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IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

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| UNITED STATES OF AMERICA,<br>Plaintiff,<br>v.<br>HUU TIEU,<br>Defendant. | CASE NO. 1:20-cr-0109 DAD<br>18 U.S.C. § 1341 – MAIL FRAUD [TWO COUNTS]; 21 U.S.C. § 331(a) AND 333(a)(2) – INTRODUCTION OF MISBRANDED DRUG INTO INTERSTATE COMMERCE WITH INTENT TO DEFRAUD OR MISLEAD [THREE COUNTS]; 18 U.S.C. §§ 981(a)(1)(C), 982(a)(7), 21 U.S.C. § 334, and 28 U.S.C. § 2461(c) - CRIMINAL FORFEITURE |

# INDICTMENT

COUNTS ONE AND TWO: [18 U.S.C. § 1341 – Mail Fraud]

The Grand Jury charges:

HUU TIEU,

defendant herein, as follows:

## I. INTRODUCTION

At all relevant times:

1. Defendant HUU TIEU ("TIEU") was a resident of Porterville, California, within the State and Eastern District of California, and was the President and Chief Executive Officer of Golden Sunrise Pharmaceutical, Inc. and Golden Sunrise Nutraceutical, Inc. (collectively, the "Golden Sunrise

Companies" or "Golden Sunrise"). He was also the Chief Executive Officer and Chief Financial Officer of EDM Industries, Inc. ("EDM").

2. Golden Sunrise Pharmaceutical, Inc., was registered as a California corporation with the California Secretary of State on or about September 2011. Golden Sunrise Nutraceutical, Inc. was registered as a Delaware corporation with the California Secretary of State on or about March 2018. EDM was registered as a California corporation with the California Secretary of State on or about May 2000.

3. The Golden Sunrise Companies manufactured, marketed, and sold products that, the companies claimed, effectively treated a variety of medical conditions. EDM manufactured certain products for the Golden Sunrise Companies. The Golden Sunrise Companies were located in Porterville, California, in the State and Eastern District of California. EDM was located in Lindsay, California, in the State and Eastern District of California.

4. The United States Food and Drug Administration ("FDA") was the federal agency responsible for protecting the health and safety of the American public by enforcing the federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*. The FDCA was a federal law which, among other things, regulated the manufacture and distribution of foods, drugs, medical devices, and cosmetics.

5. One primary purpose of the FDCA was to ensure that drugs sold for use in humans and other animals were safe and effective for their intended uses, and bore labeling containing only truthful and non-misleading information and directions adequate for a layperson to use the drugs safely and for all the purposes for which it was intended. The FDA's responsibilities under the FDCA included regulating the manufacture, labeling, and distribution of all animal drugs introduced, delivered, and caused to be introduced or delivered in interstate commerce.

6. Under the FDCA, the definition of "drugs" included articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals, 21 U.S.C. § 321(g)(1)(B), and articles (other than food) intended to affect the structure or function of the body of humans, 21 U.S.C. § 321(g)(1)(C). The "intended use" of an article meant the objective intent of the persons legally responsible for the labeling of that article, as determined by such persons' expressions or the circumstances surrounding the distribution of the article. 21 C.F.R. § 201.128.

7. Under the FDCA, a "new drug" was any drug the composition of which was not generally recognized by experts as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling. 21 U.S.C. § 321(p). With limited exceptions not relevant here, before a new drug could be lawfully shipped in interstate commerce, its sponsor (usually the manufacturer) had to first obtain FDA approval of a New Drug Application ("NDA") for that drug. 21 U.S.C. § 355(a). In order to obtain FDA approval for an NDA, the sponsor of the NDA had to demonstrate to the FDA's satisfaction that, among other things, its new drug was safe and effective for its intended uses. 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.50.

8. Under the FDCA, a "prescription drug" was any drug intended for use in humans that, because of its toxicity or potential for harmful effect, the method of its use, or the collateral measures necessary for its use, was not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or a drug which was limited by an approved application under 21 U.S.C. § 355 for use under the professional supervision of a practitioner licensed by law to administer such drugs. 21 U.S.C. § 353(b)(1).

