UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

February 2023 Grand Jury

UNITED STATES OF AMERICA,

Plaintiff,

v.

SUKHJIT SINGH GHUMAN (1),
aka "Sukhi",
KIRANJIT GHUMAN (2),
aka "Kiran",
MOHAMMAD RAY KHAN (3),
JOSHUA SCHWASS (4),
BENJAMIN LOUSTAUNAU (5),
JASWINDER SHANKER (6),
aka "Jesse",
VENIN PATEL (7),

Defendants.

Case No. 23CR2019-RBM

I N D I C T M E N T
(Superseding)

Title 18, U.S.C., Secs. 371 and 545 and Title 21, U.S.C., Secs. 331(d), 355(a), 333(a)(2), and 331(c) - Conspiracy to Smuggle Drugs, Introduce Unapproved New Drugs, and Receive and Deliver Misbranded Drugs; Title 21, U.S.C., Sec. 545 - Smuggling Drugs; Title 21, U.S.C., Secs. 331(d), 355(a), and 333(a)(2) - Introducing Unapproved New Drugs; Title 18, U.S.C., Secs. 1347 and 1349 - Conspiracy to Commit Health Care Fraud; Title 18, U.S.C., Sec. 1347 - Health Care Fraud; Title 18, U.S.C., Sec. 2 - Aiding and Abetting; Title 18, U.S.C., Secs. 371, 1343 and Title 21, U.S.C., Secs. 331(t), 353(e)(1)(A), 333(b)(1)(D) - Conspiracy to Engage in the Unlawful Wholesale Distribution of Drugs and Commit Wire Fraud; Title 18, U.S.C., Secs. 981(a)(1)(C), 982(a)(2)(B), 982(a)(7), and Title 28, U.S.C., Sec. 2461(c) - Criminal Forfeiture

The grand jury charges:

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GVM:nlv(2):San Diego:10/13/23

Introductory Allegations

Defendants

1. At times material to this Indictment, Colton Health, LLC, was a California limited liability company that employed or was otherwise associated with the following individuals:

a. Defendant SUKHJIT SINGH GHUMAN, aka "Sukhi", was a member (owner) of Colton Health, LLC.

b. Defendant KIRANJIT GHUMAN, aka "Kiran", was a senior vice-president and Chief Financial Officer of Colton Health, LLC.

c. Defendant MOHAMMAD RAY KHAN was the Chief Operating Officer of Colton Health, LLC.

d. Defendant JOSHUA SCHWASS was a registered nurse and medical assistant supervisor at Colton Health, LLC.

2. On or about March 1, 2018, Colton Health, LLC, purchased a hematology and oncology medical practice, which thereafter did business as Colton Health, and later as South Bay Cancer Center (SBCC), located at 480 Fourth Avenue, Suite 409, Chula Vista, California, 91910.

3. At times material to this Indictment, defendant SUKHJIT SINGH GHUMAN, aka "Sukhi", also owned Colton Health AZ, LLC, an Arizona limited liability company. Colton Health AZ, LLC, did business, at least in part, as AZ Cancer Center (AZCC), a hematology and oncology medical practice located at 1755 Airway Ave, Kingman AZ 86409 until in or about February 2023 when it relocated to 890 Airway Avenue, Kingman, Arizona, 86409. AZCC employed defendant BENJAMIN LOUSTAUNAU as a pharmacy technician.

4. At times material to this Indictment, defendant JASWINDER SHANKER, aka "Jesse", was employed as a Business Development Manager by

Octavian, a security company owned by SUKHJIT SINGH GHUMAN, aka "Sukhi", and lived in Yuba City, California.

5. At times material to this Indictment, Celtis Healthcare, LLC, aka Healthcare UK, aka HCUK (Celtis), was a Pennsylvania limited liability company registered on December 20, 2017, that employed defendant VENIN PATEL as a director.

The FDA And The Federal Food, Drug, and Cosmetic Act

6. The United States Food and Drug Administration (FDA) is the federal agency responsible for protecting the public health by ensuring, among other things, that drugs are safe and effective for their intended uses and have labeling that contain true and accurate information. The FDA carries out its responsibilities, in part, by enforcing the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (FDCA) and other pertinent laws and regulations governing the manufacture, packaging, labeling, and distribution of drugs in the United States.

7. The FDCA, at 21 U.S.C. § 321(g)(1), defines a "drug" to include, among other things:

a. "Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals," and

b. "Articles (other than food) intended to affect the structure or any function of the body of man or other animals."

8. The FDCA, at 21 U.S.C. § 321(p)(1), defines a "new drug" as, among other things, a drug, the composition of which is "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe

and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . ."

9. "Biological product" is defined at 42 U.S.C. § 262(i)(1) to mean "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings."[1] Biological products are generally produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are generally larger, more complex molecules than drugs.

10. Many products meet the definitions of both "drugs" and "biological products." Pursuant to 42 U.S.C. § 262(j), the FDCA applies to biological products subject to regulation under Title 42.

11. Applications for FDA approval of new drugs and biological products are subject to a rigorous review process. New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and Biologic License Applications (BLAs) discuss in great detail how a particular drug or biological product works, how it is manufactured, and precisely what is stated on the label and labeling. For a drug or biological product to be used in the United States, its manufacturing process, label and

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[1] This definition became effective on December 20, 2019. Previously, "biologic product" was defined as "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. § 262 (2017).

labeling, and packaging, as set forth in the pertinent type of application, must be approved by the FDA.

12. FDA approval of a drug or biological product is specific to each manufacturer and each product. Approval granted to a particular manufacturer for a particular drug or biological product to be distributed in the United States does not constitute approval of a drug or biological product with labeling different from the labeling in the FDA-approved application to be imported into and distributed in the United States, even if the imported drug or biological product has the same chemical composition as the FDA-approved drug or biological product.

13. Under the FDCA, at 21 U.S.C. § 353(b), a prescription drug is any drug 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 for use except under the supervision of a practitioner licensed by law to administer such drug" or if the FDA requires it to be administered under the supervision of a practitioner licensed to administer such drug as a condition of the FDA's approval of the drug.

14. The FDCA defines "label" as "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. § 321(k).

15. The FDCA defines "labeling" more broadly as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

16. Under the FDCA, at 21 U.S.C. § 352, a drug is deemed to be misbranded under the following conditions, among other things:

a. "If any word, statement, or other information required by or under authority of [the FDCA] 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." 21 U.S.C. § 352(c).

1. Regulations require all words, statements, and other information required to appear on labeling to be in the English language unless the drug is solely distributed in Puerto Rico or a United States territory. 21 C.F.R. § 201.15(c)(1).

b. "Unless its labeling bears . . . adequate directions for use." 21 U.S.C. § 352(f)(1).

1. Regulations define "adequate directions for use" as meaning "directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5.

2. If the drug is a new drug, the labeling must be the same in language and emphasis as labeling approved by FDA in the NDA. 21 C.F.R. § 201.100(d)(1).

c. If it "was imported or offered for import by a commercial importer of drugs not duly registered" with the Secretary of Health and Human Services (HHS) as required by 21 U.S.C. § 381(s). 21 U.S.C. § 352(o).

17. The FDCA, at 21 U.S.C. §§ 331(d) and 355(a), (b), (i), (j), prohibits any person to introduce or deliver for introduction into

interstate commerce any new drug unless an approved NDA or ANDA is effective with respect to such drug, or unless the drug is the subject of an approved investigational new drug (IND) application. The FDCA, at 21 U.S.C. § 321(b)(1) defines "interstate commerce" to include "commerce between any State or Territory and any place outside thereof." Therefore, the importation of a drug that lacks FDA approval into the United States from a foreign country, violates the FDCA.

18. Similarly, no person shall introduce or deliver for introduction into interstate commerce any biological product unless, among other things, a biologics license is in effect pursuant to the approval of a BLA. See 42 U.S.C. § 262(a), (k); 21 C.F.R., Part 601.

19. Under the FDCA, "wholesale distribution" of drugs requiring a prescription means distribution to a person other than a consumer or patient, or receipt of such drugs by a person other than the consumer or patient, unless a specified exception applies. *See* 21 U.S.C. § 353(e)(4). A "wholesale distributor" is "a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution." 21 U.S.C. § 360eee(29).

20. The FDCA, at 21 U.S.C. § 353(e)(1)(A), prohibits engaging in wholesale distribution of any drug requiring a prescription without the appropriate license(s).

The Medicare and Medi-Cal Programs

21. The Medicare Program (Medicare) was established under Title XVIII of the Social Security Act (SSA). Medicare is a federally funded health care benefit program for persons over 65 years old and certain disabled individuals. Medicare is administered by the Center for

Medicare and Medicaid Services (CMS), an agency of HHS. Individuals who receive benefits under Medicare are referred to as Medicare "beneficiaries." An individual or entity that is authorized to provide healthcare services to a beneficiary is referred to as a "provider." Medicare is a health care benefit program as defined by 18 U.S.C. § 24(b).

22. Medicare is administered in several parts.[2] Medicare Part B (medical insurance) covers certain doctors' services, outpatient care, medical supplies, and preventative services. For instance, Medicare Part B generally pays for chemotherapy and adjunct therapy provided to beneficiaries with cancer treated in an outpatient setting, including covering both the cost of the drug and for the healthcare providers who administer it.

23. Generally, Medicare only pays for health services that are reasonable and necessary. *See, e.g.*, 42 U.S.C. § 1395y(a)(1). A provider seeks payment from Medicare by filing a claim. Generally, Medicare Part B reimburses a provider 80% of their claim, while the remaining 20%, known as the "co-payment," may be covered by a secondary insurance plan or paid directly by the beneficiary. The provider receives payment from Medicare directly to their bank account via Electronic Funds Transfer.

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[2] Medicare Part A (hospital insurance) covers certain hospital stays, care in a skilled nursing facility, hospice care, and home health care; Part D (prescription drug coverage) covers the cost of certain prescription drugs, including many recommended shots or vaccines; and Part C (Medicare Advantage) is an alternative to traditional Medicare coverage administered by Medicare-approved private insurance companies that receive prospective "capitated" payments from the Government to provide similar benefits as offered by Parts A, B, and D.

24. An individual or entity must apply to be a provider, or make certain changes to their provider status, by executing a Medicare Enrollment Application. Individual physician and non-physician practitioners use a Form CMS-855I; clinics, group practices, and certain other suppliers use a Form CMS-855B; institutional providers use a Form CMS-855A. These applications can be submitted online through Medicare's Provider Enrollment, Chain, and Ownership Systems (PECOS). If such applications are approved, an individual or entity can submit claims to Medicare under their National Provider Identifier (NPI) number.

25. Medicare Enrollment Applications obligate applicants to abide by applicable Medicare laws, regulations and program instructions, and condition payment of a claim by Medicare on compliance with such laws, regulations and program instructions. Applicants must certify that they will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

a. Defendant SUKHJIT SINGH GHUMAN, aka "Sukhi", signed Medicare Enrollment Applications as an authorized official for Colton Health, LLC, on July 2, 2020, July 9, 2020, and August 5, 2020; and signed Medicare Enrollment Applications as an authorized official for Colton Health AZ, LLC, on January 14, 2021, January 28, 2021, March 3, 2021, November 11, 2021, December 16, 2021, and February 13, 2023.

26. CMS publishes the CMS Online Manual System, located at http://www.cms.hhs.gov/manuals, which, among other things, provides instructions to providers on when they can appropriately bill Medicare. Enrolled providers are provided with online access to the online Medicare

Manual System, as well as services bulletins, describing proper billing procedures and billing rules and regulations.

27. Section 1832(a)(2)(B) of the SSA, 42 U.S.C. § 1395k, authorizes Medicare Part B payment for "medical and other health services." Section 1861(s) of the SSA, 42 U.S.C. § 1395x(s), defines "medical and other health services" to include drugs that are not usually self-administered and are administered incident to certain physician services. Section 1861(t) of the SSA, 42 U.S.C. § 1395x(t), allows payment by Medicare Part B for a drug used in an "anticancer chemotherapeutic regimen" only if the use is "for a medically accepted indication." Section 1861(t) defines "medically accepted indication" to include only such drugs that are approved by the FDA (either for such use or if such use is supported by certain medical literature).

a. According to the Medicare Benefit Policy Manual (Publication 100-02, Ch. 15, § 50.4.1, Drugs and Biologicals), in order to be eligible for Medicare Part B reimbursement, drugs must be safe and effective. Drugs approved for marketing by the FDA are considered safe and effective for purposes of this requirement when used for indications specified on the labeling. Therefore, Medicare will generally pay for the use of an FDA-approved drug, if: it was provided on or after the date of the FDA's approval; it is reasonable and necessary for the individual patient; and all other applicable coverage requirements are met. Furthermore, the Medicare Benefit Policy Manual (Publication 100-02, Ch. 15, § 50.4.2) provides that an unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA. FDA-approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if it is

determined to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. Medicare does not, however, pay for drugs which are not FDA approved, unless CMS had made a specific exception and instructed otherwise.

28. Accordingly, a Medicare claim for a drug requires the claimant submitting the claim to represent that, among other things, the drug was FDA-approved or that CMS made a specific exception for coverage of the drug.

29. The Medicare Prescription Drug, Improvement, and Modernization Act ("MMA") of 2003 established a methodology for Medicare Part B reimbursement for most covered drugs. Effective January 1, 2005, reimbursement for drugs was generally based on the average sales price (ASP). *See* 42 U.S.C. §§ 1395u(o), 1395w-3(a)(2)(A), 1395w-3a, 1395w-3b. ASP is defined as a manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter.

30. Medicaid is a federal and state-funded health insurance program for children, disabled individuals, and families and individuals who fall below certain income levels. California's Medicaid Program is commonly known as "Medi-Cal." Medi-Cal reimburses health care providers for certain services that are certified as medically necessary by such providers. Medi-Cal is a "health care benefit program," as defined by 18 U.S.C. § 24(b).

