UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. JOHN WARRINGTON KOSOLCHAROEN, aka "John W. Kosolcharoen," aka "John Kosolcharoen," Defendant.	No. 8:24-cr-00088-FWS I N F O R M A T I O N [21 U.S.C. §§ 331(d), 333(a)(2), 355(a): Introducing an Unapproved New Drug into Interstate Commerce with Intent to Defraud]

The United States Attorney charges:

[21 U.S.C. §§ 331(d), 333(a)(2), and 355(a); 18 U.S.C. § 2]

I. INTRODUCTORY ALLEGATIONS

At all relevant times:

A. DEFENDANT AND RELATED ENTITIES

1. Defendant JOHN WARRINGTON KOSOLCHAROEN, also known as ("aka") "John W. Kosolcharoen," aka "John Kosolcharoen," was a resident of Irvine, California. Defendant KOSOLCHAROEN had no education, training, or experience in health care.

2. Liveyon LLC ("Liveyon") was a Nevada limited liability corporation, that defendant KOSOLCHAROEN caused to be incorporated on or about June 10, 2016, with its principal place of business in Yorba Linda, California. Defendant KOSOLCHAROEN was the founder, Chief Executive Officer ("CEO"), and sole owner of Liveyon. Liveyon was engaged in the business of distributing injectable products derived from human umbilical cord blood ("HUCB") for use in the treatment of medical conditions in humans. Liveyon later opened satellite clinics in Cancun, Mexico, Ho Chi Minh City, Vietnam, Jakarta, Indonesia, and other locations that also advertised, sold, and administered injectable products similar to those alleged herein below.

3. Genetech Inc. ("Genetech") was a California corporation that INDIVIDUAL ONE caused to be incorporated in the State of California on or about May 26, 2016, with its principal place of business in San Diego, California. Although, in a public filing, INDIVIDUAL ONE described Genetech as a "research lab," Genetech did not conduct any research. Instead, Genetech was formed and operated solely to produce injectable products derived from HUCB for exclusive distribution by Liveyon and its national salesforce under the product name, "ReGen Series" ("ReGen"). ReGen was sold to physicians, chiropractors, and other healthcare providers to administer to patients for non-research, clinical commercial profit to purportedly mitigate, treat, or cure a variety of human diseases and illnesses as more fully alleged herein below.

4. Genetech purchased the HUCB that it used to manufacture ReGen from SUPPLIER ONE, a blood bank located in Puerto Rico, an area identified by the U.S. Centers for Disease Control and Prevention

("CDC") as at high risk for transmission of the Zika virus, a mosquito-borne virus associated with serious flu-like symptoms and that can cause birth defects.

5. "Liveyon Premier," "Liveyon PremierMax," and "Liveyon Pure" were products (sometimes collectively referred to herein, together with ReGen, as "Liveyon Products") that Liveyon marketed as similar to, and as the successors of, ReGen, namely, products derived from HUCB for injection into humans.

B. APPLICABLE FEDERAL LAWS AND REGULATIONS

FDA Pre-Market Approval

6. The U.S. Food and Drug Administration ("FDA") was a federal agency within the U.S. Department of Health and Human Services. The FDA was responsible for, among other things, protecting public health by ensuring the safety and efficacy of human drugs and biological products.

7. Pursuant to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. ("FDCA"), the FDA regulated, among other things, the manufacture, labeling, and distribution of all drugs and, pursuant to the Public Health Service Act, 42 U.S.C. § 201 et seq. ("PHSA"), the FDA regulated, among other things, the manufacture, labeling, and distribution of all biological products that were shipped or received in interstate commerce.

8. A "drug" under the FDCA was defined as, among other things, any "article[] intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man[,]" any "article[] (other than food) intended to affect the structure or any function of the

body[,]" or any article intended for use as a component of any "drug." 21 U.S.C. §§ 321(g)(1)(B), (C), (D).

9. A "new drug" under the FDCA was defined as, among other things, "any drug . . . the composition of which is such that such drug 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 . . . ." 21 U.S.C. § 321(p)(1).

