

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TENNESSEE  
WESTERN DIVISION

FILED BY

Robert R. Di Troia, Clerk  
U.S. DIST. COURT  
W.D. OF TENN. - MEMPHIS

UNITED STATES OF AMERICA,

PLAINTIFF,

vs.

GEORGE KINDNESS,  
AND  
AMSCOT MEDICAL LABS, INC.  
(A CORPORATION)

DEFENDANTS.

CR. NO.

03-204338 V

18 U.S.C., § 2  
18 U.S.C., § 371  
21 U.S.C., § 331(a)  
21 U.S.C., § 333(a)(2)**INDICTMENT**

THE GRAND JURY CHARGES

**COUNT 1:****INTRODUCTION****The Food, Drug, and Cosmetic Act**

1. The United States Food and Drug Administration (hereinafter "FDA") is the federal agency within the United States Department of Health and Human Services (hereinafter "DHHS") charged with the responsibility for protecting the health and safety of the American public by ensuring that drugs are safe and effective for their intended uses before they may be legally marketed in interstate commerce. In order to legally market a drug in interstate commerce, the drug's manufacturer must comply with all applicable provisions of the Federal Food, Drug, and Cosmetic Act (hereinafter "the Act"), 21 U.S.C. § 321, et seq., and its implementing regulations.

2. The Act prohibits causing the introduction or delivery for introduction into

A

interstate commerce of misbranded drugs and introducing or delivering for introduction into interstate commerce misbranded drugs. 21 U.S.C. § 331(a).

3. The Act defines drugs to include articles intended for use in the cure, mitigation, treatment, or prevention of disease in man or other animals or intended to affect the structure or any function of the human body and components of such articles. 21 U.S.C. § 321(g). The term "drug" includes "articles intended for use as a component" of the drug. 21 U.S.C. § 321(g)(1)(D). "Components" are further defined to include "any ingredient intended for use in the manufacture of a drug product." 21 C.F.R. § 210.3(b)(3).

4. Certain autologous vaccines manufactured by Defendant AMSCOT MEDICAL LABS, INC., commonly known as Gene Activated Therapy (GAT) and Theracine, (hereinafter one or more of these substances are sometimes referred to generically as "Defendant AMSCOT's autologous vaccines") were intended for use in the cure, mitigation, treatment, or prevention of disease in man and were drugs within the meaning of the Act, 21 U.S.C. §§ 321(g)(1)(B);

5. Under the Act, a drug is deemed to be misbranded for any one of a number of reasons. Relevant to this indictment, a drug is misbranded if it fails to bear adequate directions for its use, 21 U.S.C. § 352(f)(1).

6. A drug is "adulterated" if: 1) if it has been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or 2) if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good

manufacturing practice to assure that such drug meets the requirements of the Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess. 21 U.S.C. § 351(a)(2)(B) and (C).

#### **The Defendants**

7. Defendant GEORGE KINDNESS, currently a resident of Middletown, Ohio, was president and part-owner of Defendant AMSCOT MEDICAL LABS, INC., from January 2, 1992, to the date of this indictment. Defendant GEORGE KINDNESS has also been the lab director of Defendant AMSCOT from January 2, 1992, to present and active in the day-to-day operation of the business.

8. From on and after January 2, 1992, to the date of this indictment, Defendant AMSCOT MEDICAL LABS, INC. was an Ohio for-profit corporation part-owned and operated by Defendant GEORGE KINDNESS, with its principal place of business initially in Hamilton, OH and later in Cincinnati, OH.

#### **The Conspiracy Charge**

9. From in or about September 1997, through in or about April 2001 in the Western District of Tennessee, and elsewhere, defendants did knowingly and intentionally combine, conspire, confederate and agree together and with diverse other persons both known and unknown to the Grand Jury to violate laws of the United States, to wit, introducing and delivering and causing the introduction and delivery into interstate commerce of misbranded and adulterated drugs with the intent to defraud or mislead in violation of 21 U.S.C. §§ 331(a) and 333(a)(2).

