

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

08 CR 10.04.9 JLT

UNITED STATES OF AMERICA,

) Criminal No.
)
)

v.

) Violations:
)
)

THOMAS FARINA,

) Obstruction:
) 18 U.S.C. Section 1519
)

Defendant.

) Aiding and Abetting:
) 18 U.S.C. Section 2
)
)

INDICTMENT

The Grand Jury charges that:

GENERAL ALLEGATIONS

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

BACKGROUND

1. **THOMAS FARINA** (hereinafter "**FARINA**"), is an individual currently residing in Fairport, New York. From 2001 through March 2005, **FARINA** was a District Manager of a corporation hereinafter referred to as ABC Corp. ABC Corp. was a corporation engaged, *inter alia*, in the manufacture and sale of pharmaceutical drugs for human use, including a drug known as X-Drug. In his capacity as an ABC Corp. District Manager, **FARINA** directed and oversaw approximately 10 sales representatives in the Brooklyn area of New York.

2. Prior to 2002, ABC Corp. submitted a new drug application ("NDA") to the United States Food and Drug Administration ("FDA") seeking approval of X-Drug. In that application, ABC Corp. sought approval to market the drug for the treatment of the signs and

symptoms of osteoarthritis and adult rheumatoid arthritis, primary dysmenorrhea (menstrual cramps), and acute pain, including to prevent or decrease post-operative surgical pain and opioid sparing. In its NDA, ABC Corp. sought approval of X-Drug for dosages ranging from 10-40 mg.

3. The FDA performed a detailed medical review of ABC Corp.'s NDA for X-Drug and, prior to 2002, the FDA approved X-Drug for the signs and symptoms of osteoarthritis and adult rheumatoid arthritis and primary dysmenorrhea, but specifically declined to approve it for the other indications sought by ABC Corp. Moreover, although ABC Corp. sought approval for 10 mg, 20 mg and 40 mg doses for all uses, the FDA only approved the 20 mg dose (twice a day) as needed for short term use for primary dysmenorrhea, and only the 10 mg dose (once a day) for osteoarthritis and adult rheumatoid arthritis. The FDA declined to approve X-Drug for the other uses and at the higher dosages sought, at least in part, based upon safety concerns, including in particular concerns about potential cardiovascular risks.

4. From approximately the Spring of 2002 through at least the Spring of 2004, **FARINA** and others at ABC Corp. promoted the sale and use of X-Drug for a variety of uses and at dosages other than the approved uses, including, among other things, promoting X-Drug for pre- and post-op surgical pain, dental pain and oral surgery pain, for acute pain generally, for the pain of injuries and, at the 20 mg dosage and above, for all types of pain, among other unapproved uses.

5. One of the means by which **FARINA** and others promoted X-Drug for these unapproved uses was to draft, promote and implement protocols, standing orders, pain pathways and patient briefing sheets for doctors, medical practices and hospitals. These documents then constituted labeling of the product, which labeling called for the routine or even automatic use of

X-Drug for each surgical or other procedure, including at off-label dosages, even though X-Drug was not approved for that use or at those dosages in that context.

DOCUMENT DESTRUCTION AND ALTERATION

6. In or around February, 2004, ABC Corp. and representatives from the United States, including representatives of the United States Attorney's Office from the District of Massachusetts, had a meeting in which ABC Corp. was informed that the United States was investigating ABC Corp.'s marketing practices with respect to X-Drug.

7. After being told that its marketing practices of X-Drug were under government investigation, on or around March 12, 2004, ABC Corp.'s legal department sent an e-mail to its employees, including **FARINA**, forwarding a March 5, 2004 memorandum that informed the recipients that "ABC Corp. is involved in litigation involving X-Drug." The memorandum defined documents in detail and instructed that "[a]ny potential documentary evidence, records, files or documents, whether paper, electronic or otherwise, that relate to X-Drug must be retained and preserved." The memorandum also stated "**[i]t is vitally important that you preserve all documents relating to X-Drug.**" **FARINA** received and forwarded this email to his sales representatives on March 12, 2004.

8. On or around May 25, 2004, **FARINA** carried out mandatory compliance training for his sales team. The training included instructions for X-Drug's promotion, and specifically prohibited certain practices, such as obtaining protocols for pre- and post-operative surgery settings. As part of this training, **FARINA** showed his team a compliance video. This video specifically reviewed the fact that ABC Corp. was under government investigation with respect to X-Drug. **FARINA** reviewed and discussed this information with his team.

9. In or around August or September, 2004, after being made aware of the government's investigation regarding X-Drug, **FARINA** altered documents on his own computer in an attempt to erase evidence of promotion of X-Drug for protocols that contained uses and dosages that were not FDA approved. He did this by opening an electronic copy of a protocol that he had previously received from a sales representative and that was stored on his work computer. That protocol contained references to the use of X-Drug for an off-label use, such as before surgery, as well as at the unapproved dosage for that use of 20 mg. He altered the opened document by deleting the reference to X-Drug or the 20 mg dosage. **FARINA** also reset the time clock and date on his computer so that it matched an earlier time, approximately when he would have originally received the document. He then saved the document so that it would appear that it had been saved at that earlier date. After doing this, **FARINA** deleted the documents from his computer.