9. The FDCA defined "label" as a display of written, printed, or graphic matter upon the immediate container of any article, including food and drugs. 21 U.S.C. § 321(k). "Labeling" was a broader term, and was defined as "all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article." 21 U.S.C. § 321(m). Written, printed or graphic matter on internet websites operated by the persons that manufactured or distributed an article, or from which one could purchase an article, or linked to a website from which one could purchase an article, could be labeling for that article.

10. Under the FDCA, a drug was deemed to be misbranded for any of a number of reasons. Relevant to this indictment, a drug was misbranded :

a) If its labeling was false or misleading in any particular. 21 U.S.C. § 352(a)(1).

b) Unless its labeling bore adequate directions for use. 21 U.S.C. § 352(f)(1). "Adequate directions for use" was defined as directions under which a layman could use a drug safely and for the purposes for which it was intended. 21 C.F.R. § 201.5. Because prescription drugs, by definition, can only be used safely, if at all, at the direction, and under the supervision, of a

physician, directions could not be written under which a layperson could use a prescription drug safely.

11. At all times relevant to this Indictment, the FDCA prohibited causing the introduction or delivery for introduction into interstate commerce of misbranded drugs. 21 U.S.C. § 331(a).

12. Under certain conditions, a drug was eligible for a "regenerative medicine advanced therapy" (RMAT) designation by the FDA if it was a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products; it was intended to treat, modify, reverse, or cure a specific serious or life-threatening disease or condition; and preliminary clinical evidence indicated that the drug had the potential to address unmet medical needs for such disease or condition. 21 U.S.C. § 356g, the FDA had the sole authority to designate regenerative medicine therapy drugs. To obtain an RMAT designation, the drug sponsor had to first request the FDA to grant this designation and await FDA's decision.

13. Cellular therapy ("CT") products included cellular immunotherapies, cancer vaccines, and other types of cells (including stem cells) for certain therapeutic indications, as well as the practice of injecting humans with foreign proteins like the placenta or lungs of unborn lambs.

14. The Medicare program was a Federal health care program established by the Social Security Act of 1965 to provide medical services to aged, blind, and disabled individuals who qualified under the Social Security Act. The United States Department of Health and Human Services, through its agency, the Centers for Medicare & Medicaid Services, administered Medicare. Medicare had federally-funded programs that paid for medically necessary services and prescription drug benefits for eligible beneficiaries.

15. The Medicaid program was a Federal health care program authorized by Title XIX of the Social Security Act. 42 U.S.C. §§ 1396 *et seq*. Medicaid was a joint federal-state program that provided health care benefits, including coverage of medical office visits and prescription drugs, for certain groups including the poor and disabled. The California Medicaid program was also known as "Medi-Cal."

16. UnitedHealthcare of California ("UHC") provided medical insurance to certain California residents and reimbursed health care providers, pharmacies, and other providers for qualifying goods

and services provided to UHC beneficiaries.

17. The Healthcare Common Procedure Coding System ("HCPCS") was a standardized coding system used to identify certain supplies, services, and products provided to a given patient. Billing providers used HCPCS on health insurance reimbursement claim forms to indicate the specific good or service for which they are requesting reimbursement. M0075 was the HCPCS code for cellular therapy.

## II. THE SCHEME TO DEFRAUD

18. From a date unknown but no later than on or about February 4, 2020, through on or about July 9, 2020, in the State and Eastern District of California and elsewhere, defendant TIEU, with the intent to defraud, knowingly devised and intended to devise a scheme and artifice to defraud insurers including UHC, Medicare, and Medi-Cal, of money and property and to obtain money and property from customers and insurers, including UHC, Medicare, and Medi-Cal, by means of materially false and fraudulent pretenses, representations, and promises.