10. On or about April 12 – 13, 1999, FDA conducted an inspection of Defendant AMSCOT, located at 11365 Williamson Road., Cincinnati, Ohio, pursuant to its regulatory authority, 21 U.S.C. 374. The FDA discovered that Defendant AMSCOT had been and was currently manufacturing autologous vaccines from cancer patients' own tumor tissue and blood samples. The vaccines were intended as a treatment for cancer. The patients were administered these vaccines. The vaccine was being administered to patients as part of a study known as the Gene Activated Therapy (GAT) study.

11. Unnamed co-conspirator 1 was the clinical investigator for the GAT study and had an office located in Memphis, Tennessee.

12. The FDA inspection revealed that unnamed co-conspirator 1 would prescribe the vaccine for the cancer patients. Unnamed co-conspirator 1 would extract or cause to be extracted a blood and/or tumor tissue sample from the patients and subsequently ship the samples in interstate commerce to Defendant AMSCOT. Defendant AMSCOT, under the direction of Defendant GEORGE KINDNESS, would process the blood and tumor samples into a finished vaccine. The vaccine was then shipped in interstate commerce from Defendant AMSCOT in Cincinnati to either unnamed co-conspirator 1 in Memphis or directly to patients and/or others in states other than Tennessee. Defendant AMSCOT and Defendant GEORGE KINDNESS were informed by FDA investigators during the inspection that the GAT study required an Investigational New Drug Application (IND) to be in effect. Defendant GEORGE KINDNESS was informed by FDA investigators that conducting the GAT study without an IND in effect was a violation of the Food, Drug, and Cosmetic Act.

13. On or about April 15, 1999, Defendant AMSCOT submitted an IND application for the GAT study to the FDA. Defendant AMSCOT was listed as the study sponsor and vaccine production site in the IND application. The IND for the GAT study was never approved by FDA.

14. On or about May 14, 1999, FDA placed the IND for the GAT study on clinical hold. A clinical hold requires that all clinical work requested under an IND is either delayed or suspended until the IND is approved. (See 21 CFR 312.42(a)).

15. On or about December 7 – 9, 1999, the FDA inspected unnamed co-conspirator 1's office in Memphis. The FDA learned that after the IND for the GAT study was placed on hold, unnamed co-conspirator 1 continued to treat patients taking part in the GAT study with the same autologous tumor vaccine manufactured by Defendant AMSCOT. The FDA also learned that unnamed co-conspirator 1 had treated patients with an almost identical vaccine called Theracine. Like the GAT study vaccine, the Theracine was also manufactured by Defendant AMSCOT. The FDA had neither received, evaluated nor approved an IND application for the study of the Theracine vaccine.

16. On or about May 2 – 10, 2000, the FDA inspected Defendant AMSCOT and found evidence that since June 1999 Defendant AMSCOT had been manufacturing Theracine. Defendant GEORGE KINDNESS acknowledged in a sworn statement to FDA investigators on May 10, 2000, that an IND for Theracine had not been submitted to the FDA. The inspection also revealed that 63 Theracine vaccines had been processed since November 14, 1999, all of which were shipped to unnamed co-conspirator 1 and others prior to performing sterility, endotoxin and mycoplasma testing.

**OBJECTS OF THE CONSPIRACY**

17. It was the object of the conspiracy: (A) to produce and distribute in interstate commerce to health care professionals and consumers misbranded drugs, i.e. one or more autologous vaccines, with the intent to deceive or defraud, and (2) to produce and distribute in interstate commerce to health care professionals and consumers adulterated drugs, i.e. one or more of autologous vaccines, with the intent to deceive or defraud, in violation of 21 U.S.C., Section 331(a) and 333(a)(2).

