UNITED STATES DISTRICT COURT

for the

Eastern District of California

SEALED

FILED
Oct 18, 2023
CLERK, U.S. DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

United States of America
v.
JIA BEI ZHU, aka Jesse Zhu, Qiang He, and David He

Case No. **1:23-mj-00123-SKO**

Defendant(s)

CRIMINAL COMPLAINT

I, the complainant in this case, state that the following is true to the best of my knowledge and belief.

On or about the date(s) of December 2020 to March 2023 in the county of Fresno in the Eastern District of California, the defendant(s) violated:

Code Section	*Offense Description*
21 U.S.C. §§ 331(a) and (c)	Misbranded medical devices
18 U.S.C. §§ 1001(a)(1)-(3)	False statements

This criminal complaint is based on these facts:

See attached affidavit, which is incorporated by reference as though fully set forth herein.

☑ Continued on the attached sheet.

Jeffrey Maurice - S
Digitally signed by Jeffrey Maurice -S
Date: 2023.10.17 09:59:28 -07'00'

Complainant's signature

Jeffrey Maurice, FDA-OCI Special Agent

Printed name and title

Sworn to me under oath by telephone pursuant to FRCP 4.1

Date: 10/18/2023

Sheila K. Oberto

Judge's signature

City and state: Fresno, California

Hon. Sheila K. Oberto, U.S. Magistrate Judge

Printed name and title

AFFIDAVIT OF JEFFREY A. MAURICE

I, Jeffrey A. Maurice, being duly sworn, hereby depose and state as follows:

Introduction and Agent Background

1. I am a Special Agent with the United States Food and Drug Administration ("FDA") – Office of Criminal Investigations (together, "FDA OCI") and have been so employed since April 2018. Prior to my employment with FDA OCI, I was a Special Agent with the Internal Revenue Service, Criminal Investigations, for over eight years. I have participated in several criminal investigations involving violations of the federal Food, Drug, and Cosmetic Act, federal mail, wire, and health care fraud statutes, federal tax code, federal money laundering statutes, and other federal laws. I successfully completed the FDA OCI Special Agent Training course in Charleston, South Carolina, and completed an additional legal course regarding the federal Food, Drug, and Cosmetic Act.

2. I make this affidavit in support of an application for a criminal complaint and arrest warrant for Jia Bei Zhu, aka Jesse Zhu, Qiang He, and David He, for manufacturing and distributing misbranded medical devices in violation of the federal Food, Drug, and Cosmetic Act at 21 U.S.C. §§ 331(a) and (c). I also make this affidavit in support of an application for a criminal complaint and arrest warrant for Zhu for making false statements to the FDA in violation of the federal false statements statute at 18 U.S.C. §§ 1001(a)(1), (a)(2), and (a)(3).

3. The facts in this affidavit come from my personal observations, training and experience, and information obtained from other agents and witnesses involved in this case. This affidavit is meant to show that there is probable cause for the requested complaint and arrest warrant. It does not set forth all of my knowledge about this case.

Applicable Law

Federal Food, Drug, and Cosmetic Act

4. The FDA is the federal agency charged with protecting the health and safety of the American public by enforcing the federal Food, Drug, and Cosmetic Act ("FDCA"). The FDA's responsibilities under the FDCA include regulating the manufacture, labeling, and distribution of medical devices in interstate commerce. This ensures that medical devices are safe and effective for human use.

5. For the purposes of the FDCA, the following definitions apply:

a. Interstate commerce means, in relevant part, commerce between any state or territory, and any place outside thereof. 21 U.S.C. § 321(b);

b. A person includes any individual, partnership, corporation, and association. 21 U.S.C. § 321(e);

c. Label means any display of written, printed, or graphic matter upon the immediate container of any article. 21 U.S.C. § 321(k);

d. Labeling is a broader term, and means all labels and other printed or graphic matter upon any article, or any of its containers or wrappers, or accompanying such article. 21 U.S.C. § 321(m). Accompanying an article does not require physical attachment to the article. If the article and information are part of an integrated distribution program, and the information is textually related to the article and how to use the article, it may be labeling. So, for example, customer testimonials and reviews shared by a distributor on its website, that are related to the intended use for the article, may be labeling;

e. Intended use of an article means the objective intent of the persons legally responsible for the labeling of that article. The intent is determined by the persons' expressions and may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, and oral and written statements by such persons or their representatives. It may also be shown by the circumstances where the article is, with the knowledge of such persons, offered and used for a purpose for which it is neither labeled nor advertised. 21 C.F.R § 201.128; and

f. Medical device means "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or . . . intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h).

