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18 UNITED STATES OF AMERICA

19 UNITED STATES DISTRICT COURT

20 FOR THE CENTRAL DISTRICT OF CALIFORNIA

21 UNITED STATES OF AMERICA,

22 Plaintiff,

23 v.

24 JOHN WARRINGTON KOSOLCHAROEN,
aka "John Kosolcharoen" and
25 "John W. Kosolcharoen,"

26 Defendant.
27
28

No. 8:24-cr-00088-FWS

PLEA AGREEMENT FOR DEFENDANT JOHN
WARRINGTON KOSOLCHAROEN

1 1. This constitutes the plea agreement between JOHN WARRINGTON
2 KOSOLCHAROEN, also known as ("aka") John Kosolcharoen, aka John W.
3 Kosolcharoen ("defendant"), the United States Department of Justice,
4 Consumer Protection Branch ("CPB"), and the United States Attorney's
5 Office for the Central District of California ("USAO," and
6 collectively with CPB, the "Government"), in the investigation of
7 defendant's conduct related to the manufacturing, marketing, and
8 distribution of stem cell products. This agreement is limited to the
9 Government and cannot bind any other federal, state, local, or
10 foreign prosecuting, enforcement, administrative, or regulatory
11 authorities.

12 DEFENDANT'S OBLIGATIONS

13 2. Defendant agrees to:

14 a. Give up the right to indictment by a grand jury and,
15 at the earliest opportunity requested by the Government and provided
16 by the Court, appear and plead guilty to an Information in the form
17 attached to this agreement as Exhibit A, or a substantially similar
18 form, which charges defendant with one count of introducing and
19 causing the introduction of an unapproved new drug into interstate
20 commerce with intent to defraud or mislead, in violation of 21 U.S.C.
21 §§ 331(d), 333(a)(2), and 355(a).

22 b. Not contest facts agreed to in this agreement.

23 c. Abide by all agreements regarding sentencing contained
24 in this agreement.

25 d. Make restitution in accordance with the Court's order.

26 e. Appear for all court appearances, surrender as ordered
27 for service of sentence, obey all conditions of any bond, and obey
28 any other ongoing court order in this matter.

1 f. Not commit any crime; however, offenses that would be
2 excluded for sentencing purposes under United States Sentencing
3 Guidelines ("USSG" or "Sentencing Guidelines") § 4A1.2(c) are not
4 within the scope of this agreement.

5 g. Be truthful at all times with the United States
6 Probation and Pretrial Services Office and the Court.

7 h. Pay the applicable special assessment at or before the
8 time of sentencing unless defendant has demonstrated a lack of
9 ability to pay such assessment.

10 i. Defendant agrees that any and all criminal debt
11 ordered by the Court will be due in full and payable immediately.
12 The Government is not precluded from pursuing, in excess of any
13 payment schedule set by the Court, any and all available remedies by
14 which to satisfy defendant's payment of the full financial
15 obligation, including referral to the Treasury Offset Program.

16 j. Authorize the Government to obtain a credit report
17 immediately upon defendant's entry of a guilty plea.

18 k. Consent to the Government inspecting and copying all
19 of defendant's financial documents and financial information held by
20 the United States Probation and Pretrial Services Office.

21 l. Complete the Financial Disclosure Statement on a form
22 provided by the USAO and, within 30 days of defendant's entry of a
23 guilty plea, deliver the signed and dated statement, along with all
24 of the documents requested therein, to the USAO by either email at
25 usacac.FinLit@usdoj.gov or mail to the USAO Financial Litigation
26 Section at 300 N. Los Angeles St., Suite 7516, Los Angeles, CA 90012.
27 Defendant agrees that defendant's ability to pay criminal debt shall
28 be assessed based on the completed Financial Disclosure Statement and

1 all required supporting documents, as well as other relevant
2 information relating to ability to pay.

3 m. Defendant understands and agrees that he will be
4 prohibited from engaging in the business of manufacturing, marketing,
5 selling, or distributing any products that are subject to the
6 provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.
7 § 301 *et. seq.*, pursuant to U.S.S.G. § 5F1.5 and 18 U.S.C.
8 §§ 3563(b)(5), 3583(d).

9 THE GOVERNMENT'S OBLIGATIONS

10 3. The Government agrees to:

11 a. Not contest facts agreed to in this agreement.

12 b. Abide by all agreements regarding sentencing contained
13 in this agreement.

14 c. At the time of sentencing, provided that defendant
15 demonstrates an acceptance of responsibility for the offense up to
16 and including the time of sentencing, recommend a two-level reduction
17 in the applicable Sentencing Guidelines offense level, pursuant to
18 USSG § 3E1.1, and recommend and, if necessary, move for an additional
19 one-level reduction if available under that section.

