. Ed. 37 (1820).

However, “[u]ndoubtedly Congress may make it a crime to violate a regulation.” Whitman, 135 S. Ct. at 353 (mem)(Scalia, J., joined by Thomas, J., concurring in denial of certiorari)(citing United States v. Grimaud, 220 U.S. 506, 519, 31 S. Ct. 480, 55 L. Ed. 563 (1911); see generally United States v. Pastor, 419 F. Supp. 1318, 1336 (S.D.N.Y. 1975)(noting that the defendants “explicitly disclaim[ed], as they must, any contention that Congress cannot authorize administrative agencies (including Executive departments) to promulgate regulations necessary or relevant to their effective functioning, violation of which would constitute a criminal offense.”)(citing Grimaud). Indeed, “[t]he Supreme Court has also upheld particular delegations of authority to define criminal offenses, Dhafir, 461 F.3d at 216, although not yet in the context of FDCA.

For example, in Curtiss–Wright Export Corp., 299 U.S. 304, 57 S. Ct. 216, 81 L. Ed. 255 (1936), the Supreme Court upheld a Congressional resolution empowering the President to declare illegal the sale of arms to certain countries (specified by the President), without discussing any special considerations that may be implicated when the President is granted the power to define crimes. See Grimaud, 220 U.S. at 517, 31 S. Ct. 480, 55 L. Ed. 563 (“[W]hen Congress had legislated and indicated its will, it could give to those who were to act under such general provisions ‘power to fill up the details’ by the establishment of administrative rules and regulations, the violation of which could be punished by fine or imprisonment fixed by Congress, or by penalties fixed by Congress, or measured by the injury done.”).

In Touby v. United States, 500 U.S. 160, 111 S. Ct. 1752, 114 L. Ed. 2d 219 (1991), the Supreme Court upheld a delegation of power to the Attorney General to expedite the designation of a substance as “controlled” by bypassing (for a limited time) several of the requirements for permanent scheduling. The Touby Court weighed the Petitioner’s argument that “something

more than an ‘intelligible principle’ is required when Congress authorizes another Branch to promulgate regulations that contemplate criminal sanctions,” but declined to decide whether more specific guidance was required, because the statute passed muster even under a heightened standard:

Our cases are not entirely clear as to whether more specific guidance is in fact required. We need not resolve the issue today. We conclude that § 201(h) passes muster even if greater congressional specificity is required in the criminal context.

Id. at 165–66, 111 S. Ct. 1752 (internal citations omitted).

The Court concluded that the statute “meaningfully constrain[ed] the Attorney General’s discretion to define criminal conduct,” by requiring that the powers only be exercised when “necessary to avoid an imminent hazard to the public safety,” by specifying what constitutes “an imminent hazard,” and by requiring notice to and consideration of comments from the Secretary of HHS. Id. at 166–67, 111 S. Ct. 1752 (quoting the statute at issue); see United States v. Mango, 199 F.3d 85, 89 (2d Cir. 1999)(concluding that the Clean Water Act provided more than an intelligible principle to aid the Secretary or his delegee in setting permit conditions, the violation of which triggered criminal liability under certain circumstances); but see Whitman, 135 S. Ct. at 353 (mem)(expressing that Congress could not give agencies, nor could courts presume that Congress gave agencies, the power to resolve ambiguities in criminal legislation”)(Scalia, J., joined by Thomas, J., concurring in denial of certiorari).

However, while “Congress may make it a crime to violate a regulation,” Whitman, 135 S. Ct. at 353 (mem)(Scalia, J., joined by Thomas, J., concurring in denial of certiorari), also potentially at play in this case is the rule of lenity.

“The rule of lenity requires ambiguous criminal laws to be interpreted in favor of the defendants subjected to them.” United States v. Santos, 553 U.S. 507, 514, 128 S. Ct. 2020, 170

L. Ed. 2d 912 (2008); Rewis v. United States, 401 U.S. 808, 812, 91 S. Ct. 1056, 28 L. Ed. 2d 493 (1971)(“[A]mbiguity concerning the ambit of criminal statutes should be resolved in favor of lenity.”). The rule of lenity is premised on two ideas: First, “a fair warning should be given to the world in language that the common world will understand, of what the law intends to do if a certain line is passed”; second, “legislatures and not courts should define criminal activity.” Babbitt v. Sweet Home Chapter of Communities for a Great Oregon, 515 U.S. 687, 704 n. 18, 115 S. Ct. 2407, 2416, 132 L. Ed. 2d 597 (1995)(quoting McBoyle v. United States, 283 U.S. 25, 27, 51 S. Ct. 340, 341, 75 L. Ed. 816 (1931)); see Whitman, 135 S. Ct. at 354 (mem)(noting that the rule of lenity vindicates “equally important” principles of fair notice to would-be violators and “that only the *legislature* may define crimes and fix punishments.”).

Further, when, as here, a statute “has both criminal and noncriminal applications,” the Supreme Court has stated “the rule of lenity applies.” Leocal v. Ashcroft, 543 U.S. 1, 11 n. 8, 125 S. Ct. 377, 160 L. Ed. 2d 271 (2004)); see Scottrade, Inc. v. BroCo Investments, Inc., 774 F. Supp. 2d 573, 584 (S.D.N.Y. 2011)(“when a statute has both civil and criminal application, th[e] rule of lenity must be applied consistently to both.”)(citing Leocal).

The Court notes that, in Babbitt, decided before Leocal, the Supreme Court stated, in a footnote, that it has “never suggested that the rule of lenity should provide the standard for reviewing facial challenges to administrative regulations whenever the governing statute authorizes criminal enforcement.” 515 U.S. at 704 n. 18.

However, under Supreme Court precedent in Grimaud and United States v. Eaton, 144 U.S. 677, 688, 12 S. Ct. 764, 36 L. Ed. 591 (1892), if Congress wants to assign the executive branch discretion to define criminal conduct, it must speak “distinctly.”

Thus, interpreting Babbitt footnote 18 to hold that deference to administrative regulations under Chevron v. Natural Resources Defense Council, 467 U.S. 837, 104 S. Ct. 2778, 81 L.Ed.2d 694 (1984) defeats the rule of lenity would “eclipse[] the just-mentioned Grimaud/Eaton line of cases.” Carter, 736 F.3d at 734 (Sutton, J., concurring opinion); see Whitman, 135 S. Ct. at 353-54 (mem)(noting that Babbitt’s footnote 18 regarding the rule of lenity “contradicts the many cases before and since holding that, if a law has both criminal and civil applications, the rule of lenity governs its interpretation in both settings” and that this “drive-by ruling [regarding the rule of lenity], in short, deserves little weight.”)(Scalia, J., joined by Thomas, J., concurring in denial of certiorari).

As Judge Sutton observed in his concurring opinion in Carter,

The [Babbitt] footnote merely acknowledges the possibility of a pre-enforcement facial challenge to an agency’s regulation — because the agency had no interpretive authority in the first place, because the agency failed to follow the procedures for promulgating the regulation or because the statute plainly forecloses the agency’s interpretation. Yet not one of these challenges depends on, or demands consideration of, the rule of lenity. Why else would the Court distinguish cases involving “specific factual dispute[s]” from cases “reviewing facial challenges”? What purpose could this distinction serve unless the Court meant to create a rule for facial challenges? Although the footnote mentions that the Interior Department’s two-decade-old regulation comports with one of the rule of lenity’s objectives (promoting fair notice), it says nothing about other regulations or the rule of lenity’s separation-of-powers objective (reinforcing that Congress, not courts or agencies, define crimes). Before accepting the government’s broad reading of the footnote, one would have expected the Court to say more before allowing agencies to trump a doctrine Chief Justice Marshall described as “perhaps not much less old than construction itself.” 5 Wheat. At 95.

736 F.3d at 735.

Further, not only would automatic Chevron deference to an administrative regulation be at odds with Grimaud and Eaton, it “would allow one administration to criminalize conduct within the scope of the ambiguity, the next administration to decriminalize it, and the third to recriminalize it, all without any direction from Congress.” Id. at 729; see Whitman, 135 S. Ct.

