

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA

v.

RAHIM SHAFa and
NAHID TORMOSI SHAFa, A/K/A NAHID
TORMOSI,

Defendants

Case No. 4:20-cr-40021-MRG

GOVERNMENT'S TRIAL BRIEF

The United States respectfully submits this trial brief to identify relevant issues regarding the trial in the above-captioned matter scheduled to begin on January 22, 2024.

I. The Indictment and Case Status

The Superseding Indictment alleges that defendants and spouses Rahim Shafa (“SHAFa”) and Nahid Tormosi Shafa, a/k/a Nahid Tormosi (“TORMOSI”), engaged in two schemes.

A. Scheme #1: Fraudulent Importation of Pharmaceutical Implants Not Approved by the FDA

From approximately June 2008 through January 2018, SHAFa, a psychiatrist licensed in the Commonwealth of Massachusetts, and TORMOSI, his office manager, participated in a long-running scheme to purchase drugs not approved by the Food & Drug Administration (“FDA”), naltrexone pellet implants, disulfiram pellet implants and disulfiram injections (the “naltrexone and disulfiram products”)¹, from a supplier in Hong Kong. These pellet implants contain ingredients to help drug and alcohol addicts remain drug-free. The defendants worked with their

¹ The pellet implants are referred to herein as the pellets, implants, and pellet implants, all of which should be understood as meaning the same thing.

Hong Kong-based supplier to conceal from the United States government the drugs they were importing. As part of the scheme, the supplier falsified shipping documents to conceal that the packages contained the implants, and SHAFa and TORMOSI accepted packages knowing that the United States government was being defrauded.

SHAFa inserted or implanted the illegally imported pellets into patients at his clinic, Novel Psychopharmacology, in Natick and Milford, Massachusetts.² SHAFa ran his implant program typically after-hours at his clinic requiring implant patients to wait long hours well into the night before they would receive the implant. TORMOSI, SHAFa's wife, was in charge of all administrative aspects of the implant program. Because the implants are not FDA-approved and thus are deemed misbranded under the Food, Drug & Cosmetic Act (FDCA), they have not been properly tested and evaluated by the FDA to assure that they are safe and effective. The government expects that witnesses will testify about the permanent harm that they have suffered because of the implant procedures.

The government expects that the evidence will show that SHAFa and TORMOSI knew that the implants were illegal, and in fact told SHAFa's patients the same. Nevertheless, they and the supplier took steps to conceal the implant program from the United States government by falsifying shipping documents to conceal that the packages contained the implants, and SHAFa and TORMOSI accepted packages knowing that the United States government was being defrauded. SHAFa and TORMOSI used credit cards in their names to pay for the Hong Kong implants and they in turn used their bank accounts to pay off the credit cards they used. The government expects that the evidence will further show that the defendants misled patients about

² SHAFa also owned and operated Rahim Shafa M.D., P.C. at the same clinic locations, through which he provided psychotherapy services. TORMOSI was also the practice manager of this entity.

the effectiveness and duration of the implants, and that they declined to assist patients when complications from the implants arose after the procedures took place.

Counts One Through Nine pertain to the scheme to import illegal pharmaceuticals. Count One charges SHAFa and TORMOSI with conspiracy to commit international money laundering, in violation of 18 U.S.C. § 1956(h). Counts Two Through Nine pertain to SHAFa only: international money laundering and aiding abetting the same, in violation of 18 U.S.C. §§ 1956(a)(2)(A) and 2 (Counts Two through Four); conspiracy to defraud the United States, in violation of 18 U.S.C. § 371 (Count Five); importing merchandise contrary to law and aiding and abetting the same, in violation of 18 U.S.C. §§ 545 and 2 (Counts Six through Eight); and receipt and delivery of misbranded drugs, in violation of 18 U.S.C. §§ 331(c) and 333 (Count Nine).

B. Scheme #2: Billing Medicare for Services not Rendered

The second scheme pertains to SHAFa and TORMOSI's billing Medicare for services not rendered, specifically for office visits that supposedly occurred while SHAFa was, in fact, out of the country, between approximately April 2016 and January 2019. The government expects the evidence to show that SHAFa and TORMOSI submitted or caused to be submitted claims for services SHAFa did not provide. Specifically, TORMOSI, who had primary responsibility for billing Medicare, submitted or caused to be submitted claims for in office visits supposedly covered by SHAFa for dates on which SHAFa was, in fact, traveling out of the country on at least five occasions, which are noted in the Superseding Indictment.

