IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF OHIO

WESTERN DIVISION

UNITED STATES OF AMERICA,	)	INDICTMENT
	)	
Plaintiff,	)	3:20 CR 89
	)	CASE NO. JUDGE ZOUHARY
v.	)	MAG. JUDGE KNEPP
	)	Title 18, United States Code, Sections 2
ERIC TAYLOR,	)	and 545; Title 21, United States Code,
	)	Sections 331(c), 331(d), 333(a)(1), 352(f)
Defendant.	)	and 355
	)	

COUNT 1

(Smuggling Goods into the United States, in violation of 18 U.S.C. § 545)

The Grand Jury charges:

1. Beginning in around April 2017 and continuing to March 2018, Defendant ERIC TAYLOR, in the Northern District of Ohio, Western Division, did willfully and knowingly import and bring into the United States certain merchandise, that is prescription drugs Armodafinil and Modafinil, Schedule IV controlled substances and misbranded unapproved new drugs, and Etizolam, a misbranded and unapproved new drug, contrary to the Federal Food, Drug, and Cosmetic Act (FDCA) and the Controlled Substances Act , and did receive, conceal, sell, and facilitate the transportation and concealment after importation, knowing the same to have been imported or brought into the United States contrary to the same laws, in violation of Title 18, United States Code, § 545.

COUNT 2
(Misbranded Drugs, in violation of 21 U.S.C. § 331(c))

The Grand Jury further charges:

2. Title 21, United States Code, Section 331(c) prohibits the receipt in interstate commerce of any drug that is misbranded and the delivery or proffered delivery of that drug for pay or otherwise. Under Title 21, United States Code, Section 352 (f), a drug is misbranded if its labeling does not bear adequate directions for use, and it did not otherwise qualify for an exemption to that requirement.

3. What constitutes "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. Prescription drugs by definition may only safely be used under the supervision of a licensed medical practitioner so they must qualify for an exemption to move in interstate commerce. See Title 21, United States Code, Section 353(b)(1). The exemption for prescription drugs is set out in 21 C.F.R. § 201.100 and it requires *all* the conditions of the regulation be met for the exemption to apply. These conditions include that the drug is: (1)(i) in the possession of a person regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs; or (ii) in the possession of a retail, hospital, or clinic pharmacy, or a public health agency regularly and lawfully engaged in dispensing prescription drugs; or (iii) in the possession of a practitioner licensed by law to administer or prescribe such drugs; and (2) it is to be dispensed under the supervision of a practitioner licensed by law to administer the drug, i.e. pursuant to a valid prescription. The label of the drug also must bear a label with the symbol "Rx only" and the labeling within the package from which the drug is dispensed must bear adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects and precautions for the practitioner to use

the drug safely. 21 C.F.R. § 201.100 (b), (c)(1). If the drug is a new drug that requires approval under the FDCA before it may be marketed, the labeling must be the labeling authorized by the approved new drug application. 21 C.F.R. § 201.100(c)(2).

4. Defendant ERIC TAYLOR, who was not a licensed wholesaler, pharmacist, or medical practitioner, purchased prescription drugs Armodafinil and Modafinil, Schedule IV controlled substances and unapproved new drugs, from a foreign drug wholesaler located in the country of India, between April 2017 and March 2018. These drugs ordered and received by TAYLOR did not bear labels stating they were "Rx only", nor did they bear any labeling at all that provided directions for a medical practitioner to safely administer the drugs. The drugs were also subject to the new drug approval statute, 21 U.S.C. § 355, and therefore any labeling had to be the FDA-authorized labeling to be legally marketed in the United States. The Armodafinil and Modafinil received by TAYLOR in interstate commerce did not bear the FDA-approved labeling. The drugs were also not dispensed or offered for dispensing pursuant to a valid prescription from a practitioner licensed by law to administer such drugs.

5. Beginning in around April 2017 and continuing to March 2018, Defendant ERIC TAYLOR, in the Northern District of Ohio, Western Division, with the intent to defraud or mislead, received in interstate commerce and proffered delivery for pay and otherwise, the prescription drugs Armodafinil and Modafinil, Schedule IV controlled substances, that were misbranded for lacking adequate directions for use.

All in violation of Title 21, United States Code, Sections 331(c), 352(f), and 333(a)(1).

COUNT 3
(Misbranded Drugs, in violation of 21 U.S.C. § 331(c))

The Grand Jury further charges:

6. Title 21, United States Code, Section 331(c) prohibits the receipt in interstate commerce of any drug that is misbranded and the delivery or proffered delivery of that drug for pay or otherwise. Under Title 21, United States Code, Section 352, a drug is misbranded if its labeling does not bear adequate directions for use or if it is manufactured in a facility that is not registered with FDA. 21 U.S.C. § 352(f), (o).

7. Beginning in around April 2017 and continuing to March 2018, Defendant ERIC TAYLOR, in the Northern District of Ohio, Western Division, with the intent to defraud or mislead, received in interstate commerce and delivered or proffered delivery for pay or otherwise the drug "Etilaam - 1" and "ELM-2" or Etizolam, which were misbranded for: (1) lacking adequate directions for use, and (2) being manufactured in a facility that was not registered with FDA in violation of Title 21, United States Code, Sections 331(c) and 333(a)(1); and Title 18, United States Code, Section 2

A TRUE BILL.

Original document - Signatures on file with the Clerk of Courts, pursuant to the E-Government Act of 2002.