

ORIGINAL

FILED IN OPEN COURT
U.S.D.C. Atlanta

SEP 28 2017

James N. Hatten, Clerk
By: Deputy Clerk *JNH*

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA

v.

JARED WHEAT,
JOHN BRANDON SCHOPP, AND
HI-TECH PHARMACEUTICALS,
INC.

UNDER SEAL

First Superseding Criminal
Indictment

No. 1:17-CR-0229

THE GRAND JURY CHARGES THAT:

Count One

Conspiracy to Commit Wire Fraud
(18 U.S.C. § 1349)

1. Beginning in or about March 2011, and continuing to on or about at least July 17, 2012, the exact dates being unknown, in the Northern District of Georgia and elsewhere, the defendants, JARED WHEAT, JOHN BRANDON SCHOPP, and HI-TECH PHARMACEUTICALS, INC., did knowingly and willfully combine, conspire, confederate, agree, and have a tacit understanding with each other and with other persons known and unknown to the Grand Jury to devise and intend to devise a scheme and artifice to defraud, and to obtain money and property by means of materially false and fraudulent pretenses and representations, and by the omission of material facts, well knowing and having reason to know that said pretenses and representations were and would be false and fraudulent when made and caused to be made and that said omissions were and would be material, and, in so doing, causing interstate wire communications

to be made in furtherance of the scheme and artifice to defraud, in violation of Title 18, United States Code, Section 1343.

Background

2. The United States Food and Drug Administration (“FDA”) is the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the Federal Food, Drug, and Cosmetic Act, Title 21, United States Code, Sections 301-399f (“FDCA”). The FDA ensures, among other things, that drugs are safe and effective for their intended uses and that drugs and foods bear labeling containing true and accurate information. The FDA’s responsibilities under the FDCA include regulating the manufacturing, labeling, and distribution of all drugs and foods shipped or received in interstate commerce.

3. HI-TECH PHARMACEUTICALS, INC. (“HI-TECH”) is a company incorporated in Georgia. HI-TECH manufactures and sells purported “dietary supplements,” which are regulated as a “food” by the FDA.

4. JARED WHEAT owns and operates HI-TECH. WHEAT serves as the Chief Executive Officer, Chief Financial Officer, and Secretary for HI-TECH.

5. JOHN BRANDON SCHOPP worked as the Director of Contract Manufacturing for HI-TECH.

Export Certificates

6. Businesses that export products from the United States are sometimes requested by foreign customers to supply “export certificates” for FDA-regulated

products. The FDA is not required by law to issue export certificates, although it does provide this service as agency resources permit.

7. Upon application by a food manufacturer, the FDA's Center for Food Safety and Nutrition ("CFSAN") will issue a "Certificate of Free Sale" for a particular food product, including a dietary supplement, indicating that the food product is marketed in the United States and eligible for export if certain statutory provisions are met.

Current Good Manufacturing Practice Compliance

8. Under the FDCA, a dietary supplement is deemed adulterated if it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice ("GMP") regulations. Because the FDA does not "certify" that dietary supplement manufacturers comply with current GMP regulations, in some instances dietary supplement manufacturers will seek GMP audit reports and certificates from third-party independent companies or bodies. Such GMP audit reports and certificates are sought by dietary supplement manufacturers as a means to, among other things, substantiate the quality of their products. In addition, some foreign countries will not allow the importation of dietary supplements from the United States without documentation that the dietary supplement manufacturer is GMP compliant.

Manner and Means

9. WHEAT, SCHOPP and HI-TECH sought to enrich themselves unjustly by distributing to prospective and current customers, via email, false, fraudulent, and misleading documents and representations

regarding the regulatory compliance of HI-TECH and its products, including false, fraudulent, and misleading FDA Certificates of Free Sale, GMP certificates, and GMP audit reports.

10. WHEAT and SCHOPP caused false and fraudulent documents purporting to be FDA Certificates of Free Sale to be delivered via email to customers and prospective customers of HI-TECH. In fact, the FDA had not issued Certificates of Free Sale to HI-TECH on the dates listed for the products identified therein. The purported Certificates of Free Sale transmitted via email by WHEAT and SCHOPP contained unauthorized signatures of government officials, as well as unauthorized government agency seals, to make them appear legitimate.