10. A "new drug" under the FDCA could not be introduced or delivered for introduction into interstate commerce unless the FDA had approved a New Drug Application ("NDA") or an Abbreviated New Drug Application ("ANDA") with respect to the new drug, or it qualified for an exemption as an Investigational New Drug. 21 U.S.C. §§ 355(a), 331(d). The manufacturer of a new drug was required to submit information in the NDA or ANDA showing to the FDA's satisfaction that its new drug was safe and effective for its intended use. 21 U.S.C. §§ 355(b)(1), (j), (l); 21 C.F.R. § 314.50.

11. A drug under the FDCA was also a "biological product" under the PHSA if it was, among other things, "blood, [or a] blood component or derivative . . . or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. § 262(i)(1).

12. Unless explicitly exempted by law or regulation, the PHSA prohibited any person from introducing into interstate commerce any drug, as defined under the FDCA, that was also a biological product unless there was a valid, approved biologics license application

("BLA") in effect for the product. 42 U.S.C. § 262(a)(1)(A). An application for a biologics license must have demonstrated that the product was "safe, pure, and potent," and "the facility in which the biological product [was] manufactured, processed, packed, or held me[t] standards designed to assure that the biological product continue[d] to be safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i)(I), (II).

13. Under 42 U.S.C. § 262(j), biological products for which a BLA had been approved and that met the FDCA's definition of a drug were exempt from compliance with the FDCA's "new drug" approval provisions. Biological products for which a BLA had not been approved that met the FDCA's definition of a drug were subject to the FDCA provision requiring all "new drugs" to have an approved NDA before the drug was marketed.

14. Biological products "containing or consisting of human cells or tissues that [were] intended for implantation, transplantation, infusion, or transfer into a human recipient" were classified as "human cells, tissues, or cellular or tissue-based products" or "HCT/Ps" and were subject to regulation under 21 C.F.R. part 1271. 21 C.F.R. § 1271.3(d). This definition explicitly included "hematopoietic stem/progenitor cells derived from peripheral and cord blood." Id.

15. The only stem-cell based products that had been approved by the FDA for allogeneic use (transplanting, infusing, or transferring from a donor into an unrelated recipient) consisted of blood-forming stem cells derived from HUCB. The FDA approved these products solely for use in treating patients with disorders that

affected the body system that was involved in the production of blood, such as leukemia, sickle-cell disease, or aplastic anemia.

16. Stem-cell based products that were intended to treat other conditions, including rheumatologic, neurologic, or orthopedic conditions such as joint problems, rheumatoid arthritis, lupus, Parkinson's disease, Alzheimer's disease, amyotrophic lateral sclerosis ("ALS" or "Lou Gehrig's disease"), erectile dysfunction, autism, a bulging or herniated disc, spinal cord injuries, or metabolic disorders such as Type II diabetes, were "drugs" under the FDCA and "biological products" under the PHSA. Because no BLA had been approved for such products, they were required to have an approved NDA before they were marketed.

Exemptions from FDA Pre-Market Approval

17. Notwithstanding the foregoing, the FDA did not require pre-market approval for the manufacturing or distribution of HCT/Ps where such products were to be used "solely for non-clinical scientific or educational purposes." 21 C.F.R. § 1271.15(a).

18. Similarly, where HCT/Ps met *each* of four specific criteria set forth at 21 C.F.R. § 1271.10(a) (the "section 361 criteria"), the FDA did not require pre-market approval for the manufacture or distribution of those products, and those products were regulated solely under section 361 of the PHSA.

19. One such section 361 criterion was that the HCT/P "[wa]s intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's [or distributor's] objective intent." 21 C.F.R. § 1271.10(a)(2). Such "labeling, advertising, or other indications of the manufacturer's

[or distributor's] objective intent" included written, printed, or graphic materials that supplemented or explained the product. Such indications of the manufacturer's objective intent also included Internet websites or advertising, sales presentations, brochures, directions for product use, and statements of company representatives.

