UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON

UNITED STATES OF AMERICA

v. CRIMINAL NO. 2:14-CR-00279

18 U.S.C. § 1347
21 U.S.C. § 331(k)
21 U.S.C. § 352(a)
21 U.S.C. § 333(a)(2)

TRIVILLIAN'S PHARMACY

# I N F O R M A T I O N

The United States Attorney Charges:

At all times relevant to this Information:

## Background

1. Defendant TRIVILLIAN'S PHARMACY, a corporate entity, was located at 215 35th Street, SE, Charleston (or, Kanawha City), West Virginia, within Kanawha County and the Southern District of West Virginia. TRIVILLIAN'S PHARMACY was a retail and compounding pharmacy which was licensed by the West Virginia Board of Pharmacy, and registered with the Drug Enforcement Administration to dispense controlled substances.

2. Compounding involved the combining, mixing, or altering of ingredients to create a drug or medication tailored to the needs of the individual patient.

3. TRIVILLIAN'S PHARMACY was also an authorized Medicare and Medicaid provider, and was therefore bound by the laws, rules and regulations that govern Medicare and Medicaid. As an authorized Medicare and Medicaid provider, TRIVILLIAN'S PHARMACY submitted claims for reimbursement (or, billing claims) to Medicare and Medicaid for drugs and medications (including compounding medications).

4. Since at least 1999, Paula Jane Butterfield was the president, owner and pharmacist-in-charge of TRIVILLIAN'S PHARMACY. TRIVILLIAN'S PHARMACY retained the services of several other pharmacists and pharmacy technicians, as well as other employees.

**The Pertinent Health Care Benefit Programs**

5. Medicare and Medicaid were health care benefit programs as defined in 18 U.S.C. § 24(b) and as referenced in 18 U.S.C. § 1347 - i.e., a "public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual."

**The Food, Drug, and Cosmetic Act**

6. Under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., a drug was any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of

a disease, or an article intended to affect the structure or any function of the body. 21 U.S.C. § 321(g)(2), (3).

7. In order for a drug or medication to be legally distributed in the United States, it had to comply with laws and regulations regarding manufacturing and labeling. For example, the FDCA proscribed causing a drug to be misbranded after it had moved in interstate commerce and while it was held for sale. 21 U.S.C. § 331(k). Also, a drug was misbranded if its labeling was false or misleading in any particular manner. 21 U.S.C. § 352(a).

8. While the FDCA did not require the National Drug Code ("NDC") number to appear on all drug labels, if the NDC number was included on a drug label, it should have been displayed in accordance with the pertinent federal regulations governing the inclusion of NDC numbers on drug labels. 21 C.F.R. § 207.35(b). A National Drug Code number consisted of a labeler code which identified the manufacturer, repacker or distributor; the product code identifying the specific strength, dose or formulation of a specific drug; and a package code identifying the form and size of the package. NDC numbers were used for the billing of drugs or medications.

9. The United States Food and Drug Administration ("FDA") was responsible for protecting the health and safety of the public by enforcing the FDCA, and ensuring, among other things, that drugs intended for use in humans were safe and effective for their intended use and that the labeling of such drugs bore true and accurate information.

10. The FDA therefore required pharmacies, including those with compounding services, to dispense correctly-labelled drugs and medications to their customers.

**The Scheme and Artifice to Defraud**

11. Beginning in or around January 2010 and continuing through approximately September 2014, at or near Charleston, Kanawha County, within the Southern District of West Virginia, defendant TRIVILLIAN'S PHARMACY did knowingly and willfully execute a scheme and artifice to defraud the Medicare and Medicaid programs and to obtain, by means of materially false and fraudulent pretenses and representations, money owned and under the control or custody of the Medicare and Medicaid programs in connection with the payment for drugs or medications.