352 (Mem)(“With deference to agency interpretations of statutory provisions to which criminal prohibitions are attached, federal administrators can in effect create (and uncreate) new crimes at will, so long as they do not roam beyond ambiguities that the laws contain.”)(Scalia, J., joined by Thomas, J., concurring in denial of certiorari).

However, while the rule of lenity is not automatically trumped by Chevron deference, it is also true that Chevron deference is not trumped by the rule of lenity. See Oppedisano v. Holder, 769 F.3d 147, 153 (2d Cir. 2014)(the rule of lenity “does not trump Chevron’s requirement of deference to reasonable interpretations by administrative agencies of statutes for which they are responsible.”); Sash v. Zenk, 439 F.3d 61, 67 (2d Cir. 2006)(post-Leocal case interpreting Babbitt footnote 18 to reject the idea that the rule of lenity should trump the deference traditionally afforded to reasonable administrative regulations); Mansour v. Zenk, No. CV-04-5106 (CPS), 2005 WL 1962045, at *3 (E.D.N.Y. Aug. 15, 2005)(“Nor does the rule of lenity foreclose application of Chevron deference.”).

The question then becomes how these two doctrines interact. The Supreme Court has stated that, within the Chevron framework, a court need “accept only those agency interpretations that are reasonable in light of the *principles of construction courts normally employ.*” Morrison v. Nat’l Australia Bank Ltd., 561 U.S. 247, 272, 130 S. Ct. 2869, 2887, 177 L. Ed. 2d 535 (2010)(emphasis added)(quoting EEOC v. Arabian American Oil Co., 499 U.S. 244, 260, 111 S. Ct. 1227, 113 L. Ed. 2d 274 (1991)(Scalia, J., concurring in part and concurring in the judgment)(superseded by statute on other grounds as recognized in Arbaugh v. Y & H Corp., 546 U.S. 500, 512 n. 8, 126 S. Ct. 1235, 163 L. Ed. 2d 1097 (2006)).

Citing this principle of Chevron interpretation, in Carter, Judge Sutton, in his concurring opinion, took the position that the rule of lenity is a relevant interpretive rule that should be

applied before deferring to an otherwise reasonable regulation. 736 F.3d at 731-32 (“All manner of presumptions, substantive canons and clear-statement rules take precedence over conflicting agency views . . . Why treat the rule of lenity, the most venerable and venerated of interpretive principles, differently?”).

However, this view, although logically coherent, is contrary to Second Circuit precedent. Indeed, Sash stated, also in a footnote, that “where an agency gives clear notice of the meaning of a statute by regulation, and where it is reasonable to charge defendants with notice of the agency’s interpretation, *Chevron* deference will apply prior to the rule of lenity.”

439 F.3d at 67 n. 6 (emphasis added); see United States v. Piper, No. 1:12-CR-41(JGM), 2013 WL 4052897, at *7 n. 3 (D. Vt. Aug. 12, 2013)(according *Chevron* deference to regulations issued by the Department of Justice in interpreting the federal Sex Offender Registration and Notification Act and declining to apply the rule of lenity)(citing Babbitt footnote 18).

In this case, the Court finds that 21 C.F.R. 201.15 (c)(1), although it does not specifically cite Section 352(c) of the FDCA, gives clear notice that “misbranding” under Section 352(c), a statutory term of art, encompasses, except as provided in the regulation, drugs or devices that contain words, statements, or other information, required by the FDCA and the regulations promulgated under that statute, that are not in English. See 1500 90-Tablet Bottles, 384 F. Supp. 2d at 1208 (“Defendant Genendo admits that a drug held for sale in interstate commerce that fails to meet the requirements of 21 U.S.C. § 352(c) and 21 C.F.R. § 201.15(c)(1) is deemed to be misbranded as a matter of law unless exempt by the Act.”).

As to the question of what constitutes reasonable notice to a defendant of an agency’s interpretation of criminal conduct, case law in the Second Circuit is sparse at best. Outside this circuit, in General Elec. Co. v. EPA, 53 F.3d 1324, 1329 (D.C. Cir. 1995), the D.C. Circuit stated

that a court must look to the text of the regulation itself to determine whether it provides the required notice of the agency's interpretation:

[W]e must ask whether the regulated party received, or should have received, notice of the agency's interpretation in the most obvious way of all: by reading the regulations. If, by reviewing the regulations and other public statements issued by the agency, a regulated party acting in good faith would be able to identify, with "ascertainable certainty," the standards with which the agency expects parties to conform, then the agency has fairly notified a petitioner of the agency's interpretation.

Id. (citing Diamond Roofing Co. v. Occupational Safety & Health Review Comm'n, 528 F.2d 645, 649 (5th Cir. 1976)); Fabi Const. Co. v. Sec'y of Labor, 508 F.3d 1077, 1088 (D.C. Cir. 2007)(quoting General Elec Co.); see Univ. Med. Ctr., Inc. v. Sebelius, 856 F. Supp. 2d 66, 85 (D.D.C. 2012)("when the agency's interpretation of its regulation may actually contradict the regulatory text, then the obligation on the agency to provide adequate notice is at its peak.")(citation and quotation marks omitted).

The Court acknowledges that this examination mirrors the first prong of Sash, whether an agency has given clear notice of the meaning of a statute by regulation. In any event, absent clear Second Circuit guidance, the Court adopts this approach and finds that that it is reasonable to charge defendants with notice of the FDA's interpretation of FDCA, provided by 21 C.F.R. 201.15(c)(1), particularly given the plain language of that regulation. This is so despite the fact that the Government has apparently not pursued this interpretation in other cases aside from Shrum, a district court case in Arkansas, and 1500 90-Tablet Bottles, a district court case in Illinois.

As an aside, the Court notes that it is not clear that the rule of lenity applies to this particular issue at all. This is because Section 352(c) is not necessarily ambiguous, at least not unintentionally so, about the requirements for "Prominence of information on label." Rather,

given the broad language in that statutory provision, it appears that, contrary to the Defendant's argument, Congress deliberately delegated or charged the FDA with specifically defining the requirements, criminal and civil, for "Prominence of information on label" of a drug or device.

Indeed, the Court notes that the "under authority of this chapter" only appears in subsection (c) of 352. Indeed, this language of delegation to the FDA does not appear elsewhere in Section 352 or Section 353, which again sets forth the numerous ways in which drugs or devices can be "misbranded."

The Defendant also does not directly contend that Section 352(c) of the FDCA results in an unconstitutional delegation of Congress's power to enact criminal laws. However, because the Defendant notes that an FDA regulation cannot form the basis for criminal liability absent a proper delegation by Congress, the Court will address whether this provision raises any non-delegation issues.

As background, "[d]elegations of congressional authority are upheld '[s]o long as Congress 'shall lay down by legislative act an intelligible principle to which the person or body authorized to [exercise the delegated authority] is directed to conform.'" Dhafir, 461 F.3d at 215 (quoting Mistretta v. United States, 488 U.S. 361, 372, 109 S. Ct. 647, 102 L. Ed. 2d 714 (1989)).

"The Supreme Court has applied the intelligible principle test to regulations that may be enforceable through criminal penalties." United States v. Nichols, 784 F.3d 666, 672 (10th Cir. 2015)(citing United States v. O'Hagan, 521 U.S. 642, 695 n. 10, 117 S. Ct. 2199, 138 L. Ed. 2d 724 (1997) and Yakus v. United States, 321 U.S. 414, 424-25, 64 S. Ct. 660, 88 L. Ed. 834 (1944)); see United States v. Hill, 896 F. Supp. 1057, 1062 (D. Colo. 1995)("The Supreme Court has never rejected the intelligible principle test in the criminal context.")(citing Mistretta, Yakus,

and J.W. Hampton, Jr., & Co. v. United States, 276 U.S. 394, 409, 48 S. Ct. 348, 352, 72 L. Ed. 624 (1928); but see Nichols, 784 F.3d 666, 672 (10th Cir. 2015) (“the Court has never expressly held that an intelligible principle alone suffices to save a putative delegation when the criminal law is involved.”); Carter, 736 F.3d at 734 (describing O’Hagan as “honor[ing] the principle that “greater congressional specificity [*may be*] required in the criminal context.” (Sutton, J., concurring opinion)(emphasis added)(citation omitted).