20 NATURE OF THE OFFENSE

21 4. Defendant understands that for defendant to be guilty of
22 the crime charged in the Information, namely, introducing or causing
23 the introduction of an unapproved new drug into interstate commerce
24 with intent to defraud or mislead, in violation of 21 U.S.C.
25 §§ 331(d), 333(a)(2), and 355(a), the following must be true: (1) the
26 stem cell product sold under various brand names including "ReGen"
27 and "Pure" (sometimes referred to herein as the "Product" or
28 "Products"), more fully described in the factual basis attached

1 hereto as Exhibit B, was a "drug" within the meaning of 21 U.S.C.
2 § 321(g)(1); (2) the Product was a "new drug" within the meaning of
3 21 U.S.C. § 321(p)(1); (3) defendant introduced or caused the
4 introduction of the Product into interstate commerce; (4) the Product
5 was an unapproved new drug within the meaning of 21 U.S.C. § 355(a);
6 and (5) defendant acted with intent to defraud or mislead on material
7 matters, that is, the intent to deceive and cheat.

8 PENALTIES AND RESTITUTION

9 5. Defendant understands that the statutory maximum sentence
10 that the Court can impose for a violation of Title 21, United States
11 Code, Sections 331(d), 333(a)(2), and 355(a), introducing or causing
12 the introduction of an unapproved new drug into interstate commerce
13 with intent to defraud or mislead, a felony, as charged in the
14 Information, is: three years' imprisonment; a fine of \$10,000; a one-
15 year period of supervised release; and a mandatory special assessment
16 of \$100.

17 6. Defendant agrees to make full restitution to the victim(s)
18 of the offense to which defendant is pleading guilty. Defendant
19 agrees that, in return for the USAO's compliance with its obligations
20 under this agreement, the Court may order restitution to persons
21 other than the victim(s) of the offense to which defendant is
22 pleading guilty and in amounts greater than those alleged in the
23 count to which defendant is pleading guilty. In particular,
24 defendant agrees that the Court may order restitution to any victim
25 of any of the following for any losses suffered by that victim as a
26 result: (a) any relevant conduct, as defined in U.S.S.G. § 1B1.3, in
27 connection with the offense to which defendant is pleading guilty.

1 7. Defendant understands that supervised release is a period
2 of time following imprisonment during which defendant will be subject
3 to various restrictions and requirements. Defendant understands that
4 if defendant violates one or more of the conditions of any supervised
5 release imposed, defendant may be returned to prison for all or part
6 of the term of supervised release authorized by statute for the
7 offense that resulted in the term of supervised release, which could
8 result in defendant serving a total term of imprisonment greater than
9 the statutory maximum stated above.

10 8. Defendant understands that, by pleading guilty, defendant
11 may be giving up valuable government benefits and valuable civic
12 rights, such as the right to vote, the right to possess a firearm,
13 the right to hold office, and the right to serve on a jury.
14 Defendant understands that he is pleading guilty to a felony and that
15 it is a federal crime for a convicted felon to possess a firearm or
16 ammunition. Defendant understands that the conviction in this case
17 may also subject defendant to various other collateral consequences,
18 including but not limited to revocation of probation, parole, or
19 supervised release in another case, and suspension or revocation of a
20 professional license. Defendant understands that unanticipated
21 collateral consequences will not serve as grounds to withdraw
22 defendant's guilty plea.

23 9. Defendant and his counsel have discussed the fact that, and
24 defendant understands that, if defendant is not a United States
25 citizen, the conviction in this case makes it practically inevitable
26 and a virtual certainty that defendant will be removed or deported
27 from the United States. Defendant may also be denied United States
28 citizenship and admission to the United States in the future.

1 Defendant understands that while there may be arguments that
2 defendant can raise in immigration proceedings to avoid or delay
3 removal, removal is presumptively mandatory and a virtual certainty
4 in this case. Defendant further understands that removal and
5 immigration consequences are the subject of a separate proceeding and
6 that no one, including his attorney or the Court, can predict to an
7 absolute certainty the effect of his conviction on his immigration
8 status. Defendant nevertheless affirms that he wants to plead guilty
9 regardless of any immigration consequences that his plea may entail,
10 even if the consequence is automatic removal from the United States.

11 FACTUAL BASIS

12 10. Defendant admits that defendant is, in fact, guilty of the
13 offense to which defendant is agreeing to plead guilty. Defendant
14 and the Government agree to the statement of facts attached hereto as
15 Exhibit B, and further agree that this statement of facts is
16 sufficient to support a plea of guilty to the charge alleged in the
17 Information and as described in this agreement and to establish the
18 Sentencing Guidelines factors set forth in paragraph 12 below.
19 However, defendant acknowledges that the statement of facts in
20 Exhibit B is not meant in any way to be a complete recitation of all
21 facts relevant to defendant's criminal conduct or all facts known to
22 either party that relate to that conduct.

