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7 UNITED STATES DISTRICT COURT FOR THE  
8 WESTERN DISTRICT OF WASHINGTON  
9 AT SEATTLE

10 UNITED STATES OF AMERICA,

11 Plaintiff,

12  
13 v.

14 JOHNNY T. STINE,

15 Defendant.  
16

CASE NO. CR21-011 MLP

**INFORMATION (Misdemeanor)**

17 The United States Attorney charges that:

18 **INTRODUCTION**

19 At all times relevant to this Information:

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

24 2. Under the FDCA, "interstate commerce" meant commerce between any  
25 State or Territory and any place outside thereof, and commerce within the District of  
26 Columbia or within any other Territory not organized with a legislative body. 21

27 U.S.C. § 321(b)

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

1 matter upon the immediate container of any article. 21 U.S.C. § 321(k). The term  
2 “labeling” was defined as all labels and other printed or graphic matter upon any article  
3 or any of its containers or wrappers, or accompanying such article. 21 U.S.C. § 321(m).

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

8 5. The “intended use” of an article meant the objective intent of the persons  
9 legally responsible for its labeling. The intent was determined by such persons’  
10 expressions, or could be shown by the circumstances surrounding the distribution of the  
11 article. It could, for example, be shown by labeling claims, advertising matter, or oral or  
12 written statements by such persons or their representatives; or by the circumstances in  
13 which the article was, with the knowledge of such persons or their representatives,  
14 offered and used for a purpose for which it was neither labeled nor advertised. 21 C.F.R.  
15 § 201.128.

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

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

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

1 | which it was intended without a doctor's supervision. Directions under which a  
2 | layperson could use a drug safely could not be written for a prescription drug because  
3 | such drugs could, by definition, only be used safely at the direction, and under the  
4 | supervision, of a licensed practitioner. Prescription drugs dispensed pursuant to a valid  
5 | prescription were exempt from the requirement for adequate directions for use by a  
6 | layperson. But prescription drugs dispensed without a valid prescription were necessarily  
7 | misbranded for lacking adequate directions for use. 21 U.S.C. § 353(b); 21 C.F.R.  
8 | § 201.5.

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

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

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

#### 20 |                                   BACKGROUND OF JOHN T. STINE

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

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

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

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

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

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

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

3 **COUNT 1**

4 **(Introduction of a Misbranded Drug into Interstate Commerce)**

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

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

- 12 a. The drug was a prescription drug pursuant to 21 U.S.C. § 353(b)(1), because  
13 the drug’s method of use, and the collateral measures necessary for its use,  
14 rendered it not safe for use except under the supervision of a licensed  
15 practitioner, and the drug was dispensed without a valid prescription from a  
16 licensed practitioner (21 U.S.C. § 353(b)(1));
- 17 b. The labeling failed to bear adequate directions for use (21 U.S.C.  
18 § 352(f)(1)); and
- 19 c. The drug was manufactured, prepared, propagated, compounded, and  
20 processed in establishments not registered with the FDA, as required by 21  
21 U.S.C. § 360 (21 U.S.C. § 352(o)).

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

23 **COUNT 2**

24 **(Introduction of a Misbranded Drug into Interstate Commerce)**

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


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


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

- 4 a. The drug was a prescription drug pursuant to 21 U.S.C. § 353(b)(1), because  
5 the drug's method of use, and the collateral measures necessary for its use,  
6 rendered it not safe for use except under the supervision of a licensed  
7 practitioner, and the drug was dispensed without a valid prescription from a  
8 licensed practitioner (21 U.S.C. § 353(b)(1));
- 9 b. The labeling failed to bear adequate directions for use (21 U.S.C.  
10 § 352(f)(1)); and
- 11 c. The drug was manufactured, prepared, propagated, compounded, and  
12 processed in establishments not registered with the FDA, as required by 21  
13 U.S.C. § 360 (21 U.S.C. § 352(o)).

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

15  
16 DATED this 21<sup>st</sup> day of January 2021.

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19 \_\_\_\_\_  
20 BRIAN T. MORAN  
21 United States Attorney

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23 \_\_\_\_\_  
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