

1 PHILLIP A. TALBERT
United States Attorney
2 JOSEPH D. BARTON
ARELIS M. CLEMENTE
3 HENRY Z. CARBAJAL III
4 Assistant United States Attorneys
2500 Tulare Street, Suite 4401
5 Fresno, CA 93721
Telephone: (559) 497-4000
6 Facsimile: (559) 497-4099

7 Attorneys for Plaintiff
8 United States of America



9
10 IN THE UNITED STATES DISTRICT COURT
11 EASTERN DISTRICT OF CALIFORNIA

12 UNITED STATES OF AMERICA,

13 Plaintiff,

14 v.

15 JIA BEI ZHU,
16 aka Jesse Zhu, Qiang He, and David He, and
17 ZHAOYAN WANG,

18 Defendants.

CASE NO. 1:23-cr-00219-NODJ-BAM

18 U.S.C. § 1349 – Conspiracy to Commit Wire
Fraud; 18 U.S.C. § 1343 – Wire Fraud; 21 U.S.C. §§
331(a) and 333(a)(2) – Distribution of Adulterated
and Misbranded Medical Devices; 18 U.S.C. §
1001(a)(2) – False Statements; 18 U.S.C. §
981(a)(1)(C) and 28 U.S.C. § 2461(c) –
Criminal Forfeiture

19
20 FIRST SUPERSEDING INDICTMENT

21 COUNT ONE: [18 U.S.C. § 1349 – Conspiracy to Commit Wire Fraud]

22 The Grand Jury charges:

23 JIA BEI ZHU, aka Jesse Zhu, Qiang He, and David He, and

24 ZHAOYAN WANG,

25 defendants herein, as follows:

26 I. INTRODUCTION

27 1. At all relevant times, defendants ZHU and WANG owned and controlled Ai De
28 Diagnostic Co. LTD (“Ai De”), which had its principal place of business in China, and Universal

1 Meditech Incorporated (“UMI”) and Prestige Biotech Incorporated (“PBI”), which had their principal
2 places of business in Fresno County, State and Eastern District of California.

3 2. At all relevant times, Ai De, UMI, and PBI were alter egos of one another.

4 **II. RELEVANT BACKGROUND ON THE FDA**

5 3. The Food and Drug Administration (“FDA”) is the federal agency that is responsible for
6 protecting the health and safety of the American public by enforcing the federal Food, Drug, and
7 Cosmetic Act (“FDCA”). Its responsibilities include regulating the distribution of medical devices in
8 interstate commerce to ensure that the devices are safe and effective for human use.

9 4. COVID-19 in vitro diagnostic test kits (“COVID-19 test kits”) collect, prepare, and
10 examine samples taken from the human body to detect diseases or other conditions in humans.
11 Therefore, COVID-19 test kits are medical devices under the FDCA.

12 5. Medical devices are classified into one of three categories: Class I, II, or III. Class III
13 medical devices are the most highly regulated.

14 6. Generally speaking, for Class III medical devices, anyone who proposes to introduce, or
15 deliver for introduction, such devices into interstate commerce for distribution is required to obtain pre-
16 market approval, pre-market clearance, emergency use authorization, or other approval from the FDA.

17 7. At all relevant times, COVID-19 test kits were Class III medical devices. Therefore,
18 obtaining pre-market approval, pre-market clearance, emergency use authorization, or other approval
19 from the FDA was required before distributing such test kits in the United States.

20 8. At all relevant times, any COVID-19 test kits distributed in the United States without
21 obtaining pre-market approval, pre-market clearance, emergency use authorization, or other applicable
22 approval from the FDA were adulterated and misbranded medical devices under the FDCA.

23 9. At all relevant times, any COVID-19 test kits whose packaging did not bear labels
24 containing the names and places of business of the actual manufacturers, packers, and distributors were
25 also misbranded medical devices under the FDCA.

26 **III. CONSPIRACY**

27 10. Beginning on a date unknown to the Grand Jury, but not later than in or around August
28 2020, and continuing at least until in or around March 2023, in Fresno and Tulare Counties, State and

1 Eastern District of California, and elsewhere, defendants ZHU and WANG, and others known and
2 unknown to the Grand Jury, did knowingly conspire, combine, and confederate with each other to cause
3 writings, signs, signals, pictures, and sounds to be transmitted by means of wire and radio
4 communications in interstate commerce, in furtherance of a material scheme and artifice to defraud
5 buyers of UMI and PBI's COVID-19 test kits, and to obtain money and property from the buyers, by
6 means of materially false and fraudulent pretenses, representations, and promises, in violation of 18
7 U.S.C. § 1343.