10. On or around August 10 or 11, 2004, **FARINA** contacted one of his sales representatives, NB, and explained to NB how NB should alter documents and alter the date and time settings on his computer, so the documents would appear to have been last altered at an earlier date. NB followed **FARINA's** instructions and altered documents by deleting references to off-label promotion, and changing the date and time settings on his computer.

11. On or around September 16, 2004, certain ABC Corp. sales representatives received an email from the legal department of ABC Corp. instructing them to turn in copies of paper documents relating to X-Drug, and to ship their computers to ABC Corp.'s representative within 48 hours.

12. After one of **FARINA'S** representatives, AA, received a request to turn in his computer, **FARINA** instructed AA on how to search his computer for documents with certain buzzwords, such as X-Drug and pain. AA performed such a search of his computer and identified documents on his computer that contained the buzzwords.

13. AA reported to **FARINA** that he had located documents on his computer that contained the buzzwords and the two discussed whether or not to keep the documents on AA's computer. As a result of the conversation, AA deleted documents that contained the buzzwords. AA secretly saved a copy of the deleted documents in hard copy and on a disk. AA told **FARINA** that he had deleted the documents from his computer.

14. **FARINA** also instructed AA to meet with NB and another sales representative, IG, both of whom had also been asked by ABC Corp. to turn in their computers. At that meeting, AA identified, altered and deleted documents that contained references to promotion for unapproved uses or dosages from NB's and IG's computers. During the meeting, **FARINA** and AA spoke by telephone and discussed what AA should do with the documents at issue.

Count One: (18 U.S.C. § 1519 - Destruction, alteration or falsification of record in Federal investigation)

The Grand Jury further charges that:

15. The allegations contained in paragraphs 1 through 9 are realleged and incorporated herein as if set forth in full.

16. In or about August or September, 2004, on a date uncertain to the Grand Jury, in the District of Massachusetts and elsewhere, defendant,

THOMAS FARINA

did knowingly alter and destroy a record and document with the intent to impede, obstruct and influence the investigation and proper administration of a matter within the jurisdiction of an agency of the United States, and in relation to and in contemplation of any such matter or case, in that he altered and destroyed documents concerning the promotion of X-Drug for unapproved usages and dosages.

All in violation of Title 18, United States Code, Section 1519.

Count Two: (18 U.S.C. § 1519 - Destruction, alteration or falsification of record in Federal investigation; 18 U.S.C. § 2 - Aiding and Abetting)

17. The allegations contained in paragraphs 1 through 10 are realleged and incorporated herein as if set forth in full.

18. In or about August 10 or 11, 2004, in the District of Massachusetts and elsewhere, defendant,

THOMAS FARINA

did knowingly alter and destroy a record and document with the intent to impede, obstruct and influence the investigation and proper administration of a matter within the jurisdiction of an agency of the United States, and in relation to and in contemplation of any such matter or case, by causing a sales representative, NB, to alter and destroy documents concerning the promotion of X-Drug for unapproved usages and dosages.

All in violation of Title 18, United States Code, Sections 1519 and 2.

Count Three: (18 U.S.C. § 1519 - Destruction, alteration or falsification of record in Federal investigation; 18 U.S.C. § 2 - Aiding and Abetting)

19. The allegations contained in paragraphs 1 through 13 are realleged and incorporated herein as if set forth in full.

20. In or about August or September, 2004, on a date uncertain to the grand jury, in the District of Massachusetts and elsewhere, defendant,

THOMAS FARINA

did knowingly alter and destroy a record and document with the intent to impede, obstruct and influence the investigation and proper administration of a matter within the jurisdiction of an agency of the United States, and in relation to and in contemplation of any such matter or case, by causing a sales representative, AA, to alter and destroy documents concerning the promotion of X-Drug for unapproved usages and dosages.

All in violation of Title 18, United States Code, Sections 1519 and 2.

Count Four: (18 U.S.C. § 1519 - Destruction, alteration or falsification of record in Federal investigation; 18 U.S.C. § 2 - Aiding and abetting)

21. The allegations contained in paragraphs 1 through 14 are realleged and incorporated herein as if set forth in full.

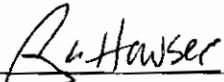
22. On or about September 16 and 17, 2004, in the District of Massachusetts and elsewhere, defendant,

THOMAS FARINA


did knowingly alter and destroy a record and document with the intent to impede, obstruct and influence the investigation and proper administration of a matter within the jurisdiction of an agency of the United States, and in relation to and in contemplation of any such matter or case, by causing sales representatives, AA, NB and IG, to alter and destroy documents concerning the promotion of X-Drug for unapproved usages and dosages.

All in violation of Title 18, United States Code, Section 1519 and 2.

A TRUE BILL



Foreperson of the Grand Jury



SARA MIRON BLOOM
SUSAN M. POSWISTILO
ASSISTANT U.S. ATTORNEYS

MARK JOSEPHS
AMY GOLDFRANK
TRIAL ATTORNEYS
OFFICE OF CONSUMER LITIGATION

DISTRICT OF MASSACHUSETTS; March 4, 2008. @ 3:30pm
Returned into the District Court by the Grand Jurors and filed.



DEPUTY CLERK