As a result, Count 10 charges SHAFa and TORMOSI with conspiracy to commit health care fraud, in violation of 18 U.S.C. § 1349.

C. Trial Status

Trial is scheduled to begin on January 22, 2024. The government expects to call approximately 15-20 witnesses in its case-in-chief, including law enforcement witnesses, expert

witnesses, former employees and interns from SHAFAs clinic, a representative of SHAFAs and TORMOSIs billing company, and former patients. The government may call additional witnesses depending on cross-examination and any witnesses called by the defense. The government expects the trial to last approximately two weeks.

II. Legal Elements of the Charged Offenses³

A. Counts 1, 2-4: Conspiracy to Commit International Money Laundering and International Money Laundering⁴

- (1) an agreement;
- (2) to transport, transmit, or transfer;
- (3) monetary instruments or funds;
- (4) from a place in the United States to or through a place outside the United States, or to a place in the United States from or through a place outside the United States; and
- (5) with the intent to promote the carrying on of specified unlawful activity (as defined in 18 U.S.C. § 1956(c)(7)).

B. Count 5: Conspiracy to Defraud the United States⁵

- (1) That the agreement specified in the indictment, and not some other agreement or agreements, existed between at least two people to defraud the United States, or one of its agencies or departments, by dishonest means as charged in the Indictment;
- (2) That the defendant willfully joined in that agreement; and

³ A more comprehensive description of the legal elements of the charged offenses is found in the Government’s Request for Jury Instructions.

⁴ The superseding indictment contains a scrivener’s error related to Count Four. The words “January 3, 3018” should be “January 3, 2018.” SHAFAs, the sole defendant charged in this count, agrees that this count applies to conduct occurring on or about January 3, 2018.

⁵ The government anticipates that the trial evidence will show that SHAFAs and his co-conspirators defrauded several federal agencies, including the Department of Homeland Security (“DHS”), U.S. Customs and Border Patrol (“CBP”), U.S. Immigrations and Customs Enforcement (“ICE”), and the FDA. The government has notified SHAFAs, the sole defendant charged in this count, of the underlying theory of this charge through the indictment, superseding indictment, discovery, and by letter dated December 28, 2023.

- (3) That one of the conspirators committed an overt act during the period of the conspiracy in an effort to further the purpose of the conspiracy.

C. Counts 6-8: Importing Merchandise Contrary to Law

Whoever:

- (1) fraudulently or knowingly;
- (2) imports or brings into the United States, any merchandise; and
- (3) 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.

D. Count 9: Receipt and Delivery of Misbranded Drug

- (1) the receipt in interstate commerce;
- (2) of any food, drug, device, tobacco product, or cosmetic;
- (3) that is adulterated or misbranded; and
- (4) the delivery or proffered delivery thereof for pay or otherwise.

This crime can be a felony or a misdemeanor. In accordance with 21 U.S.C. 333(a)(2), it is a felony if the crime is committed with “an intent to defraud or mislead.”

E. Count 10: Conspiracy to Commit Health Care Fraud

- (1) an agreement to commit:
- (2) a scheme, substantially as charged in the indictment, to defraud a health care benefit program, or to obtain by false or fraudulent pretenses, representations, or promises any money owned by or under the custody or control of such a program;
- (3) defendant’s knowing and willful participation in this scheme with the intent to defraud;
- (4) that the scheme was in connection with the delivery of, or payment for, health care benefits, items or services.

III. Relevant Law

A. Food Drug and Cosmetic Act

The Food Drug and Cosmetic Act defines key terms for purposes of this case.

A “drug” is defined by the FDCA as, among other things, an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease in a human or other animal; an article (other than food) intended to affect the structure or any function of the body of human or other animal; and an article intended for use as a component of any such articles. *See* 21 U.S.C. §§ 321(g)(1)(B), (C), (D). The government’s experts will opine that naltrexone implants and disulfiram implants and injections each qualify as a “drug” because they are intended to treat the disease of opioid and/or alcohol addiction in humans.