## III. MANNER AND MEANS

19. The scheme to defraud was carried out, in substance, generally through the following manner and means, among others:

20. Defendant TIEU, with the intent to defraud, submitted and intended to submit false and fraudulent claims for reimbursement to UHC, Medicare, and Medi-Cal representing that beneficiaries had received cellular therapy from Golden Sunrise when, in fact, they had not.

21. TIEU devised this scheme and artifice to defraud for the purpose of receiving money and property in the form of claim reimbursements from the insurers. In addition to distributing products at Golden Sunrise and seeking reimbursement from insurers, TIEU also provided products to S.H., the Golden Sunrise Companies' "Education Director," so she could sell them at her own business, F.H.E.L.M. TIEU's scheme to defraud also included conveying false information regarding Golden Sunrise products so that customers would purchase them from S.H.

### A. False Statements about Golden Sunrise Products to Obtain Beneficiaries' Medical Insurance Information

22. Beginning at least on or about March 23, 2020, TIEU caused false statements to be made

to members of the media, to potential customers of Golden Sunrise, and to the general public that Golden Sunrise products were FDA approved for the specific indication of treating the disease the World Health Organization has named COVID-19, which stands for coronavirus disease of 2019 and is caused by SARS-CoV-2, which stands for severe acute respiratory syndrome coronavirus 2. Among other means, TIEU caused these false statements to be made through electronic mail, the Golden Sunrise Companies' websites, posts on a social media platform, and verbal and written representations to potential customers and the public. TIEU made these misrepresentations in part to induce customers to provide their medical insurance information, which he intended to use and caused to be used in furtherance of the scheme to defraud.

23. At all relevant times, the Golden Sunrise Companies marketed and sold products that, when combined, were represented to constitute various "plans of care" and purportedly treated a variety of medical conditions. For example, "ImunStem" was a product marketed and sold by the Golden Sunrise Companies and was manufactured by EDM. The claimed ingredients of ImunStem, according to the Golden Sunrise Companies, were olive leaf, yarrow, rosemary, yucca, and cassia oil. ImunStem was variously marketed through website claims, emails, and printed material sent with the product to customers as being intended to treat HIV, cancer, Hepatitis, and COVID-19.

24. When a customer with insurance, including insurance through UHC, Medicare, or Medi-Cal, acquired Golden Sunrise products from the Golden Sunrise Companies, TIEU and others acting at his direction obtained the customer's insurance information and submitted and caused to be submitted a reimbursement claim to the customer's insurer by U.S. Mail, other common carriers, and by electronic means. In furtherance of the scheme to defraud and in part to induce customers to provide their medical insurance information, TIEU provided products to customers in person and, for patients and practitioners residing outside the Porterville, California area, mailed and caused to be mailed Golden Sunrise products by U.S. Mail and other common carriers.

25. At a date unknown to the grand jury but no later than on or about March 23, 2020, TIEU began promoting ImunStem as a treatment for COVID-19. On or about March 23, 2020 TIEU sent an email to J.M., with an attachment titled "Letter to Media." The attachment was a letter describing Golden Sunrise products and made the following false and fraudulent statements, which TIEU knew to

be false and fraudulent:

a) "In this time of great emergency in our country, it is urgent to raise the awareness of the availability of a product, ImunStem, which has already been screened and approved by the United States Food and Drug Administration (FDA) for the COVID-19 virus. It is an alternative medicine approved by the FDA. This was accomplished under their new Department of Regenerative Advanced Therapy formed in February 2017. This department was created to screen and evaluate the emergence on the market of these types of products. The 2016 Cures Act, passed by the 114th United States Congress, established the criteria for these regenerative drugs / medicinals. These medicinals must be able to regenerate our cells 1) at a cellular level, 2) they can treat, modify, reverse or cure Serious or Life-threatening conditions, and 3) they have the potential to address unmet medical needs for such conditions. ImunStem, an herbal product, produced by Golden Sunrise Nutraceutical, met these strict criteria."