31. Healthcare providers that enroll with the Medi-Cal program and provide services to Medi-Cal beneficiaries submit claims to Medi-Cal for payment for services rendered.

32. Medi-Cal maintains a Contract Drugs List (CDL) that identifies, and covers for payment, drugs, subject to limitations, when prescribed by a licensed practitioner within the scope of his or her practice. *See* 22 Cal. Code Regs. § 51313(a). In general, the Director of the California Department of Health Care Services (DHCS) shall include in the CDL any drug approved for the treatment of cancer by the FDA.

33. Drugs not on Medi-Cal's CDL can generally only be covered if prior authorization is obtained from DHCS or the specific managed care treatment organization[3] through submission and approval of a Treatment Authorization Request (TAR). *See* 22 Cal. Code Regs. §§ 51003, 51313(c). TAR authorization requests for drugs not on the CDL must demonstrate the medical necessity of the drug and be accompanied by a licensed medical practitioner's signed prescription or inpatient doctor's order indicating the type, number, and frequency of the drug sought.

34. For Medicare and Medi-Cal to ensure that claims are processed in an orderly and consistent manner, standardized coding for such claims have been established. These include the National Drug Code and the Current Procedural Terminology.

a. The FDCA, at 21 U.S.C. § 360(j), requires registered drug establishments, including foreign establishments, to provide the FDA with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution in the United States. Drugs are identified and reported using a unique, ten-digit,

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[3] A Medi-Cal managed care plan is an individual, organization, or entity that enters into a comprehensive risk contract with DHCS to provide covered full-scope health care service to enrolled Medi-Cal beneficiaries.

three-segment number called the National Drug Code (NDC) which serves as the FDA's identifier for drugs.

b. Current Procedural Terminology (CPT) codes are a uniform language for coding medical services and procedures. CPT codes are used to, among other things, communicate to health care benefit programs what medical services or procedures a claim seeks payment for.

Facts About Drugs Relevant to this Indictment

35. A prescription drug typically has both a nonproprietary name (also known as a generic name) and a brand name (also known as a trade name).

a. The nonproprietary name is typically assigned by the United States Adopted Names (USAN) Council.

b. The brand name is given by the drug's manufacturer.

36. Foreign manufacturers of drugs containing the same active ingredient as FDA-approved drugs often use the same nonproprietary name but a different brand name.

37. Often, drugs manufactured in foreign countries appear to have the same names and perhaps even the same ingredients as FDA-approved drugs manufactured in the United States. Sometimes these drugs are even manufactured outside of the United States by an NDA holder at the facility identified in the NDA. However, unless FDA has approved the specific foreign-manufactured drug and that drug is manufactured, processed, packaged (including labeled), and held in full compliance with the FDA-approved NDA, it is an "unapproved new drug" within the meaning of 21 U.S.C. § 355.

38. Unless a statutory exception applies, such as 21 U.S.C. § 384(b)-(h), which allows certain Canadian prescription drugs to be

sold if the Secretary of HHS certifies that such drugs pose no additional risk to public health and safety and that such imports would provide significant cost savings to American consumers, non-FDA-approved foreign-sourced drugs may not be legally imported into, introduced, or delivered for introduction into the interstate commerce of, or prescribed in, the United States since the safety and efficacy of such drugs has not been verified by the FDA.

39. Dangerous aspects of foreign unapproved drugs can include, among other things, the lack of controls over how the drug is stored and shipped, such that its original condition is safely preserved until it is used for patient treatment.

40. Some drugs intended for parenteral administration (injection or infusion) are placed into single-dose or single-use vials. Single-dose or single-use vials are labeled as such by the manufacturer and typically lack an antimicrobial preservative. Such drugs are meant to be given to a single patient for a single case, procedure, or injection, in order to reduce the risk of infection. In other words, even if there is more drug available in a single-dose or single-use vial than is needed for a single patient at a single period of time, that vial should not be used for more than one patient nor stored for future use on the same patient; the remaining drugs should be discarded.

41. When a healthcare provider must discard the remainder of a single-use vial or other single-use package after administering a dose/quantity of a drug to a Medicare or Medi-Cal patient, the programs provide, at least sometimes, payment for the discarded drug amount. Such payment is claimed, at least at times, by using a JW modifier on the CPT code.

42. A drug "lot" is defined, at 21 C.F.R. § 210.3(b)(10), as "a batch, or a specific identified portion of a batch, having uniform character and quality within specified limits; or, in the case of a drug product produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures its having uniform character and quality within specified limits." A "lot number" is defined, at 21 C.F.R. § 210.3(b)(11) as "any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined."

43. Drugs have expiration dates on their label reflecting the time period during which the product is known to retain its strength, quality, and purity when it is stored according to its labeled storage conditions.

44. Healthcare offices in the United States, including SBCC and AZCC, frequently purchase drugs and other medical supplies from large medical supply wholesalers such as Cardinal Health, McKesson, AmerisourceBergen (and its subsidiary Oncology Supply), and ProficientRx. Such wholesalers often sell chemotherapeutics and other drugs intended to be used at a healthcare clinic to treat patients for cheaper prices than they would sell those drugs to other customers.

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Count 1

Conspiracy to Smuggle Drugs Into the United States, Introduce Unapproved New Drugs Into Interstate Commerce, and Receive and Deliver Misbranded Drugs

(18 U.S.C. § 371)

45. Paragraphs 1 through 44 are realleged and incorporated by reference.

46. Beginning no later than September 2019 and continuing through in or around April 2023, within the Southern District of California, and elsewhere, defendants SUKHJIT SINGH GHUMAN, aka "Sukhi", KIRANJIT GHUMAN, aka "Kiran", MOHAMMAD RAY KHAN, JOSHUA SCHWASS, BENJAMIN LOUSTAUNAU, and JASWINDER SHANKER, aka "Jesse", conspired and agreed with each other and with others known and unknown to the Grand Jury to commit one and more of the following offenses against the United States:

a. To fraudulently and knowingly import and bring into the United States merchandise, that is, drugs, contrary to law, in violation of Title 18, United States Code, Section 545;

b. To introduce unapproved new drugs into interstate commerce, with the intent to defraud and mislead as to a material matter, in violation of Title 21, United States Code, Sections 331(d), 355(a), and 333(a)(2);

c. To receive in interstate commerce from locations outside the United States and cause the delivery and proffered delivery thereof for pay and otherwise, one and more drugs that were misbranded, with the intent to defraud and mislead as to a material matter, in violation of Title 21, United States Code, Sections 331(c) and 333(a)(2).

Object of the Conspiracy

47. The object of the conspiracy was for defendants to engage in a scheme to unlawfully enrich themselves by smuggling, introducing, receiving, and delivering for pay foreign unapproved drugs with the intent to defraud and mislead as to a material matter, that is to defraud and mislead Medicare and Medi-Cal by presenting claims based on FDA-approved versions of drugs, and mislead patients into believing they were receiving FDA-approved drugs.

Manner and Means of the Conspiracy

48. The conspirators used the following manner and means, among others, in pursuit of their fraudulent purpose:

a. Defendants purchased foreign unapproved drugs to be delivered to the homes of coconspirators, including defendants JASWINDER SHANKER, aka "Jesse", MOHAMMAD RAY KHAN and BENJAMIN LOUSTAUNAU.

b. Shipments of the foreign unapproved drugs were sometimes labeled as being for "personal use" despite the fact the drugs were intended to be distributed to medical facilities for administration to patients who were not the named recipients.

c. Defendants paid the recipients for accepting delivery of the foreign unapproved drugs.

d. Defendants, at least at times, removed the foreign unapproved drugs from the boxes or other containers they came in before transporting them to SBCC and AZCC to conceal the fact that these drugs were produced for foreign markets.

e. Defendants, at least at times, stored the foreign unapproved drugs separately from FDA-approved drugs, including in

separate rooms and separate refrigerators, to conceal their scheme from other SBCC and AZCC employees and others.

f. Defendants, at least at times, failed to ensure that the drugs containing labels requiring storage at 2° to 8°C (36° to 46°F), were stored and transported in an appropriate "cold chain," that is using an uninterrupted process of maintaining end-to-end temperature-controlled conditions from the manufacturing site to the point of care.

g. Defendants obtained drugs from establishments not duly registered as producers of drugs under the FDCA to obtain them more cheaply than they could otherwise.

h. Defendants imported drugs without the use of duly registered commercial importers to obtain them more cheaply than they could otherwise.

Overt Acts

49. In furtherance of the conspiracy and to effect and accomplish the objects of it, one and more of the defendants and conspirators committed, among others, the following overt acts, in the Southern District of California and elsewhere:

a. On or about September 3, 2019, defendant JASWINDER SHANKER, aka "Jesse", agreed to allow a shipment containing the following drugs:

Foreign Non-FDA-Approved Drug Brand Name	Size/Amount	Nonproprietary / Generic Name	Brand Name of FDA-Approved Version
Strantas	20 50-mg kits	Fulvestrant	Faslodex
Pegasta	9 6-mg kits	Pegfilgrastim	Neulasta
Endoxan-N	9 1-gm vials	Cyclophosphamide	Cytoxan

to be sent from PVPHPL, Gujarat, India 380060, to his home in Yuba City, CA. The shipment was addressed to "Jacob Pagany," and was intercepted at J.F.K. airport in New York, New York.

b. On or about July 6, 2021, defendant BENJAMIN LOUSTAUNAU sent a spreadsheet to defendant SUKHJIT SINGH GHUMAN's, aka "Sukhi", Personal Assistant listing drugs to be ordered from foreign countries and delivered to the United States to be used at AZCC. Those drugs included:

Foreign Non-FDA-Approved Drug Brand Name	Size/Amount	Nonproprietary / Generic Name	Brand Name of FDA-Approved Version
Esentra	5 60-mg kits	Denosumab	Prolia
Luprodex	10 22.5 mg kits	Leuprolide	Lupron
Celostatin	4 20-mg kits	Octreotide	Sandostatin
Enfira	12 500-mg vials	Rituximab	Rituxan
Enfira	24 100-mg vials	Rituximab	Rituxan
Infimab	10 100-mg vials	Infliximab	Remicade
Biceltis	5 420-mg vial[4]	Trastuzumab	Herceptin
Pemexane[5]	15 500-mg vials	Pemetrexed	Alimta
Pemexane[6]	30 100-mg vials	Pemetrexed	Alimta
Nanotin	20 100-mg vials	Paclitaxel	Abraxane
Carflinat	16 60-mg kits	Carfilzomib	Kyprolis
Fluro-5	20 1000-mg vials	5-Fluorouracil	Adrucil
Somatuline by GEN	5 120-mg kits	Lanreotide	Somatuline Depot
Altuzan	6 400-mg vials	Bevacizumab	Mvasi
Altuzan	12 100-mg vials	Bevacizumab	Mvasi

c. On or about July 14, 2021, defendant BENJAMIN LOUSTAUNAU sent a spreadsheet to defendant SUKHJIT SINGH GHUMAN's, aka "Sukhi", Personal Assistant listing drugs to be ordered from foreign countries and delivered to the United States to be used at AZCC. Those drugs included:

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[4] As stated on the order sheet, although typically available in 440-mg vials.

[5] Written as "Pexemane" on order spreadsheet.

[6] Written as "Pexemane" on order spreadsheet.

Foreign Non-FDA-Approved Drug Brand Name	Size/Amount	Nonproprietary / Generic Name	Brand Name of FDA-Approved Version
Opdyta	10 100-mg vials	Nivolumab	Opdivo
Opdyta	5 40-mg vials	Nivolumab	Opdivo

d. On or about August 5, 2021, defendant BENJAMIN LOUSTAUNAU sent a spreadsheet to defendant SUKHJIT SINGH GHUMAN's, aka "Sukhi", Personal Assistant listing drugs to be ordered from foreign countries and delivered to the United States to be used at AZCC. Those drugs included:

Foreign Non-FDA-Approved Drug Brand Name	Size/Amount	Nonproprietary / Generic Name	Brand Name of FDA-Approved Version
Esentra	8 60-mg kits	Denosumab	Prolia
Luprodex	8 22.5 mg kits	Leuprorelin	Lupron
Celostatin	4 20-mg kits	Octreotide	Sandostatin
Enfira	10 500-mg vials	Rituximab	Rituxan
Enfira	20 100-mg vials	Rituximab	Rituxan
Infimab	10 100-mg vials	Infliximab	Remicade
Biceltis	8 420-mg vial[7]	Trastuzumab	Herceptin
Nanotin	10 100-mg vials	Paclitaxel	Abraxane
Carflinat	20 60-mg kits	Carfilzomib	Kyprolis
Fistent[8]	10 250-mg kits	Fluvestrant	Faslodex
Fluro-5	20 1000-mg vials	5-Fluorouracil	Adrucil
Somatuline by GEN	4 120-mg kits	Lanreotide	Somatuline Depot
Altuzan	6 400-mg vials	Bevacizumab	Avastin
Altuzan	12 100-mg vials	Bevacizumab	Avastin
Opdyta	20 100-mg vials	Nivolumab	Opdivo
Opdyta	10 40-mg vials	Nivolumab	Opdivo

e. On or about August 10, 2021, defendant JASWINDER SHANKER, aka "Jesse", agreed to allow a shipment containing the following drugs:

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[7] As stated on the order sheet, although typically available in 440-mg vials.

[8] Written as "Fistenat" on order sheet.