Under the FDCA, drugs that only may be dispensed upon a written prescription of a licensed practitioner include any “drug intended for use by man which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed by law to administer such drug.” 21 U.S.C. § 353(b)(1)(A). A drug may also be limited to prescription use by its FDA-approved application. *See* 21 U.S.C. § 353(b)(1)(B). Naltrexone pellets and disulfiram pellets and injections are prescription drugs because they should only be administered under the care of a licensed practitioner.

A drug is deemed to be “misbranded” if it does not meet certain requirements of the FDCA, including, among other things, if its labeling fails to bear adequate directions for use. 21 U.S.C. § 352(f)(1). “Adequate directions for use” means that the directions are sufficient for a layperson to safely use the drug for the purposes for which it is intended. 21 C.F.R. § 201.5. Because prescription drugs, by definition, are not safe for use except under the supervision of a licensed medical practitioner, it is not possible for a prescription drug to bear labeling with adequate directions that would enable a layperson to use the drug safely.

FDA-approved prescription drugs bearing FDA-approved labeling are exempt from having labeling with adequate directions for use by a layperson under specific circumstances. 21 C.F.R. § 201.100. However, non FDA-approved prescription drugs do not meet the conditions for an exemption from the requirement of having labeling with adequate directions for use and are, therefore, as a matter of law, misbranded.

Moreover, the FDCA prohibits the introduction, or causing the introduction, of a misbranded drug into interstate commerce. 21 U.S.C. §331(a). The FDCA prohibits the receipt in interstate commerce of any misbranded drug and the delivery or proffered delivery thereof for pay or otherwise. 21 U.S.C. § 331(c). The term “interstate commerce” includes “commerce between any State or Territory and any place outside thereof.” 21 U.S.C. § 321(b).

B. Import Laws and Regulations – CBP and FDA

The shipping of drugs into the United States is regulated and enforced by DHS, CBP, ICE and the FDA. It is a violation of federal law to intentionally misidentify the contents and value of the contents of packages imported into the United States.

C. Medicare Claims

It is a violation of federal law and Medicare’s program rules and regulations, for a Medicare participant like SHAFa to submit or cause the submission of claims to Medicare for services that were not reasonable and necessary, including services not rendered and services not otherwise payable by Medicare. Federal law likewise prohibited TORMOSI from submitting or causing the submission of claims that she knew were not rendered because, among other reasons, SHAFa was not in the country at the time the services were supposedly rendered.

IV. Statement of Facts

A. The Naltrexone and Disulfiram Offenses (Counts One Through Nine)

SHAFa is a psychiatrist by training and licensure. SHAFa graduated from the National University of Iran in 1982. He has been licensed to practice medicine in Massachusetts since 1992 and specializes in psycho-pharmacology, which is the use of medications in treating mental health conditions. SHAFa especially focused on patients with substance and alcohol abuse issues. He, along with TORMOSI, his wife, operated a clinic called Novel Psychopharmacology (“Novel”) with offices in Natick and Milford, Massachusetts. TORMOSI is the office manager for Novel.

From 2008 through 2018, SHAFa and TORMOSI purchased drugs that were not approved by the FDA from an individual in Hong Kong (“Person 1”), who sent the illegal pellets from Hong Kong to SHAFa and TORMOSI in Massachusetts. SHAFa then implanted the pellets into drug- and alcohol-addicted patients at his Novel offices. Several of SHAFa’s patients experienced complications from the procedure and/or did not find the drug effective. When patients with complications sought follow up care from SHAFa, at times after meeting confusion from emergency room doctors about their implants, SHAFa failed to provide after-care. Despite reports of complications and complaints of ineffectiveness, SHAFa continued to import and implant these non-approved drugs into patients.

1. Naltrexone and Disulfiram

Naltrexone is an opioid blocker. It blocks the euphoria experienced by a drug user in an effort to eliminate the person’s desire to use opioids. The FDA has approved drugs for use in the United States that contain and deliver naltrexone in two forms: a tablet ingested orally or in injectable liquid form.

A third form that naltrexone can be delivered is by implanting a pellet into the body, which then releases the naltrexone over time. Naltrexone implants are manufactured in locations outside the United States, including China and Australia, and are designed to last varying durations, e.g., 6 months, 10 months or 12 months. The FDA has not approved the sale and/or use of naltrexone implants in the United States.