b) "[Imunstem] became the first and only dietary supplement, unlike any other dietary supplement on the market, to be qualified as a prescription drug human medicine by the FDA in July 02, 2018 . . . . In order for ImunStem to qualify as a prescription medicine, it had to meet the very arduous testing that the FDA requires for all prescription drugs, even though it was not a drug."

c) "The FDA established [Imunstem] as safe and effective to treat, modify, reverse, or cure Serious or Life-threatening conditions, such as hypertension, cancer, fibromyalgia, Lyme's disease, and in this case, the COVID-19 virus."

d) "Lastly, but crucially important, is the fact that the FDA has not only approved the ImunStem herbal dietary supplement, but all of the herbal products and treatments produced thus far by Golden Sunrise Nutraceutical. When the FDA physically came to Golden Sunrise Nutraceutical's location in March 2019, they inspected all of the therapies, claims, and production. They found Golden Sunrise Nutraceutical dietary supplements to be legitimate and valid to treat, modify, or reverse Serious or Life-threatening conditions and illnesses. Unlike other businesses that have been forced to close their business or drop claims on their web site, the FDA approved the web site and the therapies developed by Golden Sunrise Nutraceutical to

rejuvenate and transform our cells."

26. As TIEU was aware, contrary to these statements, no Golden Sunrise product, including Imunstem, had ever been approved by the FDA for any purpose. No drug by any manufacturer had been approved by the FDA to treat COVID-19. ImunStem did not receive an RMAT designation from the FDA. In 2017, the FDA expressly informed TIEU that ImunStem did not qualify for an RMAT designation. On or about November 15, 2018, the FDA's Electronic Drug Registration and Listing staff informed TIEU, by email, that ImunStem "was never approved." On or about September 16, 2019, the FDA's Center for Drug Evaluation and Research reminded TIEU that ImunStem had been rejected for an RMAT designation in 2017, "was not approved by the FDA," and was not cell therapy.

27. Additionally, ImunStem did not meet FDA testing requirements for prescription drugs, and the FDA did not establish ImunStem as safe and effective for treating any condition. An FDA inspector did conduct an on-site inspection of Golden Sunrise in 2019. However, he did not make any finding that any Golden Sunrise product was legitimate or valid to treat any condition. The inspector did not approve the Golden Sunrise Companies' websites. In fact, he addressed, with TIEU, the false claim on a website TIEU managed, ImunStem.com, that ImunStem was FDA approved, leading TIEU to remove the claim from the website. TIEU knew each of these facts when he sent the letter to J.M.

28. In furtherance of the scheme to defraud and to recruit additional customers from whom he could obtain medical insurance information, TIEU caused J.M. to send the "Letter to Media" document by email, between on or about March 24, 2020 to on or about March 31, 2020, to various media outlets with the subject line "FDA Approved Alternative Medicine for COVID – 19." J.M. carbon copied TIEU on each email. The domain names of the recipients of the emails included cbs.com, foxtv.com, bos.lacounty.gov (the Los Angeles County Board of Supervisors), nytimes.com, ktla.com, msnbc.com, and cnn.com.

29. Also in furtherance of the scheme to defraud and to recruit additional customers, at a date unknown to the grand jury but no later than April 25, 2020, TIEU began marketing a plan of care called the "Emergency D-Virus Plan of Care" that purportedly treated COVID-19. TIEU marketed the plan of care as a box containing the Golden Sunrise products "AnterFerron-1, AnterFerron-2, ImunStem, and Aktiffvate." Like ImunStem, the main ingredients of Anterferron-1, AnterFerron-2, and Aktiffvate were

herbal, including "Bilberry leaf," "Mistletoe," and "Eucalyptus extract.