23 SENTENCING FACTORS

24 11. Defendant understands that in determining defendant's
25 sentence, the Court is required to calculate the applicable
26 Sentencing Guidelines range and to consider that range, possible
27 departures under the Sentencing Guidelines, and the other sentencing
28 factors set forth in 18 U.S.C. § 3553(a). Defendant understands that

1 the Sentencing Guidelines are advisory only, that defendant cannot
 2 have any expectation of receiving a sentence within the calculated
 3 Sentencing Guidelines range, and that after considering the
 4 Sentencing Guidelines and the other § 3553(a) factors, the Court will
 5 be free to exercise its discretion to impose any sentence it finds
 6 appropriate up to the maximum set by statute for the crime of
 7 conviction.

8 12. Defendant and the Government agree to the following
 9 applicable Sentencing Guidelines factors:

| | | | |
|----|--------------------------|-----|-------------------------------|
| 10 | Base Offense Level: | 6 | [USSG §§ 2N2.1, 2B1.1] |
| 11 | Loss (between | | |
| 12 | \$1.5 and \$3.5 million) | +16 | [USSG § 2B1.1(b) (1) (I)] |
| 13 | More than 10 victims | +2 | [USSG § 2B1.1(b) (2) (A) (i)] |
| 14 | Commission on release | +3 | [USSG § 3C1.3] |

15 The Government will agree to a two-level downward adjustment for
 16 acceptance of responsibility (and, if applicable, move for an
 17 additional one-level downward adjustment under USSG § 3E1.1(b)) only
 18 if the conditions set forth in paragraphs 2 and 3(c) are met and if
 19 defendant has not committed, and refrains from committing, acts
 20 constituting obstruction of justice within the meaning of USSG
 21 § 3C1.1, as discussed below. Defendant and the Government agree not
 22 to seek, argue, or suggest in any way, either orally or in writing,
 23 that any other specific offense characteristics, adjustments, or
 24 departures relating to the offense level be imposed. Defendant
 25 agrees, however, that if, after signing this agreement but prior to
 26 sentencing, defendant were to commit an act, or the Government were
 27 to discover a previously undiscovered act committed by defendant
 28 prior to signing this agreement, which act, in the judgment of the

1 Government, constituted obstruction of justice within the meaning of
2 USSG § 3C1.1, the Government would be free to seek the enhancement
3 set forth in that section and to argue that defendant is not entitled
4 to a downward adjustment for acceptance of responsibility under USSG
5 § 3E1.1.

6 13. Defendant understands that there is no agreement as to
7 defendant's criminal history or criminal history category.

8 14. Defendant and the Government reserve the right to argue
9 for a sentence outside the sentencing range established by the
10 Sentencing Guidelines based on the factors set forth in 18 U.S.C.
11 §§ 3553(a)(1), (a)(2), (a)(3), (a)(6), and (a)(7).

12 WAIVER OF CONSTITUTIONAL RIGHTS

13 15. Defendant understands that by pleading guilty, defendant
14 gives up the following rights:

15 The right to persist in a plea of not guilty.

16 The right to a speedy and public trial by jury.

17 The right to be represented by counsel -- and if necessary have
18 the Court appoint counsel -- at trial. Defendant understands,
19 however, that defendant retains the right to be represented by
20 counsel -- and if necessary have the Court appoint counsel -- at
21 every other stage of the proceeding.

22 The right to be presumed innocent and to have the burden of
23 proof placed on the Government to prove defendant guilty beyond a
24 reasonable doubt.

25 The right to confront and cross-examine witnesses against
26 defendant.

1 The right to testify and to present evidence in opposition to
2 the charge, including the right to compel the attendance of witnesses
3 to testify.

4 The right not to be compelled to testify, and, if defendant
5 chose not to testify or present evidence, to have that choice not be
6 used against defendant.

7 Any and all rights to pursue any affirmative defenses, Fourth
8 Amendment or Fifth Amendment claims, and other pretrial motions that
9 have been filed or could be filed.

10 WAIVER OF STATUTE OF LIMITATIONS

11 16. Having been fully advised by defendant's attorney
12 regarding application of the statute of limitations to the offense to
13 which defendant is pleading guilty, defendant hereby knowingly,
14 voluntarily, and intelligently waives, relinquishes, and gives up:
15 (a) any right that defendant might have not to be prosecuted for the
16 offense to which defendant is pleading guilty because of the
17 expiration of the statute of limitations for that offense prior to
18 the filing of the information alleging that offense; and (b) any
19 defense, claim, or argument defendant could raise or assert that
20 prosecution of the offense to which defendant is pleading guilty is
21 barred by the expiration of the applicable statute of limitations,
22 pre-indictment delay, or any speedy trial violation.