6. Medical devices are classified into one of three categories: Class I, II, or III. 21 U.S.C. § 360c. Class III medical devices are the most highly regulated devices and must be approved by the FDA prior to being manufactured and distributed in the United States.

7. An in vitro diagnostic device ("IVD") test kit is a type of medical device that is "intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae." It is intended

for use in the collection, preparation, and examination of specimens taken from the human body. 21 C.F.R. § 809.3.

8. While some types of IVD test kits may be classified as Class I or Class II medical devices, prior to June 2023, COVID-19 IVD test kits were Class III medical devices. 21 C.F.R. §§ 809.3, Parts 862, 864, and 866.; 21 U.S.C. § 360c(f)(1).

9. Notwithstanding the requirement for Class III medical devices to be approved by the FDA prior to being distributed in the United States, the FDA Commissioner may issue Emergency Use Authorizations for unapproved devices after the Secretary of the United States Department of Health and Human Services ("HHS") has made an emergency declaration. 21 U.S.C. § 360bbb-3.

10. On February 4, 2020, the HHS Secretary made an emergency declaration for the COVID-19 pandemic. The FDA Commissioner subsequently issued Emergency Use Authorizations for hundreds of different COVID-19 IVD test kits.

11. The FDA explained in public guidance: "In the context of a public health emergency involving pandemic infectious disease, it is critically important that tests are validated because false results not only can negatively impact the individual patient, but also can have a broad public health impact." FDA Center for Devices and Radiological Health, Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) (5th ed. May 11, 2020). As a result, companies that could not provide the FDA with adequate evidence demonstrating the validity of their COVID-19 IVD test kits did not receive EUAs.

12. The FDA also instituted a policy that stated the FDA did not intend to object to distribution of COVID-19 IVD test kits to clinical laboratories or healthcare workers for public testing by certified laboratories prior to an EUA being issued for those test kits if the test kits had

been properly validated, notification was provided to the FDA, and an EUA request was submitted to the FDA within fifteen days of the notification and ultimately approved, among other requirements.

13. The emergency declaration for the COVID-19 pandemic ended on May 11, 2023.

14. Under 21 U.S.C. § 360(b) and (c), and 21 C.F.R. § 807.20, every person and company, who engages in the preparation, propagation, compounding, or processing of a medical device, or who acts as an initial importer for such a device, must register its facility with the FDA each year.

15. A medical device is misbranded if, among other things:

a. Its labeling is false or misleading "in any particular." 21 U.S.C. 352(a);

b. Its packaging does not bear a label containing the name and place of business of the actual manufacturer, packer, and distributor. 21 U.S.C. § 352(b);

c. It is manufactured, prepared, propagated, compounded, or processed in a facility that is not registered with the FDA. 21 U.S.C. § 352(o).

16. The introduction, delivery for introduction, or causing the introduction or delivery for introduction into interstate commerce, of any misbranded medical device is prohibited. 21 U.S.C. § 331(a).

17. Likewise, the receipt in interstate commerce of any misbranded device, and the delivery or proffered delivery of such device, is prohibited. 21 U.S.C. § 331(c).

18. Violations of the FDCA can be misdemeanors or felonies, depending on the circumstances. Violations committed with the intent to defraud and mislead others are felonies. Such violations carry maximum penalties of up to three years in prison, and fines of up to $250,000 for individuals or $500,000 for corporations. If any person derives pecuniary gain

from the violations, or if the offense results in pecuniary loss to someone other than the defendant, the defendant may be fined not more than the greater of twice the gross gain or loss. 21 U.S.C. § 333(a); 18 U.S.C. § 3571.

False statements

19. Under 18 U.S.C. § 1001, anyone who, in any matter within the jurisdiction of the executive, legislative, or judicial branch of United States, knowingly and willfully:

a. Falsifies, conceals, or covers up by any trick, scheme, or device a material fact;

b. Makes any materially false, fictitious, or fraudulent statement or representation; or

c. Makes or uses any false writing or document, knowing the same to contain any materially false, fictitious, or fraudulent statement or entry;

May be imprisoned for up to five years, or eight years if the offense involves international or domestic terrorism, and fined up to $250,000.

