IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA	*	
	*	
v.	*	**CRIMINAL NO.** RWT 10 CR 0694
	*	
LAUREN STEVENS,	*	**(Obstruction of Proceeding, 18 U.S.C. §**
	*	**1512; Falsification/Concealment of**
Defendant	*	**Documents, 18 U.S.C. § 1519; False**
	*	**Statements, 18 U.S.C. § 1001; Aiding and**
	*	**Abetting, 18 U.S.C. § 2)**
	*	

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INDICTMENT

The Grand Jury for the District of Maryland charges that:

INTRODUCTORY ALLEGATIONS

At times material to this Indictment, unless otherwise alleged:

Background

1. Defendant **LAUREN STEVENS** was the Vice President and Associate General Counsel of a corporation hereinafter referred to as K-Corp.

2. K-Corp. was a corporation that manufactured, promoted, and distributed for sale prescription drugs, including the drug hereinafter referred to as W-Drug.

3. On or about October 9, 2002, the United States Food and Drug Administration ("FDA") sent a letter to K-Corp. that stated that the FDA had become aware of information that K-Corp. had possibly promoted the use of W-Drug for an unapproved use – specifically for weight loss. The FDA asked K-Corp. about its W-Drug promotional programs and asked K-Corp. to provide materials related to W-Drug promotional programs, including copies of all slides, videos, handouts, and other materials presented or distributed at any K-Corp. program or

activity related to W-Drug. In the letter, the FDA also asked K-Corp. to identify any compensation provided to individuals involved in programs or activities related to W-Drug.

4. **STEVENS** was the Vice President and attorney at K-Corp. who was in charge of K-Corp.'s response to the FDA's inquiry and investigation. As part of that response, **STEVENS** led a team of lawyers and paralegals who gathered documents and information.

The FDA and the FDCA

5. The FDA was the federal agency of the United States responsible for protecting the health and safety of the public by enforcing the FDCA. The FDA's headquarters are located within the District of Maryland.

6. With certain limited exceptions not pertinent here, a prescription drug could not be distributed in interstate commerce without FDA approval. To gain FDA approval for a particular use, data from well-controlled clinical studies had to demonstrate that the drug would be safe and effective. As part of the approval process, the FDA also had to approve the drug's labeling, which set forth detailed information about the drug, including the approved medical conditions of use, dosages, and patient population(s).

7. Uses that were not in the approved labeling were known as off-label uses.

8. Under the FDCA, the drug's manufacturer, its representatives, and those speaking on its behalf could not lawfully market and promote the drug for off-label uses.

9. The FDCA prohibited the distribution in interstate commerce of an unapproved new drug or a misbranded drug. Promoting a drug for an unapproved use rendered the drug misbranded.

10. The Division of Drug Marketing, Advertising, and Communications ("DDMAC")

was the office within the FDA responsible for reviewing and investigating complaints about alleged promotional violations and initiating enforcement actions for promotional activities that were not truthful, balanced, and consistent with the approved labeling.

11. W-Drug was approved by the FDA for a single use: the treatment of major depressive disorder in patients age 18 or older.

STEVENS' Collection of Information and Evidence of K-Corp.'s Promotion of W-Drug for Unapproved Uses

12. On or about October 25, 2002, **STEVENS** participated in a telephone conference call with representatives of the FDA in which the FDA informed K-Corp. that it expected K-Corp. to attempt to obtain and provide to the FDA materials and documents presented at K-Corp.-sponsored promotional programs by health-care professionals who were acting on behalf of K-Corp., even if such materials and documents were not created by or under the custody or control of K-Corp. During that call, **STEVENS** and K-Corp. agreed to seek to obtain and provide to the FDA such presentation materials.

13. On or about October 29, 2002, **STEVENS** sent a letter to the FDA in Rockville, Maryland, in which she stated, in part:

> You further confirmed that it is your expectation that [K-Corp.] attempt to obtain and provide to you materials and documents presented at [K-Corp.]-sponsored promotional programs, even if not created by, or under the custody or control of [K-Corp.] We have committed to making a good-faith effort to obtain additional presentation materials, and to provide them to you if we are able to obtain the consent of the owner of such materials. We both recognize that some individuals may refuse to provide the requested materials. In this event, we have agreed to keep you informed of our inability to secure such materials.

14. In her October 29, 2002 letter, **STEVENS** also confirmed that the time period covered by the FDA's request for information and materials was from January 1, 2001, to October 9, 2002.

15. In a teleconference with the FDA on or about November 5, 2002, **STEVENS** agreed that K-Corp. would send a letter asking all health-care professionals who spoke on behalf of K-Corp. regarding W-Drug within the specified time period to provide K-Corp. with any materials used during their presentations on behalf of K-Corp. regarding W-Drug.