Foreign Non-FDA-Approved Drug Brand Name	Size/Amount	Nonproprietary / Generic Name	Brand Name of FDA-Approved Version
Apritax	20 150-mg vials	Fosaprepitant	Emend
Ristova	14 500-mg vials	Rituximab	Rituxan

to be sent from THPL, 301 Arth Complex, B/h LG Showroom, Mithakhali Circle, Navrangpura, Ahmedabad, Gujarat, India 380060 to his home in Yuba City, CA. The shipment, addressed to "Jas Shanker," and declared as "medicine for personal use," was intercepted at J.F.K. airport in New York, New York.

f. On or about May 31, 2022, defendant SUKHJIT SINGH GHUMAN, aka "Sukhi", emailed Colton Health's Finance Director that she should wire $2,000 to defendant BENJAMIN LOUSTAUNAU monthly until further notice. Defendant KIRANJIT GHUMAN, aka "Kiran", added that the payment should be set up to be paid on the last day of each month.

g. On or about December 8, 2022, defendant BENJAMIN LOUSTAUNAU emailed defendant KIRANJIT GHUMAN, aka "Kiran", and defendant SUKHJIT SINGH GHUMAN's, aka "Sukhi", Personal Assistant a link to AZCC's monthly order of foreign unapproved drugs.

h. On or about December 29, 2022, defendant SUKHJIT SINGH GHUMAN's, aka "Sukhi", Personal Assistant emailed defendants BENJAMIN LOUSTAUNAU and KIRANJIT GHUMAN, aka "Kiran", a "reminder to update your new order list." Later that day defendant BENJAMIN LOUSTAUNAU replied with an updated order list for foreign unapproved drugs.

i. On or about March 6, 2023, defendant SUKHJIT SINGH GHUMAN's, aka "Sukhi", Personal Assistant emailed defendant BENJAMIN LOUSTAUNAU two attachments listing foreign unapproved drugs that were being ordered for SBCC and AZCC, and stating, in part, "What you will

note is that Kingman is marked up at 5% of supplier cost and CA is 10%. So for items you both order, it is more expensive to CA. These markups are Sukhi's costs."

j. On or about March 23, 2023, defendant BENJAMIN LOUSTAUNAU sent defendant SUKHJIT SINGH GHUMAN's, aka "Sukhi", Personal Assistant an email attaching a spreadsheet entitled "BioSim_MASTER-CA-Kingman-March_7th_2023(a).xlsx," listing approximately 157 FDA-approved drugs and showing, for many of those drugs, the prices those drugs cost from domestic wholesalers, and the cheaper prices from alternative suppliers outside of the United States.

k. On or about March 24, 2023, defendant JOSHUA SCHWASS sent an email to defendant BENJAMIN LOUSTAUNAU providing a list of medications needed at SBCC for the weeks of April 3, 2023, April 10, 2023, and April 17, 2023, stating "For the Herceptin/Kanjinti orders, if we cannot get the profitable vials, I do have 15 boxes of the 150mg Herceptin I can use."

l. On or about April 6, 2023, defendant BENJAMIN LOUSTAUNAU picked up foreign unapproved drugs at the house of defendant MOHAMMAD RAY KHAN.

m. On or about April 17, 2023, in response to an email about how SBCC lost money from using Zoladex on a patient since the reimbursement from Medicare and Medi-Cal was less than the cost of purchasing the drug from domestic drug wholesalers, defendant JOSHUA SCHWASS emailed defendant BENJAMIN LOUSTAUNAU and others, "We are losing even getting it from the outside source?"

All in violation of Title 18, United States Code, Section 371.

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Counts 2-9

Smuggling Drugs Into the United States Contrary to Law

(18 U.S.C. § 545)

50. Paragraphs 1 through 49 are realleged and incorporated by reference.

51. On or about the dates listed in the table below, within the Southern District of California, and elsewhere, the defendants listed in the table below did fraudulently and knowingly import and bring into the United States merchandise, that is, drugs, as further described in the table below, contrary to law, in that:

a. The introduction and delivery for introduction into interstate commerce of unapproved new drugs with intent to defraud and mislead as to a material matter, that is to defraud and mislead Medicare and Medi-Cal by presenting claims based on FDA-approved versions of drugs, and mislead patients into believing they were receiving FDA-approved drugs, is contrary to Title 21, United States Code, Sections 331(d), 333(a)(2), and 355(a).

b. The introduction and delivery for introduction into interstate commerce of misbranded drugs, that is with words, statements, and other information required by and under authority of [the FDCA] to appear on the label and labeling 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, without adequate directions for use, and imported by a commercial importer not duly registered with the Secretary of HHS, with the intent to defraud and mislead as to a material matter,

that is to defraud and mislead Medicare and Medi-Cal by presenting claims based on FDA-approved versions of drugs, and mislead patients into believing they were receiving FDA-approved drugs, is contrary to Title 21, United States Code, Sections 331(a) and 333(a)(2).

Count	Defendants	Approx-imate Date	Foreign Non-FDA-Approved Drug Brand Name	Size/Amount	Nonproprietary/Generic Name	Brand Name of FDA-Approved Version
2	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran"	9/3/19	Strantas	20 50-mg kits	Fulvestrant	Faslodex
3	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran"	9/3/19	Pegasta	9 6-mg kits	Pegfilgrastim	Neulasta
4	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran"	9/3/19	Endoxan-N	9 1-gm vials	Cyclophosphamide	Cytoxan

5	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran" MOHAMMAD RAY KHAN	8/10/21	Apritax	20 150-mg vials	Fosaprepitant	Emend
6	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran" MOHAMMAD RAY KHAN	8/10/21	Ristova	14 500-mg vials	Rituximab	Rituxan
7	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran" BENJAMIN LOUSTAUNAU JOSHUA SCHWASS	4/13/23	Bryxta	8 400-mg vials	Bevacizumab	Mvasi
8	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran" BENJAMIN LOUSTAUNAU JOSHUA SCHWASS	4/13/23	Augplat	5 250-mcg vials	Romiplostim	Nplate

	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran"					
9	BENJAMIN LOUSTAUNAU JOSHUA SCHWASS MOHAMMAD RAY KHAN	4/20/23	Fulzos	4 250-mg kits	Fulvestrant	Faslodex

all in violation of Title 18, United States Code, Sections 545 and 2, and *Pinkerton v. United States*, 328 U.S. 640 (1946).

Counts 10-17

Introduction of Unapproved New Drugs Into Interstate Commerce

(21 U.S.C. §§ 331(d), 355(a), and 333(a)(2))

52. Paragraphs 1 through 51 are realleged and incorporated by reference.

53. On or about the dates listed in the table below, within the Southern District of California and elsewhere, the defendants listed in the table below, with the intent to defraud and mislead as to a material matter, that is to defraud and mislead Medicare and Medi-Cal by presenting claims based on FDA-approved versions of drugs, and mislead patients into believing they were receiving FDA-approved drugs, introduced and delivered into interstate commerce, and caused to be introduced and delivered into interstate commerce, new drugs that were in violation of Title 21 United States Code, Section 355, in that they were not the subject of an approved BLA, NDA or ANDA on file with FDA, that is, the drugs specified in the table below:

Count	Defendants	Approx-imate Date	Foreign Non-FDA-Approved Drug Brand Name	Size/Amount	Nonproprietary /Generic Name	Brand Name of FDA-Approved Version
	SUKHJIT SINGH					
10	GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran"	9/3/19	Strantas	20 50-mg kits	Fulvestrant	Faslodex
11	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran"	9/3/19	Pegasta	9 6-mg kits	Pegfilgrastim	Neulasta
12	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran"	9/3/19	Endoxan-N	9 1-gm vials	Cyclophosphamide	Cytoxan
13	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran" MOHAMMAD RAY KHAN	8/10/21	Apritax	20 150-mg vials	Fosaprepitant	Emend

14	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran" MOHAMMAD RAY KHAN	8/10/21	Ristova	14 500-mg vials	Rituximab	Rituxan
15	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran" BENJAMIN LOUSTAUNAU JOSHUA SCHWASS	4/13/23	Bryxta	8 400-mg vials	Bevacizumab	Mvasi
16	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran" BENJAMIN LOUSTAUNAU JOSHUA SCHWASS	4/13/23	Augplat	5 250-mcg vials	Romiplostim	Nplate

	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran"					
17	BENJAMIN LOUSTAUNAU JOSHUA SCHWASS MOHAMMAD RAY KHAN	4/20/23	Fulzos	4 250-mg kits	Fulvestrant	Faslodex

all in violation of Title 21, United States Code, Sections 331(d), 355(a), and 333(a)(2), and Title 18, United States Code, Section 2, and *Pinkerton v. United States*, 328 U.S. 640 (1946).

Count 18

Conspiracy to Commit Health Care Fraud

(18 U.S.C. § 1349)

54. Paragraphs 1 through 53 are realleged and incorporated by reference.

55. Beginning no later than September 2019 and continuing through in or around April 2023, within the Southern District of California, and elsewhere, defendants SUKHJIT SINGH GHUMAN, aka "Sukhi", KIRANJIT GHUMAN, aka "Kiran", MOHAMMAD RAY KHAN, JOSHUA SCHWASS, and BENJAMIN LOUSTAUNAU, conspired and agreed with each other and with others known and unknown to the Grand Jury to commit health care fraud, that is, to knowingly and willfully execute a scheme and artifice to defraud a health care benefit program, as defined in Title 18, United States Code, Section 24(b), that is, Medicare and Medi-Cal, and to obtain money and property owned by and under the custody and control of Medicare and

Medi-Cal, by means of materially false and fraudulent pretenses, representations, and promises, in connection with the delivery of and payment for health care benefits, items and services, in violation of Title 18, United States Code, Section 1347.

Object of the Conspiracy

56. The object of the conspiracy was for defendants to unlawfully enrich themselves by defrauding Medicare and Medi-Cal by causing the submission of materially false and fraudulent claims for services.

Manner and Means of the Conspiracy

57. The conspirators used the following manner and means, among others, in pursuit of their fraudulent purpose:

a. Defendants illegally imported and received in interstate commerce non-FDA-approved drugs manufactured in foreign countries intended for use in countries other than the United States, including India, Sri Lanka, and Turkey.

b. Defendants purchased foreign unapproved drugs cheaper than they could have from domestic sources to increase the profit derived by payments from Medicare and Medi-Cal.

c. Defendants did not inform the patients being treated at SBCC and AZCC that foreign unapproved drugs were being injected into their bodies.

d. Defendants submitted, or caused to be submitted, reimbursement claims to Medicare and Medi-Cal that falsely and fraudulently represented that the patients identified in the claims received FDA-approved drugs, when the defendants knew the patients had received foreign-sourced, non-FDA-approved drugs, and further knew that Medicare and Medi-Cal would not pay for non-FDA-approved drugs.

e. Defendants submitted claims to Medicare and Medi-Cal listing CPT codes for the injection of FDA-approved drugs when, in fact, foreign unapproved drugs had been given to the patient under whom the claim was submitted.

f. Defendants collected, at least sometimes, copayment and coinsurance payments from SBCC and AZCC patients for treatment involving, without the patients' knowledge, the injection of foreign unapproved drugs.

g. Defendants typically stored the foreign unapproved drugs separately from those that were legally obtained, including at the residences of defendants MOHAMMAD RAY KHAN, BENJAMIN LOUSTAUNAU, and JASWINDER SHANKER, aka "Jesse", and in separate rooms and separate refrigerators at SBCC and AZCC, to conceal their scheme from other SBCC and AZCC employees and others.

h. Defendants frequently kept the excess drug left in a single-dose or single-use vial after the drug was given to a patient, so that the drug could be given to either the same patient or a different patient in the future, while billing Medicare, Medi-Cal, and other health insurance programs as if they discarded the waste.

i. Defendants did not inform the patients being treated at SBCC and AZCC that drugs that came from an already-used single-dose or single-use vial were being injected into their bodies.

j. Defendants submitted, or caused to be submitted, reimbursement claims to Medicare and Medi-Cal containing false and fraudulent pretenses in that they did not disclose that the patients identified in the claims received drugs that came from an already-used single-dose or single-use vial or other container, when defendants knew

that Medicare and Medi-Cal would not pay for drugs it knew were taken from a single-dose or single-use vial or other container that was used multiple times.

k. Defendants did not inform the patients being treated at SBCC and AZCC that expired drugs were being injected into their bodies.

l. Defendants submitted, or caused to be submitted, reimbursement claims to Medicare and Medi-Cal containing false and fraudulent pretenses in that they did not disclose that the patients identified in the claims received expired drugs, when defendants knew that Medicare and Medi-Cal would not pay for expired drugs.

Overt Acts

58. In furtherance of the conspiracy and to effect and accomplish the objects of it, one and more of the defendants and conspirators committed, among others, the following overt acts, in the Southern District of California and elsewhere:

a. Paragraph 49, subparagraphs a-m, are realleged and incorporated by reference.

b. On or about October 15, 2021, in an email chain between, among others, defendants KIRANJIT GHUMAN, aka "Kiran", SUKHJIT SINGH GHUMAN, aka "Sukhi", and BENJAMIN LOUSTAUNAU, as well as an AZCC Office Manager and a Business Manager, discussing using a JW modifier for drug wastage on Arizona Medicaid claims:

1. Defendant KIRANJIT GHUMAN, aka "Kiran", stated, "Can we either up the dose or store the remainder of the dose in the fridge and use on other patients and bill the correct dosages."