**OVERT ACTS**

18. In furtherance of the conspiracy and to effect the objects thereof, defendants and others known and unknown to the Grand Jury committed and caused to be committed the following overt acts, among others, in the Western District of Tennessee, and elsewhere:

A. On or about April 12, 1999 and during the course of FDA's inspection at Defendant AMSCOT, Defendant GEORGE KINDNESS falsely represented to FDA investigators that he had an M.D. in general medicine.

B. On or about January 5, 2000, unnamed co-conspirator 1 of Memphis, Tennessee, sent a blood sample and tumor biopsy drawn from patient GN to Defendant AMSCOT for the purpose of manufacturing an injectable biologic to be administered to patient GN for the treatment of cancer.

C. On or about January 12, 2000, certain employees at Defendant AMSCOT at the direction of Defendant AMSCOT owner Defendant GEORGE KINDNESS, processed the blood and tumor of patient GN into an injectable biologic



called Theracine.

D. On or about January 12, 2000, Defendant GEORGE KINDNESS caused to be transported via United Parcel Service ("UPS") the Theracine biologic manufactured from the blood and tumor of patient GN to unnamed co-conspirator 1 in Memphis for the purpose of administering it to patient GN for the treatment of cancer.

E. On or about January 6, 2000, unnamed co-conspirator 1 of Memphis, Tennessee, sent a blood sample and tumor biopsy drawn from patient KS to Defendant AMSCOT for the purpose of manufacturing Theracine to be administered to patient KS for the treatment of cancer.

F. On or about January 13, 2000, certain employees at Defendant AMSCOT at the direction of Defendant GEORGE KINDNESS, processed the blood and tumor of patient KS into the injectable biologic Theracine.

G. On or about January 17, 2000, Defendant GEORGE KINDNESS caused to be transported via UPS the Theracine manufactured from the blood and tumor of patient KS to unnamed co-conspirator 1 in Memphis for the purpose of administering it to patient KS for the treatment of cancer.

H. On or about February 4, 2000, unnamed co-conspirator 1 of Memphis, Tennessee, sent a blood sample and tumor biopsy from patient KN to Defendant AMSCOT for the purpose of manufacturing Theracine to be administered to patient KN for the treatment of cancer.

I. On or about February 11, 2000, certain employees at Defendant AMSCOT at the direction of Defendant GEORGE KINDNESS, processed the blood and tumor of patient KN into the injectable biologic Theracine.

J. On or about February 14, 2000, Defendant GEORGE KINDNESS caused to be transported via UPS the Theracine processed from the blood and tumor samples of patient KN to unnamed co-conspirator 1 in Memphis for the purpose of treating patient KN for cancer.

K. On or about February 8, 2000, unnamed co-conspirator 1 in Memphis, Tennessee, caused to be transported to Defendant AMSCOT a blood sample and tumor biopsy from patient SW for the purpose of manufacturing Theracine to be administered to patient SW for the treatment of cancer.

L. On or about February 16, 2000, certain employees at Defendant AMSCOT at the direction of Defendant GEORGE KINDNESS processed the blood and tumor sample of patient SW into the injectable biologic Theracine.

M. On or about February 16, 2000, Defendant GEORGE KINDNESS caused to be transported via UPS the Theracine processed from the blood and tumor samples of patient SW to unnamed co-conspirator 1 in Memphis, Tennessee, for the purpose of administering the Theracine to patient SW for the treatment of cancer.

N. On or about February 21, 2000, unnamed co-conspirator 1 in Memphis caused a blood sample and tumor biopsy from patient YJ to be transported to Defendant AMSCOT for the purpose of manufacturing Theracine to be administered to patient YJ for the treatment of cancer.

O. On or about February 26, 2000, certain employees at Defendant AMSCOT at the direction of Defendant GEORGE KINDNESS processed the blood and tumor sample of patient YJ into the injectable biologic Theracine.

P. On or about February 29, 2000, Defendant GEORGE KINDNESS



caused to be transported via UPS the Theracine processed from the blood and tumor samples of patient YJ to unnamed co-conspirator 1 in Memphis for the purpose of administering the Theracine to patient YJ for the treatment of cancer.

