

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA

v.

MARGARET LUTHRA  
a/k/a RITA LUTHRA,

Defendant.

CRIMINAL NO. 15cr 30032

**VIOLATIONS:**

42 U.S.C. § 1320a – Violation of Anti-Kickback Statute

42 U.S.C. § 1320d-6 – Violation of the Health Information Portability and Accountability Act

18 U.S.C. § 1518 – Obstruction of Criminal Health Care Investigation

18 U.S.C. § 982(a)(7) – Forfeiture Allegation

SEALED

**INDICTMENT**

The Grand Jury charges:

**PRELIMINARY ALLEGATIONS**

At all times material to this Indictment, unless otherwise alleged:

1. The defendant **MARGARET LUTHRA a/k/a RITA LUTHRA** (“LUTHRA”), a resident of Massachusetts, was a gynecologist at the Women’s Health and Education Center in Springfield, Massachusetts.

**Warner Chilcott**

2. Warner Chilcott was a pharmaceutical company incorporated in Ireland with headquarters in Rockaway, NJ. Warner Chilcott distributed and sold in interstate commerce pharmaceuticals, including Actonel<sup>®</sup> and Atelvia<sup>®</sup>, which are drugs taken to prevent and treat osteoporosis.

3. Warner Chilcott gave its sales representatives unlimited expense accounts and directed its sales representatives to spend money on doctors and to sign up doctors as paid

“speakers” for purported medical education or “med ed” events where there was little, if any, medical education. Warner Chilcott instructed its sales representatives to aggressively ask doctors for business, using the free meals and “speaker” payments as leverage.

#### **The Federal Health Care Program**

4. The Medicare Program (“Medicare”) was a federal health insurance program established by the Social Security Act of 1965 to assist qualified aged and disabled individuals, referred to as “Medicare beneficiaries.” Medicare was administered by the Centers for Medicare & Medicaid Services (“CMS”), a federal agency under the United States Department of Health and Human Services. Medicare reimbursed health care providers and suppliers for the costs of health care services and items provided to Medicare beneficiaries. Through its Part D program, Medicare provided for the coverage of certain prescription drugs.

#### **The HIPAA Privacy Regulations**

5. The Health Insurance Portability and Accountability Act (“HIPAA”) was passed, in part, to “combat waste, fraud, and abuse in health insurance and health care delivery” and to “simplify the administration of health insurance.” In connection with the HIPAA law, the United States Department of Health and Human Services enacted regulations to safeguard the privacy of patients’ medical records. *See* 45 C.F.R. § 160.103, *et seq.* A major purpose of the HIPAA law and privacy regulations was to limit the circumstances in which patients’ confidential medical information (“individually identifiable health information” or “protected health information”) could be used or disclosed. The HIPAA law and privacy regulations apply to health plans, health care clearinghouses, and health care providers who transmit any health information in electronic form in connection with a transaction covered by the law and privacy regulations. *See* 45 C.F.R. §§ 160.102(a) and 103 (“covered entity”).

**Prior Authorizations**

6. Insurance companies typically identified the drugs that they paid for on behalf of their members (“covered”) in a list called a formulary. Insurance companies typically allocated covered drugs into three or four specified tiers within the formulary. Generally, Tier 1 contained generic drugs, which were the least expensive. In each ascending tier, the insurance company contributed less, and the member contributed more, to the cost of the drug.

7. When a drug was not covered on formulary, many insurance companies would not pay for the drug unless the company received a prior authorization (“PA”) from a physician for the drug. The physician was required to explain in the PA why the drug was medically necessary for the patient. Because PAs contained sensitive medical information, the PA process was restricted to the patient, the physician (and the physician’s staff), and the insurance company.

**COUNT ONE**

**42 U.S.C. § 1320a-7b(1)(B) (Violation of the Anti-Kickback Law)**

8. The allegations set forth in paragraphs 1 through 7 are re-alleged and herein incorporated in full.

9. Between in or around October 2010 and November 2011, in the District of Massachusetts, the defendant,

**MARGARET LUTHRA a/k/a RITA LUTHRA**

knowingly and willfully solicited and received remuneration from Warner Chilcott in the amount of approximately \$23,500 in exchange for purchasing and ordering, and arranging for the purchase and order of, prescriptions for Warner Chilcott's osteoporosis drugs, for which payment was made in whole or in part under a Federal health care program, namely Medicare.