20. The FDA defined "homologous use" as "the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor." 21 C.F.R. § 1271.3(c). In its guidance issued in November 2017, the FDA informed industry that for purposes of determining homologous use, the "[b]asic functions of a cellular or nonstructural tissue would generally be a metabolic or biochemical function, such as, hematopoietic, immune, and endocrine functions." HCT/Ps derived from HUCB were cellular or nonstructural tissues.

21. Another section 361 criterion was that the HCT/P did not "have a systemic effect and [wa]s not dependent upon the metabolic activity of living cells for its primary function" or that such HCT/Ps "ha[d] a systemic effect or [wa]s dependent upon the metabolic activity of living cells for its primary function" and was for autologous use[,] allogenic use in a first-degree or second-degree blood relative[,] or [wa]s for reproductive use." 21 C.F.R. § 1271.10(a)(4). "Autologous use" meant that the donor and recipient of an HCT/P were one and the same person. See 21 C.F.R. § 1271.3(a).

22. Establishments that manufactured, repackaged, relabeled, or distributed HCT/Ps that met an exemption stated above were

nonetheless required to register and list their HCT/Ps with the FDA within five days of beginning operation and were required to update their registration with the FDA annually each December. 21 C.F.R. § 1271.21.

C. WARNINGS KNOWN TO DEFENDANT KOSOLCHAROEN

23. For many years before defendant KOSOLCHAROEN was engaged in the manufacture or distribution of Liveyon Products, the FDA published readily available guidance and alerts about the safety and efficacy of HUCB as a source of stem cell products. For example, in 2014, the FDA stated in a website alert to consumers that:

> "Cord blood stored for use by a patient unrelated to the donor meets the legal definitions of both a 'drug' and a 'biological product.' Cord blood in this category must meet additional requirements and be licensed under a biologics license application, or be the subject of an investigational new drug application before use. The FDA requirements help to ensure that these products are safe and effective for their intended use[,]
>
> . . . [and
>
> "b]ecause cord blood contains stem cells, there have been stem cell fraud cases related to cord blood . . . "Consumers may think that stem cells can cure any disease, but science doesn't show this to be the case. Patients should be skeptical if cord blood is being promoted for uses other than blood stem cell regeneration."

https://www.fda.gov/consumers/consumer-updates/cord-blood-what-you-need-know (July 30, 2014)

24. Furthermore, in 2017, FDA cautioned that "if an HCT/P is intended for use as an unproven treatment for a myriad of diseases and conditions . . . the HCT/P is likely not intended for homologous use only" and, therefore, such HCT/P would not be exempt from pre-market approval. See, e.g., https://www.fda.gov/media/109176/download at note 21.

25. In addition to readily available FDA guidance and alerts, those who desired in good faith to manufacture and distribute stem cell products from HUCB could, before undertaking the time and expense of production or distribution, obtain a formal FDA decision regarding the regulatory identity or classification of an HCT/P, including whether such product(s) qualified for regulation solely under Section 361. See https://www.fda.gov/CombinationProducts/RFDProcess/default.htm.

26. Neither defendant KOSOLCHAROEN, nor anyone acting on his behalf, applied to the FDA for approval to manufacture or distribute Liveyon Products. As such, none of the Liveyon Products ever had an approved NDA, ANDA, or BLA in effect.

27. Similarly, neither defendant KOSOLCHAROEN, nor anyone acting on his behalf, sought input from the FDA to determine whether any of the Liveyon Products would meet any exemption for pre-market approval.

28. In or about July 2016, before the manufacture or distribution of any Liveyon Products, defendant KOSOLCHAROEN was advised by legal counsel that the Liveyon Products could not be lawfully distributed without FDA pre-market approval. In a written legal opinion provided to defendant KOSOLCHAROEN, his attorney advised him that the Liveyon Products did not meet the Section 361 criteria or the criteria for any other exemption from FDA pre-market approval.