## Manner and Means of Execution of the Scheme

12. Defendant TRIVILLIAN'S PHARMACY carried out this scheme by billing, and causing to be billed, Medicare and Medicaid for drugs or medications which were never dispensed, were expired, or were misbranded. Based on these fraudulent claims, TRIVILLIAN'S PHARMACY received reimbursement from Medicare and Medicaid to which it was not legally entitled. Specifically:

- TRIVILLIAN'S PHARMACY dispensed less expensive compounded drugs and medications while submitting billing claims which falsely reflected that said drugs and medications were more expensive non-compounded and FDA-approved manufactured drugs and medications, i.e., caffeine, Diflorasone, Halobetasol, Neomycin-Polymyxin-HC Ear Suspension, Tamiflu, Ultravate, and Vancomycin;

- TRIVILLIAN'S PHARMACY dispensed and submitted claims for drugs and medications which were compounded outside a safe and clean environment, i.e., Estradiol and Progesterone;

- TRIVILLIAN'S PHARMACY dispensed generic drugs and medications, but submitted claims for more expensive brand name drugs and medications i.e., Lovenox, Plavix, and Methylin;

- TRIVILLIAN'S PHARMACY dispensed and submitted claims for expired drugs and medications, i.e., Belladonna, Donnatel, Epogen, and Procrit; and

- TRIVILLIAN'S PHARMACY billed for drugs and medications that it did not dispense, i.e., Avalox, Levaquin, Lovenox, and Tamiflu.

**Introduction of Misbranded Drugs in Interstate Commerce**

13. The factual allegations contained in paragraphs one through twelve are incorporated as if fully set forth here.

14. Beginning in or about January 2010 and continuing through approximately September 2014, defendant TRIVILLIAN'S PHARMACY compounded drugs and medications that bore misleading labeling which contained NDC numbers of their FDA-approved brand name counterparts for Vancomycin, Diflorasone, Halobetasol, Ultravate, Tamiflu, and caffeine, and then sold these misbranded drugs and medications to its customers;

15. The base drugs for the compounded drugs and medications described above in paragraph fourteen had been shipped to TRIVILLIAN'S PHARMACY in West Virginia from other states; and

16. TRIVILLIAN'S PHARMACY also dispensed less expensive generic drugs and medications with NDC numbers for more expensive brand name drugs, specifically, Lovenox, Plavix, and Methylin. These generic drugs and medications had been shipped to TRIVILLIAN'S PHARMACY in West Virginia from other states.

## COUNT ONE

17. The allegations contained in paragraphs one through twelve are alleged and incorporated as if fully set forth here.

18. From in or about January 2010 through approximately September 2014, in the Southern District of West Virginia and elsewhere, the defendant, TRIVILLIAN'S PHARMACY, did knowingly and willfully execute, and attempt to execute, the above-described scheme and artifice to defraud as to a material matter health care benefit programs, affecting commerce, as defined in Title 18, United States Code, Section 24(b), and to obtain any of the money and property owned by, and under the custody and control of, said health care benefit program, by means of materially false and fraudulent pretenses, representations, and promises, and material omissions, in connection with the payment for health care benefits, items, and services.

All in violation of Title 18, United States Code, Section 1347.

**COUNT TWO**

1. The allegations contained in paragraphs one through sixteen are incorporated as if fully set forth here.

2. From in or about January 2010 through approximately September 2014, in the Southern District of West Virginia and elsewhere, the defendant, TRIVILLIAN'S PHARMACY, with the intent to defraud and mislead, did introduce into interstate commerce, and cause the introduction into interstate commerce, of quantities of Vancomycin, Difazon, Diflorasone, Halobetasol, Hydrophilic, Ultravate, Tamiflu, caffeine, Lovenox, Plavix, and Methylin, all drugs within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(p), which were misbranded under 21 U.S.C. § 352(a), and held for sale after being shipped in interstate commerce, a prohibited act under 21 U.S.C. § 331(k).

All in violation of Title 21, United States Code, Sections 331(k), 352(a) and 333(a)(2).

UNITED STATES OF AMERICA

R. BOOTH GOODWIN II
United States Attorney

By: Eumi L. Choi

EUMI L. CHOI
Assistant United States Attorney