10. In or around the summer of 2010, Warner Chilcott Sales Representative #1 began calling on **LUTHRA** to promote Actonel<sup>®</sup>. Actonel<sup>®</sup>, and its successor product, Atelvia<sup>®</sup>, belong to a class of pharmaceuticals called bisphosphonates, which physicians prescribe for the treatment and prevention of osteoporosis.

11. **LUTHRA** was a high volume prescriber of bisphosphonates in western Massachusetts. For that reason, in or around October 2010, Sales Representative #1 asked **LUTHRA** to be a speaker for Warner Chilcott. Sales Representative #1 told **LUTHRA** that they could do "med ed" events in her office, whereby Sales Representative #1 would bring food for her and her staff and she could earn a "speaker" fee by talking to Sales Representative #1. **LUTHRA** agreed to be a speaker for Warner Chilcott.

12. Between October 2010 and November 2011, Warner Chilcott paid **LUTHRA** a total of \$23,500 for "speaker" training and approximately 31 "med ed" events at which she earned a "speaking" fee. The "med ed" events consisted of Sales Representative #1 bringing

breakfast or lunch into **LUTHRA'S** office for her staff and her and talking with **LUTHRA** for 25 to 30 minutes while she ate. For each "med ed" event, **LUTHRA** was paid \$750 for "speaking." In addition, Warner Chilcott paid for a barbeque that **LUTHRA** hosted for her friends at her home. Sales Representative #1 brought food into **LUTHRA'S** office, paid **LUTHRA** as a "speaker," and paid for the barbeque at her home because Sales Representative #1 wanted her to write more prescriptions for Warner Chilcott's products.

13. In exchange for the free meals and "speaker" fees, **LUTHRA** wrote more prescriptions for Warner Chilcott's products, including prescriptions that were paid for by federal programs. Between 2010 and 2011, **LUTHRA'S** prescriptions for Warner Chilcott's bisphosphonate products significantly increased. In December 2011, Sales Representative #1 left Warner Chilcott and **LUTHRA** was no longer paid to write prescriptions for Warner Chilcott's bisphosphonate products. Thereafter, **LUTHRA'S** prescriptions for Warner Chilcott's bisphosphonate products significantly decreased.

All in violation of Title 42, United States Code, Section 1320a-7b(b)(1)(B).

**COUNT TWO**

**42 U.S.C. §1320d-6 (Wrongful Disclosure of Individually Identifiable Health Information)**

14. The allegations in paragraphs 1 through 8 and 10 through 13 are herein re-alleged and incorporated in full.

15. From in or around January 2011 to in or around November 2011, in the District of Massachusetts, the defendant

**MARGARET LUTHRA a/k/a RITA LUTHRA**

did knowingly and without authorization disclose protected individually identifiable health information relating to an individual, that was maintained by a covered entity, as defined in 45 C.F.R. § 160.103, to another person, to wit: Warner Chilcott Sales Representative #1.

16. **LUTHRA** is a covered entity under the HIPAA law and privacy regulations. **LUTHRA** was a health care provider who maintained records for patients that contained protected health information and transmitted such information in electronic form.

17. In January 2011, Warner Chilcott launched Atelvia<sup>®</sup> as a replacement for Actonel<sup>®</sup>. By and large, insurance plans did not include Atelvia<sup>®</sup> on their formularies, primarily because a far less expensive generic bisphosphonate—generic Fosamax<sup>®</sup>—was available. These insurance plans would not pay for Atelvia<sup>®</sup> unless a physician submitted a PA explaining why the patient needed Atelvia<sup>®</sup> instead of generic Fosamax<sup>®</sup>, Actonel<sup>®</sup>, or any other bisphosphonate on the market.

18. Preparing a PA was burdensome for **LUTHRA**, especially when a cheaper drug was available. For that reason, prior to being paid by Warner as a “speaker,” **LUTHRA** would sometimes not prescribe drugs that required a PA because she did not want to have to go through the process of submitting a PA.

19. When Warner launched Atelvia<sup>®</sup>, LUTHRA started receiving numerous denials from insurance companies. Because the volume of denials coming into her office was significant, LUTHRA asked Sales Representative #1 to help Medical Assistant #1 with the PAs. Sales Representative #1 agreed, and started to help Medical Assistant #1 with the PAs. Sales Representative #1 went to LUTHRA'S office on Friday afternoons, when LUTHRA was not seeing patients, and worked on the PAs with Medical Assistant #1. Sales Representative #1 had access to LUTHRA'S patients' protected health information, and used the information to fill out the PAs. Medical Assistant #1 would then give LUTHRA the PAs to sign.

All in violation of Title 42, United States Code, Section 1320d-6 and (b)(1).