29. Defendant KOSOLCHAROEN, and others known and unknown to the United States Attorney, well knew about the regulatory approval process associated with the lawful manufacture and distribution of

the Liveyon Products and understood that it would be lengthy and expensive. For example, defendant KOSOLCHAROEN, a self-described "Wikipedia junkie," remarked in a ReGen promotional video to INDIVIDUAL TWO, who became Liveyon's "Director of Medical Education," that, "after [my] first meeting with the attorneys[, I] found out that it takes two years . . . to actually get through the regulatory and standard operating procedures and validations to build [a] lab [to manufacture ReGen]," and that "I cried when I found out what it was going to cost to get to that point." https://liveyon.com/media/liveyon-pure-cast-who-is-liveyon-the-origin-story-e01/.

30. Further acknowledging his understanding of the lengthy and expensive pre-market approval process, defendant KOSOLCHAROEN falsely described Genetech as an *existing* stem cell product manufacturer from which Liveyon would obtain ReGen, stating in a similar Liveyon promotional video that "we had found a third-party manufacturer that already holds a [Current Good Manufacturing Practices] facility" and that "already had their [Standard Operating Procedures] in place [s]o it was real easy to have . . . scientists that we had doing our research . . . to give them our protocol to manufacture . . . [s]o we started out as Liveyon as a distributor . . . selling a third [party's] product . . . ." https://liveyon.com/media/liveyon-pure-cast-who-is-liveyon-the-origin-story-e01/.

31. In or about November 2016, before the distribution of any Liveyon Products, defendant KOSOLCHAROEN was advised by INDIVIDUAL THREE, an FDA regulatory expert hired by INDIVIDUAL ONE to provide advice regarding the manufacture and distribution of ReGen, that

ReGen could only lawfully be distributed "for research use only" or for use in specific therapeutic applications that had been approved by the FDA.

D. DEFENDANT KOSOLCHAROEN'S INTENT TO DEFRAUD AND MISLEAD THE FDA

32. To circumvent the federal regulatory requirements and release the Liveyon Products immediately into the market, defendant KOSOLCHAROEN actively undertook efforts to mislead the FDA about the nature of Liveyon's business activities and the uses for which the Liveyon Products were being marketed and distributed. For instance, defendant KOSOLCHAROEN ensured that every Liveyon purchase order included a disclaimer stating that the Liveyon Products were to be used "for research use only," "for research purposes, non-systemic and homologous use only," or similar language. Defendant KOSOLCHAROEN also caused the words "Research Only" to be included on the label for some Liveyon Products.

33. Because Liveyon distributed HCT/Ps in interstate commerce, the company was required to register with the FDA within five days of beginning operation. Defendant KOSOLCHAROEN, however, did not cause Liveyon to file an annual registration with the FDA until October 9, 2017, nearly a year after Liveyon began selling its products and *after* more than $5,000,000 worth of ReGen had been manufactured and distributed.

34. When defendant KOSOLCHAROEN finally caused Liveyon to submit a registration to the FDA in 2017, the registration contained numerous false statements, including: that Liveyon was not labeling product, that the Liveyon Products were not "HCT/Ps regulated as

drugs or biological drugs," that Liveyon was distributing HCT/Ps that met the section 361 criteria, and that Liveyon was engaged in "satellite distribution" only.

II. INTRODUCTION OF AN UNAPPROVED NEW DRUG INTO INTERSTATE COMMERCE

35. On or about September 12, 2018, in Orange County, within the Central District of California, and elsewhere, defendant KOSOLCHAROEN, aided and abetted by others known and unknown to the Grand Jury, with intent to defraud and mislead on material matters, introduced and delivered for introduction, and caused to be introduced and delivered for introduction, into interstate commerce, from Liveyon in Yorba Linda, California, to PHYSICIAN ONE, in Houston, Texas, ReGen, a stem cell product derived from human umbilical cord blood, which was an unapproved new drug within the

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meaning of 21 U.S.C. § 321(p)(1) in that it was not the subject of an approved marketing or investigation application on file with FDA as required by 21 U.S.C. § 355(a).

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