Statement of Probable Cause

Overview

20. Beginning no later than December 2020, and continuing through at least March 2023, Jia Bei Zhu and others manufactured, sold, and distributed hundreds of thousands of COVID-19 IVD test kits, in addition to IVD test kits for HIV, pregnancy, clinical urinalysis, and other conditions, throughout the United States. They did so through the companies Universal Meditech Incorporated ("UMI") and Prestige Biotech Incorporated ("PBI"), which were based in the Cities of Fresno and Reedley, State and Eastern District of California. UMI and PBI did not obtain the required authorizations to manufacture and distribute the test kits, and mislabeled some of the test kits, which makes the test kits misbranded medical devices under the FDCA.

21. When these activities were discovered by FDA officials, Zhu made false statements to the officials. This included information about Zhu's own identity, his ownership and control of UMI and PBI, and the activities of UMI and PBI.

Background on Zhu and UMI

22. Zhu's fingerprints were obtained by government officials when he entered, or attempted to enter, the United States from abroad seven times from 2003 through 2008. Customs and Border Patrol records show that he is a citizen of China.

23. Media reports show that, in 2016, Zhu was the owner of the Canadian company IND Diagnostic Incorporated ("IND"), and that he and IND were sued civilly in Canada and ordered to pay over $300,000,000 for misappropriating technology related to the separation of sex chromosomes from bull semen.[1]

24. According to California Secretary of State filings, UMI was formed in 2015.

25. FDA records show that UMI first registered as a medical device manufacturer with the FDA in November 2015. The company was initially based in the City of Tulare, State and Eastern District of California, and moved to Fresno in 2018.

26. In October 2022, UMI filed a Statement of Information with the California Secretary of State that listed UMI Employee One as the CEO, Secretary, and CFO of the company. The Statement of Information also listed UMI Employee Two as the CEO, Secretary, and CFO, but his/her name had been crossed out.

27. On December 21, 2022, Federal Bureau of Investigation ("FBI") special agents interviewed UMI Employee Three, who was the general manager for the company from

[1] https://vancouversun.com/news/local-news/canadian-businessman-employees-ordered-to-pay-330m-plus-in-damages.

September 2018 through March 2022. UMI Employee Three told the agents that Zhu's title at the company was "Tech Office Consultant" but that Zhu ran most of the company's operations. UMI Employee Three also told the agents that UMI Employee Two was the company's CEO but that UMI Employee Two was only a "puppet" CEO.

UMI's FDA registration lapsed

28. As previously discussed, to lawfully manufacture medical devices in the United States, a company must be registered with the FDA and meet other requirements.

29. Although UMI first registered with the FDA in November 2015, FDA records show that its registration lapsed in December 2022 and has not been renewed since that time.

30. Therefore, UMI was not permitted to manufacture any IVD test kits in the United States after December 2022, and any test kits that the company manufactured after that date would be misbranded medical devices under the FDCA.

UMI did not obtain Emergency Use Authorization for COVID-19 IVD test kits

31. As previously discussed, to manufacture and distribute COVID-19 IVD test kits in the United States during the pandemic, a company must have applied for, and ultimately received, an Emergency Use Authorization ("EUA") from the FDA.

32. According to FDA records, on May 17, 2020, UMI applied for an EUA for a COVID-19 IVD antibody test kit. On July 17, 2020, however, UMI withdrew its application.

33. On May 28, 2020, UMI again applied for an EUA for a COVID-19 polymerase chain reaction IVD test kit. On July 22, 2020, however, an FDA official informed UMI that the FDA had identified major deficiencies in UMI's test studies. UMI did not respond to the FDA's concerns, and its application was denied on October 28, 2020.

34. According to FDA records, UMI did not receive an EUA for any COVID-19 IVD test kits. Therefore, UMI was never authorized to manufacture and distribute COVID-19 IVD test kits in the United States, and any such test kits that the company manufactured and distributed were misbranded medical devices under the FDCA.