In O’Hagan, the Supreme Court, faced with a claim that an administrative regulation exceeded the authority of the Securities and Exchange Commission (the “SEC”) under § 14(e) of the 1934 Act, upheld the validity of a rule that imposed liability on persons who trade on material, nonpublic information in connection with a tender offer “without regard to whether the trader owes a pre-existing fiduciary duty to respect the confidentiality of the information.” O’Hagan, 521 U.S. at 693, 117 S. Ct. 2199, 2217 (citations and quotation marks omitted).

Section 14(e) prohibited “fraudulent . . . acts . . . in connection with any tender offer,” and authorizes the SEC to “define, and prescribe means reasonably designed to prevent, such acts.” Adopted under that statutory authorization, Rule 14e–3(a) forbade any person to trade on the basis of material, nonpublic information that concerns a tender offer and that the person knows or should know has been acquired from an insider of the offeror or issuer, or someone working on their behalf, unless within a reasonable time before any purchase or sale of such information and its source are publicly disclosed. Id. at 669. Rule 14e–3(a) imposed a duty to disclose or abstain from trading whether or not the trader owed a fiduciary duty to respect the confidentiality of the information.

The Supreme Court held that, under § 14(e), the SEC could properly prohibit acts not themselves fraudulent under the common law or § 10(b), if the prohibition was reasonably

designed to prevent acts and practices that were “fraudulent.” Id. at 673. Relying on Chevron, the Court found that the rule was not arbitrary, capricious, or manifestly contrary to the statute.

In Mistretta, a criminal defendant/petitioner challenged the constitutionality of Congress’s delegation of authority to the Sentencing Commission to promulgate determinative-sentence guidelines. The Court upheld this delegation on the basis of the intelligible principle test, although it noted that the delegation there “set[] forth more than merely an ‘intelligible principle.’” Mistretta, 488 U.S. at 379, 109 S. Ct. 647; see United States v. Cooper, 750 F.3d 263, 270 (3d Cir. 2014)(describing holding of Mistretta), cert. denied, 135 S. Ct. 209, 190 L. Ed. 2d 160 (2014). Upholding the delegation, the Court concluded that the grant of authority to the Sentencing Commission contained sufficient guidance and details in order to pass constitutional muster. Id. at 374, 109 S. Ct. 647.

In Yakus, the Supreme Court upheld a delegation to the Price Administrator (an executive official appointed by the President) to fix commodity prices that “in his judgment will be generally fair and equitable and will effectuate the purposes of th[e Emergency Price Control Act]’ when, in his judgment, their prices ‘have risen or threaten to rise to an extent or in a manner inconsistent with the purposes of this Act.’” 321 U.S. at 420, 64 S. Ct. 660, 667, 88 L. Ed. 834. The Supreme Court noted that “Congress ha[d] stated the legislative objective, ha[d] prescribed the method of achieving that objective — maximum price fixing — and ha[d] laid down standards to guide the administrative determination of both the occasions for the exercise of the price-fixing power, and the particular prices to be established. Id. at 423.

At least one circuit court has interpreted this aspect of Yakus as resting on an “intelligible principle” analysis, United States v. Goodwin, 717 F.3d 511, 517 (7th Cir. 2013) cert. denied, 134 S. Ct. 334, 187 L. Ed. 2d 234 (2013), although the Supreme Court did not use those precise

words. But see Carter, 736 F.3d at 734 (suggesting Yakus held that heightened congressional specificity may be required in criminal cases)(Sutton, J., concurring opinion).

As noted above, in Touby, the Supreme Court considered whether Congress must provide “more than an intelligible principle” when it “authorizes another Branch to promulgate regulations that contemplate criminal sanctions,” but the court did not answer the question. See Mango, 199 F.3d at 89 n.3; compare Nichols, 784 F.3d at 672 (“the [Supreme] Court has repeatedly and long suggested that in the criminal context Congress must provide more ‘meaningful[]’ guidance than an ‘intelligible principle.’”); see Fahey v. Mallonee, 332 U.S. 245, 249–50, 67 S. Ct. 1552, 91 L. Ed. 2030 (1947); United States v. Robel, 389 U.S. 258, 272–73, 88 S. Ct. 419, 19 L. Ed. 2d 508 (1967)(Brennan, J., concurring); Barenblatt v. United States, 360 U.S. 109, 140 n. 7, 79 S. Ct. 1081, 3 L. Ed. 2d 1115 (1959)(Black, J., dissenting).

In this case, the Court finds that only an “intelligible principle” is required when Congress authorizes the executive branch to promulgate regulations that contemplate criminal punishment. In this regard, absent a clear holding of the Supreme Court or the Second Circuit, the Court declines to find that more is required based on dicta in Supreme Court and other cases.

Applying that standard here, the Court notes that “impermissible delegation has been rarely found.” Dhafir, 461 F.3d at 215; United States v. Fernandez-Dilone, 668 F. Supp. 245, 250 (S.D.N.Y. 1987)(“Statutes . . . have only rarely been struck down on nondelegation grounds.”). Indeed, only twice in the Supreme Court’s history, and not since A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495, 521, 542, 55 S. Ct. 837, 79 L. Ed. 1570 (1935) and Panama Refining Co. v. Ryan, 293 U.S. 388, 421, 55 S. Ct. 241, 248, 79 L. Ed. 446 (1935) has it invalidated a statute on the ground of excessive delegation of legislative authority. See United

States v. Ambert, 561 F.3d 1202, 1213 (11th Cir. 2009)(“since 1935, the Supreme Court has not struck down a single statute as an impermissible delegation of legislative power.”).

Rather, “[the Supreme Court’s] application of the nondelegation doctrine principally [was] limited to the interpretation of statutory texts, and, more particularly, to giving narrow constructions to statutory delegations that might otherwise by thought to be unconstitutional.” Mistretta, 488 U.S. at 373 n. 7, 109 S. Ct. 647.

As to the non-delegation challenges to other provisions of the FDCA, the Court takes note of United States v. Travia, 180 F. Supp. 2d 115 (D.C. 2001).

There, the defendants were charged with violations under §§ 331(a) and (f) of the FDCA for selling balloons filled with nitrous oxide (laughing gas) at a rock concert. At issue was whether nitrous oxide was a drug since the balloons had no labels. The intent of the defendants was found sufficient to classify nitrous oxide as a drug under § 321(g)(1)(c). The defendants challenged the FDCA as violative of the non-delegation doctrine.

The District Court rejected this argument, reasoning in part that “Congress ha[d] provided in the FDCA clear proscriptions, as discussed above, that can be consistently followed by the FDA in enforcing them.” Id. at 123-24.

The Court recognizes that Travia did not involve Section 352(c) of the FDCA, at issue here, which was promulgated under, among other provisions, 21 U.S.C. § 371(a), through which Congress vested in the Secretary of HHS “[t]he authority to promulgate regulations for the efficient enforcement” of the FDCA, with certain specified exceptions.

As noted above, Section 352(c) provides that a drug or device is “misbranded” under the statute “[i]f any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such

conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.”

The Defendant argues that, unlike in Grimaud, where Congress specifically wrote that violations of the Secretary of Agriculture’s “rules and regulations shall be punished,” here, the FDCA only “vested in the Secretary” “[t]he authority to promulgate regulations for the efficient enforcement of this chapter.” 21 U.S.C. § 371(a).

As an initial matter, the Court notes that courts, including the Supreme Court, have recognized that violations of certain FDA regulations can result in criminal penalties. Brown v. Williamson, 134 F. Supp. 2d 1286, 1293 (M.D. Ala. 2001)(“Violations of these FDA regulations could result in civil and criminal penalties.”)(relying on Abbott Labs. v. Gardner, 387 U.S. 136, 151-52, 87 S. Ct. 1507, 18 L. Ed. 2d 681 (1967))(“if within the Commissioner [of Food and Drugs’] authority, [FDA regulations] have the status of law and violations of them carry heavy criminal and civil sanctions”), abrogated on other grounds by Califano v. Sanders, 430 U.S. 99, 97 S. Ct. 980, 51 L. Ed. 2d 192 (1977)); Bansemmer v. Smith Labs., Inc., No. CIV. A. 86-C-1313 (TTE), 1990 WL 132579, at *3 (E.D. Wis. Sept. 12, 1988)(“Companies that violate FDA rules are subject to injunctions, *misdemeanor criminal penalties, and fines.*”)(emphasis added).