2. Defendant SUKHJIT SINGH GHUMAN, aka "Sukhi", stated, "We save the dose and it works fine."

c. On or about January 17, 2022, in response to an email from an AZCC Office Manager explaining that during an inventory, among other things, "we found plenty of expired medications" and AZCC was "reusing single dose vials []Some vials state 'Must use within 8 hours of opening vial, discard remaining portion' however the remaining portion was not discarded. (I am not sure if these vials were used for multiple patients or on different days, nothing is documented.)" Defendant SUKHJIT SINGH GHUMAN, aka "Sukhi", responded, "We also don't need to copy [AZCC's oncologist] on this."

d. On or about March 9, 2023, defendants submitted, and caused to be submitted, a claim for $7,740.00 to Medicare, falsely representing that patient O.H. had been administered an injection of FDA-approved trastuzumab.

e. On or about March 30, 2023, defendants submitted, and caused to be submitted, a claim for $7,740.00 to Medicare, falsely representing that patient O.H. had been administered an injection of FDA-approved trastuzumab.

f. On or about April 19, 2023, defendants submitted, and caused to be submitted, a claim for $18,750.00 to Medicare, falsely representing that patient S.M. had been administered an injection of FDA-approved rituximab.

g. On or about April 19, 2023, defendants submitted, and caused to be submitted, a claim for $1,250.00 to Medicare for "rituximab waste," falsely representing that excess FDA-approved rituximab prescribed to patient S.M. had been unused and discarded.

h. On or about April 20, 2023, defendants submitted, and caused to be submitted, a claim for $17,640.00 to Medicare, falsely

representing that patient O.H. had been administered an injection of FDA-approved pertuzumab.

i. On or about April 20, 2023, defendants submitted, and caused to be submitted, a claim for $7,740.00 to Medicare, falsely representing that patient O.H. had been administered an injection of trastuzumab.

All in violation of Title 18, United States Code, Section 1349.

Counts 19-24

Health Care Fraud

(18 U.S.C. § 1347)

59. Paragraphs 1 through 58 are realleged and incorporated by reference.

60. Beginning no later than September 2019 and continuing through in or around April 2023, within the Southern District of California, and elsewhere, defendants SUKHJIT SINGH GHUMAN, aka "Sukhi", KIRANJIT GHUMAN, aka "Kiran", MOHAMMAD RAY KHAN, JOSHUA SCHWASS, and BENJAMIN LOUSTAUNAU, knowingly and willfully executed and attempted to execute a scheme and artifice to defraud, and obtain by means of materially false and fraudulent pretenses, representations, and promises, money and property owned by and under the custody and control of, Medicare and Medi-Cal, health care benefit programs as defined in Title 18, United States Code, Section 24(b), in connection with the delivery of and payment for health care benefits, items, and services.

EXECUTIONS OF THE SCHEME

61. On or about the dates listed in the table below, within the Southern District of California and elsewhere, defendants SUKHJIT SINGH GHUMAN, aka "Sukhi", KIRANJIT GHUMAN, aka "Kiran", MOHAMMAD RAY KHAN,

JOSHUA SCHWASS, and BENJAMIN LOUSTAUNAU, for the purpose of executing the scheme, knowingly caused the following bills for reimbursement to be submitted to Medicare:

Count	Claim Submittal Date & Date of Service	Patient's Initials & Claim Number	CPT Code	Procedure Description	Amount Billed
19	3/9/2023; 3/8/2023	O.H.; 551823068002580 - line # 2	J9355	Injection, trastuzumab, excludes biosimilar	$7,740.00
20	3/30/2023; 3/29/2023	O.H.; 551823089066240 - line # 2	J9355	Injection, trastuzumab, excludes biosimilar	$7,740.00
21	4/19/2023; 4/6/2023	S.M.; 551123109748960 - line # 1	J9312	Injection, rituximab	$18,750.00
22	4/19/2023; 4/6/2023	S.M.; 551123109748960 - line # 2	J9312-JW	Rituximab Waste	$1,250.00
23	4/20/2023; 4/19/2023	O.H.; 551823110045570 - line # 1	J9306	Injection, pertuzumab	$17,640.00
24	4/20/2023; 4/19/2023	O.H.; 551823110045570 - line # 2	J9355	Injection, trastuzumab, excludes biosimilar	$7,740.00

All in violation of Title 18, United States Code, Sections 1347 and 2, and *Pinkerton v. United States*, 328 U.S. 640 (1946).

Count 25

Conspiracy to Engage in the Unlawful Wholesale Distribution of Drugs and Commit Wire Fraud

(18 U.S.C. § 371)

62. The introductory allegations set forth in paragraphs 1 through 44 are realleged and incorporated by reference.

63. Beginning no later than September 2021 and continuing through in or around April 2023, within the Southern District of California and elsewhere, defendants SUKHJIT SINGH GHUMAN, aka "Sukhi", KIRANJIT

GHUMAN, aka "Kiran", BENJAMIN LOUSTAUNAU, and VENIN PATEL, conspired and agreed with each other and with others known and unknown to the Grand Jury to commit one and more of the following offenses against the United States:

a. To knowingly engage in the unlicensed wholesale distribution of prescription drugs in interstate commerce, in violation of Title 21, United States Code, Sections 331(t), 353(e)(1)(A), and 333(b)(1)(D);

b. To commit wire fraud, that is to devise and intend to devise a scheme to defraud Cardinal Health and Oncology Supply, and to obtain money and property by means of materially false and fraudulent pretenses, representations and promises in violation of Title 18, United States Code, Section 1343.

Object of the Conspiracy

64. The object of the conspiracy was for defendants to unlawfully enrich themselves by purchasing drugs from medical supply wholesalers Cardinal Health and Oncology Supply for the lower prices available to healthcare providers purchasing drugs to give to their patients, but instead selling those drugs to Celtis, who would have had to pay higher prices to purchase the drugs from those wholesalers directly.

Manner and Means of the Conspiracy

65. The conspirators used the following manner and means, among others, in pursuit of their fraudulent purpose:

a. Conspirators associated with AZCC purchased and caused to be purchased drugs from medical supply wholesalers, agreeing to the wholesalers' terms and conditions that were meant, among other things, to prevent AZCC from reselling the drugs.

1. Conspirators purchased drugs from Oncology Supply, which imposed the following terms and conditions, among others:

> CONFIDENTIALITY. Buyer may not use or disclose Seller's trade secretes or confidential information. Pricing terms are strictly confidential and may not be disclosed to any third party or competitor of Seller unless required by law.

2. Conspirators also purchased drugs from Cardinal Health, which imposed the following terms and conditions, among others:

> Non-Wholesale customers are final dispensers that are purchasing for their own use and will not redistribute prescription pharmaceuticals to any other entity.

b. Employees of Celtis typically identified specific drugs, often described with specific NDC numbers, and sometimes specific lot numbers and expirations dates, that they were interested in buying from AZCC.

c. AZCC employees typically responded by sending information regarding the price they could purchase drugs from wholesalers, including Cardinal Health and Oncology Supply, and the markup they would charge to resell the drugs to Celtis.

d. AZCC typically marked up the price of the drugs between the price for which they could purchase the drugs and the price that Celtis would have to pay to purchase those same drugs directly from the same wholesaler.

e. Employees of Celtis then typically sent employees of AZCC a purchase order detailing what drugs they wanted AZCC to resell to them.

f. AZCC purchased the specified drugs from medical supply wholesalers, including Cardinal Health and Oncology Supply, with the

express purpose to resell those drugs to Celtis, directly in violation of the wholesalers' terms and conditions of sale.

g. AZCC typically then sent Celtis an invoice for the drugs they purchased from wholesalers and resold to Celtis.

h. Early on, AZCC would charge Celtis for the commercial shipping cost for the drugs they purchased from wholesalers, but later Celtis would pay for a shipping label for AZCC to use.

i. AZCC never obtained a license to act as a wholesale distributor of drugs from Arizona or Pennsylvania.

Overt Acts

66. In furtherance of the conspiracy and to effect and accomplish the objects of it, one and more of the defendants and conspirators committed, among others, the following overt acts, in the Southern District of California and elsewhere:

a. On or about May 5, 2022, defendant KIRANJIT GHUMAN, aka "Kiran", emailed defendant BENJAMIN LOUSTAUNAU asking for an updated spreadsheet regarding Celtis, so that she could advise defendant SUKHJIT SINGH GHUMAN, aka "Sukhi", of the profit to date.

b. On or about May 9, 2022, defendant KIRANJIT GHUMAN, aka "Kiran", emailed defendant SUKHJIT SINGH GHUMAN, aka "Sukhi", that she and defendant BENJAMIN LOUSTAUNAU "have spoken today regarding a call with [defendant VENIN PATEL]. Please can you confirm you are happy for us to give [defendant VENIN PATEL] access to our Cardinal account so he can go and see availability of products and prices. This way we are hoping he will look at alternatives and place the order. [Defendant BENJAMIN LOUSTAUNAU] is currently going back and forth with $ and we are

only meeting 20-30% of [PATEL's] requests due to availability. Without this [PATEL] advised we may not be able to continue."

c. On or about May 23, 2022, after defendant VENIN PATEL stated that he had not been given access to AZCC's Cardinal account, defendant SUKHJIT SINGH GHUMAN, aka "Sukhi", emailed defendants KIRANJIT GHUMAN, aka "Kiran", and BENJAMIN LOUSTAUNAU that it was "fine" to give defendant VENIN PATEL the login information for AZCC's Cardinal accounts for oncology products and non-oncology products.

d. On or about July 22, 2022, defendant BENJAMIN LOUSTAUNAU emailed defendants VENIN PATEL and SUKHJIT SINGH GHUMAN, aka "Sukhi", and an employee of Celtis, the price that AZCC would charge Celtis per pack for seven drugs, as requested by Celtis.

e. On or about August 4, 2022, defendant BENJAMIN LOUSTAUNAU emailed defendant VENIN PATEL, and an employee of Celtis, the price at which that AZCC could purchase nine drugs from AmerisourceBergen, as requested by Celtis.

f. On or about August 23, 2022, defendant KIRANJIT GHUMAN, aka "Kiran", emailed a copy of an invoice for Celtis' purchase of seven drugs from AZCC for $97,569.03, including shipping charges, to defendants BENJAMIN LOUSTAUNAU and VENIN PATEL, as well as two other Celtis employees.

g. On or about August 31, 2022, defendant BENJAMIN LOUSTAUNAU emailed defendant KIRANJIT GHUMAN, aka "Kiran", the cost AZCC paid for 13 drugs sold to Celtis in three purchase orders, and the price AZCC charged Celtis for those drugs.

h. On or about November 4, 2022, Celtis paid defendant BENJAMIN LOUSTAUNAU $4,000 as a commission for the drugs that AZCC sold to Celtis.

i. On or about January 25, 2023, defendant VENIN PATEL caused to be sent a purchase order from Celtis to AZCC for three lots of Abraxane for $325,117.26.

j. On or about February 8, 2023, defendant KIRANJIT GHUMAN, aka "Kiran", authorized the sale of 136 units of the drug Prolia (nonproprietary/generic name Denosumab) to Celtis for $190,326.56.

k. On or about February 20, 2023, defendant VENIN PATEL caused to be sent a purchase order from Celtis to AZCC for eight drugs, including Coly-Mycin, for $446,699.74.

l. On or about February 20, 2023, a Celtis employee emailed defendant KIRANJIT GHUMAN, aka "Kiran", and others a table listing the eight drugs with the prices that Colton and Celtis could purchase the drugs for, the difference between the two prices, and dividing that difference into "Celtis Share" and "Colton Share." defendant KIRANJIT GHUMAN, aka "Kiran", forwarded that email to defendant BENJAMIN LOUSTAUNAU and stated, "Please see below and advise if this is correct and worth doing."

m. On or about February 24, 2023, defendant VENIN PATEL emailed defendants BENJAMIN LOUSTAUNAU and KIRANJIT GHUMAN, aka "Kiran", and others, indicating his priorities for which drugs he wanted AZCC to purchase in order to sell to Celtis, including Colymycin.

n. On or about February 27, 2023, defendant BENJAMIN LOUSTAUNAU emailed McKesson asking for 10 units of Coly-Mycin with the

same expiration date and stating, "he wants to keep in stock, but I need a long expiration date, so they don't sit."

All in violation of Title 18, United States Code, Section 371.

Criminal Forfeiture Allegation

67. The allegations contained in Counts 1 through 32 are re-alleged and by their reference fully incorporated herein for the purpose of alleging forfeiture to the United States of America pursuant to the provisions of Title 18, United States Code, Sections 981(a)(1)(C), 982(a)(2)(B), 982(a)(7), and Title 28, United States Code, Section 2461(c).

68. Upon conviction of one and more of the offenses of this Indictment indicated in the following table, and pursuant to the statutes listed in that table, defendants shall forfeit to the United States all property constituting, or derived from, any proceeds defendants obtained, directly or indirectly, as the result of the offenses, including, but not limited to, the real property located at 9457 East Adobe Drive, Scottsdale, Arizona:

Counts	Statutes Justifying Forfeiture
1 (Conspiracy)	Title 18, U.S.C., Sec. 981(a)(1)(C), and Title 28, U.S.C., Sec. 2461(c)
2-9 (18 U.S.C. 545)	Title 18, U.S.C., Sec. 982(a)(2)(B)
10-17 (21 U.S.C. §§ 331(d), 355(a), and 333(a)(2);	Title 18, U.S.C., Sec. 982(a)(7)
18 (Conspiracy)	Title 18, U.S.C., Sec. 981(a)(1)(C), and Title 28, U.S.C., Sec. 2461(c)
19-24 (18 U.S.C. 1347, 1349)	Title 18, U.S.C., Sec. 982(a)(7)
25 (Conspiracy)	Title 18, U.S.C., Sec. 981(a)(1)(C), and Title 28, U.S.C., Sec. 2461(c)

69. If any of the above-described forfeitable property, as a result of any act or omission of defendants:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of the Court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be subdivided without difficulty;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), Title 18, United States Code, Section 982(b), and Title 28, United States Code, Section 2461(c), to seek forfeiture of any other property of defendants up to the value of the property listed above as being subject to forfeiture.

All pursuant to Title 18, United States Code, Sections 981(a)(1)(C), 982(a)(2)(B), and 982(a)(7), and Title 28, United States Code, Section 2461(c).

DATED: October 13, 2023.

A TRUE BILL:

[redacted]

TARA K. MCGRATH
United States Attorney

By: _____
GEORGE V. MANAHAN
Assistant U.S. Attorney

SEALED

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

February 2023 Grand Jury

UNITED STATES OF AMERICA,

Plaintiff,

v.

