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2015 OCT 16 PM 3 01
U.S. DISTRICT COURT
DISTRICT OF MASSACHUSETTS

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

)
UNITED STATES OF AMERICA)
)
v.)
)
)
LONDON ECKLES)
_____)

CRIMINAL NO. 15cr10320

**VIOLATION:
42 U.S.C. § 1320d-6 – Wrongful
Disclosure of Individually Identifiable
Health Information**

INFORMATION

The United States Attorney charges that:

THE DEFENDANT

1. The defendant **LONDON ECKLES** (“**ECKLES**”), who was at all relevant times a resident of Pennsylvania, was an employee of Warner Chilcott.
2. Warner Chilcott was a pharmaceutical company incorporated in Ireland with headquarters in Rockaway, NJ. Warner Chilcott manufactured and distributed a number of pharmaceuticals, including Actonel and Atelvia, which were drugs taken to prevent and treat osteoporosis.
3. **ECKLES** worked at Warner Chilcott between 2007 and 2012. From 2010 to 2011, **ECKLES** was a District Manager in Warner Chilcott’s osteoporosis division, which sold Actonel and Atelvia. **ECKLES** supervised a team of 10-12 sales representatives covering portions of Pennsylvania, Delaware and New Jersey (the “district”).

THE HIPAA PRIVACY REGULATIONS

4. 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 “simply 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”).

5. **ECKLES** and the sales representatives that he supervised frequently called on physicians within the district, attempting to convince them to prescribe Actonel and/or Atelvia. These physicians maintained records for patients which contained protected health information. Because these physicians were health care providers who transmitted patients’ protected health information in electronic form, they were covered by the HIPAA law and privacy regulations.

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 most inexpensive. 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 1

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

8. The allegations in paragraphs one through seven are herein re-alleged and incorporated in full.

9. From in or about February 2011 to in or about November 2011, in the Eastern District of Pennsylvania, the District of Delaware, the District of New Jersey, and elsewhere, the defendant

LANDON ECKLES

did knowingly and without authorization obtain individually identifiable health information maintained by a covered entity relating to an individual, and disclose individually identifiable health information to another person, with intent to use such information for commercial advantage, in violation of Title 42, United States Code, Section 1320d-6 and Title 18, United States Code, Section 2, as set forth below.

THE PRIOR AUTHORIZATIONS SCHEME

10. In 2011, Warner Chilcott began marketing Atelvia, an osteoporosis drug that was a successor to Actonel. Atelvia (and Actonel) belonged to a class of drugs called bisphosphonates. When Warner Chilcott introduced Atelvia, there were at least three additional bisphosphonates in the market, including Fosamax, which was available in generic form.

11. Throughout 2011, most insurance companies in **ECKLES's** district covered generic Fosamax at Tier 1 in their formularies. Atelvia either was not covered at all or was placed within a more expensive tier in the formulary. By and large, insurance companies in the district only covered Atelvia if a physician submitted a PA for the patient that included a medical justification explaining why the patient needed Atelvia.

12. In January and early February 2011, Warner Chilcott instructed managers, including **ECKLES**, to ensure that PAs for Atelvia were being submitted and to do so by becoming highly involved with the PA process. **ECKLES**, in turn, instructed the sales representatives in his district to become highly involved with the PA process. **ECKLES** encouraged his sales representatives to provide PA forms to physicians and staff, give physicians and staff “canned” medical justifications that would most likely result in a successful PA, and provide free meals, drinks and snacks for physicians’ employees who were responsible for preparing the PAs.

13. On or about February 11, 2011, Warner Chilcott disseminated a memorandum concerning PAs (the “February 2011 memo”). The memorandum stated, among other things, that a sales representative cannot “be involved with any aspect of the completion or submission of a

Coverage Determination and/or Prior Authorization request, nor should you see any patient information, pursuant to HIPAA.”

14. While Warner Chilcott executives and directors did not emphasize or discuss the February 2011 memo at length, **ECKLES** nonetheless reviewed the memo, understood its contents, and disseminated the memo to the sales representatives in his district.

15. Even after receiving the February 2011 memo, **ECKLES** continued to instruct the sales representatives in his district to make sure that Atelvia PAs went through. **ECKLES** continued to instruct his sales representatives to share PA medical justifications with physicians and staff and to take out PA staff for free meals.

16. **ECKLES** also informed certain sales representatives that, if the physician or staff would not prepare the PA, the sales representative should prepare the PA. Moreover, on more than one occasion, **ECKLES** himself filled out PAs for patients in connection with Atelvia prescriptions. In so doing, **ECKLES** obtained and disclosed individually identifiable health information maintained by a covered entity for commercial advantage.

THE “CHART FLAGGING” SCHEME

17. Beginning in or about summer 2011, Warner Chilcott instructed managers, including **ECKLES**, to identify patients in physicians’ offices who were candidates for Atelvia and to ensure that an Atelvia brochure was placed in (“flag”) their medical charts. **ECKLES**, in turn, encouraged his sales representatives to “flag” patient charts in physicians’ offices to obtain Atelvia prescriptions. **ECKLES** explained to his sales representatives that, during the patient’s next visit, when the physician reviewed the patient’s medical chart, the physician would see the Atelvia brochure and be reminded to prescribe Atelvia for the patient. **ECKLES** instructed his

sales representatives to either ask the physician's staff to "flag" the medical charts or, if necessary, to "flag" the charts themselves.

18. On or about September 21, 2011, **ECKLES** and a sales representative visited a physician in Philadelphia, Pennsylvania. During this visit, **ECKLES** and the sales representative convinced the physician's nurse to pull the medical charts of all patients who were using a bisphosphonate. Left unsupervised, **ECKLES** and/or the sales representative placed Atelvia brochures inside each of the patients' medical charts. Patients' protected health information maintained by a covered entity was available to **ECKLES** during this incident.

19. Subsequent to this visit, **ECKLES** left a voicemail message for his entire district. **ECKLES** described the chart-flagging exercise and stated, "we're literally doing everything that we can besides writing scripts ourselves to get [the physician] to use the drug." **ECKLES** also stated, "I guarantee you that this is going to drive business." **ECKLES** encouraged all of the sales representatives to use the chart-flagging tactic.

20. In part due to **ECKLES's** PA and chart-flagging practices and instructions, physicians in **ECKLES's** district prescribed a substantial amount of Atelvia. As a result, **ECKLES** achieved a large bonus and received a promotion.

All in violation of 42 U.S.C. § 1320d-6 and 18 U.S.C. §2.

CARMEN M. ORTIZ
United States Attorney

By:



A handwritten signature in black ink, appearing to read 'DS Schumacher', is written over a horizontal line.

DAVID S. SCHUMACHER
MIRANDA HOOKER
Assistant U.S. Attorneys

Dated: October 16, 2015