Here, the Defendant ignores Sections 331 and 333 of the FDCA. Section 331(a) “prohibit[s] “[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or *misbranded*” and Section 331(c) “prohibit[s]” “[t]he 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.” (emphasis added). As noted above, Section 352 and Section 353 sets forth the

numerous ways in which drugs or devices can be “misbranded,” which encompasses regulations issued “under authority” of the FDCA under Section 352(c).

Importantly, Section 333(a)(1) provides that “[a]ny person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than \$1,000, or both” and Section 333(a)(2) provides, in pertinent part, that any person who commits a violation of Section 331 “with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than \$10,000, or both.”

Further, in the Court’s view, the language of Section 352(c) of the FDCA provides a constitutionally permissible “intelligible principle” to which the FDA is required to conform when issuing binding regulations under that provision.

The Defendant also does not directly argue that Section 352(c) of the FDCA is void for vagueness. Therefore, the Court declines to address any such argument. However, the Court notes that “Courts . . . have repeatedly upheld the constitutionality of the misbranding provisions [other than 352(c)] of the FDCA in the face of vagueness challenges . . .” United States v. Caronia, 576 F. Supp. 2d 385, 402 n. 13 (E.D.N.Y. 2008), vacated and remanded on other grounds, 703 F.3d 149 (2d Cir. 2012)(vacating conviction of FDCA misbranding provisions on other grounds); United States v. Gen. Nutrition, Inc., 638 F. Supp. 556, 564 (W.D.N.Y. 1986)(“The [FDCA] on numerous occasions has been upheld against vagueness challenges . . . this Court is unaware of any case holding any provision of the Act void for vagueness in any circumstance.”); see United States v. Sullivan, 332 U.S. 689, 695, 68 S. Ct. 331, 335, 92 L. Ed. 297 (1948)(finding no ambiguity in the misbranding language of the Act and accordingly upholding the provision requiring adequate directions for use and adequate warning against use); United States v. Article of Drug Labeled “White Quadrisect”, 484 F.2d 748, 751 (7th Cir.

1973)(finding that the phrase “current good manufacturing practice,” as used in the FDCA, relating to adulterated drugs and devices, was not unconstitutionally vague); United States v. 2600 State Drugs, Inc., 235 F.2d 913 (7th Cir. 1956)(upheld the FDCA against the defendants’ vagueness challenge, specifically holding that the “provisions of th[e] Act are sufficiently definite to support a criminal charge for the violation of the Act.”); United States v. Forester, 346 F.2d 685, 686 (4th Cir. 1965)(per curiam)(citing 2600 Stat Drugs, Inc. and affirming a judgment denying a motion to dismiss an information based on unconstitutional vagueness of Section 503(b)(1)(B)); Travia, 180 F. Supp. at 122-23 (rejecting the defendant’s void for vagueness challenge to the FDCA and holding that “Congress has provided sufficient notice through these provisions; they are not so vague or standardless that the ordinary public is left uncertain as to what is prohibited”); United States v. Reece, No. CRIM. 12-00146 (EEF)(PJH), 2013 WL 5234124, at *7-8 (W.D. La. Sept. 13, 2013)(agreeing with Travia); United States v. Carlson, No. CRIM. 12-305 (DSD)(LIB), 2013 WL 5125434, at *2 (D. Minn. Sept. 12, 2013)(agreeing with magistrate judge and rejecting vagueness challenge to the FDCA and associated regulations).

The Court will address the other points made by the Defendant. As noted above, there is an exception to the English language labeling contained in 21 C.F.R. § 201.15(c)(1) for “Puerto Rico or in a Territory where the predominant language is one other than English.” In Court, counsel for the Defendant argued as follows:

[I]f English language label was a statutory requirement, the FDA could not, through a regulation, make an exception to it.

For example, the FDA could not say that it is lawful to sell heroin in Puerto Rico because that is a statutory crime clearly defined.

But they create an exception for English language labeling because it is found nowhere in the statute. They would have no power to make that exception

otherwise, other than this requirement is solely regulatorily created and made.

(Trans, at 7.)

However, as noted above, under Grimaud and Eaton, Congress may properly delegate to the executive branch discretion to define criminal conduct, that is, “distinctly” and with an “intelligible principle” to which the executive branch must conform. If, as here, Congress has done that, then the executive branch, by necessity, may include exceptions to such criminal conduct.

Relatedly, the Defendant notes that Congress enacted specific requirements with regard to “Rx Only”, see 21 U.S.C. § 353(b)(4)(A)). According to the Defendant, “Congress could have easily included that requirement – indeed, Congress was very specific as to other requirements such as the ‘Rx Only’ wording – but Congress chose not to address the language issue or create a law requiring an English-language label.” (Doc No. 44, at 4.).

It is true that the prospect of non-English labeling was likely not an inconceivable scenario not envisioned by Congress when the FDCA “misbranding” provisions were enacted. However, even if Congress *could have easily* specifically proscribed such labeling, enforceable by criminal punishment, and even if such labeling was easily foreseeable, it does not follow that an FDA regulation defining “misbranding” to include such labeling cannot be enforced with criminal punishment, provided no constitutional right or doctrine is violated.

Accordingly, for the foregoing reasons, the Court denies the Defendant’s motion to strike all counts based in whole or part on any FDA regulations.

C. As to Count Seventy Three of the Indictment

The Defendant also moves to dismiss Count Seventy Three of the Indictment, which charges him with knowingly and intentionally trafficking in counterfeit drugs between

approximately April 6, 2012 and April 24, 2012 in violation of 18 U.S.C. §§ 2320(a)(4). The Defendant challenges this count on the basis that it lacks evidentiary support, is highly prejudicial, and will inflame the jury.

According to the Defendant, “[t]he only reason count 73 exists is to transform a complicated regulatory case about the sale in the United States of pharmaceutical products approved for sale in Europe – a practice that Mr. Scully’s attorneys advised him was lawful – into a nefarious tale of someone intentionally trying to harm cancer patients as highlighted in [then] United States Attorney Lynch’s press release.” (Doc No. 44., at 22.) The Defendant notes that Lamah did not plead guilty to the trafficking in counterfeit drugs count. For these reasons, the Defendant contends that a Rule 29 motion following a potential conviction on this count will not suffice to address these concerns.

Of course, “[a] court may dismiss an indictment that is legally insufficient.” United States v. Thomas, 492 F. Supp. 2d 405, 412 (S.D.N.Y. 2007)(citing United States v. Tanu, 589 F.2d 82, 86-87 (2d Cir. 1978)). However, “[a] defendant faces a high standard in seeking to dismiss an indictment, because an indictment need provide the defendant only a plain, concise, and definite written statement of the essential facts constituting the offense charged.” United States v. Post, 950 F. Supp. 2d 519, 527 (S.D.N.Y. 2013)(internal quotation marks and citations omitted)(citing Fed. R. Crim. P. 7(c)(1)); United States v. Smith, 985 F. Supp. 2d 547, 561 (S.D.N.Y. 2014)(same).

“It bears recalling that [the Second Circuit has] consistently upheld indictments that do little more than to track the language of the statute charged and state the time and place (*in approximate terms*) of the alleged crime.” United States v. Bout, 731 F.3d 233, 240 (2d Cir. 2013)(emphasis and internal quotation marks omitted). “The indictment is sufficient if it

‘contains the elements of the offense charged and fairly informs a defendant of the charge against which he must defend, and . . . enables him to plead an acquittal or conviction in bar of future prosecutions for the same offense.’” Post, 950 F. Supp. 2d at 527 (alteration in original) (quoting Hamling v. United States, 418 U.S. 87, 117, 94 S. Ct. 2887, 41 L. Ed. 2d 590 (1974)); see also United States v. Alfonso, 143 F.3d 772, 776 (2d Cir. 1998)(same).

