UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

CLERK'S OFFICE U.S. DISTRICT COURT
AT ABINGDON, VA
FILED
NOV 19 2026
LAURA A. AUSTIN, CLERK
BY: K. Campbell
DEPUTY CLERK

UNITED STATES OF AMERICA :
:
v. :
:
JOHN THOMAS HOWARD :

Criminal No. 1:26CR42

Violation: **18 U.S.C. § 371**

INDICTMENT

THE GRAND JURY CHARGES THAT:

GENERAL ALLEGATIONS

At all times relevant to this Indictment:

FDA's REGULATION OF PRESCRIPTION DRUG IMPORTATION

1. The Food and Drug Administration ("FDA") of the United States Department of Health and Human Services is the federal agency responsible for protecting the health and safety of the American public by enforcing the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 301, *et seq.* ("FDCA"). The FDCA, among other things, governs the premarket approval, manufacturing, labeling, and distribution—to include the regulation of the supply chain and importation—of prescription drugs.[1] The requirements

[1] Prescription drugs are defined as those drugs that either (a) because of their toxicity and other potential for harmful effects, or the method of their use, or the collateral measures necessary to their use, are not safe for use except under the supervision of a licensed practitioner; or (b) are limited to such use by their FDA approval, either in a new drug application (NDA) for a pioneer drug, or an abbreviated new drug application (ANDA) for a generic equivalent of a pioneer drug. *See* 21 U.S.C. § 353(b)(1).

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of the FDCA, in part, are meant to ensure that drugs sold for human use are safe and effective and bear labeling that contains accurate and adequate information.

2. A Congressional goal in enacting the premarket approval, labeling, secure supply chain, and importation provisions of the FDCA is to ensure the integrity of America's drug supply. Congress determined that the public interest in the safety and efficacy of prescription drugs distributed to American consumers is so great as to warrant imposition of the highest standard of care on those who distribute these products to the public. Under the FDCA, the responsibility for maintaining the quality and safety of drugs is not placed on the innocent public who purchase drugs, but rather on those who manufacture and distribute them. Congress has determined that consumers have a right to expect that those who distribute and dispense drugs will be vigilant and responsible in matters that affect the public health. Furthermore, consumers expect that prescription drugs they receive are safe, effective, and are, in fact, the products approved by FDA for the United States market.

3. In the United States, with exceptions not applicable here, prescription drugs are distributed in a closed and tightly controlled supply chain from the time they leave the manufacturer to when they are dispensed to or administered to the patient. The Drug Supply Chain Security Act ("DSCSA"), enacted as part of the Drug Quality and Security Act in 2013, amended the FDCA to require, among other things, product tracing, product identifier, verification, and authorized trading partner requirements for manufacturers, repackagers, wholesale distributers, and dispensers to facilitate the tracing of products through the supply chain. 21 U.S.C. § 360eee-1. Trading partners involved in transactions

involving prescription drugs also must be either registered with FDA (manufacturers) or licensed with the relevant state and/or federal authorities (wholesalers and dispensers). These supply chain integrity safeguards were enacted to enhance the ability of the FDA to protect consumers from counterfeit, stolen, diverted, and contaminated drugs by establishing a national framework for electronic drug tracing throughout the supply chain.

4. Prescription drugs that are manufactured in the United States and exported to other countries may only be reimported by the manufacturers themselves. 21 U.S.C. § 381(d)(1)(A). Prescription drugs that are manufactured outside the United States may only be imported to the U.S. market if the manufacturer or importer complies with all applicable laws and regulations of the United States to assure the drugs meet FDA's standards for quality, safety, and effectiveness. FDA and HHS have provided two pathways to allow importation of certain prescription drugs that were originally intended for foreign markets.

5. One pathway, enacted by Congress in the 2017 Amendments to the FDCA and further described in a final guidance for industry, describes procedures manufacturers can follow to facilitate the importation of prescription drugs that are FDA-approved, manufactured abroad, authorized for sale in any foreign country, and originally intended for sale in that country (known as "multi-market approved product" or MMA product). 21 U.S.C. § 381(d)(1)(B).[2]

[2] The requirements include, among other things, that the manufacturer has authorized the drug to be marketed in the United States and has caused the drug to bear the FDA-approved labeling. 21 U.S.C. §§ 331(t), 381(d)(1)(B). The importer of the drug must still comply with the Drug Supply Chain Security Act, meaning the drugs would need to be imported by either the manufacturer (defined as the holder of the new drug application or biological license) or an authorized trading partner to ensure that the appropriate product safety and supply chain integrity safeguards are in place. As previously described in paragraph 3, authorized trading partners can only be federally or