UMI manufactured and distributed misbranded COVID-19 IVD test kits

35. The Wayback Machine[2] was used to review UMI's website, located at https://universal-meditech.com,[3] as it was published on March 23, 2022. On the subpage[4] located at: https://universal-meditech.com/about-us, UMI said:

> Our Mission
>
> Universal Meditech Inc. is an innovative solution provider who develops, manufactures, and markets state-of-the-art In Vitro Diagnostic medical devices. UMI's IVD reagent manufacturing service includes formulation, testing, filling, label control, inspection, packaging and shipping.
>
> UMI was established in 2015 in Central California with the vision of a major international diagnostics business providing patients, doctors, hospitals, and healthcare providers with diagnostic testing for disease identification and disease predisposition.
>
> UMI also conducts research and develops new IVD products with our team of technical. scientists who have over 20 years of experience in the in vitro diagnostic area.
>
> UMI is one of the few full-service companies which offers the complete range of diagnostic product services from R&D through to manufacturing, regulatory approval and global commercialization. UMI's IVD reagent manufacturing service includes formulation, testing, filling, label control, inspection, packaging and shipping.

[2] The "Wayback Machine" is a digital archive of the internet founded by the Internet Archive, which is a nonprofit organization. It allows users to see how websites looked in the past. I have used the Wayback Machine in prior investigations and have corroborated the information that it provides through other reliable sources such as witness testimony.
[3] This is the home page for UMI's internet presence.
[4] The term subpage means an internet page that can be accessed by clicking links or buttons on the home page of a particular website.

36. Also displayed on the same subpage was the following image:



Great Quality! Unbeatable Prices! Fast Delivery!
PROUD TO BE "MADE IN USA"

37. Another relevant image was displayed on the subpage located at: https://universal-meditech.com/covid-19:



COVID-19

Since the worldwide pandemic began, United Meditech Inc. has been working on manufacturing and perfecting the Lateral Flow Devices. Under consistent effort, we developed four types of testing to be used effectively for the pandemic. They are Made in USA of excellent quality COVID-19 Antigen and Antibody rapid test kits that show positive results in a couple minutes.

We use very unique production technology and a production system. We can provide you with the best service and products in USA with the lowest prices for OEM volume and CE Mark

Our Brand New Products

We successfully collaborated with Medical Laboratory 1, a CLIA-certified laboratory, for our production of lab developed test (LDT) of SARS-CoV-2 Antigen Rapid Test Kit. Our company is the manufacturer and distributor for the Test Kit. It is affordable, easy to use and a result can be shown under two minutes. It is available for sale in the USA and worldwide.

38. Additional images of COVID-19 IVD test kits, with labels saying that the kits were manufactured by Medical Laboratory 1, were displayed on the same subpage. The false representation on the label that Medical Laboratory 1 was the only manufacturer makes the test kits misbranded medical devices under the FDCA.

UMI entered into contract to make and distribute misbranded COVID-19 IVD test kits

39. According to a civil complaint filed in Alabama, in August 2021, Medical Laboratory 1 entered into a Manufacturing Supply Agreement ("MSA") with UMI where UMI agreed to manufacture COVID-19 IVD test kits for the laboratory. Once the test kits were made, they would become Medical Laboratory 1-branded test kits and enter into a supply chain where Distributor 1 was the master distributor. Importantly, the MSA was executed after UMI failed to obtain an EUA for any COVID-19 IVD test kits, which would make the test kits misbranded medical devices under the FDCA.

40. In February 2022, the FDA received complaints from two medical device distributors that Distributor 1 was illegally distributing Medical Laboratory 1-branded COVID-19 IVD test kits that were manufactured by UMI.

41. On March 7, 2022, an FDA official emailed UMI to inform the company that the FDA learned it was manufacturing misbranded COVID-19 IVD test kits. The email was sent to general "admin" and "sales" email addresses that UMI had on file with the FDA. On March 9, 2022, there was a phone call between the FDA and UMI Employee Three, who was then UMI's general manager, about the issue. After the call, FDA officials received an email from UMI Employee Three saying: "UMI has not personally sold this test to US customers," referring to the Medical Laboratory 1-branded COVID-19 IVD test kits.