16. In preparing its response to this FDA inquiry, K-Corp. identified approximately 2,700 K-Corp. speakers who had given promotional talks on behalf of K-Corp. about W-Drug in 2001-2002.

17. On or about December 12, 2002, **STEVENS** sent a letter to approximately 550 of the 2,700 K-Corp. speakers who had given promotional talks on behalf of K-Corp. for W-Drug and asked that they send in the slides and materials they used during these promotional talks. In her letter, **STEVENS** stated "FDA has requested that [K-Corp.] provide all materials and documents presented at [K-Corp.]- sponsored speaker programs for [W-Drug] during the years of 2001-2002."

18. K-Corp. received slides and other materials from approximately 40 of the approximately 550 promotional speakers to whom **STEVENS** sent her December 12, 2002 letter.

19. **STEVENS** reviewed the slides and other materials produced by the approximately 40 promotional speakers who responded to her December 12, 2002 letter.

20. Thereafter, **STEVENS** sent letters to 28 of these promotional speakers in which she stated that the slides and materials they had sent her contained information about unapproved uses of W-Drug, in violation of the FDA's requirements. In each letter, **STEVENS** stated:

> We have reviewed the content of your presentations and determined that they contain material relating to [K-Corp.] products (e.g. [W-Drug]) and uses that are not currently FDA-approved indications for those products. Any affirmative

> presentation in a [K-Corp.]-sponsored non-independent program suggesting that a [K-Corp.] product is effective in conditions that are not approved indications is inconsistent with FDA's requirements, [K-Corp.] policy, and your contract with [K-Corp.]

STEVENS' Collection of Information about Dr. P

21. While responding to the FDA's inquiry, **STEVENS** gathered information that demonstrated that a physician in Michigan (hereinafter "Dr. P.") had spoken at 488 W-Drug promotional events sponsored by K-Corp. in 2001-2002.

22. In or about January 2003, **STEVENS** met with Dr. P. Around that time she received his presentation slides, handouts distributed during his promotional presentations on behalf of K-Corp., notes of his presentation, and an audio cassette of his lecture, which showed that Dr. P repeatedly promoted the use of W-Drug for unapproved uses, including weight loss.

STEVENS' Collection of Information about Dr. H

23. While responding to the FDA's inquiry, **STEVENS** gathered information that demonstrated that a physician in Vermont (hereinafter "Dr. H") had spoken at 511 W-Drug promotional events sponsored by K-Corp. in 2001-2002.

24. Prior to sending her responses to the FDA's inquiry, **STEVENS** learned that during these events Dr. H had repeatedly promoted the use of W-Drug for unapproved uses.

STEVENS' False Representations To and Concealing of Evidence from the FDA

25. **STEVENS** signed and sent to the FDA a series of letters, with documents enclosed, in which she made materially false statements and concealed and covered up documents and other evidence that showed the extent of K-Corp.'s promotion of W-Drug for unapproved uses.

26. **STEVENS** made the false statements and withheld documents she recognized as incriminating with the goal of curtailing further FDA investigation and avoiding or minimizing any FDA regulatory action against K-Corp. and any other potential government investigations or potential enforcement actions against K-Corp.

27. Despite her representation to the FDA in October 2002 that she would gather and produce the slides used by promotional speakers on behalf of K-Corp., **STEVENS** nonetheless:

a. represented that she had completed the production requested by the FDA when in fact she had withheld from the FDA the slides she gathered from the 40 doctors who produced their slides in response to **STEVENS'** December 12, 2002 letter, which she had promised to produce and which she recognized contained incriminating evidence of potential off-label promotion by K-Corp.;

b. denied that K-Corp. had activities promoting W-Drug for uses other than those consistent with the label even though she had determined that 28 of those 40 doctors were using materials that discussed the use of W-Drug for unapproved uses during W-Drug promotional presentations on behalf of K-Corp;

c. claimed that K-Corp.'s activities were consistent with the product label when she knew but did not disclose to the FDA that Dr. P, who had been a top speaker for K-Corp. in 2001-2002, had routinely discussed off-label uses of W-Drug in his promotional slides and handouts; and that she had not produced the documents requested and promised by K-Corp., including the speaker slides, handouts, and audio cassette of Dr. P's standard lecture that K-Corp. had gathered from Dr. P that reflected this promotion for uses not consistent with the W-Drug label;

d. claimed that K-Corp.'s activities were consistent with the product label when she knew, but did not disclose to the FDA, that Dr. H, the other top W-Drug promotional speaker, had routinely used off-label materials in his promotional slides and handouts; and she did not produce to the FDA the speaker slides and handouts that K-Corp. had gathered from Dr. H.