11. WHEAT and SCHOPP caused false and fraudulent GMP certificates and audit reports from a purported third-party independent auditor, "PharmaTech", to be delivered via email to customers and prospective customers of HI-TECH. For example, a GMP certificate delivered via email to customer M.M. on or about July 17, 2012, contained a forged and unauthorized signature of an individual with initials G.G., who was falsely identified on the certificate as a "General Manager" for PharmaTech. In fact, G.G. never worked for PharmaTech. In addition, the email communication to customer M.M. contained a material omission in that it failed to disclose that PharmaTech was not an independent third-party auditor of HI-TECH, but was actually operated and controlled by WHEAT himself.

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

Counts Two Through Three

Wire Fraud

(18 U.S.C. §§ 1343 and 2)

12. The Grand Jury re-alleges and incorporates by reference the factual allegations set forth above in paragraphs 1 through 11 as if fully set forth herein.

13. Beginning in or about March 2011, and continuing to on or about at least July 17, 2012, the exact dates being unknown, in the Northern District of Georgia and elsewhere, the defendants, JARED WHEAT, JOHN BRANDON SCHOPP and HI-TECH PHARMACEUTICALS, INC., aided and abetted by each other and others known and unknown to the Grand Jury, knowingly devised and intended to devise a scheme and artifice to defraud, and to obtain money and property by means of materially false and fraudulent pretenses and representations, and by the omission of material facts, well knowing and having reason to know that said pretenses and representations were and would be false and fraudulent when made and caused to be made and that said omissions were and would be material.

14. On or about the dates listed below for each count, in the Northern District of Georgia and elsewhere, the defendants WHEAT, SCHOPP, and HI-TECH, aided and abetted by each other and others known and unknown to the Grand Jury, for the purpose of executing and attempting to execute the aforementioned scheme and artifice to defraud, and to obtain money and property by means of false and fraudulent pretenses and representations, and by the omission of material facts, did, with intent to defraud, cause to be transmitted by means of wire communication in interstate and foreign commerce certain

writings, signs, signals and sounds, that is, the following email communications to a customer of HI-TECH identified by initials below:

COUNT	DATE	WIRE COMMUNICATION
2	7/17/2012	Email from WHEAT to customer M.M. transmitting false GMP certificate from PharmaTech
3	7/17/2012	Email from WHEAT to customer M.M. transmitting false GMP audit report from PharmaTech

All in violation of Title 18, United States Code, Sections 1343 and 2.

Count Four

Money Laundering Conspiracy
(18 U.S.C. § 1956(h))

15. The Grand Jury re-alleges and incorporates by reference the factual allegations set forth above in paragraphs 1 through 11 as if fully set forth herein.

16. Beginning in or about March 2011, and continuing to on or about at least July 25, 2012, the exact dates being unknown, in the Northern District of Georgia and elsewhere, the defendants, JARED WHEAT and HI-TECH PHARMACEUTICALS, INC., did knowingly combine, conspire, and agree with each other and with others, both known and unknown to the Grand Jury, to commit offenses against the United States in violation of Title 18, United States Code, Section 1957, to wit: to knowingly engage and attempt to engage in monetary transactions by, through, or to a financial institution, affecting interstate and foreign commerce, in criminally derived property of a value

greater than \$10,000, such property having been derived from a specified unlawful activity, that is, wire fraud, in violation of 18 U.S.C. § 1343; in violation of Title 18, United States Code, Section 1957.

All in violation of Title 18, United States Code, Section 1956(h).

Counts Five Through Nine

Money Laundering
(18 U.S.C. §§ 1957 and 2)

17. The Grand Jury re-alleges and incorporates by reference the factual allegations set forth above in paragraphs 1 through 11 as if fully set forth herein.

18. On or about the dates listed below for each count, in the Northern District of Georgia and elsewhere, the defendants, JARED WHEAT and HI-TECH PHARMACEUTICALS, INC., aided and abetted by each other and others known and unknown to the Grand Jury, did knowingly engage and attempt to engage in monetary transactions by, through or to a financial institution, affecting interstate commerce, as described below, each such transaction knowingly involving criminally derived property of a value greater than \$10,000, such property having been derived from a specified unlawful activity, that is, wire fraud, in violation of Title 18, United States Code, Section 1343, each transaction constituting a separate count as set forth below:

