UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

UNITED STATES OF AMERICA, Plaintiff, v. JOHNNY T. STINE, Defendant.	CASE NO. CR21-011 MLP **INFORMATION (Misdemeanor)**

The United States Attorney charges that:

INTRODUCTION

At all times relevant to this Information:

1. The Food, Drug, and Cosmetic Act (hereafter "FDCA") provided the regulatory scheme governing, among other things, the manufacture and distribution of drugs in the United States. In addition to creating requirements for these products, the FDCA also prohibited certain acts pertaining to these products.

2. Under the FDCA, "interstate commerce" meant commerce between any State or Territory and any place outside thereof, and commerce within the District of Columbia or within any other Territory not organized with a legislative body. 21 U.S.C. § 321(b)

3. Under the FDCA, "label" meant a display of written, printed, or graphic

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matter upon the immediate container of any article. 21 U.S.C. § 321(k). The term "labeling" was defined as 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).

4. Under the FDCA, "drugs" were defined as, among other things, any articles intended for use in the diagnosis, cure, mitigation, or treatment, or prevention of disease in man or other animals, and articles (other than food) intended to affect the structure or function of the body of man. 21 U.S.C. § 321(g)(1)(B) and (C).

5. The "intended use" of an article meant the objective intent of the persons legally responsible for its labeling. The intent was determined by such persons' expressions, or could be shown by the circumstances surrounding the distribution of the article. It could, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives; or by the circumstances in which the article was, with the knowledge of such persons or their representatives, offered and used for a purpose for which it was neither labeled nor advertised. 21 C.F.R. § 201.128.

6. Under the FDCA, a "prescription drug" was, among other things, a drug which, because of its toxicity and other potential for harmful effects, or the method of its use, or the collateral measures necessary to its use, was not considered safe for use except under the supervision of a practitioner licensed by State law to administer such drugs. 21 U.S.C. § 353(b)(1)(A).

7. A prescription drug could only be lawfully dispensed to a patient or consumer upon the valid prescription of a practitioner licensed by State law to dispense prescription drugs. The act of dispensing a prescription drug without a valid prescription was deemed an act which resulted in the drug being misbranded while held for sale. 21 U.S.C. § 353(b)(1).

8. A drug was also misbranded if the labeling on the drug did not bear adequate directions for use. 21 U.S.C. § 352(f)(1). "Adequate directions for use" were defined as directions under which a layperson could use a drug safely for the purposes for

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which it was intended without a doctor's supervision. Directions under which a layperson could use a drug safely could not be written for a prescription drug because such drugs could, by definition, only be used safely at the direction, and under the supervision, of a licensed practitioner. Prescription drugs dispensed pursuant to a valid prescription were exempt from the requirement for adequate directions for use by a layperson. But prescription drugs dispensed without a valid prescription were necessarily misbranded for lacking adequate directions for use. 21 U.S.C. § 353(b); 21 C.F.R. § 201.5.

9. Under the FDCA, every person, upon first engaging in the manufacture, preparation, propagation, compounding, or processing of drugs in any establishment they owned or operated was required to immediately register their name, places of business, and all such establishments with the Secretary of Health and Human Services, through the United States Food and Drug Administration (FDA). 21 U.S.C. § 360(c).

10. A drug was also misbranded if it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered with the FDA. 21 U.S.C. § 352(o).

11. Under the FDCA, the introduction, delivery for introduction, or causing the introduction or delivery for introduction into interstate commerce of a misbranded drug was prohibited. 21 U.S.C. § 331(a).

BACKGROUND OF JOHN T. STINE

12. Defendant JOHNNY T. STINE resided in the Western District of Washington. STINE was not a medical doctor or any type of medical professional. STINE did not possess a medical license in the States of Washington, Montana, or Idaho which would have allowed him to dispense prescription drugs or write a valid prescription for prescription drugs.

13. Rather, JOHNNY T. STINE operated an unlicensed drug manufacturing establishment, what he called a "garage laboratory," in Redmond, Washington. STINE's "laboratory" was not registered as a drug manufacturing establishment with the FDA.