When deciding a motion to dismiss a count of an indictment, a court must accept all the factual allegations in the indictment as true. United States v. Clarke, No. 05 Cr. 17(DAB), 2006 WL 3615111, at *1 (S.D.N.Y. Dec. 7, 2006)(citations omitted). A court should not look beyond the face of the indictment and draw inferences as to proof to be adduced at trial, for “the sufficiency of the evidence is not appropriately addressed on a pretrial motion to dismiss an indictment.” Alfonso, 143 F.3d at 776-77.

Where, however, the Government “has made what can fairly be described as a full proffer of the evidence it intends to present at trial to satisfy the jurisdictional element of the offense,” a district court may evaluate “the sufficiency of the evidence . . . on a pretrial motion to dismiss an indictment.” Id. at 777; see United States v. Gotti, 457 F. Supp. 2d 411, 421 (S.D.N.Y. 2006); cf. United States v. Mennuti, 639 F.2d 107 (2d Cir. 1981)(upholding dismissal of indictment where government had filed an affidavit making a full proffer of the evidence to be presented at trial), abrogated in part on other grounds, Russell v. United States, 471 U.S. 858, 105 S. Ct. 2455, 85 L. Ed. 2d 829 (1985); accord United States v. Flores, 404 F.3d 320, 325 (5th Cir. 2005)(finding “no error in the district court’s procedure of resolving a legal question in a pre-trial motion to dismiss the indictment”); United States v. Risk, 843 F.2d 1059, 1061 (7th Cir. 1988)(“The district court found no violation and correctly dismissed the indictment, not because the government could not prove its case, but because there was no case to prove.”). “In reviewing the sufficiency of the

evidence, the court must view all of the evidence in the light most favorable to the Government and determine if there is any evidence ‘upon which a reasonable mind might fairly conclude guilt beyond a reasonable doubt.’” Gotti, 457 F. Supp. 2d at 421 (quoting United States v. Mariani, 725 F.2d 862, 865 (2d Cir. 1984)).

Here, however, by both the Defendant’s and the Government’s estimation, the Government has not made what can fairly be described as a full proffer of the evidence it intends to present at trial to satisfy the jurisdictional element of the offense.

Accordingly, for purposes of this branch of the Defendant’s motion, the Court is limited to evaluating the face of the Indictment. In the Court’s view, Count 73 of the Indictment is sufficient under Fed. R. Crim. P. 7(c)(1). The Court also finds that the conduct described in Count 73 is a plain, concise, and definite written statement of the essential facts constituting the offense charged. See United States v. Aleynikov, 676 F.3d 71, 75–76 (2d Cir. 2012)(“Since federal crimes are solely creatures of statute, a federal indictment can be challenged on the ground that it fails to allege a crime within the terms of the applicable statute.” (citations and internal quotation marks omitted)). The Court notes that the Government presents a more detailed theory and documentary evidence supporting this count, including based on the Defendant’s apparent connections to Ozay Pharma, in its papers in opposition to the present motion. (Doc No. 48, at 19-20.).

Finally, given the documentary evidence referenced by the Government in connection with this count, the Court finds that this count is not prejudicial to the Defendant nor will it necessarily inflame the jury.

As to the Defendant’s contention that the Government has not produced sufficient evidence in support of this count, again the Court is limited to considering the four corners of the

Indictment. In any event, the Court notes that this argument presupposes that there will be no testimonial evidence. Further, as to the Defendant's contention that the Government has not produced evidence that links the lot numbers on the Altuzan vials to Pharmalogical, the Court notes the Government's response that the Defendant was trafficking in prescription drugs without lot numbers documented by pedigrees as required by 21 U.S.C. § 353(e)(1)(A) of the Prescription Drug Marketing Act, as amended by the Drug Supply Chain Security Act.

Based on the foregoing reasons, the Defendant's motion to dismiss Count seventy Three of the Indictment on the basis that it lacks evidentiary support, is highly prejudicial, and will inflame the jury, is denied.

D. As to Count Seventy Two of the Indictment

The Defendant also seeks to dismiss County Seventy Two of the Indictment, which charges him with Fraudulent Importation and Transportation of Goods between approximately February 10, 2009 and July 2013 in violation of Section 545 of the federal criminal code, on the basis that it merges with the Section 331(a) "misbranding" counts as charged.

Section 545 of the federal criminal code, entitled "Smuggling goods into the United States," states in relevant part that "[w]hoever fraudulently or knowingly imports or brings into the United States, any merchandise contrary to law, or receives, conceals, buys, sells, or in any manner facilitates the transportation, concealment, or sale of such merchandise after importation, knowing the same to have been imported or brought into the United States contrary to law . . . [s]hall be fined under this title or imprisoned not more than 20 years, or both."

As noted above, Section 331(a) of the FDCA prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded." Section 333(a)(2) provides, in pertinent part, that any person

who commits a violation of Section 331 “with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than \$10,000, or both.”

Here, in Count Seventy Two of the Indictment, the Government accuses the Defendant of “knowingly, intentionally and fraudulently import and bring into the United States merchandise contrary to law, and did receive, conceal, buy, sell and facilitate the transportation, concealment and sale of such merchandise after importation, to wit: misbranded drugs, knowing such merchandise to have been imported and brought into the United States contrary to law.”

(Indictment, at ¶ 50.)

Section 545 of the federal criminal code is not part of the FDCA and, in fact, was enacted before passage of the FDCA.

The Defendant argues that “misbranding” as defined Sections 352 and 353, and in certain FDA regulations, cannot served as a predicate offense for a Section 545 count where, as here, it punishes the same conduct.

As an initial matter, the Court notes that, even assuming a Section 545 count could not rest in whole or part on a Section 331(a) count, the Government has not limited its Section 545 count to Section 331(a) as the predicate offense “contrary to law.” Indeed, as to the alleged “misbranding” used as a partial predicate for the Section 545 count, the Indictment does not identify any subsection and only says that misbranded drugs were imported. In other words, the Defendant has simply chosen the subsection, Section 331(a), which most closely tracks the activity of the smuggling charge, as the basis for his merger argument. However, misbranding includes not only Section 331(a) but, among others, Sections 331(b), (c), and (d).

To the extent the Government intends to rely on a violation of Section 331(a) as the predicate offense for the Section 545 Count, the Court finds that it may do so.

On this issue, Roseman v. United States, 364 F.2d 18, 26-27 (9th Cir. 1966), is instructive. There, the Defendants were convicted of concealing, selling, and facilitating transportation, concealment, and sale of LSD which they knew had been imported into United States contrary to law; selling and holding for sale LSD which had been mislabeled, misbranded, or unlabeled in violation of the FDCA; and conspiracy to violate the FDCA in violation of 18 U.S.C. § 371. However, the Defendants did not face a separate charge of “misbranding” as defined in the FDCA and regulations issued under that statute.

On appeal, the Ninth Circuit acknowledged that, “[t]his appear to be the first time that a court has been asked to uphold a conviction on the contrary-to-law provision of section 545 based on a violation of the FDCA.” Id. at 26. However, the Ninth Circuit rejected the Defendants’ argument that a prosecution under the contrary-to-law provision of Section 545 based on a violation of the FDCA is incompatible with the general purposes of the FDCA. The Court noted that “[o]n its face [Section 545] contemplates that one who violates it will have also violated another existing law in force at the time.” Id.

As to Section 331(a), the Court found that “[t]he transportation in interstate commerce is essentially a jurisdictional requirement the presence of which is necessary in order for Congress to act pursuant to the commerce clause of the Constitution.” Id. at 25; see United States v. Vidal-Cruz, 67 F. Supp. 2d 35, 38-39 (D.P.R. 1999)(“The FDCA clearly contains the so-called ‘jurisdictional element,’ by specifying in multiple occasions the interstate commerce requirement.”). In other words, for purposes of Section 331(a), “it is not the transportation in interstate commerce which constitutes the offensive activity, but it is misbranding, adulterating, dispensing without a prescription, and the like, which are the prohibited acts.” Roseman, 364

F.2d at 25. “On the other hand, under 18 U.S.C. § 545 the transportation of the ‘merchandise’ into the United States is the activity which is prohibited.” Id. at 25-26.