30. In furtherance of the scheme to defraud, TIEU placed, and caused to be placed, a banner at the top of the Golden Sunrise Companies' websites that read "NEW COVID-19 TREATMENT EMERGENCY D-Virus Plan Care." If the internet user clicked on the banner, the website would redirect to a .pdf file (the "Emergency D-Virus Pdf"), which TIEU had uploaded and caused to be uploaded, that contained the following false and fraudulent representations regarding the Emergency D-Virus Plan of Care:

a) "Patients with late stages of Hepatitis C, and AIDS / HIV have responded with greatly improved quality-of-life and extending their lives when treated with ImunStem and Aktiffvate. For viral colds, Aktiffvate, when given in frequent dosing, as frequent as every one half (½) hour to one (1) hour, will not only alleviate the symptoms quickly, but stop the cold virus itself, usually in less than 2 – 3 days. Now AnterFeerons has been added to the ImunStem and Aktiffvate and shown added improvement for a variety of infections associated with cancer patients and the chronically ill, whether it be viral or bacterial."

b) "Golden Sunrise Nutraceutical metabolic therapies will treat Serious or Life-threatening conditions."

c) "ImunStem, Aktiffvate, and AnterFeerons herbs are the basis of the whole cellular therapy developed by Golden Sunrise Nutraceutical. They have proven themselves to the United States Food & Drug Administration (FDA)."

d) "ImunStem, an herbal product, was the first dietary supplement in the United States to be approved as a prescription medicine and also for the indication to treat Serious or Life-threatening conditions. It qualified for both of these under the Regenerative Medicine Advance Therapy (RMAT) designation in the 2016 Cures Act, enacted by the 114th United States Congress. This designation acknowledges not only the effectiveness of these herbs, usually only associated with pharmaceutical drugs, but also causing no side effects, a quality of dietary supplements." Golden Sunrise products, including Imunstem, are "uniquely qualified to treat and modify the course of the Coronavirus epidemic in CHINA and other countries."

31. TIEU caused these false statements and misrepresentations to be made despite knowing

that the FDA had never approved any Golden Sunrise Company product, no Golden Sunrise product had received an RMAT designation or qualified for an RMAT designation, no Golden Sunrise Product was a "cellular therapy," and that ImunStem had not been FDA approved for any intended use, including the treatment of COVID-19.

32. On or about April 29, 2020, the Federal Trade Commission ("FTC") ordered TIEU to cease and desist from advertising and claiming that the Golden Sunrise products could cure and treat COVID-19 or other diseases.

33. On or about May 8, 2020, TIEU met with an undercover investigator at the Golden Sunrise Nutraceutical, Inc. office at 219 North E Street, Porterville, California. When the undercover investigator asked if she should take her 68-year-old mother, whom she told TIEU had COVID-19 and symptoms that included shortness of breath, to the hospital, TIEU responded, in part, "No. You cannot go in there," as he claimed Golden Sunrise had the only treatment for COVID-19.

34. In addition to marketing and selling Golden Sunrise products from the Golden Sunrise Nutraceutical, Inc. office, TIEU also supplied Golden Sunrise products, including the Emergency D-Virus Plan of Care, to S.H. for S.H. to resell at her business, F.H.E.L.M, in Porterville, California. For example, on or about May 15, 2020, an undercover investigator met with S.H. at F.H.E.L.M. The investigator purchased ten doses of ImunStem and ten doses of another Golden Sunrise product, Aktiffvate. The investigator paid S.H. for the products in cash.

35. On or about June 19, 2020, TIEU told an undercover agent with the Federal Bureau of Investigation, posing as a potential Golden Sunrise customer, that the customer would not have to pay for the Emergency D-Virus Plan of Care because the treatment would be reimbursed by "the government." TIEU also mentioned billing insurance for the Plan of Care product. TIEU further falsely told the undercover agent that the Emergency D-Virus Plan of Care was FDA approved.

36. At all relevant times, TIEU caused the above misrepresentations to be made, in part, to obtain medical information from customers for use in furtherance of the scheme to submit false and fraudulent claims to insurers.

**B. False Statements to Insurers**

37. In addition to convincing customers, including patients and practitioners, to purchase

Golden Sunrise products through false and fraudulent statements, TIEU's scheme also involved submitting false claims for reimbursement to customers' insurers.