6. The second pathway to import drugs intended for the foreign market into the United States is known as the Section 804 Importation Program, which allows the limited importation of certain prescription drugs from Canada, *see* 21 U.S.C. § 384. In September 2020, the Secretary of Health and Human Services certified that importation of prescription drugs is allowed under this if done in accordance with the requirements of the regulations promulgated at 21 C.F.R. Part 251 and that such importation would "pose no additional risk to the public's health and safety" and that it "would result in a significant reduction in the cost of covered products" for American consumers. 21 U.S.C. § 384(l)(1)(A), (B).

7. By regulation, FDA developed procedures to allow the importation of drugs under section 804 [21 U.S.C. § 384], but at this time it only allows importation proposals to be submitted by States and Indian tribes.[3] This pathway specifically excludes biological products, infused drugs, and intravenously injected drugs, likely due to safety concerns with these complex products. 21 U.S.C. § 384(a)(3)(B), (C), (D). It also requires that any establishment within Canada engaged in the distribution of a prescription drug that is

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state licensed wholesalers, state licensed pharmacies, or medical practitioners licensed by law to dispense or administer prescription drugs. 21 U.S.C. § 360eee(2)(A), (B), (D).

[3] To date, the Commonwealth of Virginia has not participated in the Importation Program under 21 U.S.C. § 384. In January 2024, FDA approved Florida's Section 804 Importation Program (SIP) making it the first state in the nation to receive federal authorization to import certain prescription drugs under certain conditions. At the time of this document, there are approximately seven states that have enacted legislation to establish a drug importation program under 21 U.S.C. § 384. Virginia has passed legislation that has established a workgroup to examine the impact of a state importation program but has not established an importation program under 21 U.S.C. § 384. Regardless, defendant would not be eligible to import or facilitate importation under this program even if Virginia had an approved SIP since FDA is currently only authorizing states and not individuals to import prescription drugs under this program.

imported or offered for importation into the United States be registered with FDA and name a United States agent for the establishment. 21 U.S.C. § 384(f).

8. Section 804 [21 U.S.C. § 384], the statute discussed above that allows the importation of wholesale quantities of certain prescription drugs from Canada under limited conditions, also provides for a waiver procedure to allow individuals to import prescription drugs for personal use. 21 U.S.C. § 384(j). The Secretary of HHS has not yet provided the required certification to Congress that this pathway for importation by individuals for their personal use will not pose any "additional risk to the public's health and safety" and result in a "significant reduction in the cost of covered products to the American consumer." See 21 U.S.C. § 384(l). Consequently, this pathway is not a viable pathway to import prescription drugs and FDA cannot even consider waivers at this time. FDA has, however, published guidance on personal importation that predates the above-referenced importation legislation. In that guidance, FDA states that in most circumstances it is illegal for individuals to import drugs into the United States for personal use but that FDA personnel may be more permissive in allowing the personal importation provided that the product not for further sale or distribution in U.S. commerce and that other conditions are met. This guidance has been in place since at least August of 1997, when it was published in the Regulatory Procedures Manual.[4] These conditions to allow importation from foreign countries include if the imported drug: (1) is for a serious condition for which

[4] *See generally* https://ntrl.ntis.gov/NTRL/dashboard/searchResults/titleDetail/PB97196182.xhtml;jsessionid=d0609a107e48787b01eda35ea97f under General Guidance on page 409.

effective treatment may not be available domestically through commercial or clinical means; (2) is not further commercialized or promoted to persons in the U.S.; (3) does not present an unreasonable risk; and (4) is in a quantity that is less than a 3 month supply and the recipient provides documentation of medical supervision.[5] FDA's guidance on personal importation is not intended as a way for consumers to bring lower-priced prescription drugs into the United States; rather, FDA intended this enforcement discretion to allow individuals to access treatments not otherwise available in the United States.

9. Pharmaceuticals manufactured for foreign markets are almost always considered unapproved and misbranded drugs under U.S. law, whether counterfeit or even if made by the same manufacturer that produced the version sold in the United States. Such drugs may have different approved labeling (including different warnings, dosage recommendations, and indications for use) and may be manufactured in a place different than as listed in the New Drug Application approved by FDA. While the U.S. wholesale distribution market is highly regulated, many other markets around the world are not. Pharmaceutical distributors and brokers who circumvent U.S. law and illegally import foreign pharmaceuticals into the United States put their customers/patients at risk for receiving counterfeit, misbranded, and/or adulterated drugs.

