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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
EASTERN DIVISION

UNITED STATES OF AMERICA	)	
	)	
v.	)	**Case No.**
	)	
SHERRIE R. MCCAIN,	)	
	)	
Defendant.	)	

INFORMATION

The United States Attorney charges that:

INTRODUCTION

At all times material to this Information:

The FDA and Relevant Statutes

1. 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 and medical devices are safe and effective for their intended uses and bear labeling that contains true and accurate information. The FDA's responsibilities include regulating the manufacture and distribution of drugs, including prescription drugs, shipped or received in interstate commerce, as well as the labeling of such drugs.

2. The FDA carries out its responsibilities by enforcing the Federal Food, Drug, and Cosmetic Act (FDCA), Title 21, United States Code, Section 301 *et seq.* and other pertinent laws and regulations.

3. The FDCA prohibits the introduction, or delivery for introduction, into interstate commerce of any drug that is adulterated or misbranded. 21 U.S.C. § 331(a).

4. Under the FDCA, the term "drug" includes any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, or an article (other than food) intended to affect the structure or any function of the body of man or other animals. 21 U.S.C. § 321(g)(1).

5. Any person who owns or operates an establishment in the United States in which drugs are manufactured, prepared, propagated, compounded, processed, or repackaged must register the establishment with the FDA. 21 U.S.C. § 360.

6. Under the FDCA, a drug is misbranded if it was manufactured, prepared, propagated, compounded, or processed, including repackaged, in an establishment not duly registered with the FDA. 21 U.S.C. § 352(o).

7. The term "manufacture, preparation, propagation, compounding, or processing" includes repackaging or otherwise changing the container, wrapper, or labeling of any drug package in furtherance of the distribution of the drug from the

original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user. 21 U.S.C. § 360(a)(1).

8. Under the FDCA, dispensing a prescription drug without a valid prescription written by a licensed practitioner is deemed to be an act that resulted in the drug being misbranded while held for sale. 21 U.S.C. § 353(b)(1).

9. Under the FDCA, a "prescription drug" is: (i) any drug intended for use in humans that, because of its toxicity or potential for harmful effect, the method of its use, or the collateral measures necessary for its use, was not safe for use except under the supervision of a practitioner licensed by law to administer such drug, or (ii) a drug which was limited by a legally approved application for use under the professional supervision of a practitioner licensed by law to administer such a drug. 21 U.S.C. § 353(b)(1).

SHERRIE R. MCCAIN's Drug Distribution Operation

10. Defendant **SHERRIE R. MCCAIN** is an adult resident of the state of Alabama.

11. From in or around December 2017 until in or around July 2021, **MCCAIN** received foreign unapproved prescription drugs at her residence within the Northern District of Alabama.

12. In or around September 2019, law enforcement officers executed a search warrant at **MCCAIN's** home, finding approximately 27,950 foreign

unapproved prescription drug pills. Law enforcement officers also found shipping labels listing the description of contents as "Candy and Merchandise" and "Hair Care Product Set." These labels were inconsistent with the actual contents of the packages, which were prescription drug pills.

13. Additionally, **MCCAIN** received foreign unapproved prescription drug pills in packages that were addressed to different aliases that were variations of her actual name.

14. **MCCAIN** would remove the drugs, including but not limited to Carisoprodol, Gabapentin, and Tramadol, from their original packaging and repackage the drugs for shipment and dispensing.

15. **MCCAIN** would then ship the repackaged drugs to customers without a valid prescription, from her residence, an unregistered drug establishment, thereby misbranding the drugs.

16. In total, between in or around December 2017 and in or around July 2021, **MCCAIN** shipped misbranded drugs to individuals in approximately 25 different states outside the state of Alabama.

17. Despite receiving thousands of foreign unapproved prescription drug pills, repackaging them, and then shipping them to customers across the United States, **MCCAIN** did not register her establishment with the FDA, nor did she submit her operation for regulation by any regulatory bodies of the state of Alabama.

18. **MCCAIN** was not licensed to prescribe for dispensing to patients/customers the drugs that she distributed.

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

19. The factual allegations of paragraph 1 through 18 of this Information are re-alleged as though fully set forth herein.

20. From in or around December 2017 until in or around July 2021, in the Northern District of Alabama, and elsewhere, the defendant,

SHERRIE R. MCCAIN,

with intent to defraud and mislead, introduced and delivered for introduction into, and caused the introduction and delivery for introduction into, interstate commerce, drugs, including but not limited to Carisoprodol, Gabapentin, and Tramadol, that were misbranded within the meaning of Title 21, United States Code, Sections 352(o) and 353(b)(1), via interstate shipment from Oxford, Alabama to approximately twenty-five different states, including Indiana, Georgia, Washington, and West Virginia.

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

NOTICE OF FORFEITURE
21 U.S.C. §§ 334, 853(p), and 28 U.S.C. § 2461(c)

The United States further charges:

1. The allegations of paragraphs 1-20 of this Information are re-alleged and incorporated by reference as though set forth fully herein for the purpose of alleging forfeiture to the United States.

2. The defendant is hereby notified that upon conviction of the offense set forth in this Information, the United States will seek forfeiture in accordance with Title 21, United States Code, Section 334, which provides for the forfeiture of any article of drug that is misbranded when introduced into or while in interstate commerce.

3. If any of the above-described forfeitable property, 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 divided without difficulty;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 28, United States Code, Section 2461(c), to seek

forfeiture of any other property of the defendant up to the value of the forfeitable property described in this forfeiture allegation.

PRIM F. ESCALONA
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