COUNT	DATE	MONETARY TRANSACTION
5	6/28/2012	Check #2080 issued from Chase Bank Account *0562 in the name of Affiliated Distribution to WHEAT in the amount of \$600,000
6	7/6/2012	Check #2112 issued from Chase Bank Account *0562 in the name of Affiliated Distribution to WHEAT in the amount of \$350,000
7	7/12/2012	Transfer of \$39,080.86 by WHEAT from Chase Bank Account *0562 in the name of Affiliated Distribution to Fifth Third Bank Account in the name of Elite Manufacturing
8	7/19/2012	Transfer of \$42,065.87 by WHEAT from Chase Bank Account *0562 in the name of Affiliated Distribution to Fifth Third Bank Account in the name of Elite Manufacturing
9	7/25/2012	Transfer of \$44,000 by WHEAT from Chase Bank Account *0562 in the name of Affiliated Distribution to Fifth Third Bank Account in the name of Elite Manufacturing

All in violation of Title 18, United States Code, Sections 1957 and 2.

Count Ten

Conspiracy to Introduce Misbranded Drugs into Interstate Commerce
(18 U.S.C. § 371)

19. The Grand Jury re-alleges and incorporates by reference the factual allegations set forth above in paragraphs 2 through 4 as if fully set forth herein.

20. From in or about July 2009 through at least in or about June 2014, in the Northern District of Georgia and elsewhere, the defendants, JARED WHEAT and HI-TECH PHARMACEUTICALS, INC., did knowingly and willfully combine, conspire, confederate, agree, and have a tacit understanding with each other and with other persons known and unknown to the Grand Jury, to introduce and

deliver for introduction, and cause to be introduced and delivered for introduction, into interstate commerce, with intent to defraud and mislead, a drug within the meaning of Title 21, United States Code, Section 321(g)(1)(C), that was misbranded under Title 21, United States Code, Section 352(a), in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2).

MANNER AND MEANS

The manner and means by which the defendants and others sought to accomplish the objects of the conspiracy included:

21. WHEAT caused HI-TECH to manufacture and produce, among other things, Choleldrene, which was labeled and marketed as a dietary supplement.

22. In fact, the Choleldrene manufactured and produced by HI-TECH, at the direction of WHEAT, contained lovastatin, the active ingredient in several FDA-approved prescription drugs. Lovastatin was not listed as an ingredient on HI-TECH's labeling of Choleldrene. Due to the presence of lovastatin, Choleldrene was not a "dietary supplement" under the FDCA, and instead was a "drug" because it was an article other than food intended to affect the structure or function of the human body.

23. WHEAT caused HI-TECH to distribute and sell Choleldrene with false and misleading labeling that failed to declare lovastatin as an ingredient.

OVERT ACTS

In furtherance of the conspiracy and to affect the objects thereof, the following overt acts, among others, were committed in the Northern District of Georgia and elsewhere, by at least one co-conspirator:

24. On or about September 17, 2009, WHEAT caused HI-TECH to distribute approximately 24 bottles of Choledrene to a customer in North Carolina.

25. On or about December 1, 2009, WHEAT caused HI-TECH to distribute approximately 36 bottles of Choledrene to a customer in Florida.

26. On or about December 6, 2010, WHEAT caused HI-TECH to distribute approximately 12 bottles of Choledrene to a customer in California.

27. On or about January 31, 2011, WHEAT caused HI-TECH to distribute approximately 36 bottles of Choledrene to a customer in Florida.

28. On or about September 12, 2012, WHEAT caused HI-TECH to distribute approximately 24 bottles of Choledrene to a customer in Louisiana.

29. On or about August 22, 2013, WHEAT caused HI-TECH to distribute approximately 1 bottle of Choledrene to a customer in Louisiana.

30. On or about November 8, 2013, WHEAT caused HI-TECH to distribute approximately 12 bottles of Choledrene to a customer in North Carolina.

31. On or about February 27, 2014, WHEAT caused HI-TECH to distribute approximately 24 bottles of Choledrene to a customer in Florida.

32. On or about May 22, 2014, WHEAT caused HI-TECH to distribute approximately 2 bottles of Choledrene to a customer in North Carolina.

33. On or about June 10, 2014, WHEAT caused HI-TECH to distribute approximately 2 bottles of Choleldrene to a customer in Texas.

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

Count Eleven

Introduction into Interstate Commerce of a Misbranded Drug
(21 U.S.C. §§ 331(a) and 333(a)(2), and 18 U.S.C. § 2)

34. The Grand Jury re-alleges and incorporates by reference the factual allegations set forth above in paragraphs 2 through 4, and 20 through 23, as if fully set forth herein.

