

U.S. DISTRICT COURT  
WESTERN DISTRICT OF KENTUCKY  
MAR 20 2013  
CLERK OF COURT  
WESTERN DISTRICT OF KENTUCKY

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF KENTUCKY  
AT LOUISVILLE

UNITED STATES OF AMERICA

INDICTMENT

v.

NO. 3:13CR-48-H

**CANH JEFF VO, D.O.**  
**d/b/a BLUEGRASS WOMEN'S**  
**HEALTHCARE**

- 21 U.S.C. § 331(a)
- 21 U.S.C. § 333(a)(2)
- 21 U.S.C. § 352(c)
- 21 U.S.C. § 352(f)(1)
- 18 U.S.C. § 2
- 18 U.S.C. § 545
- 18 U.S.C. § 1341
- 18 U.S.C. § 1347

The Grand Jury charges:

COUNT 1  
(MISBRANDING)

INTRODUCTION

At all times material to this Indictment:

1. **CANH JEFF VO**, defendant herein, a Doctor of Osteopathic Medicine ("D.O."), was a licensed physician in the State of Kentucky.
2. **CANH JEFF VO** was the owner, supervising physician, and president at Bluegrass Women's Healthcare in Elizabethtown, Kentucky.
3. **CANH JEFF VO** offered gynecological and obstetric services to women, including providing forms of birth control. **CANH JEFF VO's** favored form of contraception was a levonorgestrel-releasing intrauterine device ("IUD") known as Mirena® ("Mirena"). Mirena was made for BHCP, Inc. by Bayer Schering Pharma OY ("Bayer").
4. The only version of Mirena approved by the United States Food and Drug Administration ("FDA") for distribution within the United States was approved on December

6, 2000 in New Drug Application number 21-225.

THE FOOD AND DRUG ADMINISTRATION'S REGULATION OF DRUGS

5. The FDA is the federal agency within the United States Department of Health and Human Services charged with the responsibility for protecting the health and safety of the American public by enforcing the Federal Food, Drug and Cosmetic Act ("FD&C Act"), 21 U.S.C. § 301 et seq. One of the purposes of the FD&C Act is to ensure that all drugs sold for consumption by or administration to humans bear labeling containing only true and accurate information. The FDA's responsibilities under the FD&C Act include regulating the manufacture, labeling, and distribution of all drugs and drug components shipped or received in interstate commerce.

6. The FD&C Act defines a drug to include, among other things, any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans; articles (other than food) intended to affect the structure or any function of the body of humans; and articles intended for use as a component of any such articles.

7. The FD&C Act defines "label" as a display of written, printed, or graphic matter upon the immediate container of any article. Any requirement under the FD&C Act that a word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if there is any, of the retail package of such article, or is easily legible through the outside container or wrapper.

8. The FD&C Act defines "labeling" as all labels and other written, printed, or graphic matters (a) upon any article or any of its containers or wrappers, or (b) accompanying such article.

9. A drug is misbranded if, among other things, its labeling (a) does not bear adequate directions for use, or (b) is not likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

10. For all drugs distributed in the United States, all words, statements, and other information on the label or labeling required by the FD&C Act must appear in the English language.

MISBRANDING CHARGE

11. On or about and between March 2008 until September 2009, in the Western District of Kentucky, Hardin County, Kentucky, and elsewhere, **CANH JEFF VO**, defendant herein, with the intent to defraud or mislead, caused the introduction and delivery for introduction into interstate commerce of drugs by purchasing and inserting into patients foreign, non-FDA approved Mirenas, with the meaning of the FD&C Act, which were misbranded, in the following ways:

12. Within the meaning of Title 21, United States Code, Section 352(c), in that their label or labeling was not in such terms as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use in that the labeling was not in the English language; and

13. Within the meaning of Title 21, United States Code, Section 352(f)(1), in that their labeling failed to bear adequate directions for use.

All in violation of Title 21, United States Code, Sections 331(a), 333(a)(2), 352(c), and 352(f)(1).

The Grand Jury further charges:

COUNT 2  
(HEALTH CARE FRAUD)

INTRODUCTION

14. The United States incorporates by reference paragraphs 1 through 13 as if fully set forth herein.

15. At all times to this Indictment, the Kentucky Medicaid Program was a joint federal and state program that reimbursed providers for necessary medical services to eligible persons who were not able to pay for such services. The federal government funded a portion of the Kentucky Medicaid money and the State provided the balance of the funds. The Kentucky Medicaid Program was a health care benefit program as defined by Title 18, United States Code, Section 24.

16. Bluegrass Women's Health Care was registered as a clinic with the Kentucky Medicaid Program with a valid provider number. **CANH JEFF VO** was listed as a physician affiliated with that clinic. **CANH JEFF VO** signed the Medicaid provider contract on behalf of the Bluegrass Women' Healthcare, in Elizabethtown, Kentucky.

