AO 91 (Rev. 11/11) Criminal Complaint

UNITED STATES DISTRICT COURT

for the

District of Nebraska

United States of America
v.

KARL H. GROSS

Defendant(s)

Case No. 8:20MJ236

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 June 9, 2016 in the county of Douglas in the District of Nebraska, the defendant(s) violated:

Code Section	*Offense Description*
18 U.S.C. § 1343	Wire Fraud
21 U.S.C § 331(a)	Causing the introduction into interstate commerce of a misbranded drug
21 U.S.C. § 331(d) & 21 U.S.C. §355(a)	Causing the introduction or delivery for introduction of an unapproved new drug

This criminal complaint is based on these facts:

See Attached Affidavit

☑ Continued on the attached sheet.

Complainant's signature

SA Eric Dickey, FDA

Printed name and title

☐ Sworn to before me and signed in my presence.

☑ Sworn to before me by telephone or other reliable electronic means.

Date: 5/6/2020

Judge's signature

City and state: Omaha, Nebraska

Michael D. Nelson, U.S. Magistrate

Printed name and title

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

UNITED STATES OF AMERICA v. KARL GROSS d/b/a AMERISAVE	Criminal No. 8:20MJ236

AFFIDAVIT IN SUPPORT OF CRIMINAL COMPLAINT

I, Eric Dickey, being first duly sworn, hereby depose and state as follows:

INTRODUCTION AND AGENT BACKGROUND

1. I make this affidavit in support of a criminal complaint against Karl Gross (GROSS), d/b/a AMERISAVE (AMERISAVE).

2. I am presently employed as a Special Agent of the United States Food and Drug Administration, Office of Criminal Investigations (FDA-OCI), and am assigned to the Kansas City Field Office which is responsible for the District of Nebraska. I have been employed by the FDA-OCI since September 2013. Prior to my employment with the FDA-OCI, I was a Special Agent with the United States Secret Service, from December 2001 until September 2013. I investigated financial crimes, counterfeit currency, and provided physical protection to the elected leaders of the United States and other countries. I began my law enforcement career with the Kansas City, Missouri Police Department in May 1995, and conducted duties associated with a patrol assigned Police Officer until December 2001. I completed the Criminal Investigator Training Program (CITP) located at the Federal Law Enforcement Training Center (FLETC) and have received additional training in the Federal Food Drug and Cosmetic Act (FDCA). As a

result of my training and experience, I am familiar with crimes related to the sale of misbranded and unapproved new drugs.

3. The facts in this affidavit come from information obtained from my investigation, from my training and experience, and information obtained from other agents and witnesses. This affidavit is intended to show merely that there is sufficient probable cause for the requested warrant and does not set forth all of my knowledge about this matter.

4. Based on my training and experience and the facts as set forth in this affidavit, there is probable cause to believe that violations of 18 U.S.C. § 1343 (wire fraud); 21 U.S.C. § 331(a) (causing the introduction or delivery for introduction into interstate commerce of an adulterated or misbranded drug); 21 U.S.C. § 331(d) (introducing or delivering for introduction into interstate commerce of an unapproved new drug), have been committed by GROSS, d/b/a AMERISAVE.

APPLICABLE LAW

A. The Federal Food, Drug, and Cosmetic Act

5. The United States Food and Drug Administration (FDA) is the federal agency responsible for protecting the health and safety of the American public by ensuring, among other things, that drugs are safe and effective for their intended uses and bear labeling that contains true and accurate information. FDA's responsibilities include regulating the manufacture and distribution of drugs, including prescription drugs shipped in interstate commerce, as well as the labeling of such drugs. FDA carries out its responsibilities by enforcing the FDCA and other pertinent laws and regulations.

Interstate Commerce

6. The FDCA defines interstate commerce as "(1) commerce between any state or territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other territory not organized with a legislative body." 21 U.S.C. § 321(b).

Drugs

7. The FDCA defines a "drug" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man" and "articles . . . intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1)(B) and (C).

8. Under the FDCA, a "new drug" is any drug which was not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof. 21 U.S.C. § 321(p)(1). To be lawfully introduced into interstate commerce for commercial distribution, new drugs require an approved marketing application, including new drug applications ("NDAs") or abbreviated new drug applications ("ANDAs"). 21 U.S.C. § 355.