23 WAIVER OF APPEAL OF CONVICTION

24 17. Defendant understands that, with the exception of an appeal
25 based on a claim that defendant's guilty plea was involuntary, by
26 pleading guilty defendant is waiving and giving up any right to
27 appeal defendant's conviction on the offense to which defendant is
28 pleading guilty. Defendant understands that this waiver includes,

1 but is not limited to, arguments that any of the statutes to which
2 defendant is pleading guilty are unconstitutional, and any and all
3 claims that the statement of facts provided herein is insufficient to
4 support defendant's plea of guilty.

5 LIMITED MUTUAL WAIVER OF APPEAL OF SENTENCE

6 18. Defendant agrees that, provided the Court imposes a total
7 term of imprisonment on the count of conviction of no more than the
8 statutory maximum, defendant gives up the right to appeal all of the
9 following: (a) the procedures and calculations used to determine and
10 impose any portion of the sentence; (b) the term of imprisonment
11 imposed by the Court, provided it is within the statutory maximum;
12 (c) the fine imposed by the Court, provided it is within the
13 statutory maximum; (d) to the extent permitted by law, the
14 constitutionality or legality of defendant's sentence, provided it is
15 within the statutory maximum; (e) the amount and terms of any
16 restitution order; (f) the term of probation or supervised release
17 imposed by the Court, provided it is within the statutory maximum;
18 and (g) any of the following conditions of probation or supervised
19 release imposed by the Court: the conditions set forth in Amended
20 General Order 20-04 of this Court; the drug testing conditions
21 mandated by 18 U.S.C. §§ 3563(a)(5) and 3583(d); and the alcohol and
22 drug use conditions authorized by 18 U.S.C. § 3563(b)(7).

23 19. The Government agrees that, provided all portions of the
24 sentence are within the statutory maximum specified above, the
25 Government gives up its right to appeal any portion of the sentence.

26 RESULT OF WITHDRAWAL OF GUILTY PLEA

27 20. Defendant agrees that if, after entering a guilty plea
28 pursuant to this agreement, defendant seeks to withdraw and succeeds

1 in withdrawing defendant's guilty plea on any basis other than a
2 claim and finding that entry into this plea agreement was
3 involuntary, then the Government will be relieved of all of its
4 obligations under this agreement.

5 EFFECTIVE DATE OF AGREEMENT

6 21. This agreement is effective upon signature and execution
7 of all required certifications by defendant, defendant's counsel, an
8 Assistant United States Attorney, and a Consumer Protection Branch
9 Attorney.

10 BREACH OF AGREEMENT

11 22. Defendant agrees that if defendant, at any time after the
12 effective date of this agreement, knowingly violates or fails to
13 perform any of defendant's obligations under this agreement ("a
14 breach"), the Government may declare this agreement breached. All of
15 defendant's obligations are material, a single breach of this
16 agreement is sufficient for the Government to declare a breach, and
17 defendant shall not be deemed to have cured a breach without the
18 express agreement of the Government in writing. If the Government
19 declares this agreement breached, and the Court finds such a breach
20 to have occurred, then: (a) if defendant has previously entered a
21 guilty plea pursuant to this agreement, defendant will not be able to
22 withdraw the guilty plea, and (b) the Government will be relieved of
23 all its obligations under this agreement.

24 COURT AND THE UNITED STATES PROBATION AND PRETRIAL SERVICES

25 OFFICE NOT PARTIES

26 23. Defendant understands that the Court and the United States
27 Probation and Pretrial Services Office are not parties to this
28 agreement and need not accept any of the Government's sentencing

1 recommendations or the parties' agreements to facts or sentencing
2 factors.

3 24. Defendant understands that both defendant and the
4 Government are free to: (a) supplement the facts by supplying
5 relevant information to the United States Probation and Pretrial
6 Services Office and the Court; (b) correct any and all factual
7 misstatements relating to the Court's Sentencing Guidelines
8 calculations and determination of sentence; and (c) argue on appeal
9 and collateral review that the Court's Sentencing Guidelines
10 calculations and the sentence it chooses to impose are not error,
11 although each party agrees to maintain its view that the calculations
12 in paragraph 12 are consistent with the facts of this case. While
13 this paragraph permits both the Government and defendant to submit
14 full and complete factual information to the United States Probation
15 and Pretrial Services Office and the Court, even if that factual
16 information may be viewed as inconsistent with the facts agreed to in
17 this agreement, this paragraph does not affect defendant's and the
18 Government's obligations not to contest the facts agreed to in this
19 agreement.