Disulfiram is an active ingredient used to treat alcohol and works by creating an adverse reaction in the body to any alcohol that is consumed. The effect is to make consuming alcohol extremely unpleasant for someone who is taking disulfiram. The FDA has approved several drugs that contain the active pharmaceutical ingredient disulfiram for the treatment of alcohol dependence. All forms of approved disulfiram drugs are in tablet form for oral ingestion. Disulfiram can also be administered in two additional forms: as an injectable liquid and as an implantable pellet. Neither of those forms has been approved by the FDA for use in the United States.

2. SHAFa and TORMOSI Source Unauthorized Drugs from Person 1

In or around June 2008, SHAFa and TORMOSI began purchasing unauthorized naltrexone and disulfiram pellets from Person 1's company, 1212 Ltd., in Hong Kong. SHAFa emailed his order to Person 1, including the drug he wanted—*i.e.*, naltrexone or disulfiram—the type of each—*i.e.*, 6-month, 10-month, or 12-month—and how many of each variation. Person 1 confirmed the order, also via email, providing a commercial invoice documenting the sale. SHAFa and TORMOSI then paid the purchase price using credit cards tied to bank accounts in both SHAFa and TORMOSI's names.

After the payment was initiated, Person 1 packed or caused the drugs to be packed for shipment. Because the drugs are not FDA-approved, SHAFa and Person 1 agreed to falsely

describe the contents of the packages using descriptions like “plastic beads in plastic tubes” and listed a value well below the actual value of the drugs, usually around \$60-70. The actual value of a typical shipment was thousands of dollars. This occurred over the life of the conspiracy charged in Counts 1, 2, and 5.

Upon receipt of the drugs, SHAFa implanted both the naltrexone and disulfiram pellets into patients. He required his patients to sign various forms indicating that they understood the naltrexone and disulfiram pellets were not FDA-approved. Patients were required to take a quiz where they were asked whether the drugs were FDA-approved. Patients, however, were not counseled in any detail about the risks of taking non-FDA-approved medications, or these medications in particular.

The implantation of these pellets is a surgical procedure. SHAFa is not trained to perform surgery. However, he would perform the implantation himself on massage tables in the small back rooms of his clinics. Both patients, staff, and interns reported concerns about the non-sterile environment in which these procedures were performed.

B. The Health Care Fraud Conspiracy (Count 10)

From in or about April 2016 through in or about January 2019, TORMOSI, acting as SHAFa’s office manager, submitted or caused to be submitted false claims to Medicare for services that SHAFa did not render. Specifically, TORMOSI and SHAFa submitted paperwork to their third-party biller claiming that SHAFa had provided services to patients that he in fact had not. The third-party biller then entered the codes as provided by TORMOSI and SHAFa, and submitted the claims to Medicare for reimbursement to SHAFa. Some claims were false because SHAFa was traveling outside the country for the relevant dates of service. He was required under Medicare guidelines, regulations and laws to have rendered the claimed services, but he did not.

In other instances, the claims were false and fraudulent because the services that SHAFa actually rendered were not valid for the billing codes used by SHAFa and TORMOSI. The government expects that the evidence will show that SHAFa and TORMOSI billed for services that he did not perform in violation of federal law, and Medicare rules and regulations.

V. Case-in-Chief Evidence

The government expects to present the following evidence at trial, subject to revision based on ongoing witness preparation, trial planning, and defense witnesses, arguments, or cross-examination.

A. Witnesses

- a. Expert Witnesses. The government anticipates calling Arthur Simone, M.D. and Stephen Quindoza, who have been noticed as expert witnesses.
- b. Employees of Novel. The government anticipates calling former employees of SHAFa and TORMOSI to testify about their observations as to the defendants' scheduling, patient treatment and exam conditions, and billing practices. The following employees are listed on the government's witness list as potential witnesses for the government's case-in-chief: Ray Saunders, Luanne Lombardo, Julia Taranto and Chelsea Cooper.
- c. Former Interns at Novel. The government anticipates calling physician assistant students who had monthlong internships with SHAFa to testify about their observations of defendants' conduct, including treatment of patients and treatment conditions. The following interns are listed on the government's witness list as potential witnesses for the government's case-in-chief: Maria De Vivo, Kyle Linehan, Elizabeth Aguiar, Camille Lamell, and Nicole Petrosky.
- d. Patients. The government anticipates calling former patients of SHAFa who received either naltrexone or disulfiram implants. The government also anticipates calling witnesses for whom SHAFa billed for services when he did not in fact see them for those services. The following patients are listed on the government's witness list as potential witnesses for the government's case-in-chief: David Iovino, Katie Treacy, Katrina Calamonici, Jordan Sousa, Robert Black, William Cushing, Karen Bertoni, Edward McLaughlin, Charles Drum, Vincent Caricchio, Nicole Pedro and Amber Lombardini.
- e. Agents. The government anticipates calling agents, including the case agent to describe the investigation into the defendants, including the search warrants