42. Distributor 1 subsequently filed a report with the FDA that explained, in relevant part: In October 2022, Office of Emergency Management personnel in Travis County, Texas, contacted Distributor 1 to return Medical Laboratory 1-branded COVID-19 IVD test kits the agency had purchased because Distributor 1 had issued a recall for the test kits. Distributor 1 told them that the lot numbers on the test kits did not match those that Distributor 1 had

distributed. Distributor 1 believed that UMI was manufacturing additional lots of Medical Laboratory 1-branded COVID-19 IVD test kits and distributing the test kits without Distributor 1 and Medical Laboratory 1's consent.

43. From October 28, 2022, through November 15, 2022, several emails and phone calls were exchanged between FDA officials and UMI's attorney regarding UMI's COVID-19 IVD test kits. UMI's attorney gave the officials documents that showed UMI had distributed approximately 130,000 Medical Laboratory 1-branded COVID-19 IVD test kits in the United States, but only in January 2021 and January 2022. UMI's attorney also said that UMI had approximately 500,000 to 600,000 Medical Laboratory 1-branded test kits remaining in-stock. As previously discussed, UMI was never permitted to manufacture and distribute COVID-19 IVD test kits in the United States, and any such test kits that the company manufactured and distributed were misbranded medical devices under the FDCA.

UMI purportedly became PBI

44. On November 8, 2022, Fresno County officials received an email from a person purporting to be UMI Employee One, who claimed to be the President of the company. UMI Employee One said that UMI would be leaving its facility in Fresno no later than November 15, 2022. UMI Employee One also said that in the "next 1 to 2 weeks, different creditor companies will pull their goods away …" Fresno County records show that, just before this email was sent, Fresno County officials notified UMI that they were going to inspect the facility to ensure everything was up to code following a fire that occurred at the facility in August 2020.

45. Later in November 2022, FDA officials received an email from UMI's attorney saying that the company had gone out of business and sold its assets to PBI. According to Nevada Secretary of State records, PBI was formed in Las Vegas, Nevada, in 2019. PBI

Employee One is currently listed as the President, Secretary, and Treasurer of the company.

46. Moreover, according to FDA records, PBI was never registered with the FDA to manufacture or import any IVD test kits in the United States, and never received an EUA to manufacture and distribute COVID-19 IVD test kits. Therefore, any such test kits would be misbranded medical devices under the FDCA.

47. As previously discussed, on December 21, 2022, FBI special agents interviewed UMI Employee Three, who was the general manager for UMI from September 2018 through March 2022 and told the agents that Zhu ran most of the company's operations.

48. On October 12, 2023, I conducted a follow-up interview with UMI Employee Three. UMI Employee Three told me that when he/she worked for the company, he/she spoke with Zhu at least once per week and often multiple times per day.

49. UMI Employee Three also told me that that Zhu spoke fluent English, had "superb" knowledge of the FDA's rules and regulations, and was responsible for the content of UMI's website. UMI Employee Three explained that he/she discussed obtaining an EUA for COVID-19 IVD test kits from the FDA and that Zhu wanted to obtain an EUA because Zhu had test kits ready to be sold. UMI Employee Three was not sure who handled the two EUA applications that the company submitted to the FDA in May 2020.

50. UMI Employee Three also told me that Zhu did not sign anything himself. UMI Employee Three explained that he/she likely signed the above-referenced MSA that UMI entered into with Medical Laboratory 1 to make COVID-19 IVD test kits. UMI Employee Three further explained that he/she would have signed the MSA at the direction of Zhu and, to a lesser extent, UMI Employee Two.

51. Finally, UMI Employee Three told me that he/she left the company in March 2022 because he/she felt like he/she was just hired to be a front person and that there was no future for him/her there. UMI Employee Three explained that the company owed him/her thousands of dollars in commissions when he/she left, but he/she assumed it would not be paid.

Reedley Code Enforcement received a complaint regarding PBI's warehouse and shut it down

52. On December 18, 2022, a complaint was filed with Reedley Code Enforcement officials regarding PBI's warehouse in Reedley for using non-permitted plumbing that was visible from outside the warehouse. On December 19, 2022, because of the apparent plumbing violation, Reedley Code Enforcement officials requested and were granted access to the warehouse by employees on-site. Upon entering the warehouse, the officials saw various types of IVD test kits, and related manufacturing equipment and shipping supplies. The officials also saw several employees packaging the test kits for shipment. The employees told the officials that the business had recently moved from Fresno to Reedley because of a fire.

53. On March 9, 2023, PBI applied for a business license with Reedley. The address provided on the application was the above-mentioned warehouse.