20 25. Defendant understands that even if the Court ignores any
21 sentencing recommendation, finds facts or reaches conclusions
22 different from those agreed to, and/or imposes any sentence up to the
23 maximum established by statute, defendant cannot, for that reason,
24 withdraw defendant's guilty plea, and defendant will remain bound to
25 fulfill all defendant's obligations under this agreement. Defendant
26 understands that no one -- not the prosecutor, defendant's attorney,
27 or the Court -- can make a binding prediction or promise regarding
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1 the sentence defendant will receive, except that it will be within
2 the statutory maximum.

3 NO ADDITIONAL AGREEMENTS

4 26. Defendant understands that, except as set forth herein,
5 there are no promises, understandings, or agreements between the
6 Government and defendant or defendant's attorney, and that no
7 additional promise, understanding, or agreement may be entered into
8 unless in a writing signed by all parties or on the record in court.

9 //

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11 //

PLEA AGREEMENT PART OF THE GUILTY PLEA HEARING

27. The parties agree that this agreement will be considered part of the record of defendant's guilty plea hearing as if the entire agreement had been read into the record of the proceeding.

AGREED AND ACCEPTED

FOR THE UNITED STATES OF AMERICA:

E. MARTIN ESTRADA
United States Attorney for the
Central District of California

Mark Aveis

7/12/2024

MARK AVEIS
DAVID H. CHAO
Assistant United States Attorneys

Date

AMANDA N. LISKAMM
Director
U.S. Department of Justice
Consumer Protection Branch

Meredith B. Healy

07/12/2024

ROSS S. GOLDSTEIN
Assistant Director
MEREDITH B. HEALY
KATHRYN A. SCHMIDT
PETER J. LEININGER
Trial Attorneys

Date

John W Kosolcharoen

7/11/24

JOHN W. KOSOLCHAROEN
Defendant

Date

Michael G. Freedman

7/11/24

MICHAEL FREEDMAN
Counsel for Defendant

Date

CERTIFICATION OF DEFENDANT

I have read this agreement in its entirety. I have had enough time to review and consider this agreement, and I have carefully and thoroughly discussed every part of it with my attorney. I understand the terms of this agreement, and I voluntarily agree to those terms. I have discussed the evidence with my attorney, and my attorney has advised me of my rights, of possible pretrial motions that might be filed, of possible defenses that might be asserted either prior to or at trial, of the sentencing factors set forth in 18 U.S.C. § 3553(a), of relevant Sentencing Guidelines provisions, and of the consequences of entering into this agreement. No promises, inducements, or representations of any kind have been made to me other than those contained in this agreement. No one has threatened or forced me in any way to enter into this agreement. I am satisfied with the representation of my attorney in this matter, and I am pleading guilty because I am guilty of the charge and wish to take advantage of the promises set forth in this agreement, and not for any other reason.



JOHN WARRINGTON KOSOLCHAROEN
Defendant

7/11/24

Date

CERTIFICATION OF DEFENDANT'S ATTORNEY

I am John Warrington Kosolcharoen's attorney. I have carefully and thoroughly discussed every part of this agreement with my client. Further, I have fully advised my client of his rights, of possible pretrial motions that might be filed, of possible defenses that might be asserted either prior to or at trial, of the sentencing factors set forth in 18 U.S.C. § 3553(a), of relevant Sentencing Guidelines provisions, and of the consequences of entering into this agreement. To my knowledge: no promises, inducements, or representations of any kind have been made to my client other than those contained in this agreement; no one has threatened or forced my client in any way to enter into this agreement; my client's decision to enter into this agreement is an informed and voluntary one; and the factual basis set forth in this agreement is sufficient to support my client's entry of a guilty plea pursuant to this agreement.

Michael J. Freedman

7/11/24

MICHAEL FREEDMAN
Attorney for Defendant
JOHN WARRINGTON KOSOLCHAROEN

Date

Exhibit A (Information)

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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. SA CR

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:

At all relevant times:

A. DEFENDANT AND RELATED ENTITIES

1. Defendant JOHN WARRINGTON KOSOLCHAROEN, also known as ("aka") "John W. Kosolcharoen," aka "John Kosolcharoen" ("defendant 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

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

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

23 4. Genetech purchased the HUCB that it used to manufacture
24 ReGen from SUPPLIER ONE, a blood bank located in Puerto Rico, an area
25 identified by the U.S. Centers for Disease Control and Prevention
26 ("CDC") as at high risk for transmission of the Zika virus, a
27
28

1 mosquito-borne virus associated with serious flu-like symptoms and
2 that can cause birth defects.