17. **CAHN JEFF VO** submitted claims to the Kentucky Medicaid Program under this clinic provider number, for procedure code J7302, Levonorgestrel Releasing Intrauterine Contraceptive (Mirena). This procedure code is specific to Bayer's FDA-approved Mirena product. Other IUDs have their own unique procedure codes. Any item billed under the J7302 procedure code must be the FDA-approved version of Bayer's Mirena.

18. A claim for reimbursement to the Kentucky Passport Program requires the submission of the drug's valid National Drug Code ("NDC") number. The unique NDC

number for FDA-approved Mirena is 50419-421-01.

HEALTH CARE FRAUD CHARGES

19. On or about and between May 2008 through September 2009, in the Western District of Kentucky and elsewhere, **CANH JEFF VO**, defendant herein, knowingly and willfully caused to be executed and attempted to cause to be executed a scheme and artifice to defraud the Kentucky Medicaid Program, a health care benefit program, and to obtain by means of false and fraudulent pretenses, representations, and promises, any of the money and property owned by and under the custody and control of any health care benefit program, including the Kentucky Medicaid Program.

SCHEME TO DEFRAUD

20. From on or about June 2008 through on or about September 2009, **CANH JEFF VO** caused to be submitted claims for reimbursement from the Medicaid Program, which included false representations. Specifically, **CANH JEFF VO** billed the Kentucky Medicaid Program and other insurers as if he was administering the FDA-approved version of Mirena, when he was actually administering a non-FDA approved version of Mirena.

In violation of Title 18, United States Code, Sections 1347 and 2.

The Grand Jury further charges:

COUNT 3-12  
(MAIL FRAUD)

21. The United States incorporates by reference paragraphs 1 through 20 as if fully set forth herein.

22. On or about and between March 2008 through September 2009, in the Western District of Kentucky, Hardin County, Kentucky and elsewhere, **CANH JEFF VO**, defendant herein, did knowingly and intentionally use a communication facility, to wit, the United States Mail, by receiving payment from the Kentucky Medicaid Program and private insurance companies for Mirena IUDs which were not approved for sale in the United States, thus committing, causing, and facilitating the commission of a felony offense listed in 18 U.S.C. 1347 of the United States Code, in violation of 21 U.S.C. § 1341.

COUNT	DATE	QUANTITY	SOURCE	AMOUNT	UNIT
3	03/10/08	10	Getcanandiandrugs. com	\$3,000.00	\$300.00
4	04/14/08	10	Getcanandiandrugs. com	\$3,000.00	\$300.00
5	06/23/08	10	Getcanandiandrugs. com	\$3,000.00	\$300.00
6	09/18/08	10	Getcanandiandrugs. com	\$3,000.00	\$300.00
7	10/20/08	10	Getcanandiandrugs. com	\$3,000.00	\$300.00
8	02/16/09	10	Getcanandiandrugs. com	\$3,000.00	\$300.00
9	04/15/09	10	Getcanandiandrugs. com	\$3,000.00	\$300.00
10	12/17/08	10	Usdrugstoreonline	\$2,198.00	\$219.80
11	06/10/09	10	Usdrugstoreonline	\$2,198.00	\$219.98
12	07/27/09	10	Usdrugstoreonline	\$2,198.00	\$219.98

In violation of Title 18, United States Code, Sections 1341.

The Grand Jury further charges:

COUNT 13  
(SMUGGLING)

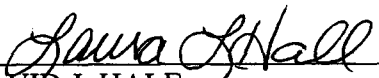
23. The allegations set forth in paragraphs 1 through 22 of this Indictment are re-alleged and incorporated as though set forth in full herein.

24. On or about and between March 2008 and September 2009, in the Western District of Kentucky, Hardin County, Kentucky, and elsewhere, **CAHN JEFF VO**, defendant herein, did fraudulently and knowingly receive, import and bring into the United States, Mirena IUDs contrary to law, and received concealed, bought, sold, and facilitated the transportation, concealment, or sale of merchandise after importation into the United States knowing the same to have been imported and brought into the United States contrary to law, that is, prescription drugs that were misbranded within the meaning of 21 U.S.C. § 352 and, therefore, unlawfully introduced into interstate commerce from various countries, including from Canada, to the United States in violation of 21 U.S.C. § 331.

In violation of Title 18, United States Code, Section 545.