54. On March 16, 2023, Reedley Code Enforcement officials executed an inspection warrant for the warehouse. The warrant was executed with assistance from various state and local agencies.

55. During the inspection, a production order form was found that showed 1,000 COVID-19 IVD test kits had been distributed to an unknown customer in July or August 2022. This was more than six months after the date UMI's attorney told the FDA the company had stopped distributing the test kits. After the inspection, Reedley Code Enforcement officials deemed the warehouse unsafe to occupy because of several building code violations and

restricted access to it.

56. On March 17, 2023, Reedley Code Enforcement officials received an email, purportedly from PBI Employee One, saying:

> "Numerous goods currently stored at [the Reedley warehouse] has caused trouble to you and your colleagues in administration … In fact, these goods mainly came from Universal Meditech Inc (UMI). This company's capital chain was broken down due to its own business problems. It has now entered bankruptcy and liquidation proceedings. My company has lent a lot of money to UMI in the past two years. So my company must be the biggest creditor of UMI. After UMI had no money to support the company's continued operation and had a bad relationship with the original landlord, all the creditors had to scramble to find a temporary warehouse … my friend in Fresno happened to introduce to [the Reedley warehouse] … so we quickly entrusted the moving company to move there."

57. On March 23, 2023, Reedley Code Enforcement officials received an email, again purportedly from PBI Employee One, that attached PBI Employee One's Chinese passport in an effort to verify his/her identity. The passport has not been authenticated by government officials. The email address that PBI Employee One used, however, displayed as "jessezhu<jituanguanli@126.com>." As discussed below, "Jesse" Zhu is a known alias of Zhu.

58. On April 26, 2023, Reedley Code Enforcement officials met with a person who identified himself as Qiang "David" He and purported to represent UMI and PBI. The meeting took place at Reedley's City Hall. Prior to the meeting, Reedley Code Enforcement officials had been working with federal, state, and local agencies to identify and research individuals whose names were associated with UMI and PBI. The officials obtained a photograph of Zhu

from a law enforcement database that pulls on thousands of public records. The officials recognized the person identifying himself as Qiang "David" He as being the same person as Zhu. Hereafter, this person will be referred to as Zhu. During the meeting, Zhu told the officials he had recently been hired by UMI and PBI to represent the companies in their dealings with government agencies.

FDA inspection found various misbranded IVD test kits

59. From May 2, 2023, through May 3, 2023, FDA officials conducted an inspection at PBI's Reedley warehouse. During the inspection, Zhu again identified himself as Qiang "David" He and told the officials he could speak on behalf of UMI and PBI. FDA OCI special agents confirmed that Qiang "David" He was the same person as Zhu because the fingerprints that government officials obtained from Qiang He when he came into the United States from China in 2021 matched the fingerprints obtained from Zhu when he came into the country seven times from 2003 through 2008.

60. The FDA officials asked Zhu for various UMI and PBI documents, including ownership records, financial records, policies and procedures, FDA registration records, and purchase orders and shipping receipts for IVD test kits. Zhu, however, told the officials that he could not access the requested documents.

61. During the inspection, FDA officials saw various types of IVD test kits, and related manufacturing equipment and shipping supplies. This included boxes of Medical Laboratory 1-branded COVID-19 IVD test kits, PBI-branded pregnancy and clinical urinalysis IVD test kits, and labeling for HIV IVD test kits. The following is a photograph of the boxes of COVID-19 test kits:



62. During the inspection, FDA officials also saw notes written on IND letterhead. As previously discussed, IND was a Canadian company owned by Zhu.

63. During the inspection, Zhu made several statements to FDA officials, including:

a. Zhu was Qiang "David" He and not anyone else;

b. Zhu was hired by UMI as a COVID-19 consultant in 2021;

c. Zhu was hired by PBI just a couple of weeks ago to communicate with government agencies and dispose of property at the warehouse as requested by those agencies;

d. Zhu did not know anything about the manufacturing or distribution histories for UMI or PBI;

e. Zhu knew that the FDA must approve a facility before it could manufacture medical devices like IVD test kits.

f. When asked about an Amazon.com webpage showing PBI-branded pregnancy IVD test kits for sale, Zhu said that he had "no idea;" and

g. When asked about a shipment of 47,500 pregnancy IVD test kits from China to UMI at an address in Las Vegas on March 21, 2023, that was recorded in FDA's databases, Zhu said that he did know about the shipment.