SUKHJIT SINGH GHUMAN (1),
aka "Sukhi",
KIRANJIT GHUMAN (2),
aka "Kiran",
MOHAMMAD RAY KHAN (3),
JOSHUA SCHWASS (4),
BENJAMIN LOUSTAUNAU (5),
JASWINDER SHANKER (6),
aka "Jesse",
VENIN PATEL (7),

Defendants.

Case No. 23CR2019-RBM

I N D I C T M E N T
(Superseding)

Title 18, U.S.C., Secs. 371 and 545 and Title 21, U.S.C., Secs. 331(d), 355(a), 333(a)(2), and 331(c) - Conspiracy to Smuggle Drugs, Introduce Unapproved New Drugs, and Receive and Deliver Misbranded Drugs; Title 21, U.S.C., Sec. 545 - Smuggling Drugs; Title 21, U.S.C., Secs. 331(d), 355(a), and 333(a)(2) - Introducing Unapproved New Drugs; Title 18, U.S.C., Secs. 1347 and 1349 - Conspiracy to Commit Health Care Fraud; Title 18, U.S.C., Sec. 1347 - Health Care Fraud; Title 18, U.S.C., Sec. 2 - Aiding and Abetting; Title 18, U.S.C., Secs. 371, 1343 and Title 21, U.S.C., Secs. 331(t), 353(e)(1)(A), 333(b)(1)(D) - Conspiracy to Engage in the Unlawful Wholesale Distribution of Drugs and Commit Wire Fraud; Title 18, U.S.C., Secs. 981(a)(1)(C), 982(a)(2)(B), 982(a)(7), and Title 28, U.S.C., Sec. 2461(c) - Criminal Forfeiture

The grand jury charges:

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GVM:nlv(2):San Diego:10/13/23

Introductory Allegations

Defendants

1. At times material to this Indictment, Colton Health, LLC, was a California limited liability company that employed or was otherwise associated with the following individuals:

a. Defendant SUKHJIT SINGH GHUMAN, aka "Sukhi", was a member (owner) of Colton Health, LLC.

b. Defendant KIRANJIT GHUMAN, aka "Kiran", was a senior vice-president and Chief Financial Officer of Colton Health, LLC.

c. Defendant MOHAMMAD RAY KHAN was the Chief Operating Officer of Colton Health, LLC.

d. Defendant JOSHUA SCHWASS was a registered nurse and medical assistant supervisor at Colton Health, LLC.

2. On or about March 1, 2018, Colton Health, LLC, purchased a hematology and oncology medical practice, which thereafter did business as Colton Health, and later as South Bay Cancer Center (SBCC), located at 480 Fourth Avenue, Suite 409, Chula Vista, California, 91910.

3. At times material to this Indictment, defendant SUKHJIT SINGH GHUMAN, aka "Sukhi", also owned Colton Health AZ, LLC, an Arizona limited liability company. Colton Health AZ, LLC, did business, at least in part, as AZ Cancer Center (AZCC), a hematology and oncology medical practice located at 1755 Airway Ave, Kingman AZ 86409 until in or about February 2023 when it relocated to 890 Airway Avenue, Kingman, Arizona, 86409. AZCC employed defendant BENJAMIN LOUSTAUNAU as a pharmacy technician.

4. At times material to this Indictment, defendant JASWINDER SHANKER, aka "Jesse", was employed as a Business Development Manager by

Octavian, a security company owned by SUKHJIT SINGH GHUMAN, aka "Sukhi", and lived in Yuba City, California.

5. At times material to this Indictment, Celtis Healthcare, LLC, aka Healthcare UK, aka HCUK (Celtis), was a Pennsylvania limited liability company registered on December 20, 2017, that employed defendant VENIN PATEL as a director.

The FDA And The Federal Food, Drug, and Cosmetic Act

6. The United States Food and Drug Administration (FDA) is the federal agency responsible for protecting the public health by ensuring, among other things, that drugs are safe and effective for their intended uses and have labeling that contain true and accurate information. The FDA carries out its responsibilities, in part, by enforcing the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (FDCA) and other pertinent laws and regulations governing the manufacture, packaging, labeling, and distribution of drugs in the United States.

7. The FDCA, at 21 U.S.C. § 321(g)(1), defines a "drug" to include, among other things:

a. "Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals," and

b. "Articles (other than food) intended to affect the structure or any function of the body of man or other animals."

8. The FDCA, at 21 U.S.C. § 321(p)(1), defines a "new drug" as, among other things, a drug, the composition of which is "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe

and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . ."

9. "Biological product" is defined at 42 U.S.C. § 262(i)(1) to mean "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings."[1] Biological products are generally produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are generally larger, more complex molecules than drugs.

10. Many products meet the definitions of both "drugs" and "biological products." Pursuant to 42 U.S.C. § 262(j), the FDCA applies to biological products subject to regulation under Title 42.

11. Applications for FDA approval of new drugs and biological products are subject to a rigorous review process. New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and Biologic License Applications (BLAs) discuss in great detail how a particular drug or biological product works, how it is manufactured, and precisely what is stated on the label and labeling. For a drug or biological product to be used in the United States, its manufacturing process, label and

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[1] This definition became effective on December 20, 2019. Previously, "biologic product" was defined as "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. § 262 (2017).

labeling, and packaging, as set forth in the pertinent type of application, must be approved by the FDA.

12. FDA approval of a drug or biological product is specific to each manufacturer and each product. Approval granted to a particular manufacturer for a particular drug or biological product to be distributed in the United States does not constitute approval of a drug or biological product with labeling different from the labeling in the FDA-approved application to be imported into and distributed in the United States, even if the imported drug or biological product has the same chemical composition as the FDA-approved drug or biological product.

13. Under the FDCA, at 21 U.S.C. § 353(b), a prescription drug is any drug 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 for use except under the supervision of a practitioner licensed by law to administer such drug" or if the FDA requires it to be administered under the supervision of a practitioner licensed to administer such drug as a condition of the FDA's approval of the drug.

14. The FDCA defines "label" as "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. § 321(k).

15. The FDCA defines "labeling" more broadly as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

16. Under the FDCA, at 21 U.S.C. § 352, a drug is deemed to be misbranded under the following conditions, among other things:

a. "If any word, statement, or other information required by or under authority of [the FDCA] 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." 21 U.S.C. § 352(c).

1. Regulations require all words, statements, and other information required to appear on labeling to be in the English language unless the drug is solely distributed in Puerto Rico or a United States territory. 21 C.F.R. § 201.15(c)(1).

b. "Unless its labeling bears . . . adequate directions for use." 21 U.S.C. § 352(f)(1).

1. Regulations define "adequate directions for use" as meaning "directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5.

2. If the drug is a new drug, the labeling must be the same in language and emphasis as labeling approved by FDA in the NDA. 21 C.F.R. § 201.100(d)(1).

c. If it "was imported or offered for import by a commercial importer of drugs not duly registered" with the Secretary of Health and Human Services (HHS) as required by 21 U.S.C. § 381(s). 21 U.S.C. § 352(o).

17. The FDCA, at 21 U.S.C. §§ 331(d) and 355(a), (b), (i), (j), prohibits any person to introduce or deliver for introduction into

interstate commerce any new drug unless an approved NDA or ANDA is effective with respect to such drug, or unless the drug is the subject of an approved investigational new drug (IND) application. The FDCA, at 21 U.S.C. § 321(b)(1) defines "interstate commerce" to include "commerce between any State or Territory and any place outside thereof." Therefore, the importation of a drug that lacks FDA approval into the United States from a foreign country, violates the FDCA.

18. Similarly, no person shall introduce or deliver for introduction into interstate commerce any biological product unless, among other things, a biologics license is in effect pursuant to the approval of a BLA. See 42 U.S.C. § 262(a), (k); 21 C.F.R., Part 601.

19. Under the FDCA, "wholesale distribution" of drugs requiring a prescription means distribution to a person other than a consumer or patient, or receipt of such drugs by a person other than the consumer or patient, unless a specified exception applies. *See* 21 U.S.C. § 353(e)(4). A "wholesale distributor" is "a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution." 21 U.S.C. § 360eee(29).

20. The FDCA, at 21 U.S.C. § 353(e)(1)(A), prohibits engaging in wholesale distribution of any drug requiring a prescription without the appropriate license(s).

The Medicare and Medi-Cal Programs

21. The Medicare Program (Medicare) was established under Title XVIII of the Social Security Act (SSA). Medicare is a federally funded health care benefit program for persons over 65 years old and certain disabled individuals. Medicare is administered by the Center for

Medicare and Medicaid Services (CMS), an agency of HHS. Individuals who receive benefits under Medicare are referred to as Medicare "beneficiaries." An individual or entity that is authorized to provide healthcare services to a beneficiary is referred to as a "provider." Medicare is a health care benefit program as defined by 18 U.S.C. § 24(b).

22. Medicare is administered in several parts.[2] Medicare Part B (medical insurance) covers certain doctors' services, outpatient care, medical supplies, and preventative services. For instance, Medicare Part B generally pays for chemotherapy and adjunct therapy provided to beneficiaries with cancer treated in an outpatient setting, including covering both the cost of the drug and for the healthcare providers who administer it.

23. Generally, Medicare only pays for health services that are reasonable and necessary. *See, e.g.*, 42 U.S.C. § 1395y(a)(1). A provider seeks payment from Medicare by filing a claim. Generally, Medicare Part B reimburses a provider 80% of their claim, while the remaining 20%, known as the "co-payment," may be covered by a secondary insurance plan or paid directly by the beneficiary. The provider receives payment from Medicare directly to their bank account via Electronic Funds Transfer.

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[2] Medicare Part A (hospital insurance) covers certain hospital stays, care in a skilled nursing facility, hospice care, and home health care; Part D (prescription drug coverage) covers the cost of certain prescription drugs, including many recommended shots or vaccines; and Part C (Medicare Advantage) is an alternative to traditional Medicare coverage administered by Medicare-approved private insurance companies that receive prospective "capitated" payments from the Government to provide similar benefits as offered by Parts A, B, and D.

24. An individual or entity must apply to be a provider, or make certain changes to their provider status, by executing a Medicare Enrollment Application. Individual physician and non-physician practitioners use a Form CMS-855I; clinics, group practices, and certain other suppliers use a Form CMS-855B; institutional providers use a Form CMS-855A. These applications can be submitted online through Medicare's Provider Enrollment, Chain, and Ownership Systems (PECOS). If such applications are approved, an individual or entity can submit claims to Medicare under their National Provider Identifier (NPI) number.

25. Medicare Enrollment Applications obligate applicants to abide by applicable Medicare laws, regulations and program instructions, and condition payment of a claim by Medicare on compliance with such laws, regulations and program instructions. Applicants must certify that they will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

a. Defendant SUKHJIT SINGH GHUMAN, aka "Sukhi", signed Medicare Enrollment Applications as an authorized official for Colton Health, LLC, on July 2, 2020, July 9, 2020, and August 5, 2020; and signed Medicare Enrollment Applications as an authorized official for Colton Health AZ, LLC, on January 14, 2021, January 28, 2021, March 3, 2021, November 11, 2021, December 16, 2021, and February 13, 2023.

26. CMS publishes the CMS Online Manual System, located at http://www.cms.hhs.gov/manuals, which, among other things, provides instructions to providers on when they can appropriately bill Medicare. Enrolled providers are provided with online access to the online Medicare

Manual System, as well as services bulletins, describing proper billing procedures and billing rules and regulations.

27. Section 1832(a)(2)(B) of the SSA, 42 U.S.C. § 1395k, authorizes Medicare Part B payment for "medical and other health services." Section 1861(s) of the SSA, 42 U.S.C. § 1395x(s), defines "medical and other health services" to include drugs that are not usually self-administered and are administered incident to certain physician services. Section 1861(t) of the SSA, 42 U.S.C. § 1395x(t), allows payment by Medicare Part B for a drug used in an "anticancer chemotherapeutic regimen" only if the use is "for a medically accepted indication." Section 1861(t) defines "medically accepted indication" to include only such drugs that are approved by the FDA (either for such use or if such use is supported by certain medical literature).

a. According to the Medicare Benefit Policy Manual (Publication 100-02, Ch. 15, § 50.4.1, Drugs and Biologicals), in order to be eligible for Medicare Part B reimbursement, drugs must be safe and effective. Drugs approved for marketing by the FDA are considered safe and effective for purposes of this requirement when used for indications specified on the labeling. Therefore, Medicare will generally pay for the use of an FDA-approved drug, if: it was provided on or after the date of the FDA's approval; it is reasonable and necessary for the individual patient; and all other applicable coverage requirements are met. Furthermore, the Medicare Benefit Policy Manual (Publication 100-02, Ch. 15, § 50.4.2) provides that an unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA. FDA-approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if it is

determined to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. Medicare does not, however, pay for drugs which are not FDA approved, unless CMS had made a specific exception and instructed otherwise.

28. Accordingly, a Medicare claim for a drug requires the claimant submitting the claim to represent that, among other things, the drug was FDA-approved or that CMS made a specific exception for coverage of the drug.

29. The Medicare Prescription Drug, Improvement, and Modernization Act ("MMA") of 2003 established a methodology for Medicare Part B reimbursement for most covered drugs. Effective January 1, 2005, reimbursement for drugs was generally based on the average sales price (ASP). *See* 42 U.S.C. §§ 1395u(o), 1395w-3(a)(2)(A), 1395w-3a, 1395w-3b. ASP is defined as a manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter.

30. Medicaid is a federal and state-funded health insurance program for children, disabled individuals, and families and individuals who fall below certain income levels. California's Medicaid Program is commonly known as "Medi-Cal." Medi-Cal reimburses health care providers for certain services that are certified as medically necessary by such providers. Medi-Cal is a "health care benefit program," as defined by 18 U.S.C. § 24(b).

