



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.

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

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

25 4. Genetech purchased the HUCB that it used to manufacture
26 ReGen from SUPPLIER ONE, a blood bank located in Puerto Rico, an area
27 identified by the U.S. Centers for Disease Control and Prevention
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1 ("CDC") as at high risk for transmission of the Zika virus, a
2 mosquito-borne virus associated with serious flu-like symptoms and
3 that can cause birth defects.

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

9 B. APPLICABLE FEDERAL LAWS AND REGULATIONS

10 *FDA Pre-Market Approval*

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

16 7. Pursuant to the Food, Drug, and Cosmetic Act, 21 U.S.C.
17 § 301 et seq. ("FDCA"), the FDA regulated, among other things, the
18 manufacture, labeling, and distribution of all drugs and, pursuant to
19 the Public Health Service Act, 42 U.S.C. § 201 et seq. ("PHSA"), the
20 FDA regulated, among other things, the manufacture, labeling, and
21 distribution of all biological products that were shipped or received
22 in interstate commerce.

23 8. A "drug" under the FDCA was defined as, among other things,
24 any "article[] intended for use in the diagnosis, cure, mitigation,
25 treatment, or prevention of disease in man[,]" any "article[]" (other
26 than food) intended to affect the structure or any function of the
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1 body[,]” or any article intended for use as a component of any
2 “drug.” 21 U.S.C. §§ 321(g)(1)(B), (C), (D).

3 9. A “new drug” under the FDCA was defined as, among other
4 things, “any drug . . . the composition of which is such that such
5 drug is not generally recognized, among experts qualified by
6 scientific training and experience to evaluate the safety and
7 effectiveness of drugs, as safe and effective for use under the
8 conditions prescribed, recommended, or suggested in the labeling
9 thereof” 21 U.S.C. § 321(p)(1).

10 10. A “new drug” under the FDCA could not be introduced or
11 delivered for introduction into interstate commerce unless the FDA
12 had approved a New Drug Application (“NDA”) or an Abbreviated New
13 Drug Application (“ANDA”) with respect to the new drug, or it
14 qualified for an exemption as an Investigational New Drug. 21 U.S.C.
15 §§ 355(a), 331(d). The manufacturer of a new drug was required to
16 submit information in the NDA or ANDA showing to the FDA’s
17 satisfaction that its new drug was safe and effective for its
18 intended use. 21 U.S.C. §§ 355(b)(1), (j), (l); 21 C.F.R. § 314.50.

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

24 12. Unless explicitly exempted by law or regulation, the PHSA
25 prohibited any person from introducing into interstate commerce any
26 drug, as defined under the FDCA, that was also a biological product
27 unless there was a valid, approved biologics license application
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1 ("BLA") in effect for the product. 42 U.S.C. § 262(a)(1)(A). An
2 application for a biologics license must have demonstrated that the
3 product was "safe, pure, and potent," and "the facility in which the
4 biological product [was] manufactured, processed, packed, or held
5 me[t] standards designed to assure that the biological product
6 continue[d] to be safe, pure, and potent." 42 U.S.C.
7 § 262(a)(2)(C)(i)(I), (II).

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

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

23 15. The only stem-cell based products that had been approved
24 by the FDA for allogeneic use (transplanting, infusing, or
25 transferring from a donor into an unrelated recipient) consisted of
26 blood-forming stem cells derived from HUCB. The FDA approved these
27 products solely for use in treating patients with disorders that
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1 affected the body system that was involved in the production of
2 blood, such as leukemia, sickle-cell disease, or aplastic anemia.

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

13 *Exemptions from FDA Pre-Market Approval*

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

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

23 19. One such section 361 criterion was that the HCT/P "[wa]s
24 intended for homologous use only, as reflected by the labeling,
25 advertising, or other indications of the manufacturer's [or
26 distributor's] objective intent." 21 C.F.R. § 1271.10(a)(2). Such
27 "labeling, advertising, or other indications of the manufacturer's
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1 [or distributor's] objective intent" included written, printed, or
2 graphic materials that supplemented or explained the product. Such
3 indications of the manufacturer's objective intent also included
4 Internet websites or advertising, sales presentations, brochures,
5 directions for product use, and statements of company
6 representatives.

7 20. The FDA defined "homologous use" as "the repair,
8 reconstruction, replacement, or supplementation of a recipient's
9 cells or tissues with an HCT/P that performs the same basic function
10 or functions in the recipient as in the donor." 21 C.F.R.
11 § 1271.3(c). In its guidance issued in November 2017, the FDA
12 informed industry that for purposes of determining homologous use,
13 the "[b]asic functions of a cellular or nonstructural tissue would
14 generally be a metabolic or biochemical function, such as,
15 hematopoietic, immune, and endocrine functions." HCT/Ps derived from
16 HUCB were cellular or nonstructural tissues.

17 21. Another section 361 criterion was that the HCT/P did not
18 "have a systemic effect and [wa]s not dependent upon the metabolic
19 activity of living cells for its primary function" or that such
20 HCT/Ps "ha[d] a systemic effect or [wa]s dependent upon the metabolic
21 activity of living cells for its primary function" and was for
22 autologous use[,] allogenic use in a first-degree or second-degree
23 blood relative[,] or [wa]s for reproductive use." 21 C.F.R.
24 § 1271.10(a)(4). "Autologous use" meant that the donor and recipient
25 of an HCT/P were one and the same person. See 21 C.F.R. § 1271.3(a).