9. NDAs and ANDAs discuss in great detail how the product works, how it is manufactured, and precisely what is stated on the label and labeling. For a drug to be distributed in the United States, its manufacturing process, label and labeling, and packaging, as set forth in the pertinent type of application, has to be approved by the FDA. The approval process addresses the chemical composition, safety and effectiveness, and distribution of the drug; methods used in, and the facilities and quality controls used for, the manufacturing, processing

and packaging of the drug; and the proposed labeling for the drug. The approval process is specific to each manufacturer and each product. Approval granted to a particular manufacturer for a particular drug to be distributed in the United States does not constitute approval of a drug with labeling that differed from the labeling in the FDA-approved application to be imported into and distributed in the United States, even if the imported drug has the same chemical composition as the FDA-approved drug.

10. Prescription drugs are drugs that, because of their toxicity and other potential for harmful effects, are not safe for use except under the supervision of a practitioner licensed by law to administer such drugs. 21 U.S.C. § 353(b)(1)(A). A drug is also a prescription drug if the FDA requires it to be administered under the supervision of a practitioner licensed by law to administer such drug as a condition of the FDA's approval of the drug. 21 U.S.C. § 353(b)(1)(B).

11. The FDCA defines "labeling" as all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. 21 U.S.C. § 321(m).

12. A drug was misbranded if, among other things, the labeling on the drug did not bear adequate directions for use. 21 U.S.C. §352(f)(1). Pursuant to FDA regulations, "adequate directions for use" is defined as directions under which a layman can safely use a drug for the purposes for which it is intended. 21 C.F.R. §201.5. By definition, prescription drugs cannot have directions for use that allow a layman to use them safely for the purposes for which they are intended. 21 U.S.C. §353(b); 201 C.F.R. §201.5; *Cf. United States v. Williams*, 549 Fed. Appx. 813, 816 (10th Cir. 2013) (noting that "prescription drugs can never bear 'adequate directions for use' under FDA's interpretation, and thus are presumptively misbranded."); *United States v. An*

Article of Device, 731 F.2d 1253 (7th Cir. 1984) (holding that prescription devices are presumptively misbranded).

13. FDA-approved prescription drugs that complied with all of the relevant FDA regulations before they were dispensed were exempt from the adequate directions for use requirement. Those regulations included, among other things, requirements that a new drug's labeling be the same as the labeling approved by FDA. 21 C.F.R. § 201.100((c)(2).

14. A drug is also deemed to be misbranded if the labeling failed to bear adequate warnings, within the meaning of 21 U.S.C. § 352(f)(2).

Prohibited Acts

15. The FDCA prohibits, among other things, doing or causing the following:

a. introducing or delivering for introduction into interstate commerce of any drug that is misbranded or adulterated. 21 U.S.C. § 331(a).

b. the introduction or delivery for introduction into interstate commerce of any unapproved new drug. 21 U.S.C. §331(d).

PROBABLE CAUSE

A. Case Summary

16. This investigation began in September 2013, when First National Bank, Omaha, Nebraska (FNB) contacted an agent from FDA-OCI regarding Karl GROSS, d/b/a AMERISAVE. FNB records show GROSS opened an account in the name of AMERISAVE, on August 1, 2007. AMERISAVE was described on account paperwork as "medical equipment sales." It was discovered that GROSS d/b/a AMERISAVE and others, to include Anthony Bianchi, conspired to have foreign-sourced misbranded and unapproved new drugs imported into

the United States and sent directly to U.S. consumers via the U.S. Postal Service and other commercial mail carriers. U.S. based customers could contact and order foreign-sourced misbranded and unapproved new drugs from GROSS d/b/a AMERISAVE by utilizing the website www.worlddrugprices.com, and GROSS d/b/a AMERISAVE would often communicate with customers offering refills and customer service via direct email communications. On June 9, 2016, a federal search warrant was executed at GROSS' residence, in the District of Nebraska, where AMERISAVE'S operation was headquartered. Much of the evidence and information in this investigation was gathered through undercover purchases of foreign-sourced misbranded and unapproved new drugs, a federal search warrant, witness interviews, and interviews provided by GROSS himself. Many of the transactions of foreign-sourced misbranded and unapproved new drugs facilitated by GROSS d/b/a AMERISAVE were conducted via website www.worlddrugprices.com, and by direct customer interaction via email and telephone.