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14. Starting in or before 2018, and continuing to August 2020, JOHNNY T. STINE created and distributed what he described as "tumor vaccines" that he represented would treat cancer patients' disease. In order to create these so-called vaccine treatments, STINE obtained tissue samples from cancer patients from across the United States. STINE used those tissue samples to prepare his own supposed vaccine treatment in his Redmond garage laboratory. STINE then traveled to administer the supposed vaccines to the patients. STINE provided some supposed vaccine treatments to patients for free, and for other patients he charged thousands of dollars.

15. Starting in March 2020, JOHNNY T. STINE created and distributed what he described as a COVID-19 vaccine. STINE claimed to use the sequence of the spike protein of the virus to create the supposed COVID-19 vaccine in his Redmond garage laboratory. STINE traveled to administer the supposed vaccine. STINE typically charged patients between $400 and $1000 for the supposed COVID-19 vaccine, but in some cases, STINE offered to accept methamphetamine or sexual contact in lieu of monetary payment.

16. On May 21, 2020, the FDA and the United States Federal Trade Commission issued a warning letter to JOHNNY T. STINE and North Coast Biologics (a business name used by STINE) for illegally offering the sale of unapproved new drugs and misbranded drugs, specifically, a "nCoV19 spike protein vaccine" intended to mitigate, prevent, treat, diagnose, or cure COVID-19. The Warning Letter instructed STINE to take immediate action to correct any violations of the FDCA, the Public Health Service Act, and FDA's implementing regulations, and to not resume selling his products for prevention of COVID-19.

17. On or about June 22, 2020, JOHNNY T. STINE entered into a Consent Decree with the State of Washington. In that Consent Decree, STINE agreed not to "market, advertise, promote, or sell vaccines, immunogens, antibodies, or any other substance or product [STINE] represent[ed] to have health benefits unless [STINE has] sufficient evidence to substantiate each claim [made] about the product's function,

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benefits, efficacy, and safety for use." STINE further agreed not to promote any vaccines without first subjecting the vaccine to rigorous scientific testing.

COUNT 1

(Introduction of a Misbranded Drug into Interstate Commerce)

18. Paragraphs 1-17 of this Information are incorporated by reference as if set forth fully herein.

19. On or about July 25, 2020, in Redmond, in the Western District of Washington and elsewhere, JOHNNY T. STINE, introduced, delivered for introduction, and caused to be delivered for introduction into interstate commerce, from Redmond, Washington, to Kalispell, Montana, a drug, to wit: a purported cancer vaccine serum, which was misbranded in the following ways:

a. The drug was a prescription drug pursuant to 21 U.S.C. § 353(b)(1), because the drug's method of use, and the collateral measures necessary for its use, rendered it not safe for use except under the supervision of a licensed practitioner, and the drug was dispensed without a valid prescription from a licensed practitioner (21 U.S.C. § 353(b)(1));

b. The labeling failed to bear adequate directions for use (21 U.S.C. § 352(f)(1)); and

c. The drug was manufactured, prepared, propagated, compounded, and processed in establishments not registered with the FDA, as required by 21 U.S.C. § 360 (21 U.S.C. § 352(o)).

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

COUNT 2

(Introduction of a Misbranded Drug into Interstate Commerce)

20. Paragraphs 1-17 of this Information are incorporated by reference as if set forth fully herein.

21. On or about August 19, 2020, in Redmond, in the Western District of Washington and elsewhere, JOHNNY T. STINE, introduced, delivered for introduction,

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and caused to be delivered for introduction into interstate commerce, from Redmond, Washington, to Wallace, Idaho, a drug, to wit: a purported "COVID-19 vaccine," which was misbranded in the following ways:

a. The drug was a prescription drug pursuant to 21 U.S.C. § 353(b)(1), because the drug's method of use, and the collateral measures necessary for its use, rendered it not safe for use except under the supervision of a licensed practitioner, and the drug was dispensed without a valid prescription from a licensed practitioner (21 U.S.C. § 353(b)(1));

b. The labeling failed to bear adequate directions for use (21 U.S.C. § 352(f)(1)); and

c. The drug was manufactured, prepared, propagated, compounded, and processed in establishments not registered with the FDA, as required by 21 U.S.C. § 360 (21 U.S.C. § 352(o)).

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

DATED this 21st day of January 2021.

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