[5] *See generally* https://www.fda.gov/industry/import-basics/personal-importation#whatis.

ADDITIONAL DRUG LAW AND PROHIBITED ACTS

10. The FDCA requires the labels and labeling[6] of all drugs to display certain information. All drugs are required to have labeling that bears adequate directions for use.[7] 21 U.S.C. § 352(f). Because a prescription drug, by definition, is safe for use only under the supervision of a licensed medical practitioner (not a layperson), all prescription drugs must qualify for an exemption to this labeling requirement before they may be introduced into interstate commerce. *See* 21 U.S.C. § 353(b)(2); 21 C.F.R. § 201.100. The exemption to this requirement for prescription drugs is set forth in 21 C.F.R. § 201.100, which imposes a number of conditions,[8] all of which must be met. Conditions relevant here are that: (1) a drug subject to the new drug statute must bear the FDA-approved labeling; and (2) a drug must be lawfully dispensed pursuant to a valid prescription, the parameters of which are determined by state law. To dispense drugs into Virginia, a non-resident pharmacy must be registered with the Virginia Board of Pharmacy and designate a pharmacist-in-charge

[6] The FDCA defines the term "label" to mean "a display of written, printed, or graphic matter upon the immediate container of any article. . ." 21 U.S.C. § 321(k). The FDCA defines "labeling" to mean "all labels and other written, printed or graphic matter (1) upon any article or any of its container or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

[7] The phrase "adequate directions for use" is defined by regulation as directions under which the layman can use a drug safely and for the purposes for which it is intended. 21 C.F.R. § 201.5.

[8] This includes that the drug is in the possession: (i) of a person regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs; or (ii) of a retail, hospital, or clinical pharmacy regularly and lawfully engaged in dispensing prescription drugs; or (iii) of a practitioner licensed by law to administer or prescribe such drugs; and the drug is to be dispensed in accordance with 21 U.S.C. § 353(b), *i.e.* by a valid written or oral prescription by a licensed medical practitioner. 21 C.F.R. § 201.100(a)(1), (2). This exemption also requires that if the drug is subject to section 505 of the Act [21 U.S.C. § 355, or the new drug[8] statute] that it bear the labeling authorized by the approved new drug application.

who is licensed in Virginia. Code of Virginia § 54.1-3434.1. 21 U.S.C. § 201.100 (a), (c). The label also must bear the notation "Rx only." 21 C.F.R. § 201.100 (b)(1); *see also* 21 U.S.C. § 353(b)(4)(A).

11. Drugs that are required but that do not comply with the new drug approval statute are "unapproved new drugs" and it would be a violation of the FDCA for them to be distributed in interstate commerce. 21 U.S.C. § 331(d).

Misbranding Provisions

12. Among other reasons, a drug is considered "misbranded" under the FDCA if any one of the following is true:

a. The drug's labeling lacks adequate directions for use, meaning directions under which a layman can use the drug safely and for the purposes for which it was intended, and fails to qualify for an exemption to the labeling requirement. *See* 21 U.S.C. § 352(f)(1) and 21 C.F.R. §§ 201.5, 201.100;

b. It is manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered with FDA as required under 21 U.S.C. § 352(o); or

c. Its label fails to bear the "Rx Only" symbol required by 21 U.S.C. § 353(b)(4).

PROHIBITED ACTS

Federal Food, Drug, and Cosmetic Act Violations

13. Under the FDCA, commission or causing the commission of the following constitute a "prohibited act" under the statute:

a. The introduction or delivery for introduction into interstate commerce of a misbranded drug. 21 U.S.C. § 331(a).

b. The introduction into interstate commerce of a new drug in violation of section 505 [21 U.S.C. § 355, i.e. the new drug statute]. 21 U.S.C. § 331(d).

c. The importation of a drug in violation of section 801(d)(1) of the FDCA [21 U.S.C. § 381(d)(1)] or the failure to comply with section 582 of the FDCA [21 U.S.C. § 360eee-1, i.e. DSCSA]. 21 U.S.C. § 331(t).

d. The importation of a drug in violation of section 804 [21 U.S.C. § 384]. 21 U.S.C. § 331(aa).