17. FNB received a return/cancellation message concerning an international wire transfer going to Sava Intertrade FZE, United Arab Emirates from GROSS d/b/a AMERISAVE. It was discovered Sava Intertrade FZE is located overseas and they sell healthcare products for humans and animals. Sava Intertrade is further identified as "trading in pharmaceuticals products, subject to the approval of relevant U.A.E. authorities." Further investigation discovered numerous deposits of checks into GROSS' account with FNB from numerous individuals throughout the United States. Many of these deposited checks bore the name of FDA-approved prescription drugs such as Crestor, Plavix, Lipitor, Zetia, and Symbicort, written in the memo section of these checks. Numerous credit card payments as well as checks had been deposited in GROSS' account, and from August 1, 2007, until September 30, 2015, all deposits into this account totaled more than $2,000,000.00.

18. Wire transfers are real-time transfers of funds. After a wire transfer is initiated from a sending bank, the sending bank's Reserve Account at the Federal Reserve Bank is immediately debited and the receiving bank's Reserve Account is immediately credited. Wire transfers are typically performed when transactions are time-sensitive or are for large dollar amounts. Recipients of wire transfers generally have immediate access to the funds through their account at the receiving financial institution.

B. Fraudulent Wire Transfers

19. Between August 19, 2014 and February 25, 2016, four (4) undercover purchases of foreign-sourced misbranded and unapproved new drugs were made using the website www.worlddrugprices.com, direct email communications, or via fax contact with AMERISAVE personnel. The undercover purchases were all made using my undercover Chase credit card, account number ending in 9204. I provided this credit card number via fax and email communication originating in Mission, Kansas, on or about August 25, 2014, to AMERISAVE Marketing Representative Suhn "Sunny" Bianchi, in the District of Nebraska. The undercover purchases triggered the delivery of foreign-sourced misbranded and unapproved new drugs to an undercover mailbox in Kansas City, Missouri. All the foreign-sourced misbranded and unapproved new drugs were mailed from foreign countries.

20. On or about April 20, 2015, an undercover transaction was initiated for the purchase of a prescription drug from AMERISAVE. Acting in an undercover capacity, I requested 30-day supplies of FDA-approved drugs, Pradaxa 150mg, and Advair 50/100mcg. These drugs were under patent and no FDA-approved generics were available at that time. The transaction in the amount of $320 U.S. Dollars was posted to my undercover credit card account,

ending in 9204, on or about May 5, 2015. The undercover credit card account bore the identity of my undercover persona, and the card was issued by Chase. The transaction triggered the transfer of funds in the amount of $320 from my undercover Chase account, to AMERISAVE via First Data Merchant Processing located in the District of Nebraska. According to information obtained in this investigation, Chase credit card transactions are processed on servers located in Delaware, Michigan, or Illinois.

21. On or about March 4, 2016, a credit card transaction was initiated for the purchase of a prescription drug from AMERISAVE. Acting in an undercover capacity, I requested a 90-day supply of FDA-approved Vytorin, 10/10mg, which had been requested via email on or about February 25, 2016. The transaction in the amount of $145 U.S. Dollars was posted to my undercover credit card account, ending in 9204, on or about March 6, 2016. The undercover credit card account bore the identity of my undercover persona, and the card was issued by Chase. The transaction triggered the transfer of funds in the amount of $145 from my undercover Chase account, to AMERISAVE via First Data Merchant Processing located in the District of Nebraska. According to information obtained in this investigation, Chase credit card transactions are processed on servers located in Delaware, Michigan, or Illinois.

C. Foreign-sourced misbranded and unapproved new drugs received in this investigation.

22. On or about May 19, 2015, as the result of the undercover purchase initiated with AMERISAVE on or about April 20, 2015, a package was received at an undercover mailbox in Kansas City, Missouri, which contained Pradaxa 150mg. Pradaxa 150mg is manufactured in the United Kingdom for the Canadian market. This package had originated in Canada. This particular drug had not been approved by the FDA and was an unapproved drug pursuant to 21

U.S.C. §355(a). In addition, this drug did not comply with all the requirements in 21 C.F.R. §201.100 and was therefore not exempt from the requirement that its labeling bear adequate directions for use. Without the exemption, the drugs are misbranded under 21 U.S.C. § 352 (f)(1).

23. Black Box Warning: FDA may require that certain contraindications or serious warnings, particularly those that may lead to death or serious injury, be presented in the labeling of a drug product. The Pradaxa manufactured for the Canadian market contained labeling that differed from FDA-approved Pradaxa. FDA-approved Pradaxa contains a "boxed warning" (sometimes referred to as a "black box warning") under 21 C.F.R. § 201.57(c)(1) on its labeling. The boxed warning for FDA-approved Pradaxa cautions that: (A) premature discontinuation of Pradaxa increases the risk of thrombotic events, and (B) epidural or spinal hematomas may occur in patients treated with Pradaxa who are receiving neuraxial anesthesia or undergoing spinal puncture. The foreign-sourced unapproved Pradaxa did not appear to contain the boxed warning, nor did it bear the "Rx only" symbol. The failure of a drug to bear adequate warnings renders the drug misbranded. 21 U.S.C. §352(f)(2).