38. TIEU submitted and caused to be submitted claims for reimbursement by mail,other common carriers, and by electronic means using a standard CMS Form 1500 claim form. This form requires the billing provider to input, among other information, the patient's name, personal information, insurance information, the dates of service, the provider who rendered services, the reimbursement amount the provider is seeking in a column titled "$ CHARGES," and the specific services the patient received by billing code, including HCPCS code, in a column titled "PROCEDURES, SERVICES, OR SUPPLIES." As a general matter, insurers use the billing codes listed on submitted Forms 1500 to determine whether the service rendered is reimbursable and, if so, the reimbursement amount.

39. The claims TIEU submitted and caused to be submitted were false because TIEU billed HCPCS code M0075 for cellular therapy despite knowing that no Golden Sunrise customer had received cellular therapy. For example, on or about May 4, 2020, TIEU submitted and caused to be submitted three reimbursement claims to UHC for customers who received the Emergency D-Virus Plan of Care. Under the column for "$ CHARGES" on each claim, TIEU input and caused to be input "$170,000" on two of the claims and "$23,000" on the third claim. Each claim contained the following false information:

a) Under "PROCEDURES, SERVICES, OR SUPPLIES," the form states "M0075," the HCPCS code for cellular therapy.

b) On the top left corner of the form, in large bolded letters, the form states "Cellular Therapy."

## IV. USE OF THE MAILS

40. On or about the dates listed below, within the State and Eastern District of California, and elsewhere, for the purpose of carrying out and executing the scheme and artifice to defraud customers and to obtain funds from customers and insurers, including UHC, Medicare, and Medi-Cal, as more fully set forth above, and attempting to do so, TIEU caused the mail matter described below to be placed in a post office or an authorized depository for mail matter, to be sent and delivered by the United States Postal Service, and knowingly caused to be delivered by mail according to the direction thereon:

| COUNT | APPROXIMATE DATE OF MAILING | DESCRIPTION |
|---|---|---|
| ONE | April 30, 2020 | Package containing Golden Sunrise Nutraceutical, Inc. products, mailed from Porterville, California to patient S.C. in West Covina, California, by United States Mail. |
| TWO | July 7, 2020 | Package containing Golden Sunrise Nutraceutical, Inc. products, mailed from Porterville, California to undercover FDA agent purporting to be health care provider in Kirkland, Washington |

All in violation of Title 18, United States Code, Section 1341.

COUNTS THREE THROUGH FIVE: [21 U.S.C. §§ 331(a) and 333(a)(2)– Introduction of Misbranded Drug Into Interstate Commerce with Intent to Defraud or Mislead]

The Grand Jury further charges:

HUU TIEU,

defendant herein, as follows:

41. Paragraphs 1 through 17 and 19 through 40 are hereby re-alleged and incorporated as though set forth in full herein.

42. Beginning on a date unknown to the grand jury but no later than March 30, 2020, TIEU began mailing the Emergency D-Virus Plan of Care, which consisted of a box containing various vials of Golden Sunrise products including ImunStem, to various practitioners, public officials, and other individuals both inside and outside the State and Eastern District of California. The boxes TIEU mailed also contained a paper copy of the Emergency D-Virus Pdf, including the misrepresentations described in paragraph 27 hereof. These shipments included shipments to public officials outside of California that attached a letter containing the following false statement: "These products have been approved by the Food and Drug Administration (FDA), and are listed in the "Regenerative Advance Therapy Designation." TIEU delivered the boxes into interstate commerce by mailing them by United States Mail from Porterville, California to various destinations outside of California. These shipments were mislabeled due to misrepresentations in the shipments themselves and misrepresentations TIEU made and caused to be made on the Golden Sunrise websites, by electronic mail, on social media, through in-

person and telephone communications, and through other means.