Conspiracy

14. Title 18 U.S.C. § 371 prohibits conspiring to commit an offense against the United States, or to defraud the United States or an agency thereof and doing an act to effect the object of the conspiracy. A violation of 18 U.S.C. § 371 is punishable by a fine and 5 years in prison if the offense that is the object of the conspiracy is a felony; if the object offense is a misdemeanor, then the penalty is equivalent to the maximum penalty for the object offense.

Smuggling

15. Title 18 U.S.C. § 545 in summary prohibits knowingly and willfully importing merchandise contrary to law or defrauding the United States government by avoiding customs duties. A violation of 18 U.S.C. § 545 is punishable by fine and/or imprisonment of not more than 20 years.

DEFENDANT

16. JOHN THOMAS HOWARD was a resident of Ontario, Canada, and a Canadian citizen.

17. JOHN THOMAS HOWARD was the Treasurer and a Director of Company A, a Canadian company that marketed that it sources drugs from "tier one countries," specifically Canada, the United Kingdon, Australia, and New Zealand, for Americans to save money on their "brand-name" maintenance medications.

18. JOHN THOMAS HOWARD acted as a responsible corporate officer of Company A.

OFFENSE CONDUCT

19. Since at least 2003, Company A has illegally facilitated the shipment of prescription drugs from foreign countries to consumers in the United States, outside of the closed and tightly controlled supply chain mandated by the FDCA. In so doing, Company A violated the importation requirements of the FDCA, as well as caused the introduction of unapproved new drugs and misbranded drugs into interstate commerce in violation of the FDCA.

20. Company A provided the roadmap for how to source international drugs for American citizens to, and also partnered with, ScriptSourcing, LLC ("ScriptSourcing"). ScriptSourcing contracted with public and private sector employers throughout the United States, including employers in the Western District of Virginia, to provide select prescription drugs to employees. Company A acted as intermediary between

ScriptSourcing and the foreign pharmacies Company A used to import foreign prescription drugs into the United States.

21. Drugs illegally imported from foreign countries are cheaper than those subject to the premarket approval, labeling, secure supply chain, and importation provisions of the FDCA.

22. JOHN THOMAS HOWARD's circumvention of the law gave Company A an unfair competitive advantage over legitimate wholesale distributors and US-licensed pharmacies in the United States. Unlike Company A, legitimate wholesale distributors and US-licensed pharmacies were required to incur the cost of compliance with all federal law.

23. JOHN THOMAS HOWARD's conduct, through Company A, exposed consumers, including individuals in the Western District of Virginia, to the risks inherent to unapproved new drugs and misbranded drugs, which do not carry the same assurances of safety and effectiveness as those drugs subject to FDA oversight. Drugs that have circumvented regulatory safeguards may be contaminated, counterfeit, contain varying amounts of active ingredients, or contain different ingredients altogether. In addition to the direct risks from the medication itself, a lack of appropriate medical supervision and clear, standard labeling can lead to medication errors and further jeopardize patient safety.[9] [10]

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[9] AMA Council on Science and Public Health. (2024, April). *What should prescribers and policy makers know about US drug importation?*. Journal of Ethics, *26*(4). https://journalofethics.ama-assn.org/article/what-should-prescribers-and-policy-makers-know-about-us-drug-importation/2024-0

[10] Mackey, T. K., & Liang, B. A. (2011). Digital danger: A review of the global public health, patient safety, and cybersecurity risks of the illicit online drug trade. *BMC Medicine*, *9*(1), 117. https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-9-117

24. Prescription medicines that are approved for use in the United States have been reviewed by FDA for safety, effectiveness, and quality and are subject to FDA-regulated manufacturing controls and FDA inspections of manufacturing facilities. Unapproved foreign drugs circumvent these safeguards, which are designed to protect patients. Unapproved drugs do not have the same assurance of safety and efficacy as drugs subject to FDA oversight and may be subpotent, superpotent, or adulterated with unknown active ingredients. Treatment with drugs that may be subpotent, superpotent, or adulterated can lead to drug resistance and/or therapeutic failures, and jeopardize the effectiveness of alternative drug therapies on patient outcomes. The FDA has also established processes to recall unsafe, substandard, and poor-quality drugs within the legitimate U.S. drug supply chain. No such safeguards exist for unapproved drugs illegally distributed in the U.S. from foreign sources, such as those sourced by Company A.