24. On or about May 19, 2015, as the result of the undercover purchase initiated with AMERISAVE on or about April 20, 2015, a package containing Seretide Accuhaler 50/100 mcg, was received at an undercover mailbox in Kansas City, Missouri. The order was for FDA-approved Advair 50/100 mcg. The package had originated in Germany. Seretide Accuhaler 50/100 mcg had not been approved by the FDA and was an unapproved new drug pursuant to 21 U.S.C. §355. The foreign sourced unapproved Seretide Accuhaler did not appear to bear the "Rx only" symbol. This drug did not comply with all the requirements in 21 C.F.R. §201.100

and was therefore not exempt from the requirement that its labeling bear adequate directions for use. Without the exemption, the drugs are misbranded under 21 U.S.C. § 352 (f)(1).

25. On or about February 25, 2016, an undercover purchase was conducted with AMERISAVE which consisted of a request for a 90- day supply of Vytorin 10/10mg. Vytorin was under patent protection at that time, and no FDA-approved generics were available for the United States market. On or about March 16, 2016, as the result of the undercover purchase from AMERISAVE, a package of Etalize-S was received at an undercover mailbox in Kansas City, Missouri. The package had originated in Germany. Etalize-S is a foreign drug product with no United States approved equivalent. Etalize-S has not been approved by the FDA, and the labeling on the package failed to contain the symbol "Rx only". Etalize-S is considered a foreign-sourced misbranded and unapproved new drug pursuant to 21 U.S.C. §331(d) and 21 U.S.C. §352(f)(1).

D. Karl GROSS Interviews.

26. On June 9, 2016, a federal search warrant was executed at Karl GROSS' residence in the District of Nebraska. During the execution of the warrant, GROSS agreed to voluntarily speak with agents and provided information as to his role as the owner of AMERISAVE. GROSS informed agents he purchased AMERISAVE from Anthony Bianchi in approximately 2007. GROSS described his duties as brokering prescription drugs from U.S. and foreign sources. GROSS said the website www.worldrugprices.com was owned and controlled by Anthony Bianchi, who directed orders for prescription drugs to AMERISAVE. It was pointed out to GROSS the website erroneously mentions the drugs being sold were from FDA-approved facilities, rather than the drugs themselves being FDA approved. GROSS told agents, "I know

the distinction between an FDA-approved drug and a Canadian or foreign sourced unapproved drug".

27. On August 15, 2016, agents from FDA-OCI interviewed Karl GROSS. GROSS confirmed he knew many of the drugs provided by AMERISAVE were not FDA-approved for distribution in the United States. GROSS said Anthony Bianchi and Suhn Bianchi referred customers and conducted sales and marketing for AMERISAVE. GROSS was shown marketing literature which contained statements such as, "providing FDA approved generics rather than expensive brands," "all are FDA approved," or "Manufactured in an FDA approved facility," and/or "FDA inspected facility." GROSS claimed Anthony Bianchi was the person responsible for the wording in the marketing literature and said, "I never would have put that in there like that, FDA approval is definitely over the top." GROSS' statement supports his knowledge that many of the drugs AMERISAVE sold were foreign-sourced misbranded and unapproved new drugs.

28. The United States will be seeking a forfeiture money judgement pursuant to 18 U.S.C. § 982(a)(8) and 21 U.S.C. § 2461(c).

CONCLUSION

29. Based on the forgoing, there is probable cause to believe that GROSS violated 18 U.S.C. § 1343 (wire fraud); 21 U.S.C. § 331 (a) (causing the introduction into interstate commerce of a misbranded drug); 21 U.S.C. § 331(d) and 21 U.S.C. §355(a) (causing the introduction or delivery for introduction of an unapproved new drug); 21 U.S.C. §333(a)(2) (penalty provision providing that committing FDCA violations with the intent to defraud or

mislead is a felony). Accordingly, I respectfully request that the Court issue a criminal complaint and summons for GROSS.

Respectfully submitted,
Eric Dickey
Special Agent
Food and Drug Administration,
Office of Criminal Investigations

Sworn to before me by reliable electronic means:

Date: 05/06/2020

City and State: Omaha, Nebraska

Michael D. Nelson, U.S. Magistrate Judge