executed at the defendants' practice, and the agency employee who analyzed the financial documents obtained during the investigation to testify to the defendants' payment for the implants, charge of the patients for the implants, and profit motive for carrying out the conspiracies charged. The government also will call an agent from U.S. Customs and Border Patrol to discuss CBP's requirements and practices with respect to customs declarations and importing drugs into the United States.

- f. Undercover Agents. The government engaged three Massachusetts State Police troopers who posed as prospective implant patients and made phone calls and conducted visits to Novel. The government may call these three State Police troopers.
- g. Other Witnesses. The government anticipates calling Bob Marraffa and/or Amanda Faria, representatives from Marraffa and Associates, which was the third-party billing service that the defendants used to process Medicare claims.

B. Exhibits

- a. Email communications between the co-conspirators. The government will introduce emails between and among SHAFa, TORMOSI, Person 1, and others that describe the details of the plan to ship naltrexone and disulfiram pellets and injections from Hong Kong to Massachusetts.
- b. Commercial invoices. The government will present invoices prepared by or at the direction of Person 1 memorializing the sale of naltrexone and disulfiram pellets to the defendants.
- c. Shipping records. The government will present business records from the shipping companies used to send the naltrexone and disulfiram to the defendants. These are relevant to demonstrate the unlawful movement of the drugs into the United States and to demonstrate the effort to disguise the contents of the shipments in order to avoid CBP and FDA inspection.
- d. Credit card records. The government will introduce business records for the defendants' credit card companies showing charges for payment for the naltrexone and disulfiram pellets and injections.
- e. Bank records. The government will introduce records of the defendants' bank accounts showing payment for the credit cards used to purchase the naltrexone and disulfiram pellets. These records are relevant to demonstrate the defendants' participation in the conspiracy to commit international money laundering, as well as their motive and intent to defraud the United States and the Medicare program. The government expects to tender a witness, as described above, to summarize and synthesize the bank records for the benefit of the jury.

- f. Summary charts. The government expects to admit summary charts summarizing the defendants' bank accounts, as well as charts summarizing the amounts paid for and charged to customers for the implants over time. The government also may seek to introduce summary charts setting forth the claims used to bill Medicare. The government may utilize other summary charts or chalks with witnesses to synthesize the evidence and make it more understandable for the jury.
- g. Patient medical records, implant records, billing records, and claims data. The government will introduce medical records, billing records, claims data, and records of the implants administered to the patients. This will include descriptions of the implants and the invoices provided to patients.
- h. Medicare contracts and policies. The government will introduce documents related to the SHAFAs' participation in the Medicare program, including his enrollment documents with Medicare, claims data, and related records.
- i. Recordings and Transcripts. The government may introduce audio/video recordings from the undercover visit and calls to SHAFAs' office. The government also may introduce audio from a consensually recorded phone call between SHAFAs and Person 1, and audio of agents' interview of SHAFAs when executing search warrants at SHAFAs and TORMOSI's practice. For these recordings, the government will also have transcripts of these audio/video recordings available for viewing by the jury. The First Circuit has held that transcripts and recordings are admissible at trial so long as a foundation and authenticity are laid for their admission. *See United States v. Carbone*, 798 F.2d 21, 26 (1st Cir. 1986).

VI. Anticipated Evidentiary Issues

A. Government's Motions in Limine

The government filed a set of motions in limine on the docket in this case.⁶

- a. Omnibus Motion to:
 - i. Preclude defendants from offering evidence of good conduct
 - ii. Preclude defendants from blaming CBP or the FDA for their misconduct
 - iii. Preclude use of law enforcement agent interview reports or notes for impeachment of government witnesses

⁶ The government reserves its right to file further motions in limine/motions to exclude evidence prior to or during trial to admit/exclude evidence that is consistent with the Federal Rules of Evidence and First Circuit precedent, including motions under Fed. R. Evid. 404(b) related to motive, opportunity, intent, preparation, plan, knowledge, identity, absence of mistake, or lack of accident.