35. On or about August 22, 2013, in the Northern District of Georgia and elsewhere, the defendants, JARED WHEAT and HI-TECH PHARMACEUTICALS, INC., aided and abetted by each other and others known and unknown to the Grand Jury, with the intent to defraud and mislead, did introduce and deliver for introduction, and cause the introduction and delivery for introduction, into interstate commerce from Georgia to Louisiana, of a drug, namely Choleldrene, that was misbranded within the meaning of Title 21, United States Code, Section 352(a), in that its labeling was false and misleading because it failed to list lovastatin as an ingredient.

All in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2), and Title 18, United States Code, Section 2.

Count Twelve

**Conspiracy to Manufacture and Distribute Controlled Substances
(21 U.S.C. § 846)**

36. The Grand Jury re-alleges and incorporates by reference the factual allegations set forth above in paragraphs 2 through 4 as if fully set forth herein.

37. Beginning in at least September 2016 through at least August 2017, in the Northern District of Georgia and elsewhere, the defendants, JARED WHEAT and HI-TECH PHARMACEUTICALS, INC., did knowingly and willfully combine, conspire, confederate, agree, and have a tacit understanding with each other and with other persons known and unknown to the Grand Jury, to knowingly and intentionally manufacture, distribute, and dispense, and possess with the intent to manufacture, distribute, and dispense, anabolic steroids, which are Schedule III Controlled Substances, in violation of Title 21, United States Code, Sections 841(a)(1) and (b)(1)(E).

MANNER AND MEANS

The manner and means by which the defendants and others sought to accomplish the objects of the conspiracy included:

38. WHEAT caused HI-TECH to manufacture and distribute purported "pro-hormone dietary supplements" for increased muscle gain, which in fact contained Schedule III Controlled anabolic steroids not properly declared as ingredients on the products' respective labeling.

39. For example, WHEAT caused HI-TECH to manufacture and distribute the following purported "dietary supplement" products, all of which contained Schedule III Controlled anabolic steroids:

- (a) Superdrol, which contained androstenedione, 4-androstenediol and/or 5-androstenediol, and boldione;
 - (b) Equibolin, which contained 4-androstenediol and/or 5-androstenediol;
 - (c) 1-AD, which contained boldione, androstenedione, 4-androstenediol and/or 5-androstenediol;
 - (d) 1-Testosterone, which contained boldione and androstenedione; and
 - (e) Androdiol, which contained 4-androstenediol and/or 5-androstenediol.
- All in violation of Title 21, United States Code, Section 846.

Counts Thirteen Through Fifteen

Manufacturing and Distributing Controlled Substances
(21 U.S.C. § 841(a)(1) and (b)(1)(E), and 18 U.S.C. § 2)

40. The Grand Jury re-alleges and incorporates by reference the factual allegations set forth above in paragraphs 2 through 4, and 37 through 39, as if fully set forth herein.

41. On or about the dates set forth below, each date constituting a separate count of the Indictment, in the Northern District of Georgia and elsewhere, the defendants, JARED WHEAT and HI-TECH PHARMACEUTICALS, INC., aided and abetted by each other and others known and unknown to the Grand Jury, did knowingly and intentionally manufacture, distribute, and dispense, and possess with the intent to manufacture, distribute, and dispense, purported “dietary supplement” products, which contained Schedule III Controlled anabolic steroids, as more fully described below:

COUNT	DATE	PRODUCTS/ SCHEDULE III CONTROLLED ANABOLIC STEROIDS
13	9/30/16	(a) 1-AD/androstanedione and boldione (b) 1-Testosterone/androstanedione and boldione (c) Androdiol/4-androstenediol and/or 5-androstenediol
14	10/10/16	(a) Superdrol/androstanedione (b) Equibolin/4-androstenediol and/or 5-androstenediol
15	8/21/17	(a) 1-AD/4-androstenediol and/or 5-androstenediol (b) Androdiol/4-androstenediol and/or 5-androstenediol (c) Superdrol/androstanedione, 4-androstenediol and/or 5-androstenediol, and boldione (d) Equibolin, 4-androstenediol and/or 5-androstenediol

All in violation of Title 21, United States Code, Section 841(a)(1) and (b)(1)(E), and Title 18, United States Code, Section 2.

Counts Sixteen Through Eighteen

Introducing Misbranded Drugs into Interstate Commerce
(21 U.S.C. §§ 331(a) and 333(a)(2), and 18 U.S.C. § 2)

42. The Grand Jury re-alleges and incorporates by reference the factual allegations set forth above in paragraphs 2 through 4, and 37 through 39, as if fully set forth herein.