26 22. Establishments that manufactured, repackaged, relabeled,
27 or distributed HCT/Ps that met an exemption stated above were
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1 nonetheless required to register and list their HCT/Ps with the FDA
 2 within five days of beginning operation and were required to update
 3 their registration with the FDA annually each December. 21 C.F.R.
 4 § 1271.21.

5 C. WARNINGS KNOWN TO DEFENDANT KOSOLCHAROEN

6 23. For many years before defendant KOSOLCHAROEN was engaged
 7 in the manufacture or distribution of Liveyon Products, the FDA
 8 published readily available guidance and alerts about the safety and
 9 efficacy of HUCB as a source of stem cell products. For example, in
 10 2014, the FDA stated in a website alert to consumers that:

11 "Cord blood stored for use by a patient unrelated to the
 12 donor meets the legal definitions of both a 'drug' and a
 13 'biological product.' Cord blood in this category must
 14 meet additional requirements and be licensed under a
 15 biologics license application, or be the subject of an
 16 investigational new drug application before use. The FDA
 17 requirements help to ensure that these products are safe
 18 and effective for their intended use[,]

19 . . . [and

20 "because cord blood contains stem cells, there have been
 21 stem cell fraud cases related to cord blood . . .
 22 "Consumers may think that stem cells can cure any disease,
 23 but science doesn't show this to be the case. Patients
 24 should be skeptical if cord blood is being promoted for
 25 uses other than blood stem cell regeneration."

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

28 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.

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

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

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

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

25 29. Defendant KOSOLCHAROEN, and others known and unknown to
26 the United States Attorney, well knew about the regulatory approval
27 process associated with the lawful manufacture and distribution of
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1 the Liveyon Products and understood that it would be lengthy and
2 expensive. For example, defendant KOSOLCHAROEN, a self-described
3 "Wikipedia junkie," remarked in a ReGen promotional video to
4 INDIVIDUAL TWO, who became Liveyon's "Director of Medical Education,"
5 that, "after [my] first meeting with the attorneys[, I] found out
6 that it takes two years . . . to actually get through the regulatory
7 and standard operating procedures and validations to build [a] lab
8 [to manufacture ReGen]," and that "I cried when I found out what it
9 was going to cost to get to that point."

10 [https://liveyon.com/media/liveyon-pure-cast-who-is-liveyon-the-
origin-story-e01/](https://liveyon.com/media/liveyon-pure-cast-who-is-liveyon-the-
11 origin-story-e01/).

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

24 31. In or about November 2016, before the distribution of any
25 Liveyon Products, defendant KOSOLCHAROEN was advised by INDIVIDUAL
26 THREE, an FDA regulatory expert hired by INDIVIDUAL ONE to provide
27 advice regarding the manufacture and distribution of ReGen, that
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1 ReGen could only lawfully be distributed "for research use only" or
2 for use in specific therapeutic applications that had been approved
3 by the FDA.

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

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

17 33. Because Liveyon distributed HCT/Ps in interstate commerce,
18 the company was required to register with the FDA within five days of
19 beginning operation. Defendant KOSOLCHAROEN, however, did not cause
20 Liveyon to file an annual registration with the FDA until October 9,
21 2017, nearly a year after Liveyon began selling its products and
22 after more than \$5,000,000 worth of ReGen had been manufactured and
23 distributed.

24 34. When defendant KOSOLCHAROEN finally caused Liveyon to
25 submit a registration to the FDA in 2017, the registration contained
26 numerous false statements, including: that Liveyon was not labeling
27 product, that the Liveyon Products were not "HCT/Ps regulated as
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1 drugs or biological drugs," that Liveyon was distributing HCT/Ps that
2 met the section 361 criteria, and that Liveyon was engaged in
3 "satellite distribution" only.

4 **II. INTRODUCTION OF AN UNAPPROVED NEW DRUG INTO INTERSTATE COMMERCE**

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

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

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5 E. MARTIN ESTRADA
6 United States Attorney

BRYAN M. BOYNTON
Principal Deputy Assistant
Attorney General

7
8 
9 MACK E. JENKINS
10 Assistant United States
11 Attorney
12 Chief, Criminal Division

ARUN G. RAO
Deputy Assistant Attorney General

AMANDA N. LISKAMM
Director, Consumer Protection
Branch, United States Department
of Justice

11 KRISTEN A. WILLIAMS
12 Assistant United States
13 Attorney
14 Chief, Major Frauds Section

ROSS S. GOLDSTEIN
Assistant Director, Consumer
Protection Branch, United States
Department of Justice

14 MARK AVEIS
15 Assistant United States
16 Attorney
17 Major Frauds Section

MEREDITH B. HEALY
KATHRYN A. SCHMIDT
PETER J. LEININGER
Trial Attorneys
Consumer Protection Branch
United States Department of
Justice

17 DAVID H. CHAO
18 Assistant United States
19 Attorney
20 Deputy Chief, General Crimes
21 Section