

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS

OCT - 8 2009

JAMES W. McDOERMACK
By: James W. McDoermack
DEP CLERK

UNITED STATES OF AMERICA)
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v.)
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KELLY DEAN SHRUM, D.O.)
d/b/a ARKANSAS CENTER for WOMEN)
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No. 4:09CR 00295 JMM
18 U.S.C. § 1347, 2
21 U.S.C. §§ 331, 355
18 U.S.C. § 1957
18 U.S.C. § 982
21 U.S.C. § 853
28 U.S.C. § 2461

INDICTMENT

THE GRAND JURY CHARGES THAT:

COUNT ONE
(Misbranding)

A. Introduction

At all times material to this Indictment:

1. KELLY DEAN SHRUM, a Doctor of Osteopathic Medicine (“D.O.”), was a licensed physician in the State of Arkansas.
2. SHRUM was the sole physician practicing at the Arkansas Center for Women at 1609 West 40th Street, Suite 203, in Pine Bluff, Arkansas.
3. SHRUM offered gynecological and obstetric services to women, including providing forms of birth control. SHRUM’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.

B. Misbranding Charge

In or about June of 2009, in the Eastern District of Arkansas and elsewhere,

KELLY DEAN SHRUM, D.O.

with the intent to defraud and mislead, caused the introduction and delivery for introduction into interstate commerce of drugs, within the meaning of the FD&C Act, which were misbranded, in one or more of the following ways:

1. 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
2. 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).

COUNT TWO
(Health Care Fraud)

A. Introduction

1. The United States incorporates by reference herein introductory paragraphs A1 through A10 from Count One above.
2. At all times material to this Indictment, the Arkansas Medicaid Program was a joint federal and state program that reimbursed for necessary medical services to eligible persons who were not able to pay for such services. The federal government funded a portion of the Medicaid money and the State provided the balance of the funds. The Arkansas Medicaid Program was a health care benefit program as defined by Title 18, United States Code, Section 24.
3. Arkansas Center for Women, Ltd. was registered as a clinic with the Arkansas Medicaid Program under provider number 136831004. SHRUM was listed as the only physician affiliated with that clinic. SHRUM signed the Medicaid provider contract on behalf of the Arkansas Center for Women, Ltd., 1609 West 40th, Suite 203, Pine Bluff, AR 71603.
4. Shrum submitted claims to the Arkansas 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.
5. A claim for reimbursement to the Arkansas Medicaid 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.

B. Scheme to Defraud

From on or about January 15, 2008 through on or about June 12, 2009, SHRUM caused to be submitted claims for reimbursement from the Arkansas Medicaid Program, which included false representations. Specifically, SHRUM billed the Arkansas Medicaid Program as if he was administering the FDA-approved version of Mirena, when he was actually administering a non-FDA approved version of Mirena.

C. Health Care Fraud Charge

From on or about January 15, 2008 through June 12, 2009, in the Eastern District of Arkansas and elsewhere,

KELLY DEAN SHRUM, D.O.

knowingly and willfully caused to be executed and attempted to cause to be executed a scheme and artifice to defraud the Arkansas Medicaid Program, a health care benefit program, and to obtain by means of fraudulent pretenses and representations any of the money under the custody and control of the Arkansas Medicaid Program, a health care benefit program.

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

COUNT THREE
(Money Laundering)

1. The United States incorporates by reference herein introductory paragraphs A1-A10 from Count One above.

2. On or about February 17, 2009, in the Eastern District of Arkansas, KELLY DEAN SHRUM, D.O. did knowingly engage and attempt to engage in a monetary transaction in criminally derived property of a value greater than \$10,000, that is, he deposited \$15,000 in the form of a business check from his Arkansas Center for Women business account, Simmons First National Bank Account Number ending in 36, to his personal account, Simmons First National Bank Account Number ending in 79, such property having been derived from a specified unlawful activity, that is the submission of false claims for reimbursement to the Arkansas Medicaid Program in violation of 18 U.S.C. § 1347 as alleged in Count Two of this Indictment and which count is incorporated herein by reference, and the defendant participated in the transfer of such property through a financial institution,

All in violation of Title 18, United States Code, Section 1957.