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

8 B. APPLICABLE FEDERAL LAWS AND REGULATIONS

9 *FDA Pre-Market Approval*

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

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

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

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

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

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

22 12. Unless explicitly exempted by law or regulation, the PHSA
23 prohibited any person from introducing into interstate commerce any
24 drug, as defined under the FDCA, that was also a biological product
25 unless there was a valid, approved biologics license application
26 ("BLA") in effect for the product. 42 U.S.C. § 262(a) (1) (A). An
27 application for a biologics license must have demonstrated that the
28

1 product was "safe, pure, and potent," and "the facility in which the
2 biological product [was] manufactured, processed, packed, or held
3 me[t] standards designed to assure that the biological product
4 continue[d] to be safe, pure, and potent." 42 U.S.C.
5 § 262(a)(2)(C)(i)(I), (II).

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

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

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

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

11 *Exemptions from FDA Pre-Market Approval*

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

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

21 19. One such section 361 criterion was that the HCT/P "[wa]s
22 intended for homologous use only, as reflected by the labeling,
23 advertising, or other indications of the manufacturer's [or
24 distributor's] objective intent." 21 C.F.R. § 1271.10(a)(2). Such
25 "labeling, advertising, or other indications of the manufacturer's
26 [or distributor's] objective intent" included written, printed, or
27 graphic materials that supplemented or explained the product. Such
28

1 indications of the manufacturer's objective intent also included
2 Internet websites or advertising, sales presentations, brochures,
3 directions for product use, and statements of company
4 representatives.

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

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

24 22. Establishments that manufactured, repackaged, relabeled,
25 or distributed HCT/Ps that met an exemption stated above were
26 nonetheless required to register and list their HCT/Ps with the FDA
27
28

1 within five days of beginning operation and were required to update
 2 their registration with the FDA annually each December. 21 C.F.R.
 3 § 1271.21.

4 C. WARNINGS KNOWN TO DEFENDANT KOSOLCHAROEN

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

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

18 . . . [and

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

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

27 24. Furthermore, in 2017, FDA cautioned that "if an HCT/P is
 28 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
28

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

13 30. Further acknowledging his understanding of the lengthy and
14 expensive pre-market approval process, defendant KOSOLCHAROEN falsely
15 described Genetech as an *existing* stem cell product manufacturer from
16 which Liveyon would obtain ReGen, stating in a similar Liveyon
17 promotional video that "we had found a third-party manufacturer that
18 already holds a [Current Good Manufacturing Practices] facility" and
19 that "already had their [Standard Operating Procedures] in place [s]o
20 it was real easy to have . . . scientists that we had doing our
21 research . . . to give them our protocol to manufacture . . . [s]o we
22 started out as Liveyon as a distributor . . . selling a third
23 [party's] product" [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-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
28

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 FDA

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

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

23 34. When defendant KOSOLCHAROEN finally caused Liveyon to
24 submit a registration to the FDA in 2017, the registration contained
25 numerous false statements, including: that Liveyon was not labeling
26 product, that the Liveyon Products were not "HCT/Ps regulated as
27 drugs or biological drugs," that Liveyon was distributing HCT/Ps that
28

1 met the section 361 criteria, and that Liveyon was engaged in
2 "satellite distribution" only.

COUNT ONE

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

35. The United States Attorney re-alleges paragraphs 1 through 34 of this Information.

36. 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 or 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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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).

4
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6 United States Attorney

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Attorney General

7
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Exhibit B (Stipulated Factual Basis)

I. Defendant, His Businesses, and Others

At all times relevant to the Information in this case:

Defendant was a resident of Irvine, California and the founder, Chief Executive Officer ("CEO"), and sole owner of Liveyon LLC ("Liveyon"). Liveyon was a Nevada limited liability corporation that defendant caused to be incorporated on or about June 10, 2016, with its principal place of business initially in Irvine, California, and later, in Yorba Linda, California.

Individual 1 caused Genetech, Inc. ("Genetech") to be incorporated in the State of California on or about May 26, 2016, with its principal place of business in San Diego, California. Individual 1 operated Genetech at the direction of defendant for the purpose of manufacturing ReGen, an injectable stem cell product made from human umbilical cord blood, for exclusive distribution by Liveyon and its sales force to physicians to administer to patients to purportedly treat a variety of human diseases and illnesses as more fully described below.

Individual 2 was variously identified in Liveyon's promotional materials, including as Liveyon's "Director of Medical Education."

In June 2016, defendant raised substantially all the capital to start and operate Genetech. Defendant did not contribute any significant amount of his own money. Beginning on approximately June 21, 2016, and continuing through May 8, 2023, defendant was released under Title 18, United States Code, Chapter 207, in another federal criminal case.

