

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA)
)
v.)
)
AEGERION PHARMACEUTICALS, INC.,)
)
Defendant.)

Criminal No. 17cr10289

Violation:
18 U.S.C. § 371 (conspiracy)

FILED
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U.S. DISTRICT COURT
DISTRICT OF MASSACHUSETTS

INFORMATION

The Acting United States Attorney charges that:

COUNT I
(18 U.S.C. § 371 (Conspiracy to Violate HIPAA))

1. At all times relevant to this Information, the defendant, AEGERION PHARMACEUTICALS, INC. ("AEGERION"), was a Delaware corporation with a principal place of business in Cambridge, Massachusetts.

2. From January 2013, through August 2015, within the District of Massachusetts, and elsewhere, AEGERION, acting by and through certain of its officers and employees in concert with certain non-AEGERION health professionals, known and unknown, did knowingly conspire, confederate, and agree to violate the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Title 42, United States Code, Sections 1320d-6(a) and 6(b)(3), by knowingly using and causing to be used unique health identifiers, obtaining individually identifiable health information relating to individuals, and disclosing individually identifiable health information to another person, without patient authorization required by 45 C.F.R. § 164.508(a)(3), with the intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm.

3. The U.S. Food and Drug Administration (“FDA”) approved AEGERION’s drug, Juxtapid (generic name: lomitapide) in December 2012 with an indication for use as an adjunct to a low-fat diet and other lipid-lowering treatments to reduce cholesterol in patients with a rare genetic disorder called homozygous familial hypercholesterolemia, or “HoFH.”

4. Prior to obtaining approval from the FDA for Juxtapid, AEGERION, by and through its employees, represented to the FDA that, based on published studies, HoFH could be expected to occur in about ~1-in-1 million persons.

5. AEGERION, by and through its then-current employee, EXECUTIVE A, stated to investors that there were more than 3,000 patients for Juxtapid in the United States and that AEGERION was very focused on how to find those patients and to work with physicians to get the patients on Juxtapid.

6. HIPAA was enacted, among other things, to limit the circumstances in which patients’ confidential medical information (“individually identifiable health information” or “protected health information”) could be used or disclosed. HIPAA, through implementing regulations, specifically forbids disclosure or use of individually identifiable health information for marketing without written patient authorization. 45 C.F.R. § 164.508(a)(3). HIPAA and these privacy regulations apply to health care providers, among others, 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 (defining “covered entity”).

7. From January 2013, through August 2015, AEGERION sales employees frequently called on physicians, attempting to convince them to prescribe Juxtapid for patients with high cholesterol. 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 HIPAA and associated privacy regulations.

8. At all times relevant to this Information, AEGERION officers and sales employees knew that they could not access HIPAA-protected patient information held by physicians without written patient authorizations, and AEGERION created and maintained patient HIPAA authorizations and officially trained its sales force not to access protected health information without obtaining patient HIPAA authorizations.

9. At all times relevant to this Information, AEGERION's sales employees were not trained medical professionals and were at no time relevant to this Information qualified or able to provide medical treatment to patients or to assist physicians in providing medical treatment.

OBJECT OF THE CONSPIRACY

10. The object of the conspiracy was for AEGERION sales employees to obtain and use HIPAA-protected health information without patient authorization in efforts to identify patients not previously diagnosed with HoFH, yet perceived by AEGERION as potentially suitable for Juxtapid treatment, and thereby achieve increased sales of Juxtapid consistent with market expectations set by EXECUTIVE A.

MANNER AND MEANS OF THE CONSPIRACY

11. To carry out the conspiracy, non-medical AEGERION employees involved in the sales and marketing of Juxtapid sought to obtain and did obtain and then use patients' protected health information possessed by physicians and their medical staff, without patient authorizations required by HIPAA regulations, for the purpose of marketing Juxtapid to physicians and, at times, directly to patients.

12. It was further part of the conspiracy that AEGERION, by and through its sales employees, acting at the direction of and at times with the direct involvement of then-current AEGERION officers and management, gained access to physicians' electronic medical record ("EMR") systems to perform searches to identify patients for whose treatment they could market Juxtapid to physicians and, at times, directly to patients, all without obtaining required HIPAA authorizations from pertinent patients.

13. It was further part of the conspiracy for many AEGERION sales employees to gain access to protected health information without patient authorization to complete or to assist with the completion of statements of medical necessity or prior authorizations to support insurance coverage of prescriptions for Juxtapid.

14. It was further part of the conspiracy for AEGERION sales employees to use protected health information obtained from physicians without patient authorization to contact patients to convince them to start Juxtapid therapy.

OVERT ACTS

15. In furtherance of the conspiracy, and to effect the object thereof, the conspirators committed and caused the commission of multiple overt acts in the District of Massachusetts and other Districts for the commercial advantage of AEGERION, located in the District of Massachusetts.

16. In February 2013, senior AEGERION employees, including then-current EXECUTIVE A, then-current EXECUTIVE B, and then-current MANAGER A, paired with AEGERION sales employees in a competition for the most new Juxtapid prescriptions in a single day. That day, EXECUTIVE A traveled from Massachusetts and met with a physician from whom EXECUTIVE A obtained protected patient information without patient authorization.

Immediately following his meeting with the physician, EXECUTIVE A sent a picture of two prescriptions (for pediatric patients without any patient authorization for access to HIPAA-protected health information) and of an EMR query report from the physician's office including approximately 250 identifiable patients (without any patient authorizations) to AEGERION sales team members to show his success with his sales employee partner in marketing Juxtapid.

EXECUTIVE B told the sales employee paired with EXECUTIVE A that the EMR query report was "gold" for AEGERION.

17. During the competition in February 2013, MANAGER A also obtained a prescription for an identified patient but without HIPAA consent from the patient to access his or her health information.

18. In March 2013, an AEGERION sales employee, with the approval of EXECUTIVE A, accessed protected patient information without patient consent, in agreement with a physician, in order to identify patients perceived by AEGERION as potentially suitable for Juxtapid treatment.

19. On or about May 10, 2013, an AEGERION sales employee accessed a physician's computer to mine for potential Juxtapid patients.

20. On or about June 19, 2013, an AEGERION sales employee accessed private patient information without HIPAA consent to market Juxtapid to a physician.

21. Between May 2013 and December 2014, an AEGERION sales employee created a false patient HIPAA authorization.

22. Between October 2013 and February 2015, an AEGERION sales employee obtained private patient information without patient consent, in agreement with health care staff

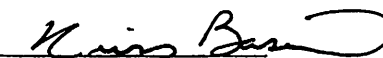
at multiple offices, and sent the private patient information to AEGERION customer service staff in Cambridge, Massachusetts.


23. In February 2014 and March 2014, an AEGERION sales employee caused the creation of a false patient HIPAA authorization, obtained protected health information without the patient's consent, passed it on to AEGERION employees in Cambridge, Massachusetts, and used it to obtain insurance payment for Juxtapid.

All in violation of 18 U.S.C. § 371.

Respectfully submitted,

WILLIAM D. WEINREB
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