- iv. Exclude any of defendants' own out of court statements *offered by the defendants* to prove the truth of the matter asserted
- v. Preclude defendants from eliciting testimony of producing evidence on:
 - 1. The presence or absence of any particular person on government's witness list / government decision to call or not call a particular witness
 - 2. Discovery disputes, including volume/nature/timing or use of federal resources
 - 3. Any argument encouraging jurors to ignore the law or this Court's instructions
 - 4. Plea negotiations/offers
 - 5. Potential punishment or other consequences arising from a conviction
 - 6. Defense counsel's personal opinion of or relationship with the defendants
 - 7. Other individuals who have or have not been charged in this or other related cases
 - 8. Arguments of prosecutor or agent misconduct
- b. Motion to admit co-conspirator statements
- c. Motion to permit use of SHAFAs proffer statements consistent with the proffer agreement
- d. Motion to preclude defendants from using evidence or information derived from *Commonwealth v. Clayton*.

B. Scrivener's Errors in the Superseding Indictment

As noted above, Count Four of the Superseding Indictment contains a clerical error in the date of the alleged conduct; the year is written as 3018 instead of 2018. Counsel for SHAFAs, the sole defendant charged in this count, agrees that this is an error and the relevant year for the purpose of Count Four is 2018.

C. Medical Records from Other Providers

The government may introduce medical records relating to complications from SHAFAs' implantation of the illegally imported, non-FDA-approved naltrexone and disulfiram pellets. Such records are admissible as statements for purposes of medical diagnosis and treatment, *see* Fed. R. Evid. 803(4); *Danaipour v. McLarey*, 386 F.3d 289, 297 (1st Cir. 2004) (the "three preconditions for admission of such statements [under this exception are] (1) the statements must be made for purposes of diagnosis or treatment[;] (2) about (i) medical history (ii) or past or present symptoms, pain, or sensations or (iii) about the inception or general character of the cause or external source thereof[; and] (3) insofar as they are reasonably pertinent to diagnosis or treatment"; the exception does not require that the speaker be the patient or that the listener be the doctor"), records of regularly conducted activity, *see* Fed. R. Evid. 803(6), and as otherwise trustworthy and probative, *see* Fed. R. Evid. 807.⁷

VII. Other Matters

A. Voir Dire and Jury Instructions

The government filed its proposed voir dire questions and proposed jury instructions on the docket pursuant to the Court's pretrial order.

B. Reciprocal Discovery from Defendants

Consistent with Rule 16(b) of the Federal Rules of Criminal Procedure and Local Rule 116.1(D), the government has requested reciprocal discovery from the defendants (for example, in automatic discovery letter on October 16, 2020 and as recently as January 2, 2024). The

⁷ Fed. R. Evid. 807(b) requires reasonable notice to the adverse party of intent to offer the evidence under that hearsay exception. The government has already provided defendants with a prospective witness list, and hereby notices the defendants that it may seek to introduce medical records produced in discovery for any of the patients identified on that list relating to issues with services that SHAFAs provided under this rule.

government has not received reciprocal discovery from the defendants as of yet and reserves its right as to such discovery in accordance with both the Local and Federal Rules.

Special Arrangements

a. *Paralegal.* The government respectfully requests that, in addition to trial counsel, the Court allow Karly Porter, a paralegal from the United States Attorney's Office, to sit at counsel table. Ms. Porter is an integral member of the prosecution team and will assist the undersigned counsel in their efforts to introduce the physical evidence, audio recordings, and video recordings in this case.

b. *Witnesses.* Certain of the government's witnesses will be traveling from out-of-town by airplane. Depending on witness schedules and the actual date that trial commences, the government may request that certain witnesses be allowed to testify out of order.

c. *Case Agent.* The government requests that FDA Special Agent Derek Roy be designated as the case agent and allowed to sit at counsel table during the trial. Special Agent Roy has been noticed as a potential witness.

Respectfully submitted,

JOSHUA S. LEVY
Acting United States Attorney

By: /s/ John T. Mulcahy
John T. Mulcahy
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By: /s/ John T. Mulcahy
John T. Mulcahy
Assistant U.S. Attorney
Dated: January 12, 2024