Q. On or about February 21, 2000, unnamed co-conspirator 1 in Memphis caused a blood sample and tumor biopsy from patient RL to be transported to Defendant AMSCOT for the purpose of manufacturing Theracine to be administered to patient RL for the treatment of cancer.

R. On or about February 27, 2000, certain employees at Defendant AMSCOT at the direction of Defendant GEORGE KINDNESS processed the blood and tumor sample of patient RL into the injectable biologic Theracine.

S. On or about February 29, 2000, Defendant GEORGE KINDNESS caused to be transported via UPS the Theracine processed from the blood and tumor samples of patient RL to unnamed co-conspirator 1 in Memphis for the purpose of administering the Theracine to patient RL for the treatment of cancer.

T. On or about February 29, 2000, unnamed co-conspirator 1 in Memphis caused a blood sample and tumor biopsy from patient DP to be transported to Defendant AMSCOT for the purpose of manufacturing Theracine to be administered to patient DP for the treatment of cancer.

U. On or about March 8, 2000, certain employees at Defendant AMSCOT at the direction of Defendant GEORGE KINDNESS processed the blood and tumor sample of patient DP into the injectable biologic Theracine.

V. On or about March 8, 2000, Defendant GEORGE KINDNESS caused to be transported via UPS the Theracine processed from the blood and tumor samples of

patient DP to unnamed co-conspirator 1 in Memphis for the purpose of administering the Theracine to patient DP for the treatment of cancer.

W. On or about March 23, 2000, unnamed co-conspirator 1 in Memphis caused to be transported to Defendant AMSCOT a blood sample and tumor biopsy from patient SD for the purpose of manufacturing Theracine to be administered to patient SD for the treatment of cancer.

X. On or about March 31, 2000, certain employees at Defendant AMSCOT at the direction of Defendant GEORGE KINDNESS processed the blood and tumor sample of patient SD into the injectable biologic Theracine.

Y. On or about April 3, 2000, Defendant GEORGE KINDNESS caused to be transported via UPS the Theracine processed from the blood and tumor samples of patient SD to unnamed co-conspirator 1 in Memphis for the purpose of administering the Theracine to patient SD for the treatment of cancer.

Z. On or about March 28, 2000, unnamed co-conspirator 1 in Memphis caused to be transported to Defendant AMSCOT a blood sample and tumor biopsy from patient VM for the purpose of manufacturing Theracine to be administered to patient VM for the treatment of cancer.

AA. On or about April 5, 2000, certain employees at Defendant AMSCOT at the direction of Defendant GEORGE KINDNESS processed the blood and tumor sample of patient VM into the injectable biologic Theracine.

BB. On or about April 5, 2000, Defendant GEORGE KINDNESS caused to be transported via UPS the Theracine processed from the blood and tumor samples of patient VM to unnamed co-conspirator 1 in Memphis for the purpose of administering

the Theracine to patient VM for the treatment of cancer.

CC. On or about March 29, 2000, unnamed co-conspirator 1 in Memphis sent a blood sample and tumor biopsy from patient EP to Defendant AMSCOT for the purpose of manufacturing Theracine to be administered to patient EP for the treatment of cancer.

DD. On or about April 6, 2000, certain employees at Defendant AMSCOT at the direction of Defendant GEORGE KINDNESS processed the blood and tumor sample of patient EP into the injectable biologic Theracine.

EE. On or about April 6, 2000, Defendant GEORGE KINDNESS caused to be transported via UPS the Theracine processed from the blood and tumor samples of patient EP to unnamed co-conspirator 1 in Memphis for the purpose of administering the Theracine to patient EP for the treatment of cancer.

FF. On or about June 7, 2000, unnamed co-conspirator 1 in Memphis caused to be transported a blood sample and tumor biopsy from patient GN to Defendant AMSCOT for the purpose of manufacturing Theracine to be administered to patient GN for the treatment of cancer.