8 **IV. MANNER AND MEANS**

9 11. Defendants ZHU and WANG, and others known and unknown to the Grand Jury, carried
10 out their scheme and artifice to defraud by using the following manner and means, among others:

11 12. Defendants ZHU and WANG, and others known and unknown to the Grand Jury, caused
12 UMI and PBI to import COVID-19 test kits from Ai De that were manufactured in China. On forms
13 used for evaluation or inspection by United States Customs and Border Protection, they caused the
14 COVID-19 test kits to be falsely declared as pregnancy test kits. This was because Ai De was not
15 authorized by any federal agency to import COVID-19 test kits into the United States, but it was
16 authorized to import pregnancy test kits. Therefore, ZHU and WANG illegally imported COVID-19 test
17 kits from China by falsely representing and declaring that the test kits were authorized pregnancy
18 test kits.

19 13. Defendants ZHU and WANG, and others known and unknown to the Grand Jury, caused
20 false and fraudulent representations to be made to the buyers of UMI and PBI's COVID-19 test kits,
21 including but not limited to the following:

22 14. Defendants ZHU and WANG, and others known and unknown to the Grand Jury, caused
23 false and fraudulent representations to be made to the buyers of UMI and PBI's COVID-19 test kits, to
24 wit: that the test kits were manufactured in the United States. They knew, however, that the test kits
25 were manufactured in China.

26 15. Defendants ZHU and WANG, and others known and unknown to the Grand Jury, caused
27 false and fraudulent representations to be made to the buyers of UMI and PBI's COVID-19 test kits, to
28 wit: that the test kits were manufactured by, or in connection with, laboratories certified by the United

1 States Centers for Disease Control and Prevention (“CDC”). They knew, however, that the test kits
2 were not manufactured by, or in connection with, CDC-certified laboratories.

3 16. Defendants ZHU and WANG, and others known and unknown to the Grand Jury, caused
4 false and fraudulent representations to be made to the buyers of UMI and PBI’s COVID-19 test kits, to
5 wit: that UMI and PBI could manufacture up to 100,000 test kits per week in the United States. They
6 knew, however, that UMI did not have the capacity to make test kits at that rate and would have to
7 import additional test kits manufactured in China.

8 17. Defendants ZHU and WANG, and others known and unknown to the Grand Jury, caused
9 false and fraudulent representations to be made to the buyers of UMI and PBI’s COVID-19 test kits, to
10 wit: that UMI and PBI had obtained the required approvals from the FDA to distribute the test kits in the
11 United States. They knew, however, that UMI and PBI had not obtained any such approvals.

12 18. Defendants ZHU and WANG, and others known and unknown to the Grand Jury, caused
13 these false and fraudulent representations to be made to the buyers of UMI and PBI’s COVID-19 test
14 kits through various methods. Those methods included text messages, WeChat messages, WhatsApp
15 messages, emails, calls, in-person meetings, UMI and PBI’s websites, and contract documents.

16 19. When certain buyers of UMI and PBI’s COVID-19 test kits requested to inspect UMI and
17 PBI’s facilities in the United States pursuant to the terms of their contracts, defendants ZHU and
18 WANG, and others known and unknown to the Grand Jury, denied them access and fabricated reasons
19 for the denial. The fabricated reasons included that UMI and PBI’s facilities were undergoing
20 construction and renovation, and that the companies had proprietary and confidential information and
21 technology inside their facilities that they could not allow anyone else to see. In reality, however, they
22 did not want the buyers to know that UMI and PBI were obtaining the COVID-19 test kits from China.

23 20. The false and fraudulent representations that defendants ZHU and WANG, and others
24 known and unknown to the Grand Jury, caused to be made to the buyers of UMI and PBI’s COVID-19
25 test kits were important to the buyers. The buyers would not have made the purchases had they known
26 that the test kits were not manufactured in the United States and were instead manufactured in China
27 because this created quality and customs concerns for them. They also would not have made the
28 purchases had they known that the test kits were not manufactured by, or in connection with, CDC-

1 certified laboratories. Nor would they have made the purchases had they known that UMI and PBI
2 could not manufacture the test kits at the promised rates. Finally, they would not have made the
3 purchases had they known that the test kits were not approved by the FDA.