For these reasons, the Court agrees with the Roseman court in that “prosecution under the contrary-to-law provision of section 545 is not foreclosed by the FDCA.” Id. at 26-27. Indeed, “[t]he second paragraph of section 545 – which is involved here – can only be interpreted as manifesting a determination by Congress that the importation itself of merchandise ‘contrary to law’ is a serious enough crime to warrant separate and rather severe punishment regardless of what the penalty is for the violation of another law.” Id. at 26.

However, as Roseman stated, “[t]his does not mean that [the Court] would sustain the imposition of consecutive sentences where the defendant is convicted under both acts. Such a sentence could pose a problem of double jeopardy.” Id. at 25 n. 10.

In other words, a conviction of County Seventy Two based on Section 545 and a conviction of the Section 331(a) “misbranding” counts could present a “merger problem” with double jeopardy implications. Black’s Law Dictionary 1078 (9th ed. 2009)(in criminal law, “merger” means “[t]he absorption of a lesser included offense into a more serious offense when a person is charged with both crimes, so that the person is not subject to double jeopardy.”).

In United States v. Santos, 553 U.S. 507, 514, 128 S. Ct. 2020, 2026, 170 L. Ed. 2d 912 (2008), the Supreme Court addressed the concept of “merger” in criminal law. In Santos, a non-FDCA case, the Supreme Court, in a fractured opinion, affirmed the Seventh Circuit’s reversal of Santos’s money laundering conviction. A four-Justice plurality (Justices Scalia, Souter, Thomas, and Ginsburg) concluded that the term “proceeds” in the money laundering statute means profits, not gross receipts. Id. at 510–14, 128 S. Ct. 2020. It reasoned that, “[f]rom the face of the statute, there is no more reason to think that ‘proceeds’ means ‘receipts’ than there is to think

that ‘proceeds’ means ‘profits,’” and from there, applied the rule of lenity to conclude that “the tie must go to the defendant.” Id. at 514, 128 S. Ct. 2020. The plurality expressed concern that if the definition of “proceeds” were not limited to profits, a money laundering charge would “merge” with the crime of running an illegal gambling business. See id. at 515, 128 S. Ct. 2020 (“If ‘proceeds’ meant ‘receipts,’ nearly every violation of the illegal-lottery statute would also be a violation of the money laundering statute, because paying a winning bettor is a transaction involving receipts that the defendant intends to promote the carrying on of the lottery.”). It noted that under this reading, prosecutors would “acquire the discretion” to charge the “greater money-laundering offense” instead of or in addition to the “lesser lottery offense” in nearly every case involving an illegal lottery. Id. at 516, 128 S. Ct. 2020. For these reasons, the plurality concluded that “proceeds” must mean “profits,” regardless of the “specified unlawful activity” at issue.

Justice Stevens provided the fifth vote in favor of the Supreme Court’s judgment affirming the Seventh Circuit’s vacatur of Santos’s conviction. In his opinion concurring in the judgment, Justice Stevens took the position that the definition of “proceeds” might depend upon the particular “specified unlawful activity” underlying the money laundering charge at issue. Id. at 524–26, 128 S. Ct. 2020 (Stevens, J., concurring in the judgment). He emphasized the lack of legislative history indicating that Congress intended the term “proceeds” to mean “gross receipts” in the context of gambling offenses. Id. at 526, 128 S. Ct. 2020. He also expressed concern about the “merger problem” identified by the plurality. See id. at 527, 128 S. Ct. 2020 (“Allowing the Government to treat the mere payment of the expense of operating an illegal gambling business as a separate offense is in practical effect tantamount to double jeopardy, which is particularly unfair in this case because the penalties for money laundering are

substantially more severe than those for the underlying offense of operating a gambling business.”). He nevertheless concluded that legislative history evinced Congress’s intent that the money laundering statute applies to transactions involving the gross revenues, not just the profits, of certain other SUAs. Id. at 528 n. 7, 128 S. Ct. 2020 (“In other applications of the statute not involving such a perverse result, I would presume that the [dissent] reflects the intent of the enacting Congress.”). For example, he reasoned, “Congress intended the term ‘proceeds’ to include gross revenues from the sale of contraband and the operation of organized crime syndicates involving such sales. . . . Thus, I cannot agree with the plurality that the rule of lenity must apply for these types of unlawful activities.” Id. at 525–26 n. 3, 128 S. Ct. 2020.

In his dissent, Justice Alito, joined by Chief Justice Roberts and Justices Kennedy and Breyer, stated he would have held that the term “proceeds” means “gross receipts” in all circumstances. Id. at 546, 128 S. Ct. 2020 (Alito, J., dissenting). The dissent noted in particular that “five Justices agree with the position” that “the term ‘proceeds’ ‘include[s] gross revenues from the sale of contraband and the operation of organized crime syndicates involving such sales.’” Id. at 531-32 n. 1, 128 S. Ct. 2020 (Alito, J., dissenting)(alteration in original).

In this case, the Court notes that Section 545 carries “substantially more severe” criminal penalties than does a Section 331(a) violation. The Court further notes that a conviction based on a Section 545 count and a Section 331(a) count, at least as charged here, could punish the same conduct.

On the other hand, the Court notes that it is not clear that Section 545 and Section 331(a) share the same *mens rea* requirement. The relevant language of Section 545 requires a fraudulent or knowing *mens rea*, while criminal punishment for a violation of Section 331(a) requires an intent to defraud. The Defendant contends that the Government has chosen to charge

“fraudulent” importation and transportation of goods based on the title of Count Seventy Two. However, the Court notes that paragraph 50 of the Indictment, contained in Count 72 accuses the Defendant of violating Section 545 “knowingly, intentionally and fraudulently.”

Further, the Court notes Roseman’s conclusion that “culpability in the FDCA is not related to the manner of transportation, nor is it the same as acting knowingly.” 364 F.2d at 26.

However, in any event, “[w]here there has been no prior conviction or acquittal, the Double Jeopardy Clause does not protect against simultaneous prosecutions for the same offense, so long as no more than one punishment is eventually imposed.” United States v. Josephberg, 459 F.3d 350, 355 (2d Cir. 2006). Accordingly, where, as here, “[n]o convictions have been entered . . . the Double Jeopardy Clause’s guarantee against multiple punishments for the same offense has not yet been triggered.” United States v. Polouizzi, 564 F.3d 142, 157 (2d Cir. 2009).

“Since Josephberg, courts in this Circuit have routinely denied pre-trial motions to dismiss potentially multiplicitous counts as premature.” United States v. Medina, No. S3 13 CR 272 (PGG), 2014 WL 3057917, at *3 (S.D.N.Y. July 7, 2014); see e.g. United States v. Burke, No. 09–CR–0135 (S–5) (SJ)(JO), 2011 WL 2609839, at *8 (E.D.N.Y. Feb. 26, 2011)(holding that — where a Section 924(c) count of the Federal Criminal Code was a lesser included offense of a Section 924(j) charge — the “overlap between the two counts [was] no bar to their simultaneous prosecution, and . . . [defendant was] instead entitled only to have the sentences on both counts merged in the event he [was] found guilty of both”), report and recommendation adopted, No. 09 CR 135 (SJ), 2011 WL 2609837, at *6 (E.D.N.Y. July 1, 2011); see also United States v. Mostafa, 965 F. Supp. 2d 451, 464 (S.D.N.Y. 2013)(“It is well established that the Double Jeopardy clause does not prohibit simultaneous prosecutions for the same offense; it prohibits duplicative punishment. Accordingly, multiplicity is properly addressed by the trial