43. In addition to containing false and misleading labeling, the ImunStem contained in the Emergency D-Virus Plan of Care was also misbranded because it was a prescription drug that lacked adequate labeling. The Emergency D-Virus Pdf stated, "ADMINISTRATION OF IMUNSTEM, AKTIFFVATE, ANTERFEERON-1, and ANTERFEERON-2, SHOULD ALWAYS BE UNDER THE SUPERVISION OF A PHYSICIAN. RECOMMENDATION FOR GOLDEN SUNRISE NUTRACEUTICAL EMERGENCY D-VIRUS PLAN OF CARE IS BASED ON MEDICAL EVALUATION OF THE PATIENT." It also stated that ImunStem "was the first dietary supplement in the United States to be approved as a prescription medicine." As a prescription drug, the ImunStem contained in the Emergency D-Virus Plan of Care could not be adequately labeled and, accordingly, was mislabeled when shipped by TIEU.

44. The ImunStem, among other articles contained in the "Emergency D-Virus Plan of Care" was a "drug" as defined above because its intended use, as expressed in the labeling of the product and in TIEU's and others' representations elsewhere, was the treatment of "Serious or Life-threatening [Medical] Conditions," including COVID-19.

45. On or about the dates set forth below, in the State and Eastern District of California and elsewhere, defendant HUU TIEU did, with the intent to defraud and mislead, introduce and deliver for introduction into interstate commerce and cause to be introduced and delivered for introduction into interstate commerce in Porterville, California, a drug, ImunStem, that was misbranded within the meaning of 21 U.S.C. § 352(a)(1) and (f)(1) in that the labeling of the drug was false and misleading and inadequate as previously described.

| COUNT | APPROXIMATE DATE OF DELIVERY INTO INTERSTATE COMMERCE | MANNER OF DELIVERY | DRUG DELIVERED INTO INTERSTATE COMMERCE | LOCATION TO WHICH DRUG WAS MAILED |
|---|---|---|---|---|
| THREE | March 30, 2020 | U.S. Mail | ImunStem | 2 Woodward Ave., Suite 1126 Detroit, Michigan 48209 |
| FOUR | March 30, 2020 | U.S. Mail | ImunStem | P.O. Box 30013, Lansing, Michigan 48909 |
| FIVE | July 7, 2020 | U.S. Mail | ImunStem | 9805 NE 116th Street #7353 Kirkland, WA 98034 |

All in violation of 21 U.S.C. §§ 331(a) and 333(a)(2).

FORFEITURE ALLEGATION: [18 U.S.C. §§ 981(a)(1)(C), 982(a)(7), 21 U.S.C. § 334, and 28 U.S.C. § 2461(c) - Criminal Forfeiture]

23. Upon conviction of the offense alleged in Count One of this Indictment, the defendant shall forfeit to the United States, pursuant to Title 18, United States Code, Section 981(a)(1)(C) and 28 U.S.C. § 2461(c), any property, real or personal, that constitutes or is derived from proceeds traceable to a violation of the offense.

24. Upon conviction of the offenses alleged in Counts Two through Five of this Indictment, the defendant shall forfeit to the United States, pursuant to Title 18, United States Code, Section 982(a)(7), property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense.

25. Upon conviction of the offenses alleged in Counts Three through Five of this Indictment, the defendant shall forfeit to the United States, pursuant to Title 21, United States Code, Section 334 and Title 28, United States Code, Section 2461(c), any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale after shipment

in interstate commerce, and any drug that is a counterfeit drug, any container of a counterfeit drug, any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit drug or drugs, and any adulterated or misbranded device as a result of such offenses.

26. If any of the property described above, as a result of any act or omission of the defendant:

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 divided without difficulty,

the United States of America shall be entitled to forfeiture of any other property of the defendant, up to the value of the property subject to forfeiture, including but not limited to a personal forfeiture money judgment, pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Section 982(b), and 28 U.S.C. § 2461(c).

A TRUE BILL.

**/s/ Signature on file w/AUSA**

FOREPERSON

MCGREGOR W. SCOTT
United States Attorney