64. Importantly, Zhu identified himself to FDA officials as Qiang "David" He by producing an employment authorization card issued by the United States Citizen and Immigration Services ("USCIS"). The USCIS card was confirmed to be authentic by government officials. As previously discussed, however, the fingerprints that government officials obtained from Qiang He when he came into the United States from China in 2021 matched the fingerprints obtained from Zhu when came into the country seven times from 2003 through 2008. Therefore, I believe that Zhu submitted false documents to the government to obtain the USCIS card in Qiang He's identity.

65. During the inspection, Zhu told FDA officials that UMI Employee Two was UMI's CEO and that PBI Employee One was PBI's president. He also told the officials that UMI Employee Two was the daughter of PBI Employee One. Zhu gave the officials the names, telephone numbers, and email addresses for UMI Employee Two and PBI Employee One.

66. When FDA officials asked to speak with UMI Employee Two and PBI Employee One directly, Zhu told the officials that UMI Employee Two and PBI Employee One did not want to speak with them. Zhu also told the officials that all communications with UMI Employee Two and PBI Employee One should either go through him or be by email.

67. Zhu made and persisted with these statements despite an FDA official warning him that making false statements to the FDA was a federal crime and reading him the text of the

federal false statements statute, 18 U.S.C. § 1001, verbatim. Zhu nodded his head up and down acknowledging that he understood the warning. Zhu also said that he should not answer any questions to which he did not know the answers. The conversation was captured on a body camera that was openly worn by a local government official who was present for the inspection.

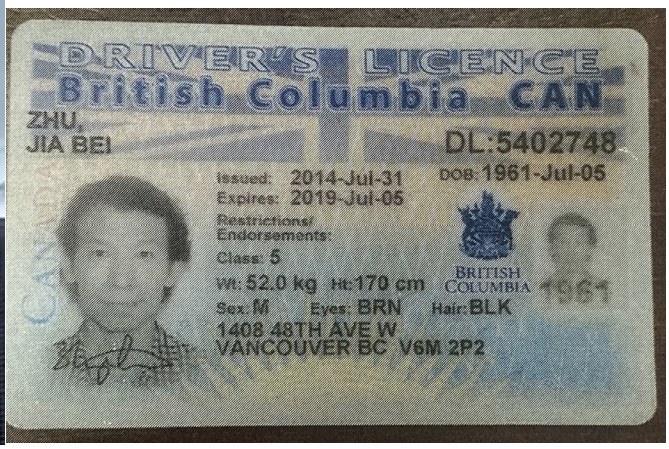
68. On May 16, 2023, an FDA official met with Zhu in Escondido, California. Zhu gave the official documents that showed UMI distributed pregnancy, urinalysis, and other, non-COVID-19 IVD test kits from December 2021 through November 2022.

69. On May 24, 2023, FDA officials received an email from Zhu regarding the March 21, 2023, shipment of the 47,500 PBI-branded pregnancy IVD test kits that they had asked about during the inspection of PBI's Reedley warehouse. Zhu again purported to be Qiang "David" He and used the email address "He David<davidmeditech@gmail.com>." The email was written in Mandarin and translated by the FDA. In the email, Zhu said that the shipment was from China and was supposed to be sent to PBI in Las Vegas. PBI, however, had a problem with customs. So, the shipping company had the shipment sent to UMI in Las Vegas instead to prevent it from going back to China.

Search warrant confirmed Zhu was in-charge all along and lied to the FDA

70. On September 13, 2023, FDA OCI special agents executed a federal search warrant for PBI's Reedley warehouse. During the search, the agents found a photocopy of a British Columbia, Canada, driver's license that was issued to "Jia Bei Zhu" in 2014. The agents compared the photograph on the front of the license to body worn camera footage of the person who identified himself as Qiang "David" He during the FDA's May 2023 inspection of the Reedley warehouse. The agents confirmed that it was the same person. The driver's license and a screenshot taken from the body worn camera footage are included below for reference:





71. During the search, the agents also found thousands more COVID-19, pregnancy, clinical urinalysis, and drug IVD test kits, among others, and related shipping receipts.