GG. On or about June 19, 2000, certain employees at Defendant AMSCOT at the direction of Defendant GEORGE KINDNESS processed the blood and tumor sample of patient GN into the injectable biologic Theracine.

HH. On or about June 27, 2000, Defendant AMSCOT transported via UPS the Theracine from the blood and tumor samples of patient GN to unnamed co-conspirator 1 in Memphis to be administered to patient GN for the treatment of cancer.

II. On or about June 13, 2000, unnamed co-conspirator 1 in Memphis

caused a blood sample and tumor biopsy from patient GK to be transported to Defendant AMSCOT for the purpose of manufacturing Theracine to be administered to patient GK for the treatment of cancer.

JJ. On or about June 21, 2000, certain employees at Defendant AMSCOT at the direction of Defendant GEORGE KINDNESS processed the blood and tumor sample of patient GK into the injectable biologic Theracine.

KK. On or about June 28, 2000, Defendant GEORGE KINDNESS shipped Theracine processed from the blood and tumor samples of patient GK to unnamed co-conspirator 1 in Memphis for the purpose of administering it to patient GK for the treatment of cancer.

LL. On or about June 26, 2000, and July 5, 2000, Defendant GEORGE KINDNESS caused a Defendant AMSCOT employee to ship Theracine via UPS to unnamed co-conspirator 1 in Memphis.

MM. On or about June 30, 2000, unnamed co-conspirator 1 caused to be transported a blood sample and tumor biopsy from patient RB to Defendant AMSCOT for the purpose of manufacturing Theracine to be administered to patient RB for the treatment of cancer.

NN. On or about July 10, 2000, certain employees at Defendant AMSCOT at the direction of Defendant GEORGE KINDNESS processed the blood and tumor sample of patient RB into the injectable biologic Theracine.

OO. On or about June 30, 2000, unnamed co-conspirator 1 in Memphis transported a blood sample and tumor biopsy from patient CH to Defendant AMSCOT for the purpose of manufacturing Theracine to be administered to patient CH for the

treatment of cancer.

PP. On or about July 10, 2000, certain employees at Defendant AMSCOT at the direction of Defendant GEORGE KINDNESS processed the blood and tumor sample of patient CH into the injectable biologic Theracine.

QQ. On or about July 14, 2000, unnamed co-conspirator 1 in Memphis transported a blood sample and tumor biopsy from patient JM to Defendant AMSCOT for the purpose of manufacturing Theracine to be administered to patient JM for the treatment of cancer.

RR. On or about July 25, 2000, certain employees at Defendant AMSCOT at the direction of Defendant GEORGE KINDNESS processed the blood and tumor sample of patient JM into the injectable biologic Theracine.

SS. On or about July 26, 2000, Defendant GEORGE KINDNESS provided the Theracine processed from the blood and tumor samples of patient JM to unnamed co-conspirator 1 in Memphis for the purpose of having it administered to patient JM for the treatment of cancer.

TT. On or about July 20, 2000, unnamed co-conspirator 1 in Memphis transported a blood sample and tumor biopsy from patient JS to Defendant AMSCOT for the purpose of manufacturing Theracine to be administered to patient JS for the treatment of cancer.

UU. On or about July 31, 2000, certain employees at Defendant AMSCOT at the direction of Defendant GEORGE KINDNESS processed the blood and tumor sample of patient JS into the injectable biologic Theracine.

VV. On or about August 7, 2000, Defendant GEORGE KINDNESS caused

to be provided the Theracine processed from the blood and tumor samples of patient JS to unnamed co-conspirator 1 in Memphis for the purpose of administering it to patient JS for the treatment of cancer.

WW. On or about August 2, 2000, unnamed co-conspirator 1 in Memphis transported a blood sample and tumor biopsy from patient AF to Defendant AMSCOT for the purpose of manufacturing Theracine to be administered to patient AF for the treatment of cancer.