1 **II. Manufacture and Distribution of ReGen and Other Liveyon Products**

2 Beginning in or about May 2016, and continuing to in or about
3 April 2019, in Orange County, within the Central District of
4 California, and elsewhere, defendant, together with others known and
5 unknown to the United States Attorney, fraudulently introduced and
6 caused the introduction of ReGen and other stem cell-derived Liveyon
7 Products, including Pure, into interstate commerce, as unapproved new
8 drugs under the Federal Food, Drug, and Cosmetic Act and applicable
9 U.S. Food and Drug Administration ("FDA") regulations, knowing of the
10 following, among other things:

11 1. Defendant caused Genetech to be created and operated as if
12 it were a business separate from Liveyon in order to insulate
13 defendant and others from civil and criminal responsibility from
14 Genetech's purportedly separate operations. In fact, defendant knew
15 that Genetech and Liveyon were essentially one and the same and
16 formed and operated in concert solely to manufacture and distribute
17 ReGen. To further the sham distinction between Genetech and Liveyon,
18 defendant caused the preparation and execution of a distribution
19 agreement between Genetech and Liveyon to create the appearance that
20 Liveyon was an arms-length, non-collusive distributor of ReGen.

21 2. In or about July 2016, defendant had retained legal counsel
22 and had been advised by such counsel that ReGen could not be
23 manufactured or distributed without premarket approval by the FDA.
24 Defendant chose to ignore his counsel's advice and sold ReGen and
25 other Liveyon Products without premarket approval, thereby assuming
26 the risk of FDA regulatory enforcement action or criminal
27 prosecution.

28 3. In or about November 2016, defendant and others had been

1 advised by Individual 3, an FDA regulatory expert, that ReGen could
2 only be distributed for research use or for specific therapeutic
3 applications that had been approved by the FDA.

4 4. On or about November 15, 2016, defendant used Liveyon
5 Purchase Order No. 0001, that falsely stated that ReGen was sold "for
6 research purposes only for investigational uses," to document the
7 first sale of ReGen for non-research, clinical use in human patients
8 for commercial profit.

9 5. On or about November 22, 2016, defendant caused to be
10 distributed to a Liveyon sales associate for the associate's use in
11 soliciting prospective physician customers to buy ReGen for non-
12 research, clinical use for commercial profit, a blank form Liveyon
13 purchase invoice that falsely stated that "[b]y signing this purchase
14 order you, you [sic] acknowledge [sic] that the FDA has not approved
15 any stem cell-based products for use, other than cord blood-derived
16 hematopoietic progenitor cells (blood forming stem cells) for certain
17 indications and that Liveyon cells are sold for research purposes
18 only for investigational uses. Liveyon makes absolutly [sic] no
19 claims on any forms of succesful [sic] treatments."

20 6. Defendant did not cause Liveyon to file its required annual
21 registration with the FDA until on or about October 9, 2017, nearly a
22 year after Liveyon began selling ReGen and *after* more than \$5,000,000
23 worth of ReGen had been manufactured and distributed.

24 7. Defendant also intended to mislead FDA by causing a Liveyon
25 employee to include numerous false statements in the company's
26 registration submission to the FDA, including: that Liveyon was not
27 labeling product, that Liveyon Products were not "HCT/Ps regulated as
28 drugs or biological drugs," that Liveyon was distributing HCT/Ps that

1 met certain criteria (the "section 361 criteria") that excepted them
2 from FDA pre-market approval requirements, and that Liveyon was
3 engaged in "satellite distribution only" of human umbilical cord
4 blood ("HUCB") products for allogeneic use when, in truth and in
5 fact, Liveyon was the sole distributor of ReGen that defendant caused
6 Genetech to manufacture exclusively for Liveyon to be distributed to
7 clinician-customers of Liveyon for treatment of their patients.

8 8. Defendant and others prepared, caused to be prepared, and
9 distributed and caused to be distributed marketing materials to
10 physicians, other health care providers, and prospective patients,
11 that included attractive brochures, "cinematics" (video commercials),
12 and a website (www.liveyon.com) that falsely touted that Liveyon
13 Products were exempt from FDA premarket approval and that
14 fraudulently misrepresented and concealed material facts about ReGen,
15 including, but not limited to, the following:

16 i. ReGen was suitable "for the treatment of conditions
17 like: chronic pain, respiratory disorders and lung disease, athletic
18 injuries, spinal cord injuries and other orthopedic conditions,
19 Parkinson's, ALS, Alzheimer's and other neurological diseases,
20 cosmetic/aesthetic issues, diabetes, heart diseases and
21 cardiovascular conditions, rheumatoid arthritis, Crohn's disease,
22 Lupus, and other autoimmune disorders, orthodontics, dermatological
23 disorders, and more," notwithstanding, among other things, that there
24 was no credible medical or scientific evidence that ReGen had been
25 shown to successfully treat any such conditions and notwithstanding
26 that the FDA had only approved the use of stem cell products like
27 ReGen to treat a limited number of blood-related diseases.