31. Healthcare providers that enroll with the Medi-Cal program and provide services to Medi-Cal beneficiaries submit claims to Medi-Cal for payment for services rendered.

32. Medi-Cal maintains a Contract Drugs List (CDL) that identifies, and covers for payment, drugs, subject to limitations, when prescribed by a licensed practitioner within the scope of his or her practice. *See* 22 Cal. Code Regs. § 51313(a). In general, the Director of the California Department of Health Care Services (DHCS) shall include in the CDL any drug approved for the treatment of cancer by the FDA.

33. Drugs not on Medi-Cal's CDL can generally only be covered if prior authorization is obtained from DHCS or the specific managed care treatment organization[3] through submission and approval of a Treatment Authorization Request (TAR). *See* 22 Cal. Code Regs. §§ 51003, 51313(c). TAR authorization requests for drugs not on the CDL must demonstrate the medical necessity of the drug and be accompanied by a licensed medical practitioner's signed prescription or inpatient doctor's order indicating the type, number, and frequency of the drug sought.

34. For Medicare and Medi-Cal to ensure that claims are processed in an orderly and consistent manner, standardized coding for such claims have been established. These include the National Drug Code and the Current Procedural Terminology.

a. The FDCA, at 21 U.S.C. § 360(j), requires registered drug establishments, including foreign establishments, to provide the FDA with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution in the United States. Drugs are identified and reported using a unique, ten-digit,

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[3] A Medi-Cal managed care plan is an individual, organization, or entity that enters into a comprehensive risk contract with DHCS to provide covered full-scope health care service to enrolled Medi-Cal beneficiaries.

three-segment number called the National Drug Code (NDC) which serves as the FDA's identifier for drugs.

b. Current Procedural Terminology (CPT) codes are a uniform language for coding medical services and procedures. CPT codes are used to, among other things, communicate to health care benefit programs what medical services or procedures a claim seeks payment for.

Facts About Drugs Relevant to this Indictment

35. A prescription drug typically has both a nonproprietary name (also known as a generic name) and a brand name (also known as a trade name).

a. The nonproprietary name is typically assigned by the United States Adopted Names (USAN) Council.

b. The brand name is given by the drug's manufacturer.

36. Foreign manufacturers of drugs containing the same active ingredient as FDA-approved drugs often use the same nonproprietary name but a different brand name.

37. Often, drugs manufactured in foreign countries appear to have the same names and perhaps even the same ingredients as FDA-approved drugs manufactured in the United States. Sometimes these drugs are even manufactured outside of the United States by an NDA holder at the facility identified in the NDA. However, unless FDA has approved the specific foreign-manufactured drug and that drug is manufactured, processed, packaged (including labeled), and held in full compliance with the FDA-approved NDA, it is an "unapproved new drug" within the meaning of 21 U.S.C. § 355.

38. Unless a statutory exception applies, such as 21 U.S.C. § 384(b)-(h), which allows certain Canadian prescription drugs to be

sold if the Secretary of HHS certifies that such drugs pose no additional risk to public health and safety and that such imports would provide significant cost savings to American consumers, non-FDA-approved foreign-sourced drugs may not be legally imported into, introduced, or delivered for introduction into the interstate commerce of, or prescribed in, the United States since the safety and efficacy of such drugs has not been verified by the FDA.

39. Dangerous aspects of foreign unapproved drugs can include, among other things, the lack of controls over how the drug is stored and shipped, such that its original condition is safely preserved until it is used for patient treatment.

40. Some drugs intended for parenteral administration (injection or infusion) are placed into single-dose or single-use vials. Single-dose or single-use vials are labeled as such by the manufacturer and typically lack an antimicrobial preservative. Such drugs are meant to be given to a single patient for a single case, procedure, or injection, in order to reduce the risk of infection. In other words, even if there is more drug available in a single-dose or single-use vial than is needed for a single patient at a single period of time, that vial should not be used for more than one patient nor stored for future use on the same patient; the remaining drugs should be discarded.

41. When a healthcare provider must discard the remainder of a single-use vial or other single-use package after administering a dose/quantity of a drug to a Medicare or Medi-Cal patient, the programs provide, at least sometimes, payment for the discarded drug amount. Such payment is claimed, at least at times, by using a JW modifier on the CPT code.

42. A drug "lot" is defined, at 21 C.F.R. § 210.3(b)(10), as "a batch, or a specific identified portion of a batch, having uniform character and quality within specified limits; or, in the case of a drug product produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures its having uniform character and quality within specified limits." A "lot number" is defined, at 21 C.F.R. § 210.3(b)(11) as "any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined."

43. Drugs have expiration dates on their label reflecting the time period during which the product is known to retain its strength, quality, and purity when it is stored according to its labeled storage conditions.

44. Healthcare offices in the United States, including SBCC and AZCC, frequently purchase drugs and other medical supplies from large medical supply wholesalers such as Cardinal Health, McKesson, AmerisourceBergen (and its subsidiary Oncology Supply), and ProficientRx. Such wholesalers often sell chemotherapeutics and other drugs intended to be used at a healthcare clinic to treat patients for cheaper prices than they would sell those drugs to other customers.

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Count 1

Conspiracy to Smuggle Drugs Into the United States, Introduce Unapproved New Drugs Into Interstate Commerce, and Receive and Deliver Misbranded Drugs

(18 U.S.C. § 371)

45. Paragraphs 1 through 44 are realleged and incorporated by reference.

46. Beginning no later than September 2019 and continuing through in or around April 2023, within the Southern District of California, and elsewhere, defendants SUKHJIT SINGH GHUMAN, aka "Sukhi", KIRANJIT GHUMAN, aka "Kiran", MOHAMMAD RAY KHAN, JOSHUA SCHWASS, BENJAMIN LOUSTAUNAU, and JASWINDER SHANKER, aka "Jesse", conspired and agreed with each other and with others known and unknown to the Grand Jury to commit one and more of the following offenses against the United States:

a. To fraudulently and knowingly import and bring into the United States merchandise, that is, drugs, contrary to law, in violation of Title 18, United States Code, Section 545;

b. To introduce unapproved new drugs into interstate commerce, with the intent to defraud and mislead as to a material matter, in violation of Title 21, United States Code, Sections 331(d), 355(a), and 333(a)(2);

c. To receive in interstate commerce from locations outside the United States and cause the delivery and proffered delivery thereof for pay and otherwise, one and more drugs that were misbranded, with the intent to defraud and mislead as to a material matter, in violation of Title 21, United States Code, Sections 331(c) and 333(a)(2).

Object of the Conspiracy

47. The object of the conspiracy was for defendants to engage in a scheme to unlawfully enrich themselves by smuggling, introducing, receiving, and delivering for pay foreign unapproved drugs with the intent to defraud and mislead as to a material matter, that is to defraud and mislead Medicare and Medi-Cal by presenting claims based on FDA-approved versions of drugs, and mislead patients into believing they were receiving FDA-approved drugs.

Manner and Means of the Conspiracy

48. The conspirators used the following manner and means, among others, in pursuit of their fraudulent purpose:

a. Defendants purchased foreign unapproved drugs to be delivered to the homes of coconspirators, including defendants JASWINDER SHANKER, aka "Jesse", MOHAMMAD RAY KHAN and BENJAMIN LOUSTAUNAU.

b. Shipments of the foreign unapproved drugs were sometimes labeled as being for "personal use" despite the fact the drugs were intended to be distributed to medical facilities for administration to patients who were not the named recipients.

c. Defendants paid the recipients for accepting delivery of the foreign unapproved drugs.

d. Defendants, at least at times, removed the foreign unapproved drugs from the boxes or other containers they came in before transporting them to SBCC and AZCC to conceal the fact that these drugs were produced for foreign markets.

e. Defendants, at least at times, stored the foreign unapproved drugs separately from FDA-approved drugs, including in

separate rooms and separate refrigerators, to conceal their scheme from other SBCC and AZCC employees and others.

f. Defendants, at least at times, failed to ensure that the drugs containing labels requiring storage at 2° to 8°C (36° to 46°F), were stored and transported in an appropriate "cold chain," that is using an uninterrupted process of maintaining end-to-end temperature-controlled conditions from the manufacturing site to the point of care.

g. Defendants obtained drugs from establishments not duly registered as producers of drugs under the FDCA to obtain them more cheaply than they could otherwise.

h. Defendants imported drugs without the use of duly registered commercial importers to obtain them more cheaply than they could otherwise.

Overt Acts

49. In furtherance of the conspiracy and to effect and accomplish the objects of it, one and more of the defendants and conspirators committed, among others, the following overt acts, in the Southern District of California and elsewhere:

a. On or about September 3, 2019, defendant JASWINDER SHANKER, aka "Jesse", agreed to allow a shipment containing the following drugs:

Foreign Non-FDA-Approved Drug Brand Name	Size/Amount	Nonproprietary / Generic Name	Brand Name of FDA-Approved Version
Strantas	20 50-mg kits	Fulvestrant	Faslodex
Pegasta	9 6-mg kits	Pegfilgrastim	Neulasta
Endoxan-N	9 1-gm vials	Cyclophosphamide	Cytoxan

to be sent from PVPHPL, Gujarat, India 380060, to his home in Yuba City, CA. The shipment was addressed to "Jacob Pagany," and was intercepted at J.F.K. airport in New York, New York.

b. On or about July 6, 2021, defendant BENJAMIN LOUSTAUNAU sent a spreadsheet to defendant SUKHJIT SINGH GHUMAN's, aka "Sukhi", Personal Assistant listing drugs to be ordered from foreign countries and delivered to the United States to be used at AZCC. Those drugs included:

Foreign Non-FDA-Approved Drug Brand Name	Size/Amount	Nonproprietary / Generic Name	Brand Name of FDA-Approved Version
Esentra	5 60-mg kits	Denosumab	Prolia
Luprodex	10 22.5 mg kits	Leuprolide	Lupron
Celostatin	4 20-mg kits	Octreotide	Sandostatin
Enfira	12 500-mg vials	Rituximab	Rituxan
Enfira	24 100-mg vials	Rituximab	Rituxan
Infimab	10 100-mg vials	Infliximab	Remicade
Biceltis	5 420-mg vial[4]	Trastuzumab	Herceptin
Pemexane[5]	15 500-mg vials	Pemetrexed	Alimta
Pemexane[6]	30 100-mg vials	Pemetrexed	Alimta
Nanotin	20 100-mg vials	Paclitaxel	Abraxane
Carflinat	16 60-mg kits	Carfilzomib	Kyprolis
Fluro-5	20 1000-mg vials	5-Fluorouracil	Adrucil
Somatuline by GEN	5 120-mg kits	Lanreotide	Somatuline Depot
Altuzan	6 400-mg vials	Bevacizumab	Mvasi
Altuzan	12 100-mg vials	Bevacizumab	Mvasi

c. On or about July 14, 2021, defendant BENJAMIN LOUSTAUNAU sent a spreadsheet to defendant SUKHJIT SINGH GHUMAN's, aka "Sukhi", Personal Assistant listing drugs to be ordered from foreign countries and delivered to the United States to be used at AZCC. Those drugs included:

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[4] As stated on the order sheet, although typically available in 440-mg vials.

[5] Written as "Pexemane" on order spreadsheet.

[6] Written as "Pexemane" on order spreadsheet.

Foreign Non-FDA-Approved Drug Brand Name	Size/Amount	Nonproprietary / Generic Name	Brand Name of FDA-Approved Version
Opdyta	10 100-mg vials	Nivolumab	Opdivo
Opdyta	5 40-mg vials	Nivolumab	Opdivo

d. On or about August 5, 2021, defendant BENJAMIN LOUSTAUNAU sent a spreadsheet to defendant SUKHJIT SINGH GHUMAN's, aka "Sukhi", Personal Assistant listing drugs to be ordered from foreign countries and delivered to the United States to be used at AZCC. Those drugs included:

Foreign Non-FDA-Approved Drug Brand Name	Size/Amount	Nonproprietary / Generic Name	Brand Name of FDA-Approved Version
Esentra	8 60-mg kits	Denosumab	Prolia
Luprodex	8 22.5 mg kits	Leuprorelin	Lupron
Celostatin	4 20-mg kits	Octreotide	Sandostatin
Enfira	10 500-mg vials	Rituximab	Rituxan
Enfira	20 100-mg vials	Rituximab	Rituxan
Infimab	10 100-mg vials	Infliximab	Remicade
Biceltis	8 420-mg vial[7]	Trastuzumab	Herceptin
Nanotin	10 100-mg vials	Paclitaxel	Abraxane
Carflinat	20 60-mg kits	Carfilzomib	Kyprolis
Fistent[8]	10 250-mg kits	Fluvestrant	Faslodex
Fluro-5	20 1000-mg vials	5-Fluorouracil	Adrucil
Somatuline by GEN	4 120-mg kits	Lanreotide	Somatuline Depot
Altuzan	6 400-mg vials	Bevacizumab	Avastin
Altuzan	12 100-mg vials	Bevacizumab	Avastin
Opdyta	20 100-mg vials	Nivolumab	Opdivo
Opdyta	10 40-mg vials	Nivolumab	Opdivo

e. On or about August 10, 2021, defendant JASWINDER SHANKER, aka "Jesse", agreed to allow a shipment containing the following drugs:

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[7] As stated on the order sheet, although typically available in 440-mg vials.

[8] Written as "Fistenat" on order sheet.