**COUNT 3**

**18 U.S.C. § 1518 (Obstruction of a Criminal Investigation of a Health Care Offense)**

20. The allegations in paragraphs 1 through 7, 10 through 13, and 16 through 19 are herein re-alleged and incorporated in full.

21. Beginning in or around February 2014 and continuing until in or around March 2014, in the District of Massachusetts, the defendant

**MARGARET LUTHRA a/k/a RITA LUTHRA**

willfully prevented, obstructed, misled, and delayed, and attempted to prevent, obstruct, mislead, and delay the communication of information and records relating to a violation of a Federal health care offense to a federal investigator, to wit: **LUTHRA** gave information she knew to be false to agents assigned to the United States Department of Health and Human Services (“HHS”) Office of the Inspector General, who were criminal investigators duly authorized by HHS to conduct and engage in investigations and prosecutions for violations of health care fraud offenses, and directed Medical Assistant #1 to do the same.

22. On or around February 10, 2014, HHS Special Agents, in the course of investigating possible violations of federal criminal health care fraud, interviewed **LUTHRA** about her relationship with Warner Chilcott and Sales Representative #1. **LUTHRA** told the HHS agents that Warner Chilcott paid her to read studies and provide her opinion. **LUTHRA** also told the HHS agents that Sales Representative #1 helped with PAs, but did not have access to patients’ protected health information.

23. After being interviewed by the HHS agents, **LUTHRA** called Medical Assistant #1. **LUTHRA** was agitated and told Medical Assistant #1, in sum and substance, to tell the HHS agents that Medical Assistant #1 did not share any medical records. **LUTHRA** told Medical Assistant #1 that Sales Representative #1 got them in trouble.



24. The following day, **LUTHRA** again ordered Medical Assistant #1 to tell the HHS agents that Medical Assistant #1 did not show any medical records to Sales Representative #1. **LUTHRA** said, in sum and substance, that there is a HIPAA law and there would be hefty fines for them both if people found out that they shared medical records.

25. On or around March 7, 2014, HHS agents, in the course of investigating potential violations of federal criminal health care fraud, again interviewed **LUTHRA** about her work for Warner Chilcott. Contrary to her prior statements that Warner Chilcott paid her to read studies and provide her opinions, **LUTHRA** told the HHS agents that Warner paid her \$3,250 in 2010 for training to become a speaker, and \$19,500 in 2011 for a research paper she wrote. Specifically, **LUTHRA** stated that Warner Chilcott paid her to read 25 abstracts of clinical trials and that she wrote a 5,000 word paper on "Osteoporosis Prevention and How to Identify Patients Early and Achieve Compliance." **LUTHRA** stated that she gave a copy of the paper to Warner and sent a copy to the World Health Organization. **LUTHRA** knew that Warner Chilcott had not paid her to write a research paper.

All in violation of Title 18, United States Code, Section 1518.

**FORFEITURE ALLEGATIONS**  
**18 U.S.C. § 982(a)(7)**

The Grand Jury further charges:

26. Upon conviction of the offenses set forth in Counts One and Three of this Indictment,

**RITA LUTHRA**

the defendant herein, shall forfeit to the United States, pursuant to 18 U.S.C. § 982(a)(7), any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the offense.

27. If any of the property described in paragraph 27 above, as a result of any act or omission of the defendant --

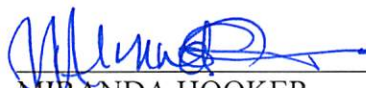
- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with, a third party;
- c. has been placed beyond the jurisdiction of this Court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property which cannot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

it is the intention of the United States, pursuant to 18 U.S.C. § 982(b)(1), incorporating 21 U.S.C. § 853(p), to seek forfeiture of any other property of the defendant up to the value of the property described in paragraph 27 above.

All pursuant to Title 18, United States Code, Section 982(a)(7).

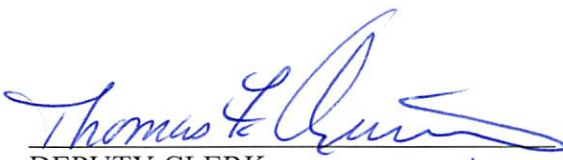
A TRUE BILL

  
FOREPERSON OF THE GRAND JURY

  
MIRANDA HOOKER  
DAVID S. SCHUMACHER  
ASSISTANT U.S. ATTORNEYS

DISTRICT OF MASSACHUSETTS; October 21, 2015

Returned into the District by the Grand Jurors and filed

  
DEPUTY CLERK  
10/21/2015  
@ 11:25 am