25. JOHN THOMAS HOWARD, through Company A, conspired with ScriptSourcing and a variety of other entities to facilitate the illegal importation of foreign drugs and to effectuate a scheme to defraud the United States. Those entities include, but are not limited to: (1) foreign pharmacies; (2) companies, including pharmacy benefit managers ("PBMs"), that facilitate the sourcing of international drugs for individuals; and (3) third party administrators and agencies/brokers who link employers to entities for the provision of international drug sourcing services and also facilitate the payments from employers to entities for the illegally imported drugs.

26. In furtherance of the conspiracy, JOHN THOMAS HOWARD, through Company A, took numerous actions, including but not limited to:

a. Coordinated communications: the conspirators coordinated with each other regarding patient orders and logistics.

b. Marketing and customer acquisition: ScriptSourcing marketed the illegal importation of prescription drugs and made statements that they operated throughout the country. ScriptSourcing worked directly with Company A for prescription fulfillment. ScriptSourcing provided enrollment materials and coordination services.

c. Physical drug shipments: Company A shipped, or caused the shipment of, prescription drugs from Canada and other countries to patients in the Western District of Virginia and elsewhere. To facilitate shipments, Company A utilized international mail services to transport drugs across international borders, some of which were detained pursuant to this investigation.

COUNT ONE
Conspiracy to Defraud and Commit Offenses Against the United States
18 U.S.C. § 371

27. The General Allegations section of this Indictment is re-alleged and incorporated by reference as though fully set forth herein.

28. From in or about February 2017 through in or about October 2026, in the Western District of Virginia and elsewhere, JOHN THOMAS HOWARD, ScriptSourcing, LLC, and others knowingly and willfully conspired to:

a. defraud the United States and its agencies by impeding, impairing, and defeating the lawful functions of the FDA to protect the health

and safety of the public by ensuring that prescription drugs distributed in the United States meet the FDA's standards for quality, safety, and effectiveness and are distributed through a secure supply chain by authorized trading partners;

b. commit an offense against the United States in violation of Title 21 United States Code, Sections 331(a) and 333(a)(2) - with the intent to defraud and mislead, cause the introduction and delivery for introduction into interstate commerce of quantities of misbranded drugs from various locations outside of the state of Virginia to the Western District of Virginia and elsewhere;

c. commit an offense against the United States in violation of Title 21 United States Code, Sections 331(aa) and 333(a)(2) - with the intent to defraud and mislead, cause the importation of a prescription drug in violation of section 384 of Title 21 of the United States Code;

d. commit an offense against the United States in violation of Title 21 United States Code, Sections 331(d), 355 and 333(a)(2) - with the intent to defraud and mislead, cause the introduction and delivery for introduction into interstate commerce quantities of unapproved new drugs from various locations outside of the state of Virginia to the Western District of Virginia and elsewhere;

e. commit an offense against the United States in violation of Title 21 United States Code, Sections 331(t) and 333(b)(1)(A) - knowingly import a drug in violation of Title 21, United States Code, Section 381(d)(1); and

f. commit an offense against the United States in violation of Title 18, United States Code, Section 545 – fraudulently and knowingly import and bring into the United States and facilitate the transportation, concealment, and sale of merchandise (in this case, prescription drugs) contrary to law.

29. It was a part of the conspiracy that JOHN THOMAS HOWARD, through Company A, and others, entered business relationships with ScriptSourcing, LLC, and others, wherein ScriptSourcing marketed its illegal drug importation services to U.S. employers and contracted with Company A to ship foreign prescription drugs directly to U.S. patients and coordinated such shipments.

30. To effect the object of the conspiracy, JOHN THOMAS HOWARD, and their co-conspirators did several acts, including, but not limited to, those acts described in the General Allegations in this Indictment.

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

NOTICE OF FORFEITURE

32. Upon conviction of one or more of the felony offenses alleged in this Indictment, the Defendant shall forfeit to the United States:

a. any property, real or personal, which constitutes or is derived from proceeds traceable to said offenses, pursuant to 18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461; and

b. any misbranded drugs that were shipped to various locations from the Western District of Virginia, pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461.

33. The property to be forfeited to the United States includes but is not limited to the following property:

a. **Money Judgment**

An undetermined sum in United States currency and all interest and proceeds traceable thereto, in that such sum in aggregate was obtained directly or indirectly as a result of said offenses or is traceable to such property.

34. If any of the property subject to forfeiture, as a result of any act or omission of the defendant:

a. cannot be located upon the exercise of due diligence;
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 which cannot be subdivided without difficulty;

the United States shall be entitled to forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p).

A TRUE BILL, this 19th day of November, 2026.

/s/ Grand Jury Foreperson

Danielle Stone
Assistant United States Attorney

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