43. On or about the dates set forth below, each date constituting a separate count of the Indictment, in the Northern District of Georgia and elsewhere, the defendants, JARED WHEAT and HI-TECH PHARMACEUTICALS, INC., aided and abetted by each other and others known and unknown to the Grand Jury, with the intent to defraud and mislead, did introduce and deliver for introduction, and cause the introduction and delivery for introduction, into interstate commerce, drugs that were misbranded within the meaning of Title 21, United States Code, Section 352(a), in that the drugs' respective labeling was false and misleading because such labeling failed to properly declare Schedule III Controlled anabolic steroids in the ingredients, as more fully described below:

COUNT	DATE	MISBRANDED DRUG/ SCHEDULE III CONTROLLED ANABOLIC STEROIDS NOT DECLARED AS INGREDIENT	SHIPMENT
16	9/30/16	(a) 1-AD/androstenedione and boldione (b) 1-Testosterone/androstenedione and boldione (c) Androdiol/4-androstenediol and/or 5-androstenediol	GA to FL

COUNT	DATE	MISBRANDED DRUG/ SCHEDULE III CONTROLLED ANABOLIC STEROIDS NOT DECLARED AS INGREDIENT	SHIPMENT
17	10/10/16	(a) Superdrol/androstanedione (b) Equibolin/ 4-androstenediol and/or 5-androstenediol	GA to FL
18	8/21/17	(a) 1-AD/4-androstenediol and/or 5-androstenediol (b) Androdiol/4-androstenediol and/or 5-androstenediol (c) Superdrol/ androstanedione, 4-androstenediol and/or 5-androstenediol, and boldione (d) Equibolin/ 4-androstenediol and/or 5-androstenediol	GA to NC

All in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2), and Title 18, United States Code, Section 2.

FORFEITURE PROVISION

44. Upon conviction of one or more of the offenses alleged in Counts One through Three of this Indictment, the defendants, JARED WHEAT, JOHN BRANDON SCHOPP, and HI-TECH PHARMACEUTICALS, INC., shall forfeit to the United States any property, real or personal, which constitutes or is derived from gross proceeds traceable to such violations, pursuant to Title 18, United States Code, Section 981(a)(1)(C) and Title 28, United States Code, Section

2461(c), including but not limited to a money judgment in the amount of the proceeds of the offenses.

45. Upon conviction of one or more of the money laundering offenses alleged in Counts Four through Nine of this Indictment, in violation of Title 18, United States Code, Sections 1956(h) and 1957, the defendants, JARED WHEAT and HI-TECH PHARMACEUTICALS, INC., shall forfeit to the United States any and all property, real or personal, involved in such offenses and all property traceable to such offenses, pursuant to Title 18, United States Code, Section 982(a)(1), including, but not limited to a money judgment in the amount of the proceeds of the offenses.

46. Upon conviction of one or more of the offenses alleged in Counts Twelve through Fifteen of this Indictment, the defendants, JARED WHEAT and HI-TECH PHARMACEUTICALS, INC., shall forfeit to the United States any property constituting or derived from proceeds obtained directly or indirectly as a result of the offenses and any property used or intended to be used, in any manner or part, to commit or facilitate the commission of the offenses, pursuant to Title 21, United States Code, Section 853, including, but not limited to a money judgment in the amount of the proceeds of the offenses.

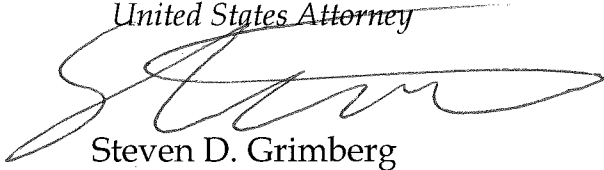
47. If, as a result of any act or omission of the defendants, JARED WHEAT, JOHN BRANDON SCHOPP, and HI-TECH PHARMACEUTICALS, INC., property subject to forfeiture cannot be located upon the exercise of due diligence; has been transferred to, sold to, or deposited with, a third party; has been placed beyond the jurisdiction of the court; has been substantially

diminished in value; or has been commingled with other property, which cannot be divided without difficulty, it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Section 982(b) and Title 28, United States Code, Section 2461(c), to seek forfeiture of any other property of the defendants up to the value of the forfeitable property.

A True BILL


FOREPERSON

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