XX. On or about August 11, 2000, certain employees at Defendant AMSCOT at the direction of Defendant GEORGE KINDNESS processed the blood and tumor sample of patient AF into the injectable biologic Theracine.

YY. On or about August 18, 2000, Defendant GEORGE KINDNESS caused to be provided the Theracine processed from the blood and tumor samples of patient AF to unnamed co-conspirator 1 in Memphis for the purpose of administering it to patient JS for the treatment of cancer.

ZZ. On or about August 3, 2000, Defendant GEORGE KINDNESS caused to be shipped via UPS Theracine processed from the blood and tumor tissue of patient RL to unnamed co-conspirator 1 in Memphis for the purpose of administering the Theracine to patient RL for the treatment of cancer.

AAA. On or about November 3, 2000, and during the course of an FDA inspection of Defendant AMSCOT, Defendant GEORGE KINDNESS falsely stated to FDA investigators that he had only manufactured Theracine for previous Theracine patients and that he did not maintain certain records documenting the manufacture of Theracine batches after approximately May 10, 2000.



BBB. During the course of the FDA inspection of Defendant AMSCOT from on or about October 29 to November 3, 2000, Defendant GEORGE KINDNESS instructed a Defendant AMSCOT employee to conceal vaccine log pages documenting the manufacture of Theracine from after May 19, 2000, from the FDA investigators. The vaccine logs were not inspected by the FDA during the inspection.

All in violation of 18 U.S.C. § 371

**COUNTS 2 THROUGH 11**

19. The allegations as set forth in paragraphs 1 through 8 and 10 through 16 in Count 1 of this indictment are incorporated by reference as if fully rewritten herein.

20. On or about the following dates as set forth for each count, within the Western District of Tennessee, and elsewhere, Defendant AMSCOT and Defendant GEORGE KINDNESS, being aided and abetted by others, known and unknown to the grand jury, did, with the intent to defraud and mislead, introduce and deliver for introduction into interstate commerce and cause to be introduced and delivered for introduction into interstate commerce, a drug that was misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that its labeling did not bear adequate directions for use:

<u>Count Number</u>	<u>Date of Violation</u>
2	January 12, 2000
3	January 17, 2000
4	February 14, 2000
5	February 16, 2000

6	February 29, 2000
7	March 8, 2000
8	April 3, 2000
9	April 5, 2000
10	April 6, 2000
11	August 3, 2000

All in violation of 21 U.S.C. §§ 331(a) and 333(a)(2) and 18 U.S.C. § 2.

**COUNTS 12 THROUGH 21**

21. The allegations as set forth above in this indictment in paragraphs 1 through 8 and 10 through 16 in Count 1 of this indictment are incorporated by reference as if fully rewritten herein.

22. On or about the following dates as set forth for each count, within the Western District of Tennessee, and elsewhere, Defendant AMSCOT and Defendant GEORGE KINDNESS, being aided and abetted, by persons known and unknown to the grand jury, did, with the intent to defraud and mislead, introduce and deliver for introduction into interstate commerce and cause to be introduced and delivered for introduction into interstate commerce, a drug that was adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, and the facilities and controls used for, its manufacture, processing, packing and holding did not conform to and were not operated and administered in conformity with then current good manufacturing practices to assure that such drug met the requirements of the Act as to safety and had the identity and

strength, and met the quality and purity characteristics, which it was purported and represented to possess:

<u>Count Number</u>	<u>Date of Violation</u>
12	January 12, 2000
13	January 17, 2000
14	February 14, 2000
15	February 16, 2000
16	February 29, 2000
17	March 8, 2000
18	April 3, 2000
19	April 5, 2000
20	April 6, 2000
21	August 3, 2000

All in violation of 21 U.S.C. §§ 331(a) and 333(a)(2) and 18 U.S.C. § 2.

**A TRUE BILL:**

Lawrence J. Lawrence  
Grand Jury Foreperson

DATED: 1-19-03

Lawrence J. Lawrence  
Assistant United States Attorney  
Western District of Tennessee