4 21. As a result of the false and fraudulent representations that defendants ZHU and WANG,
5 and others known and unknown to the Grand Jury, caused to be made to the buyers of UMI and PBI's
6 COVID-19 test kits, UMI and PBI sold hundreds of thousands of the test kits and received over
7 \$1,700,000 in payments. Many payments were made by interstate wire transfers sent from outside
8 California and deposited into UMI's bank accounts opened in Tulare County, State and Eastern District
9 of California.

10 22. At all relevant times, defendants ZHU and WANG, and others known and unknown to
11 the Grand Jury, acted with the intent to defraud.

12 All in violation of 18 U.S.C. § 1349.

13 COUNTS TWO THROUGH NINE: [18 U.S.C. § 1343 –Wire Fraud]

14 The Grand Jury further charges:

15 JIA BEI ZHU, aka Jesse Zhu, Qiang He, and David He,

16 and ZHAOYAN WANG,

17 defendants herein, as follows:

18 23. Paragraphs 1 through 9 and 11 through 22 are incorporated by reference as though fully
19 set forth herein.

20 24. Beginning on a date unknown to the Grand Jury, but not later than in or around August
21 2020, and continuing at least until in or around March 2023, in Fresno and Tulare Counties, State and
22 Eastern District of California, and elsewhere, defendants ZHU and WANG, knowingly devised,
23 intended to devise, participated in, and executed a material scheme and artifice to defraud the buyers of
24 UMI and PBI's COVID-19 test kits, and to obtain money and property from the buyers, by means of
25 materially false and fraudulent pretenses, representations, and promises.

26 25. On or about the dates set forth below, in Fresno and Tulare Counties, State and Eastern
27 District of California, and elsewhere, defendants ZHU and WANG, and others known and unknown to
28 the Grand Jury, for the purpose of executing their scheme and artifice to defraud, caused to be

1 transmitted, by means of wire and radio communication in interstate commerce, writings, signs, signals,
2 pictures, and sounds as follows:

Count	Date	Description
TWO	08/11/2020	Wire transmission of monies in the amount of \$12,000, originating from COMPANY ONE's bank account opened outside California, and sent to UMI's bank account ending - 9664 opened in Tulare County, State and Eastern District of California, that was processed on computers located outside of California through the Federal Reserve Bank's Wire Transfer Network ("Fedwire")
THREE	12/15/2020	Wire transmission of monies in the amount of \$100,000, originating from COMPANY TWO's bank account opened outside California, and sent to UMI's bank account ending - 9664 opened in Tulare County, State and Eastern District of California, that was processed on computers located outside of California through Fedwire
FOUR	12/24/2020	Wire transmission of monies in the amount of \$275,000, originating from COMPANY TWO's bank account opened outside California, and sent to UMI's bank account ending in - 9664 opened in Tulare County, State and Eastern District of California, that was processed on computers located outside of California through Fedwire
FIVE	01/13/2022	Wire transmission of monies in the amount of \$49,000, originating from COMPANY FOUR's bank account opened outside of California, and sent to UMI's bank account ending in - 9345 opened in Tulare County, State and Eastern District of California, that was processed on computers located outside of California through Fedwire
SIX	01/14/2022	Wire transmission of monies in the amount of \$24,500, originating from COMPANY FOUR's bank account opened outside of California, and sent to UMI's bank account ending in - 9345 opened in Tulare County, State and Eastern District of California, that was processed on computers located outside of California through Fedwire
SEVEN	01/14/2022	Wire transmission of monies in the amount of \$24,500, originating from COMPANY FOUR's bank account opened outside of California, and sent to UMI's bank account ending in - 9345 opened in Tulare County, State and Eastern District of California, that was processed on computers located outside of California through Fedwire
EIGHT	01/19/2022	Wire transmission of monies in the amount of \$43,000, originating from COMPANY FOUR's bank account opened outside of California, and sent to UMI's bank account ending in - 9345 opened in Tulare County, State and Eastern District of California, that was processed on computers located outside of California through Fedwire