Foreign Non-FDA-Approved Drug Brand Name	Size/Amount	Nonproprietary / Generic Name	Brand Name of FDA-Approved Version
Apritax	20 150-mg vials	Fosaprepitant	Emend
Ristova	14 500-mg vials	Rituximab	Rituxan

to be sent from THPL, 301 Arth Complex, B/h LG Showroom, Mithakhali Circle, Navrangpura, Ahmedabad, Gujarat, India 380060 to his home in Yuba City, CA. The shipment, addressed to "Jas Shanker," and declared as "medicine for personal use," was intercepted at J.F.K. airport in New York, New York.

f. On or about May 31, 2022, defendant SUKHJIT SINGH GHUMAN, aka "Sukhi", emailed Colton Health's Finance Director that she should wire $2,000 to defendant BENJAMIN LOUSTAUNAU monthly until further notice. Defendant KIRANJIT GHUMAN, aka "Kiran", added that the payment should be set up to be paid on the last day of each month.

g. On or about December 8, 2022, defendant BENJAMIN LOUSTAUNAU emailed defendant KIRANJIT GHUMAN, aka "Kiran", and defendant SUKHJIT SINGH GHUMAN's, aka "Sukhi", Personal Assistant a link to AZCC's monthly order of foreign unapproved drugs.

h. On or about December 29, 2022, defendant SUKHJIT SINGH GHUMAN's, aka "Sukhi", Personal Assistant emailed defendants BENJAMIN LOUSTAUNAU and KIRANJIT GHUMAN, aka "Kiran", a "reminder to update your new order list." Later that day defendant BENJAMIN LOUSTAUNAU replied with an updated order list for foreign unapproved drugs.

i. On or about March 6, 2023, defendant SUKHJIT SINGH GHUMAN's, aka "Sukhi", Personal Assistant emailed defendant BENJAMIN LOUSTAUNAU two attachments listing foreign unapproved drugs that were being ordered for SBCC and AZCC, and stating, in part, "What you will

note is that Kingman is marked up at 5% of supplier cost and CA is 10%. So for items you both order, it is more expensive to CA. These markups are Sukhi's costs."

j. On or about March 23, 2023, defendant BENJAMIN LOUSTAUNAU sent defendant SUKHJIT SINGH GHUMAN's, aka "Sukhi", Personal Assistant an email attaching a spreadsheet entitled "BioSim_MASTER-CA-Kingman-March_7th_2023(a).xlsx," listing approximately 157 FDA-approved drugs and showing, for many of those drugs, the prices those drugs cost from domestic wholesalers, and the cheaper prices from alternative suppliers outside of the United States.

k. On or about March 24, 2023, defendant JOSHUA SCHWASS sent an email to defendant BENJAMIN LOUSTAUNAU providing a list of medications needed at SBCC for the weeks of April 3, 2023, April 10, 2023, and April 17, 2023, stating "For the Herceptin/Kanjinti orders, if we cannot get the profitable vials, I do have 15 boxes of the 150mg Herceptin I can use."

l. On or about April 6, 2023, defendant BENJAMIN LOUSTAUNAU picked up foreign unapproved drugs at the house of defendant MOHAMMAD RAY KHAN.

m. On or about April 17, 2023, in response to an email about how SBCC lost money from using Zoladex on a patient since the reimbursement from Medicare and Medi-Cal was less than the cost of purchasing the drug from domestic drug wholesalers, defendant JOSHUA SCHWASS emailed defendant BENJAMIN LOUSTAUNAU and others, "We are losing even getting it from the outside source?"

All in violation of Title 18, United States Code, Section 371.

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Counts 2-9

Smuggling Drugs Into the United States Contrary to Law

(18 U.S.C. § 545)

50. Paragraphs 1 through 49 are realleged and incorporated by reference.

51. On or about the dates listed in the table below, within the Southern District of California, and elsewhere, the defendants listed in the table below did fraudulently and knowingly import and bring into the United States merchandise, that is, drugs, as further described in the table below, contrary to law, in that:

a. The introduction and delivery for introduction into interstate commerce of unapproved new drugs with intent to defraud and mislead as to a material matter, that is to defraud and mislead Medicare and Medi-Cal by presenting claims based on FDA-approved versions of drugs, and mislead patients into believing they were receiving FDA-approved drugs, is contrary to Title 21, United States Code, Sections 331(d), 333(a)(2), and 355(a).

b. The introduction and delivery for introduction into interstate commerce of misbranded drugs, that is with words, statements, and other information required by and under authority of [the FDCA] to appear on the label and labeling 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, without adequate directions for use, and imported by a commercial importer not duly registered with the Secretary of HHS, with the intent to defraud and mislead as to a material matter,

that is to defraud and mislead Medicare and Medi-Cal by presenting claims based on FDA-approved versions of drugs, and mislead patients into believing they were receiving FDA-approved drugs, is contrary to Title 21, United States Code, Sections 331(a) and 333(a)(2).

Count	Defendants	Approx-imate Date	Foreign Non-FDA-Approved Drug Brand Name	Size/Amount	Nonproprietary/Generic Name	Brand Name of FDA-Approved Version
2	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran"	9/3/19	Strantas	20 50-mg kits	Fulvestrant	Faslodex
3	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran"	9/3/19	Pegasta	9 6-mg kits	Pegfilgrastim	Neulasta
4	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran"	9/3/19	Endoxan-N	9 1-gm vials	Cyclophosphamide	Cytoxan

5	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran" MOHAMMAD RAY KHAN	8/10/21	Apritax	20 150-mg vials	Fosaprepitant	Emend
6	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran" MOHAMMAD RAY KHAN	8/10/21	Ristova	14 500-mg vials	Rituximab	Rituxan
7	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran" BENJAMIN LOUSTAUNAU JOSHUA SCHWASS	4/13/23	Bryxta	8 400-mg vials	Bevacizumab	Mvasi
8	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran" BENJAMIN LOUSTAUNAU JOSHUA SCHWASS	4/13/23	Augplat	5 250-mcg vials	Romiplostim	Nplate

	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran"					
9	BENJAMIN LOUSTAUNAU JOSHUA SCHWASS MOHAMMAD RAY KHAN	4/20/23	Fulzos	4 250-mg kits	Fulvestrant	Faslodex

all in violation of Title 18, United States Code, Sections 545 and 2, and *Pinkerton v. United States*, 328 U.S. 640 (1946).

Counts 10-17

Introduction of Unapproved New Drugs Into Interstate Commerce

(21 U.S.C. §§ 331(d), 355(a), and 333(a)(2))

52. Paragraphs 1 through 51 are realleged and incorporated by reference.

53. On or about the dates listed in the table below, within the Southern District of California and elsewhere, the defendants listed in the table below, with the intent to defraud and mislead as to a material matter, that is to defraud and mislead Medicare and Medi-Cal by presenting claims based on FDA-approved versions of drugs, and mislead patients into believing they were receiving FDA-approved drugs, introduced and delivered into interstate commerce, and caused to be introduced and delivered into interstate commerce, new drugs that were in violation of Title 21 United States Code, Section 355, in that they were not the subject of an approved BLA, NDA or ANDA on file with FDA, that is, the drugs specified in the table below:

Count	Defendants	Approx-imate Date	Foreign Non-FDA-Approved Drug Brand Name	Size/Amount	Nonproprietary /Generic Name	Brand Name of FDA-Approved Version
	SUKHJIT SINGH					
10	GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran"	9/3/19	Strantas	20 50-mg kits	Fulvestrant	Faslodex
11	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran"	9/3/19	Pegasta	9 6-mg kits	Pegfilgrastim	Neulasta
12	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran"	9/3/19	Endoxan-N	9 1-gm vials	Cyclophosphamide	Cytoxan
13	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran" MOHAMMAD RAY KHAN	8/10/21	Apritax	20 150-mg vials	Fosaprepitant	Emend

14	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran" MOHAMMAD RAY KHAN	8/10/21	Ristova	14 500-mg vials	Rituximab	Rituxan
15	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran" BENJAMIN LOUSTAUNAU JOSHUA SCHWASS	4/13/23	Bryxta	8 400-mg vials	Bevacizumab	Mvasi
16	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran" BENJAMIN LOUSTAUNAU JOSHUA SCHWASS	4/13/23	Augplat	5 250-mcg vials	Romiplostim	Nplate

	SUKHJIT SINGH GHUMAN aka "Sukhi" KIRANJIT GHUMAN aka "Kiran"					
17	BENJAMIN LOUSTAUNAU JOSHUA SCHWASS MOHAMMAD RAY KHAN	4/20/23	Fulzos	4 250-mg kits	Fulvestrant	Faslodex

all in violation of Title 21, United States Code, Sections 331(d), 355(a), and 333(a)(2), and Title 18, United States Code, Section 2, and *Pinkerton v. United States*, 328 U.S. 640 (1946).

Count 18

Conspiracy to Commit Health Care Fraud

(18 U.S.C. § 1349)

54. Paragraphs 1 through 53 are realleged and incorporated by reference.

55. Beginning no later than September 2019 and continuing through in or around April 2023, within the Southern District of California, and elsewhere, defendants SUKHJIT SINGH GHUMAN, aka "Sukhi", KIRANJIT GHUMAN, aka "Kiran", MOHAMMAD RAY KHAN, JOSHUA SCHWASS, and BENJAMIN LOUSTAUNAU, conspired and agreed with each other and with others known and unknown to the Grand Jury to commit health care fraud, that is, to knowingly and willfully execute a scheme and artifice to defraud a health care benefit program, as defined in Title 18, United States Code, Section 24(b), that is, Medicare and Medi-Cal, and to obtain money and property owned by and under the custody and control of Medicare and

Medi-Cal, by means of materially false and fraudulent pretenses, representations, and promises, in connection with the delivery of and payment for health care benefits, items and services, in violation of Title 18, United States Code, Section 1347.

Object of the Conspiracy

56. The object of the conspiracy was for defendants to unlawfully enrich themselves by defrauding Medicare and Medi-Cal by causing the submission of materially false and fraudulent claims for services.

Manner and Means of the Conspiracy

57. The conspirators used the following manner and means, among others, in pursuit of their fraudulent purpose:

a. Defendants illegally imported and received in interstate commerce non-FDA-approved drugs manufactured in foreign countries intended for use in countries other than the United States, including India, Sri Lanka, and Turkey.

b. Defendants purchased foreign unapproved drugs cheaper than they could have from domestic sources to increase the profit derived by payments from Medicare and Medi-Cal.

c. Defendants did not inform the patients being treated at SBCC and AZCC that foreign unapproved drugs were being injected into their bodies.

d. Defendants submitted, or caused to be submitted, reimbursement claims to Medicare and Medi-Cal that falsely and fraudulently represented that the patients identified in the claims received FDA-approved drugs, when the defendants knew the patients had received foreign-sourced, non-FDA-approved drugs, and further knew that Medicare and Medi-Cal would not pay for non-FDA-approved drugs.

e. Defendants submitted claims to Medicare and Medi-Cal listing CPT codes for the injection of FDA-approved drugs when, in fact, foreign unapproved drugs had been given to the patient under whom the claim was submitted.

f. Defendants collected, at least sometimes, copayment and coinsurance payments from SBCC and AZCC patients for treatment involving, without the patients' knowledge, the injection of foreign unapproved drugs.

g. Defendants typically stored the foreign unapproved drugs separately from those that were legally obtained, including at the residences of defendants MOHAMMAD RAY KHAN, BENJAMIN LOUSTAUNAU, and JASWINDER SHANKER, aka "Jesse", and in separate rooms and separate refrigerators at SBCC and AZCC, to conceal their scheme from other SBCC and AZCC employees and others.

h. Defendants frequently kept the excess drug left in a single-dose or single-use vial after the drug was given to a patient, so that the drug could be given to either the same patient or a different patient in the future, while billing Medicare, Medi-Cal, and other health insurance programs as if they discarded the waste.

i. Defendants did not inform the patients being treated at SBCC and AZCC that drugs that came from an already-used single-dose or single-use vial were being injected into their bodies.

j. Defendants submitted, or caused to be submitted, reimbursement claims to Medicare and Medi-Cal containing false and fraudulent pretenses in that they did not disclose that the patients identified in the claims received drugs that came from an already-used single-dose or single-use vial or other container, when defendants knew

that Medicare and Medi-Cal would not pay for drugs it knew were taken from a single-dose or single-use vial or other container that was used multiple times.

k. Defendants did not inform the patients being treated at SBCC and AZCC that expired drugs were being injected into their bodies.

l. Defendants submitted, or caused to be submitted, reimbursement claims to Medicare and Medi-Cal containing false and fraudulent pretenses in that they did not disclose that the patients identified in the claims received expired drugs, when defendants knew that Medicare and Medi-Cal would not pay for expired drugs.

Overt Acts

58. In furtherance of the conspiracy and to effect and accomplish the objects of it, one and more of the defendants and conspirators committed, among others, the following overt acts, in the Southern District of California and elsewhere:

a. Paragraph 49, subparagraphs a-m, are realleged and incorporated by reference.

b. On or about October 15, 2021, in an email chain between, among others, defendants KIRANJIT GHUMAN, aka "Kiran", SUKHJIT SINGH GHUMAN, aka "Sukhi", and BENJAMIN LOUSTAUNAU, as well as an AZCC Office Manager and a Business Manager, discussing using a JW modifier for drug wastage on Arizona Medicaid claims:

1. Defendant KIRANJIT GHUMAN, aka "Kiran", stated, "Can we either up the dose or store the remainder of the dose in the fridge and use on other patients and bill the correct dosages."