court at the sentencing stage. At that time, the district court would be required to vacate one of the two convictions. . . . This Court will not engage in a multiplicity inquiry at this time. In accordance with Second Circuit precedent, any such issues may be raised post-trial.”)(internal citations omitted); United States v. Ghavami, No. 10 Cr. 1217 (KMW), 2012 WL 2878126, at *11 (S.D.N.Y. July 13, 2012)(“To the extent that the Indictment alleges more than one conspiracy in violation of different statutory provisions . . . , Defendants’ multiplicity challenge is premature. Should the jury convict Defendants on what the Court ultimately determines to be multiplicitous counts, the Court will enter judgment on only one of the multiplicitous convictions.”)(internal citations and footnote omitted); United States v. Rivera, No. 09–CR–619 (SJF), 2011 WL 1429125, at *4 (E.D.N.Y. Apr. 13, 2011)(“Since it is possible that the jury will convict defendants on only one (1) of the respective counts that they allege are multiplicitous, and acquit defendants on all of the counts with which they allege that count is multiplicitous, the issue of whether the counts are multiplicitous in violation of the Double Jeopardy Clause is premature at the pretrial stage.”); United States v. Jahedi, 681 F. Supp. 2d 430, 436 (S.D.N.Y. 2009)(“[A] defendant’s Double Jeopardy rights are only at risk upon conviction on more than one multiplicitous count. If this occurs, the proper remedy is for the district court to enter judgment on only one of the multiplicitous convictions.”); United States v. Deas, No. 3:07–CR–73 (CFD), 2008 WL 5063903, at *2 n. 1 (D. Conn. Nov. 24, 2008)(“Where, as is the case here, a single prosecution contains counts that are potentially multiplicitous, the Double Jeopardy Clause protects against multiple *punishments*. As described . . . in Josephberg, this protection is best achieved by vacating any multiplicitous conviction at trial, rather than by premature dismissal of the counts.”); United States v. Ferguson, 478 F. Supp. 2d 220, 233 (D. Conn. 2007)(“The defendants’ motion [to dismiss allegedly duplicative counts] is denied . . . [I]t is

premature under Josephberg. Josephberg made clear that the defendants' Double Jeopardy rights are only at risk of violation after they are convicted of multiplicitous charges, not pre-trial. Because of this, district courts should dismiss multiplicitous counts only if a defendant is convicted on multiplicitous counts.”)(citations omitted).

In this case, the Defendant may be entitled to a lesser-included offense charge with regard to the Section 545 and any Section 331(a) counts. Furthermore, “[i]f the jury [ultimately] convicts on more than one multiplicitous count, the defendant’s right not to suffer multiple punishments for the same offense will be protected by having the court enter judgment on only one of the multiplicitous counts. Or, if judgment of conviction has been entered on more than one such count, the district court should vacate the conviction on all but one.” Josephberg, 459 F.3d at 355 (internal citation omitted).

However, these proceedings are currently in a pre-trial stage. Accordingly, the Court concludes that the question of whether a Section 331(a) offense is a lesser included offense of a Section 545 offense is premature and can only be determined at the trial. See United States v. Bozeman, No. 3:11-CR-129 (CCS), 2012 WL 1071207, at *16 (E.D. Tenn. Mar. 29, 2012)(“the Court concludes that the question of whether conspiracy to possess a controlled substance is a lesser included offense of conspiracy to distribute or possess with intent to distribute is premature and can only be determined by the District Judge at trial.”), aff’d, No. 3:11-CR-129-1 (TAV), 2012 WL 1565099 (E.D. Tenn. May 1, 2012).

In a similar vein, the Court finds that, at this stage, consideration of any double jeopardy issues is premature absent a conviction and consideration of the evidence at trial. See e.g. United States v. Salad, 907 F. Supp. 2d 743, 750 (E.D. Va. 2012)(“The court, therefore, finds that the Kidnapping Statute and the Hostage Taking Statute impermissibly overlap for purposes of

double jeopardy because kidnapping is a lesser included offense of hostage taking. However, the court DENIES the Defendants' request to dismiss the offending counts and agrees with the government that to do so would be premature at this juncture.”)

Accordingly, the Defendant's pre-trial motion to dismiss Count Seventy Two of the Indictment on merger grounds is denied as premature.

E. Request for Discovery/Bill of Particulars

The Defendant also seeks certain discovery that he claims the Government has improperly failed to turn over. In particular, the Defendant seeks disclosure under Rule 16 and Brady v. Maryland, 373 U.S. 83, 83 S. Ct. 1194, 10 L. Ed. 2d 215 (1963) of (1) recordings known to exist; (2) full laboratory reports, chain of custody, and notes of chemical analysis of Alutzan performed during the investigation and case; (3) communications with and records of FDA showing contact between the Defendant and the agency; (4) other statements by the Defendant, his lawyers, and other working at Pharmalogical, including in particular statements that support an advice of counsel defense; and (5) exculpatory statements of any doctors interviewed. The Defendant notes that it had to acquire some documents through a Freedom of Information Act request.

“Rule 16 of the Federal Rules of Criminal Procedure governs pre-trial discovery in criminal cases.” United States v. Delacruz, No. 14 CR 815 (KBF), 2015 WL 2211943, at *1 (S.D.N.Y. May 12, 2015)(citing In re Terrorist Bombings of U.S. Embassies in E. Africa, 552 F.3d 93, 124 (2d Cir. 2008)(citations omitted). The rule provides, in pertinent part, that a defendant is entitled to obtain from the Government documents and objects that are “within the government's possession, custody, or control” if they are “material to preparing the defense” or

will be used by the Government in its case-in-chief at trial. Delacruz, 2015 WL 2211943, at *1 (citing Rule 16).

Evidence that the Government does not intend to use in its case-in-chief at trial is material “if it could be used to counter the government’s case or to bolster a defense; information not meeting either of those criteria is not to be deemed material within the meaning of the Rule.” United States v. Stevens, 985 F.2d 1175, 1180 (2d Cir. 1993). “Rule 16(a) is not and never was [] ‘intended to provide the defendant with access to the entirety of the government’s case against him.’” Delacruz, 2015 WL 2211943, at *1 (quoting United States v. Percevault, 490 F.2d 126, 130 (2d Cir. 1974)(citation omitted)).

Indeed, “[d]iscovery of evidence in criminal prosecutions is, inevitably, more restricted than discovery in civil cases.” United States v. Tolliver, 569 F.2d 724, 728 (2d Cir. 1978). Rule 16 “does not entitle a criminal defendant to a ‘broad and blind fishing expedition among [items] possessed by the Government on the chance that something impeaching might turn up.’” United States v. Larranga Lopez, No. 05 Cr. 655 (SLT), 2006 WL 1307963, at *8 (E.D.N.Y. May 11, 2006)(alteration in original)(citing Jencks v. United States, 353 U.S. 657, 667, 77 S. Ct. 1007 (1957)(quoting Gordon v. United States, 344 U.S. 414, 419, 73 S. Ct. 369, 97 L. Ed. 447 (1953)).

Further, “[t]here is no general constitutional right to discovery in a criminal case, and Brady did not create one.” Weatherford v. Bursey, 429 U.S. 545, 559, 97 S. Ct. 837 51 L. Ed. 2d 30 (1977); see also Pennsylvania v. Ritchie, 480 U.S. 39, 59, 107 S. Ct. 989, 94 L. Ed. 2d 40 (1987)(“Defense counsel has no constitutional right to conduct his own search of the State’s files to argue relevance.” (citation omitted)); United States v. Evanchik, 413 F.2d 950, 953 (2d Cir. 1969)(“Neither [Brady] nor any other case requires the government to afford a criminal defendant a general right of discovery.”); United State v. Meregildo, 920 F. Supp. 2d 434, 440

(S.D.N.Y. 2013)(“Brady is not a rule of discovery – it is a remedial rule.” (citing United States v. Coppa, 267 F.3d 132, 140 (2d Cir. 2001))). “Rather, Brady established that the Government has a constitutional obligation to disclose favorable and material information to the defendant.” Delacruz, 2015 WL 2211943, at *2.

In this case, with regard to the known recordings, the Government represents that there are recordings of the Defendant’s conversation with the New York State Board of Pharmacy undercover; a video of a meeting the Defendant held with a customer; and that there is no other recording. The Government also states that there is a reference in paragraph 34 of the affidavits in support of the search warrant to a recording with Lameh which was in error and should have been noted as a recording with the Defendant.

The Defendant also seeks under Rule 16 recorded conversations with Courtney Fitt. The Defendant contends that these recordings may show that Pharamalogical operated overtly and gave accurate information to its customers about its processes. As to this limited request, the Court finds the Government’s conclusory assertion that these conversations are not proper Rule 16 discovery to be inadequate. Accordingly, the Court grants the Defendant’s request that these recordings be turned over.