72. During the search, the agents also found records showing Zhu's ownership of IND, and several other legal and financial records for him.

73. During the search, the agents also found FDA policy printouts, including the FDA's Policy entitled, "Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) – Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff," which the FDA published online in May 2020.

74. The agents also found a printout from the FDA's website regarding, "Notification and Emergency Use Authorization FAQs on Testing SARS-CoV-2 … What commercial manufacturers are distributing diagnostic test kits under the policy outlined in Section IV.C of the Policy for Coronavirus Disease-2019 tests?" There was a notation on the printout that showed it was printed on March 24, 2021.

75. During the search, the agents also found an FDA EUA authorization letter for Medical Laboratory 2, dated June 12, 2020, as well as an unsigned "Development Supplemental Agreement" with that laboratory. Under the agreement, UMI would have contracted with Medical Laboratory 2 to make 150,000 Medical Laboratory 2-branded COVID-19 IVD test kits from December 2020 through February 2021.

76. During the search, the agents also found two UMI invoices addressed to Medical Laboratory 2 for 50,000 test kits and 100,000 test kits, dated December 15, 2020, and December 24, 2020, respectively.

77. On September 20, 2023, agents interviewed UMI Employee Four, who was a former, lower-level UMI employee. UMI Employee Four said that he/she worked for the company from 2019 through March 2023. UMI Employee Four was shown a photograph of Zhu that agents obtained from a law enforcement database that pulls on thousands of public records. UMI Employee Four said that was "the boss" and that he/she knew him as "Jesse.' UMI Employee Four subsequently searched his/her cell phone and confirmed "Jesse's" name was Jia Bei Zhu.

78. UMI Employee Four was also shown a photograph of UMI Employee Two that agents obtained from the Nevada Department of Motor Vehicles. UMI Employee Four said that Zhu and UMI Employee Two were both "the bosses."

79. Despite media reports that UMI and PBI may have been manufacturing bioweapons, no evidence supporting those reports has been found to date. Any and all pathogens and toxins that have been found during the government's investigation appear to be related to the manufacture and distribution of various IVD test kits.

Sealing Request

80. I request that the Court order all papers in support of the requested criminal complaint and arrest warrant be sealed until further order of the Court. These documents discuss an ongoing criminal investigation that is neither public nor known to all the targets of the investigation. Therefore, there is good cause to seal these documents because their premature disclosure may jeopardize the investigation, including by giving the targets an opportunity to destroy or tamper with evidence, change patterns of behavior, notify confederates, and flee.

Conclusion

81. For these reasons, I believe that there is probable cause to issue the requested criminal complaint and arrest warrant for Zhu. Specifically, Zhu was responsible for the operations of UMI and PBI, and was aware of the FDA's rules and regulations for COVID-19 IVD test kits and other types of IVD test kits. Nonetheless, from at least December 2020 through March 2023, Zhu caused the companies to manufacture and distribute, or attempt to distribute, hundreds of thousands of COVID-19 IVD test kits across the United States, many of which were mislabeled, without obtaining an EUA from the FDA as was required. Zhu also caused the companies to import over 47,000 pregnancy IVD test kits from China and distribute, or attempt to distribute, the test kits on Amazon without being registered with the FDA as was required. Therefore, all of these IVD test kits were misbranded medical devices under the FDCA, which Zhu caused to be received, introduced, or delivered for introduction into interstate commerce in violation of 21 U.S.C. §§ 331(a) and (c).

82. Moreover, when Zhu was questioned by FDA officials, and warned that making false statements to them was a federal crime, he repeatedly lied about who he was, his involvement with UMI and PBI, and the activities of the companies in violation of 18 U.S.C. §

1001(a)(1), (a)(2), and (a)(3).

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief:

Jeffrey Maurice -S

Digitally signed by Jeffrey Maurice -S
Date: 2023.10.17 10:00:43 -07'00'

Jeffrey Maurice
Special Agent, FDA OCI

Approved as to form by:

/s/ Joseph Barton

Joseph Barton
Arelis Clemente
Assistant United States Attorneys

Affidavit submitted by email/pdf and attested to me as true and accurate by phone consistent with Fed. R. Crim P. 4.1 and 41(d)(3) before me on 10/18/2023.

Sheila K. Oberto

Honorable Sheila K. Oberto
United States Magistrate Judge