COUNT FOUR

(Money Laundering)

1. The United States incorporates by reference herein introductory paragraphs A1-A10 from Count One above.
2. On or about February 27, 2009, in the Eastern District of Arkansas, KELLY DEAN SHRUM, D.O. did knowingly engage and attempt to engage in a monetary transaction in criminally derived property of a value greater than \$10,000, that is, he deposited \$15,000 in the form of a business check from his Arkansas Center for Women business account, Simmons First National Bank Account Number ending in 36, to his personal account, Simmons First National Bank Account Number ending in 79, such property having been derived from a specified unlawful activity, that is the submission of false claims for reimbursement to the Arkansas

Medicaid Program in violation of 18 U.S.C. § 1347 as alleged in Count Two of this Indictment and which count is incorporated herein by reference, and the defendant participated in the transfer of such property through a financial institution,

All in violation of Title, 18 United States Code, Section 1957.

COUNT FIVE
(Money Laundering)

A. Introduction

1. The United States incorporates by reference herein introductory paragraphs A1-A10 from Count One above.

2. On or about March 13, 2009, in the Eastern District of Arkansas, KELLY DEAN SHRUM, D.O. did knowingly engage and attempt to engage in a monetary transaction in criminally derived property of a value greater than \$10,000, that is, he deposited \$20,000 in the form of a business check from his Arkansas Center for Women business account, Simmons First National Bank Account Number ending in 36, to his personal account, Simmons First National Bank Account Number ending in 79, such property having been derived from a specified unlawful activity, that is the submission of false claims for reimbursement from the Arkansas Medicaid Program in violation of 18 U.S.C. § 1347 as alleged in Count Two of this Indictment and which count is incorporated herein by reference, and the defendant participated in the transfer of such property through a financial institution,

All in violation of Title 18, United States Code, Section 1957.

FORFEITURE ALLEGATION ONE

Upon conviction of the offense listed in Count Two of this Indictment, the defendant, KELLY SHRUM, D.O., shall forfeit to the United States of America, pursuant to Title 18, United States Code, Section 982(a)(7), any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense. The property to be forfeited includes, but is not limited to, the following:

\$209, 787.98 in United States currency

If any of the property described above, as a result of any act or omission of the defendant:

- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with, a third party;
- c. has been placed beyond the jurisdiction of the court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property which cannot be divided without difficulty,

the United States of America shall be entitled to forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Section 982(b)(1) and Title 28, United States Code, Section 2461(c).

FORFEITURE ALLEGATION TWO

Pursuant to Title 18, United States Code, Section 982(a)(1), upon conviction of the offense set forth in Count Three of this Indictment, the defendant KELLY SHRUM, D.O., shall forfeit to the United States of America any property, real or personal, involved in such offense,

and any property traceable to such property. The property to be forfeited includes, but is not limited to, the following:

\$15,000 in United States Currency.

If any of the property described above, as a result of any act or omission of the defendant:

- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with, a third party;
- c. has been placed beyond the jurisdiction of the court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property which cannot be divided without difficulty,

the United States of America shall be entitled to forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Section 982(b)(1) and Title 28, United States Code, Section 2461(c).

FORFEITURE ALLEGATION THREE

Pursuant to Title 18, United States Code, Section 982(a)(1), upon conviction of the offense set forth in Count Four of this Indictment, the defendant KELLY SHRUM, D.O., shall forfeit to the United States of America any property, real or personal, involved in such offense, and any property traceable to such property. The property to be forfeited includes, but is not limited to, the following:

\$15,000 in United States Currency.

If any of the property described above, as a result of any act or omission of the defendant:

- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with, a third party;
- c. has been placed beyond the jurisdiction of the court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property which cannot be divided without difficulty,

the United States of America shall be entitled to forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Section 982(b)(1) and Title 28, United States Code, Section 2461(c).

FORFEITURE ALLEGATION FOUR

Pursuant to Title 18, United States Code, Section 982(a)(1), upon conviction of the offense set forth in Count Five of this Indictment, the defendant KELLY SHRUM, shall forfeit to the United States of America any property, real or personal, involved in such offense, and any property traceable to such property. The property to be forfeited includes, but is not limited to, the following:

\$20,000 in United States Currency.

If any of the property described above, as a result of any act or omission of the defendant:

- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with, a third party;

- c. has been placed beyond the jurisdiction of the court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property which cannot be divided without difficulty,

the United States of America shall be entitled to forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Section 982(b)(1) and Title 28, United States Code, Section 2461(c).

(END OF TEXT. SIGNATURE PAGE ATTACHED.)