As to the lab reports and notes regarding the chemical analysis of Altuzan, the Government has represented that it has complied with its Rule 16 obligations. In particular, the Government represents that it has turned over documents it had in its possession and has requested any other documents within these categories which will be produced upon receipt.

The Defendant has not presented any facts suggesting that the Government’s representations in this regard are inaccurate. The Defendant expresses concern that the Government failed to request these items from the FDA in a timely manner. It is not clear what

the time frame was of these requests. In any event, the Defendant provides no legal basis as to why he is entitled under Rule 16 to these lab reports and notes at this time.

However, the Government has Brady obligations with which it must comply. To the extent any of this information constitutes Brady material, the Court notes that “Brady material that is not ‘disclosed in sufficient time to afford the defense an opportunity for use’ may be deemed suppressed within the meaning of the Brady doctrine.” United States v. Douglas, 525 F.3d 225, 245 (2d Cir. 2008)(alteration omitted)(quoting Leka v. Portuondo, 257 F.3d 89, 103 (2d Cir. 2001)); see also Copp, 267 F.3d at 135 (“Brady material must be disclosed in time for its effective use at trial.” (citation omitted)). “Brady material buried within significant amounts of [18 U.S.C. §] 3500 material and provided too close to trial to permit effective use may – under certain circumstances – also be deemed suppressed.” Delacruz, 2015 WL 2211943, at *2; see also United States v. Rittweger, 524 F.3d 171, 181 n. 4 (2d Cir. 2008)(“Complying with the Jencks Act . . . does not shield the government from its independent obligation to timely produce exculpatory material under Brady – a constitutional requirement that trumps the statutory power of 18 U.S.C. § 3500.”)(citation omitted).

The Court further notes that although “[t]he plain meaning of this provision does not require production of 3500 material under the Jenks Act before trial,” “[i]n practice . . . courts in this district require the Government to produce 3500 material at least the Friday prior to the commencement of trial and sometimes earlier.” Delacruz, 2015 WL 2211943, at *2.

As to the Defendant’s request for communications or records between the FDA and the Defendant and/or his counsel, the Government represents that it has produced all these documents. The Defendant has not presented any facts suggesting that the Government’s

representations in this regard are inaccurate. Further, at this time, the Defendant cites no basis why this material is necessarily Brady material.

As noted above, the Defendant also seeks disclosure of any statements by him, his lawyers, and others that support an advice of counsel defense. The Government represents that it knows of no such statements. Again, the Defendant has not presented any facts suggesting that the Government's representations are inaccurate.

However, the Court reminds the Government that "Rule 16(a)(1)(A) provides that, upon request, the Government must disclose any written or recorded statements made by a defendant, before or after arrest, in response to interrogation by any person known to the defendant to be a Government agent; and recorded testimony of the defendant before the grand jury which relates to the offense charged." United States v. Crosby, No. 08CR186A (HBS), 2013 WL 3354422, at *5 (W.D.N.Y. July 3, 2013)(footnoted omitted). "Failure of the Government to disclose a defendant's statements to a Government agent may rise to the level of a constitutional due process violation." Id. (citing Clewis v. Texas, 386 U.S. 707, 87 S. Ct. 1338, 18 L. Ed. 2d 423 (1967)).

To the extent the Defendant also seeks other Brady material, including alleged exculpatory statements of physicians and other potential witnesses who claimed that they knew what they were buying and were given truthful information from Pharmalogical as to the source of their products, the Court reminds the Government of its Brady obligations referenced above.

Finally, the Defendant seeks a Bill of Particulars. The Defendant claims that he needs this relief in order to adequately prepare his defense. According to the Defendant, "it is unclear in each count whether the alleged 'scheme' to sell 'misbranded; drugs is limited to those drugs not approved for use in the United States, concerns the non-English label . . . is an issue only

because the label lacked the phrase ‘Rx Only,’ or is one of the other twenty ways a drug can be misbranded.” (Doc No. 44, at 28.)

“Rule 7(f) of the Federal Rules of Criminal Procedure permits a defendant to seek a bill of particulars in order to identify with sufficient particularity the nature of the charge pending against him, thereby enabling the defendant to prepare for trial, to prevent surprise, and to interpose a plea of double jeopardy should he be prosecuted a second time for the same offense.” United States v. Solnin, No. 12-CR-040 (ADS), 2015 WL 332132, at *14 (E.D.N.Y. Jan. 23, 2015). “It has become axiomatic that the function of a bill of particulars is to apprise a defendant of the essential facts of the crime for which he has been charged.” United States v. White, No. 13-CR-255 (S)(HKS), 2015 WL 72183, at *3 (W.D.N.Y. Jan. 6, 2015); see United States v. Salazar, 485 F.2d 1272, 1277–78 (2d Cir. 1973), cert. denied, 415 U.S. 985, 94 S. Ct. 1579, 39 L. Ed. 2d 882 (1974); Wong Tai v. United States, 273 U.S. 77, 47 S. Ct. 300, 71 L. Ed. 545 (1927).

“A bill of particulars should be required only where the charges of the indictment are so general that they do not advise the defendant of the specific acts of which he is accused.” United States v. Feola, 651 F. Supp. 1068, 1132 (S.D.N.Y. 1987), aff’d, 875 F.2d 857 (2d Cir. 1989) (mem.), cert. denied, 493 U.S. 834, 110 S. Ct. 110, 107 L. Ed. 2d 72 (1989); see also United States v. Leonelli, 428 F. Supp. 880, 882 (S.D.N.Y. 1977)(same).

“Whether to grant a bill of particulars rests within the sound discretion of the district court.” United States v. Panza, 750 F.2d 1141, 1148 (2d Cir. 1984)((citing United States v. Burgin, 621 F.2d 1352, 1358–59 (5th Cir. 1980), cert. denied, 449 U.S. 1015, 101 S. Ct. 574, 66 L. Ed. 2d 474 (1980))); see also United States v. Bortnovsky, 820 F.2d 572, 574 (2d Cir. 1987). “Acquisition of evidentiary detail is not the function of the bill of particulars.” Hemphill v.

United States, 392 F.2d 45, 49 (8th Cir. 1968), cert. denied, 393 U.S. 877, 89 S. Ct. 176, 21 L. Ed. 2d 149 (1968).

Here, the Defendant requests that the Government disclose to him the specific fraud alleged in each count, including the false statements alleged to have been made and the “misbranding” alleged in each count.

The Government responds that “all were fraudulent because: (i) they were unapproved new drugs which purported to be approved drugs, (ii) the website Q&A was misleading to the public, (iii) the website falsely portrayed many of the drugs with pictures of approved drugs and (iv) the drugs and devices Scully sold were illegal to sell in the United States.” (Doc No. 48, at 22.)

The Court agrees with the Defendant that this response by the Government is inadequate. Indeed, the Defendant notes that many of the drugs sold, like Botox, were apparently approved drugs.

Further, the Court notes that the Defendant is not requesting evidentiary material as part of a Bill of Particulars nor is he seeking information that has been provided in some acceptable alternate form. See generally United States v. Faux, No. 3:14-CR-28 (SRU), 2015 WL 1190105, at *5 (D. Conn. Mar. 16, 2015).

Accordingly, the Court grants the Defendant’s request to obtain a bill of particular, stating (1) the specific fraud alleged in each count, including the false statements alleged to have been made; and (2) the “misbranding” alleged in each count.

III. CONCLUSION

Based on the foregoing reasons, the Defendant’s motion is denied except to the extent the Court grants the requests for the discovery enclosed by the Government in its motion papers, the

discovery it represents it will provide, any recorded conversations with Courtney Fitt, and a Bill of Particulars as described above. The Government is directed to provide all the foregoing material to the Defendant within 30 days of the date of this order. That part of the Defendant's motion to dismiss Count Seventy Two of the Indictment on merger grounds is denied as premature.

SO ORDERED.

Dated: Central Islip, New York
June 8, 2015

Arthur D. Spatt

ARTHUR D. SPATT
United States District Judge