1 2 3 4	NINE 01/26/2022	Wire transmission of monies in the amount of \$36,000, originating from COMPANY THREE's bank account opened outside of California, and sent to UMI's bank account ending in - 9345 opened at the same bank in Tulare County, State and Eastern District of California, that was processed internally by the bank.
------------------	------------------------	---

5 All in violation of 18 U.S.C. § 1343.

6 COUNTS TEN AND ELEVEN: [21 U.S.C. §§ 331(a) and 333(a)(2) – Distribution of Adulterated and
7 Misbranded Medical Devices]

8 The Grand Jury further charges:

9 JIA BEI ZHU, aka Jesse Zhu, Qiang He, and David He, and

10 ZHAOYAN WANG,

11 defendants herein, as follows:

12 27. Paragraphs 1 through 9, 14, 15, and 17 are incorporated by reference as though fully set
13 forth herein.

14 28. On or about the dates set forth below, in Fresno and Tulare Counties, State and Eastern
15 District of California, and elsewhere, defendants ZHU and WANG, with the intent to defraud and
16 mislead, caused to be introduced and delivered for introduction into interstate commerce, medical
17 devices that were adulterated and misbranded as follows:

19	Count	Date	From	Sent To	Medical Devices
20	TEN	01/15/22	UMI in Fresno	COMPANY FIVE in Southern California and then to COMPANY FOUR in Texas	Approximately 10,000 COVID-19 test kits
21					
22					
23	ELEVEN	01/26/22	UMI in Fresno	COMPANY THREE in Texas	Approximately 10,000 COVID-19 test kits
24					
25					

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

1 COUNT TWELVE: [18 U.S.C. § 1001(a)(2) – False Statements]

2 The Grand Jury further charges:

3 JIA BEI ZHU, aka Jesse Zhu, Qiang He, and David He,
4 defendant herein, as follows:

5 29. On or about May 2, 2023, and May 3, 2023, in Fresno County, State and Eastern District
6 of California, defendant ZHU did willfully and knowingly make materially false, fictitious, and
7 fraudulent statements and representations in a matter within the jurisdiction of the executive branch of
8 the government of the United States, to wit: defendant ZHU made materially false, fictitious, and
9 fraudulent statements and representations to FDA officials, including that:

- 10 a. He was not defendant ZHU aka Jesse Zhu and was instead Qiang He aka David He;
11 b. He was hired by UMI as a COVID-19 consultant in 2021;
12 c. He was hired by PBI just a couple of weeks prior to speaking with the FDA officials to
13 coordinate the company's interactions with government agencies;
14 d. He did not know the manufacturing and distribution histories for UMI or PBI; and
15 e. He did not have access to UMI or PBI's distribution records, financial records, or
16 ownership records.

17 All in violation of 18 U.S.C. § 1001(a)(2).
18

19 FORFEITURE ALLEGATION: 18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461(c) – Criminal Forfeiture

20 30. Upon conviction of one or more of the offenses alleged in Counts One through Nine of
21 this First Superseding Indictment, defendants ZHU and WANG shall forfeit to the United States,
22 pursuant to 18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461(c), all property, real and personal, which
23 constitutes or is derived from proceeds traceable to such violations, including, but not limited to, a sum
24 of money equal to the amount of money that constitutes or is derived from proceeds traceable to the
25 offenses for which the defendants are convicted.

26 31. If any property subject to forfeiture as a result of the offenses alleged in Counts One
27 through Nine of this First Superseding Indictment for which the defendants are convicted:

- 28 a. cannot be located upon the exercise of due diligence;

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

- b. has been transferred or sold to, or deposited with, a third party;
- c. has been placed beyond the jurisdiction of the court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property that cannot be divided without difficulty;

the United States intends, pursuant to 28 U.S.C. § 2461(c), incorporating 21 U.S.C. § 853(p), to seek forfeiture of any other property of the defendants, up to the value of the property subject to forfeiture

A TRUE BILL.
/s/ Signature on file w/AUSA
FOREPERSON

PHILLIP A. TALBERT
United States Attorney
HENRY Z. CARBAJAL for

KIMBERLY A. SANCHEZ,
Assistant United States Attorney
Chief, Fresno Office