28 ii. "Liveyon provides high-quality, fully-tested, and

1 screened stem cells to physicians for use in stem cell therapies . .
2 . ,” notwithstanding that, among other things, ReGen, by Liveyon’s
3 expert’s own admissions, did not contain stem cells at or near the
4 quantity that Liveyon represented, and that ReGen was neither high-
5 quality nor properly tested in that, among other things, Genetech
6 personnel tested ReGen for sterility by holding ReGen vials up to the
7 light to determine the presence of bacteria instead of sending ReGen
8 to an independent testing laboratory according to industry standards.

9 iii. “Our adult, non-embryonic stem cells are sourced
10 from umbilical cord blood donated” from “hospitals” or “safe hospital
11 sources,” notwithstanding that ReGen was substantially made from HUCB
12 obtained from a non-hospital birthing center in Puerto Rico from
13 donors who may have been exposed to or were vectors for Zika virus
14 and who were not screened for such virus.

15 iv. ReGen was “[a] Safe and Highly-Regulated Product” and
16 that “[u]mbilical cord donation is regulated by the American
17 Association of Tissue Banks (“AATB”) for quality, safety and
18 ethics[,]” notwithstanding that AATB did not regulate or accredit
19 entities involved in HUCB harvesting or donation and that neither
20 Liveyon, Genetech, nor its Puerto Rico-based HUCB supplier had even
21 sought accreditation from AATB for anything associated with the
22 manufacture or distribution of ReGen.

23 v. ReGen was manufactured by “GeneTech Laboratory - San
24 Diego’s only sterile, FDA compliant stem cell lab,” notwithstanding
25 that Genetech was not a going concern prior to its formation at the
26 borrowed funding and direction of defendant, had no track record for
27 manufacturing any drugs, much less ReGen, and was not an FDA-
28 compliant stem cell lab.

1 vi. ReGen would "put the spark back in your life" through
2 the use of ReGen's HUCB to "stimulate regeneration within your body"
3 because ReGen was "safe[,] effective[, and] non-invasive,"
4 notwithstanding that ReGen had yet to be shown to provide any such
5 clinical results.

6 9. Defendant and others fraudulently induced Liveyon customers
7 into purchasing other stem cell-derived Liveyon Products that were
8 ReGen's successors, including Liveyon's "Premier," "PremierMax," and
9 "Pure," by, among other things, falsely reporting and concealing
10 material facts regarding the outcome of an FDA inspection of Liveyon
11 and nationwide recall of ReGen, by misleading the public about the
12 severity and cause of adverse events suffered by Liveyon patients who
13 were administered ReGen, and by hosting seminars to promote ReGen's
14 successor products that were functionally identical to ReGen and
15 equally ineligible for FDA premarket approval, among other problems.

16 **III. INTRODUCTION OF AN UNAPPROVED NEW DRUG INTO INTERSTATE COMMERCE**
17 **WITH INTENT TO DEFRAUD**

18 In addition to the above-stated facts that are incorporated
19 herein by this reference, on or about September 12, 2018, defendant,
20 knowingly and with intent to defraud as to material matters,
21 introduced and delivered for introduction into interstate commerce,
22 namely by FedEx, from Liveyon, in Yorba Linda, California, to
23 Physician 1, in Houston, Texas, an unapproved new drug namely, ReGen,
24 for non-research, clinical use for commercial profit, together with
25 Liveyon Purchase Order No. 5991 that falsely stated that "Liveyon
26 cells are sold for research purposes only."
27
28

1 **IV. CONSEQUENCES OF THE OFFENSE**

2 Defendant agrees that, for the purposes of establishing the
3 Sentencing Guidelines factors applicable to the count of conviction,
4 as stated herein:

5 (1) The actual loss caused by defendant's offense conduct, and
6 all relevant conduct, is more than \$1,500,000 and not more than
7 approximately \$3,500,000. Defendant agrees that defendant is not
8 entitled to any further offsets against such amount based on cost of
9 goods sold or any other offsets or credits.

10 (2) ReGen was administered to well more than 10 patients to whom
11 defendant and others mass-marketed via Internet and social media
12 advertisements that falsely claimed that ReGen was a safe and
13 effective, cheaper, and less invasive treatment alternative to
14 surgery or other procedures for severe, serious, and chronic diseases
15 and disorders that had left patients feeling that they had no
16 options.

17
18 *John W Kosolcharoen*

7/11/24

19 _____
JOHN WARRINGTON KOSOLCHAROEN
20 Defendant

Date