2. Defendant SUKHJIT SINGH GHUMAN, aka "Sukhi", stated, "We save the dose and it works fine."

c. On or about January 17, 2022, in response to an email from an AZCC Office Manager explaining that during an inventory, among other things, "we found plenty of expired medications" and AZCC was "reusing single dose vials []Some vials state 'Must use within 8 hours of opening vial, discard remaining portion' however the remaining portion was not discarded. (I am not sure if these vials were used for multiple patients or on different days, nothing is documented.)" Defendant SUKHJIT SINGH GHUMAN, aka "Sukhi", responded, "We also don't need to copy [AZCC's oncologist] on this."

d. On or about March 9, 2023, defendants submitted, and caused to be submitted, a claim for $7,740.00 to Medicare, falsely representing that patient O.H. had been administered an injection of FDA-approved trastuzumab.

e. On or about March 30, 2023, defendants submitted, and caused to be submitted, a claim for $7,740.00 to Medicare, falsely representing that patient O.H. had been administered an injection of FDA-approved trastuzumab.

f. On or about April 19, 2023, defendants submitted, and caused to be submitted, a claim for $18,750.00 to Medicare, falsely representing that patient S.M. had been administered an injection of FDA-approved rituximab.

g. On or about April 19, 2023, defendants submitted, and caused to be submitted, a claim for $1,250.00 to Medicare for "rituximab waste," falsely representing that excess FDA-approved rituximab prescribed to patient S.M. had been unused and discarded.

h. On or about April 20, 2023, defendants submitted, and caused to be submitted, a claim for $17,640.00 to Medicare, falsely

representing that patient O.H. had been administered an injection of FDA-approved pertuzumab.

i. On or about April 20, 2023, defendants submitted, and caused to be submitted, a claim for $7,740.00 to Medicare, falsely representing that patient O.H. had been administered an injection of trastuzumab.

All in violation of Title 18, United States Code, Section 1349.

Counts 19-24

Health Care Fraud

(18 U.S.C. § 1347)

59. Paragraphs 1 through 58 are realleged and incorporated by reference.

60. Beginning no later than September 2019 and continuing through in or around April 2023, within the Southern District of California, and elsewhere, defendants SUKHJIT SINGH GHUMAN, aka "Sukhi", KIRANJIT GHUMAN, aka "Kiran", MOHAMMAD RAY KHAN, JOSHUA SCHWASS, and BENJAMIN LOUSTAUNAU, knowingly and willfully executed and attempted to execute a scheme and artifice to defraud, and obtain by means of materially false and fraudulent pretenses, representations, and promises, money and property owned by and under the custody and control of, Medicare and Medi-Cal, health care benefit programs as defined in Title 18, United States Code, Section 24(b), in connection with the delivery of and payment for health care benefits, items, and services.

EXECUTIONS OF THE SCHEME

61. On or about the dates listed in the table below, within the Southern District of California and elsewhere, defendants SUKHJIT SINGH GHUMAN, aka "Sukhi", KIRANJIT GHUMAN, aka "Kiran", MOHAMMAD RAY KHAN,

JOSHUA SCHWASS, and BENJAMIN LOUSTAUNAU, for the purpose of executing the scheme, knowingly caused the following bills for reimbursement to be submitted to Medicare:

Count	Claim Submittal Date & Date of Service	Patient's Initials & Claim Number	CPT Code	Procedure Description	Amount Billed
19	3/9/2023; 3/8/2023	O.H.; 551823068002580 - line # 2	J9355	Injection, trastuzumab, excludes biosimilar	$7,740.00
20	3/30/2023; 3/29/2023	O.H.; 551823089066240 - line # 2	J9355	Injection, trastuzumab, excludes biosimilar	$7,740.00
21	4/19/2023; 4/6/2023	S.M.; 551123109748960 - line # 1	J9312	Injection, rituximab	$18,750.00
22	4/19/2023; 4/6/2023	S.M.; 551123109748960 - line # 2	J9312-JW	Rituximab Waste	$1,250.00
23	4/20/2023; 4/19/2023	O.H.; 551823110045570 - line # 1	J9306	Injection, pertuzumab	$17,640.00
24	4/20/2023; 4/19/2023	O.H.; 551823110045570 - line # 2	J9355	Injection, trastuzumab, excludes biosimilar	$7,740.00

All in violation of Title 18, United States Code, Sections 1347 and 2, and *Pinkerton v. United States*, 328 U.S. 640 (1946).

Count 25

Conspiracy to Engage in the Unlawful Wholesale Distribution of Drugs and Commit Wire Fraud

(18 U.S.C. § 371)

62. The introductory allegations set forth in paragraphs 1 through 44 are realleged and incorporated by reference.

63. Beginning no later than September 2021 and continuing through in or around April 2023, within the Southern District of California and elsewhere, defendants SUKHJIT SINGH GHUMAN, aka "Sukhi", KIRANJIT

GHUMAN, aka "Kiran", BENJAMIN LOUSTAUNAU, and VENIN PATEL, conspired and agreed with each other and with others known and unknown to the Grand Jury to commit one and more of the following offenses against the United States:

a. To knowingly engage in the unlicensed wholesale distribution of prescription drugs in interstate commerce, in violation of Title 21, United States Code, Sections 331(t), 353(e)(1)(A), and 333(b)(1)(D);

b. To commit wire fraud, that is to devise and intend to devise a scheme to defraud Cardinal Health and Oncology Supply, and to obtain money and property by means of materially false and fraudulent pretenses, representations and promises in violation of Title 18, United States Code, Section 1343.

Object of the Conspiracy

64. The object of the conspiracy was for defendants to unlawfully enrich themselves by purchasing drugs from medical supply wholesalers Cardinal Health and Oncology Supply for the lower prices available to healthcare providers purchasing drugs to give to their patients, but instead selling those drugs to Celtis, who would have had to pay higher prices to purchase the drugs from those wholesalers directly.

Manner and Means of the Conspiracy

65. The conspirators used the following manner and means, among others, in pursuit of their fraudulent purpose:

a. Conspirators associated with AZCC purchased and caused to be purchased drugs from medical supply wholesalers, agreeing to the wholesalers' terms and conditions that were meant, among other things, to prevent AZCC from reselling the drugs.

1. Conspirators purchased drugs from Oncology Supply, which imposed the following terms and conditions, among others:

> CONFIDENTIALITY. Buyer may not use or disclose Seller's trade secretes or confidential information. Pricing terms are strictly confidential and may not be disclosed to any third party or competitor of Seller unless required by law.

2. Conspirators also purchased drugs from Cardinal Health, which imposed the following terms and conditions, among others:

> Non-Wholesale customers are final dispensers that are purchasing for their own use and will not redistribute prescription pharmaceuticals to any other entity.

b. Employees of Celtis typically identified specific drugs, often described with specific NDC numbers, and sometimes specific lot numbers and expirations dates, that they were interested in buying from AZCC.

c. AZCC employees typically responded by sending information regarding the price they could purchase drugs from wholesalers, including Cardinal Health and Oncology Supply, and the markup they would charge to resell the drugs to Celtis.

d. AZCC typically marked up the price of the drugs between the price for which they could purchase the drugs and the price that Celtis would have to pay to purchase those same drugs directly from the same wholesaler.

e. Employees of Celtis then typically sent employees of AZCC a purchase order detailing what drugs they wanted AZCC to resell to them.

f. AZCC purchased the specified drugs from medical supply wholesalers, including Cardinal Health and Oncology Supply, with the

express purpose to resell those drugs to Celtis, directly in violation of the wholesalers' terms and conditions of sale.

g. AZCC typically then sent Celtis an invoice for the drugs they purchased from wholesalers and resold to Celtis.

h. Early on, AZCC would charge Celtis for the commercial shipping cost for the drugs they purchased from wholesalers, but later Celtis would pay for a shipping label for AZCC to use.

i. AZCC never obtained a license to act as a wholesale distributor of drugs from Arizona or Pennsylvania.

Overt Acts

66. In furtherance of the conspiracy and to effect and accomplish the objects of it, one and more of the defendants and conspirators committed, among others, the following overt acts, in the Southern District of California and elsewhere:

a. On or about May 5, 2022, defendant KIRANJIT GHUMAN, aka "Kiran", emailed defendant BENJAMIN LOUSTAUNAU asking for an updated spreadsheet regarding Celtis, so that she could advise defendant SUKHJIT SINGH GHUMAN, aka "Sukhi", of the profit to date.

b. On or about May 9, 2022, defendant KIRANJIT GHUMAN, aka "Kiran", emailed defendant SUKHJIT SINGH GHUMAN, aka "Sukhi", that she and defendant BENJAMIN LOUSTAUNAU "have spoken today regarding a call with [defendant VENIN PATEL]. Please can you confirm you are happy for us to give [defendant VENIN PATEL] access to our Cardinal account so he can go and see availability of products and prices. This way we are hoping he will look at alternatives and place the order. [Defendant BENJAMIN LOUSTAUNAU] is currently going back and forth with $ and we are

only meeting 20-30% of [PATEL's] requests due to availability. Without this [PATEL] advised we may not be able to continue."

c. On or about May 23, 2022, after defendant VENIN PATEL stated that he had not been given access to AZCC's Cardinal account, defendant SUKHJIT SINGH GHUMAN, aka "Sukhi", emailed defendants KIRANJIT GHUMAN, aka "Kiran", and BENJAMIN LOUSTAUNAU that it was "fine" to give defendant VENIN PATEL the login information for AZCC's Cardinal accounts for oncology products and non-oncology products.

d. On or about July 22, 2022, defendant BENJAMIN LOUSTAUNAU emailed defendants VENIN PATEL and SUKHJIT SINGH GHUMAN, aka "Sukhi", and an employee of Celtis, the price that AZCC would charge Celtis per pack for seven drugs, as requested by Celtis.

e. On or about August 4, 2022, defendant BENJAMIN LOUSTAUNAU emailed defendant VENIN PATEL, and an employee of Celtis, the price at which that AZCC could purchase nine drugs from AmerisourceBergen, as requested by Celtis.

f. On or about August 23, 2022, defendant KIRANJIT GHUMAN, aka "Kiran", emailed a copy of an invoice for Celtis' purchase of seven drugs from AZCC for $97,569.03, including shipping charges, to defendants BENJAMIN LOUSTAUNAU and VENIN PATEL, as well as two other Celtis employees.

g. On or about August 31, 2022, defendant BENJAMIN LOUSTAUNAU emailed defendant KIRANJIT GHUMAN, aka "Kiran", the cost AZCC paid for 13 drugs sold to Celtis in three purchase orders, and the price AZCC charged Celtis for those drugs.

h. On or about November 4, 2022, Celtis paid defendant BENJAMIN LOUSTAUNAU $4,000 as a commission for the drugs that AZCC sold to Celtis.

i. On or about January 25, 2023, defendant VENIN PATEL caused to be sent a purchase order from Celtis to AZCC for three lots of Abraxane for $325,117.26.

j. On or about February 8, 2023, defendant KIRANJIT GHUMAN, aka "Kiran", authorized the sale of 136 units of the drug Prolia (nonproprietary/generic name Denosumab) to Celtis for $190,326.56.

k. On or about February 20, 2023, defendant VENIN PATEL caused to be sent a purchase order from Celtis to AZCC for eight drugs, including Coly-Mycin, for $446,699.74.

l. On or about February 20, 2023, a Celtis employee emailed defendant KIRANJIT GHUMAN, aka "Kiran", and others a table listing the eight drugs with the prices that Colton and Celtis could purchase the drugs for, the difference between the two prices, and dividing that difference into "Celtis Share" and "Colton Share." defendant KIRANJIT GHUMAN, aka "Kiran", forwarded that email to defendant BENJAMIN LOUSTAUNAU and stated, "Please see below and advise if this is correct and worth doing."

m. On or about February 24, 2023, defendant VENIN PATEL emailed defendants BENJAMIN LOUSTAUNAU and KIRANJIT GHUMAN, aka "Kiran", and others, indicating his priorities for which drugs he wanted AZCC to purchase in order to sell to Celtis, including Colymycin.

n. On or about February 27, 2023, defendant BENJAMIN LOUSTAUNAU emailed McKesson asking for 10 units of Coly-Mycin with the

same expiration date and stating, "he wants to keep in stock, but I need a long expiration date, so they don't sit."

All in violation of Title 18, United States Code, Section 371.

Criminal Forfeiture Allegation

67. The allegations contained in Counts 1 through 32 are re-alleged and by their reference fully incorporated herein for the purpose of alleging forfeiture to the United States of America pursuant to the provisions of Title 18, United States Code, Sections 981(a)(1)(C), 982(a)(2)(B), 982(a)(7), and Title 28, United States Code, Section 2461(c).

68. Upon conviction of one and more of the offenses of this Indictment indicated in the following table, and pursuant to the statutes listed in that table, defendants shall forfeit to the United States all property constituting, or derived from, any proceeds defendants obtained, directly or indirectly, as the result of the offenses, including, but not limited to, the real property located at 9457 East Adobe Drive, Scottsdale, Arizona:

Counts	Statutes Justifying Forfeiture
1 (Conspiracy)	Title 18, U.S.C., Sec. 981(a)(1)(C), and Title 28, U.S.C., Sec. 2461(c)
2-9 (18 U.S.C. 545)	Title 18, U.S.C., Sec. 982(a)(2)(B)
10-17 (21 U.S.C. §§ 331(d), 355(a), and 333(a)(2);	Title 18, U.S.C., Sec. 982(a)(7)
18 (Conspiracy)	Title 18, U.S.C., Sec. 981(a)(1)(C), and Title 28, U.S.C., Sec. 2461(c)
19-24 (18 U.S.C. 1347, 1349)	Title 18, U.S.C., Sec. 982(a)(7)
25 (Conspiracy)	Title 18, U.S.C., Sec. 981(a)(1)(C), and Title 28, U.S.C., Sec. 2461(c)

69. If any of the above-described forfeitable property, as a result of any act or omission of defendants:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of the Court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be subdivided without difficulty;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), Title 18, United States Code, Section 982(b), and Title 28, United States Code, Section 2461(c), to seek forfeiture of any other property of defendants up to the value of the property listed above as being subject to forfeiture.

All pursuant to Title 18, United States Code, Sections 981(a)(1)(C), 982(a)(2)(B), and 982(a)(7), and Title 28, United States Code, Section 2461(c).

DATED: October 13, 2023.

A TRUE BILL:

Foreperson

TARA K. MCGRATH
United States Attorney

By: GEORGE V. MANAHAN
Assistant U.S. Attorney