A TRUE BILL

FOREPERSON

  
\_\_\_\_\_  
DAVID J. HALE  
UNITED STATES ATTORNEY

DJH:LJW:nbw:03/13/2013

UNITED STATES OF AMERICA v. CANH JEFF VO

**PENALTIES**

Count 1:	NM 3 yrs./\$10,000/both/NM 1 yr. Supervised Release
Count 2:	NM 10 yrs./\$250,000/both/NM 3 yrs. Supervised Release
Counts 3-12:	NM 20 yrs./\$250,000/both/NM 3 yrs. Supervised Release (each count)
Count 13:	NM 20 yrs./\$250,000/both/NM 3 yrs. Supervised Release

**NOTICE**

**ANY PERSON CONVICTED OF AN OFFENSE AGAINST THE UNITED STATES SHALL BE SUBJECT TO SPECIAL ASSESSMENTS, FINES, RESTITUTION & COSTS.**

**SPECIAL ASSESSMENTS**

18 U.S.C. § 3013 requires that a special assessment shall be imposed for each count of a conviction of offenses committed after November 11, 1984, as follows:

Misdemeanor:	\$ 25 per count/individual	Felony:	\$100 per count/individual
	\$125 per count/other		\$400 per count/other

**FINES**

In addition to any of the above assessments, you may also be sentenced to pay a fine. Such fine is due immediately unless the court issues an order requiring payment by a date certain or sets out an installment schedule. You shall provide the United States Attorney's Office with a current mailing address for the entire period that any part of the fine remains unpaid, or you may be held in contempt of court. 18 U.S.C. § 3571, 3572, 3611, 3612

**Failure to pay fine as ordered may subject you to the following:**

1. **INTEREST** and **PENALTIES** as applicable by law according to last date of offense.

For offenses occurring after December 12, 1987:

No **INTEREST** will accrue on fines under \$2,500.00.

**INTEREST** will accrue according to the Federal Civil Post-Judgment Interest Rate in effect at the time of sentencing. This rate changes monthly. Interest accrues from the first business day following the two week period after the date a fine is imposed.

**PENALTIES** of:

10% of fine balance if payment more than 30 days late.

15% of fine balance if payment more than 90 days late.

2. Recordation of a **LIEN** shall have the same force and effect as a tax lien.
3. Continuous **GARNISHMENT** may apply until your fine is paid.

18 U.S.C. §§ 3612, 3613

If you **WILLFULLY** refuse to pay your fine, you shall be subject to an **ADDITIONAL FINE** of not more than the greater of \$10,000 or twice the unpaid balance of the fine; or



**IMPRISONMENT** for not more than 1 year or both. 18 U.S.C. § 3615

RESTITUTION

If you are convicted of an offense under Title 18, U.S.C., or under certain air piracy offenses, you may also be ordered to make restitution to any victim of the offense, in addition to, or in lieu of any other penalty authorized by law. 18 U.S.C. § 3663

APPEAL

If you appeal your conviction and the sentence to pay your fine is stayed pending appeal, the court shall require:

1. That you deposit the entire fine amount (or the amount due under an installment schedule during the time of your appeal) in an escrow account with the U.S. District Court Clerk, or
2. Give bond for payment thereof.

18 U.S.C. § 3572(g)

PAYMENTS

If you are ordered to make payments to the U.S. District Court Clerk's Office, certified checks or money orders should be made payable to the Clerk, U.S. District Court and delivered to the appropriate division office listed below:

LOUISVILLE: Clerk, U.S. District Court  
106 Gene Snyder U.S. Courthouse  
601 West Broadway  
Louisville, KY 40202  
502/625-3500

BOWLING GREEN: Clerk, U.S. District Court  
120 Federal Building  
241 East Main Street  
Bowling Green, KY 42101  
270/393-2500

OWENSBORO: Clerk, U.S. District Court  
126 Federal Building  
423 Frederica  
Owensboro, KY 42301  
270/689-4400

PADUCAH: Clerk, U.S. District Court  
127 Federal Building  
501 Broadway  
Paducah, KY 42001  
270/415-6400

If the court finds that you have the present ability to pay, an order may direct imprisonment until payment is made.

FORM DBD-34  
JUN.85

No. \_\_\_\_\_

**UNITED STATES DISTRICT COURT**

Western District of Kentucky

Louisville Division

FILED  
MAR 20 2013  
CLERK

THE UNITED STATES OF AMERICA

vs.

CANH JEFF VO, D.O.

d/b/a Bluegrass Women's Healthcare

**INDICTMENT**

**Title 21 U.S.C. §§ 331(a); 333(a)(2); 352(c);  
352(f)(1);**

**Title 18 U.S.C. §§ 1347; 2; 1341; 545:**

**Introduction and Delivery of Misbranded Drugs  
into Interstate Commerce with the Intent to  
Defraud or Mislead; Healthcare Fraud; Aiding  
and Abetting; Mail Fraud; Smuggling.**

*A true bill.*

*Filed in open court this 20<sup>th</sup> day of March, 2013.*

*Clerk*

*Bail, \$*