STEVENS' February 28, 2003 Letter

28. On or about February 28, 2003, **STEVENS** sent a letter to the FDA that included the following false and misleading representations:

a. "[K-Corp.] has not developed, devised, established, or maintained any program or activity to promote or encourage, either directly or indirectly, the use of [W-Drug] as a means to achieve weight loss or treat obesity. . . . [K-Corp.]'s promotional material and activities for [W- Drug] are consistent with the approved Prescribing Information and the supporting clinical data."

b. "[K-Corp.] has not developed or maintained promotional plans or activities to directly or indirectly promote [W-Drug] for weight loss or the treatment of obesity."

c. "[K-Corp.] has two types of advisory boards – National Advisory Boards and Local Advisory Boards. . . . [K-Corp.], through its field-based Market Development Managers, has established Local Advisory Boards in certain sales regions for the purpose of obtaining specific advice from health care professionals in that locale for [W-Drug] and/or issues relating to the therapeutic area of depression. Pursuant to [K-Corp.] policy, no sales region may have more than two Local Advisory Boards, and no such board may meet more than twice per year."

29. By February 28, 2003, **STEVENS** knew that K-Corp. had maintained programs and activities that directly and indirectly promoted and encouraged the use of W-Drug to achieve weight loss and treat obesity, and that K-Corp.'s promotional activities for W-Drug had not been consistent with the approved prescribing information.

30. By February 28, 2003, **STEVENS** knew that K-Corp. had paid numerous physicians in 2001-2002 to give promotional talks about W-Drug that included slide presentations about unapproved uses of W-Drug, including for weight loss.

31. By February 28, 2003, **STEVENS** knew that K-Corp. held many "special issue boards" – in addition to national and local advisory boards concerning W-Drug. Dr. H and Dr. P

presented information at many of these "special issue boards." Unapproved uses of W-Drug were presented and promoted at many of the "special issue boards " that physicians were paid by K-Corp. to attend.

STEVENS' March 28, 2003 Letter

32. On or about March, 28, 2003, **STEVENS** continued to conceal information and materials from the FDA and sought to further mislead the FDA by sending the FDA a letter that included the false and misleading representation with respect to speaker programs that: "Attendees were not paid, reimbursed, or otherwise compensated to attend these events, with the exception of reimbursement for parking fees in some cases."

33. By March 28, 2003, **STEVENS** also knew that attendees sometimes received gifts, entertainment, and other compensation as part of W-Drug promotional events, but she deliberately withheld this information from the FDA and falsely represented that no compensation or reimbursement other than parking fees had been provided.

STEVENS' May 21, 2003 "Final" Letter and Completion of Production

34. As K-Corp. prepared to finish its response to the FDA's inquiry, **STEVENS** discussed with the other lawyers involved in responding to the FDA whether to produce the slide sets and presentation materials gathered from the physicians who had made promotional presentations on behalf of K-Corp. concerning W-Drug. **STEVENS** requested that other lawyers involved in the response to the FDA prepare a memorandum summarizing their conversations about the pros and cons of producing these slide sets to the FDA, even though **STEVENS** had already committed to the FDA in writing that she would produce such materials.

35. On or about March 18, 2003, other lawyers involved in responding to the FDA provided the memorandum that **STEVENS** had requested. This memorandum stated:

"As you have requested, we are providing a list of the pros and cons of submitting physician presentations on [W-Drug] to FDA . . .

Pros	Cons
–Responds to FDA's request 5(a) for copies of all materials presented by individuals identified in response to item 3 and relating to [W-Drug]	– Provides information that appears to promote off-label uses of [W-Drug] for weight loss as well as ADHD, sexual dysfunction, and other unapproved uses
–Potentially garners credibility with FDA	– Potentially demonstrates [K-Corp.]'s lack of control over [K-Corp.] sales representatives
	–Potentially demonstrates [K-Corp.]'s lack of control over physician speakers.
	–Provides incriminating evidence about potential off-label promotion of [W-Drug] that may be used against [K-Corp.] in this or in a future investigation."

36. **STEVENS** determined not to produce any of the slide sets to the FDA with the final production. Instead, on or about May 21, 2003, **STEVENS** sent a letter to the FDA which stated that it was K-Corp.'s "final" response to the FDA's requests and falsely stated: "With this final submission, we complete our production of information and documents in response to the requests in your letter dated October 9, 2002 and additional requests raised in your teleconference with [K-Corp.] on January 21, 2003 concerning [W-Drug]."

37. In this final letter, **STEVENS** also continued to falsely represent that K-Corp. had been promoting W-Drug consistently with the product label. She stated:

a. "In the final analysis, all of the information consistently and clearly points to the same conclusion – [K-Corp.] has not developed, devised, established, or maintained any program or activity to promote, either directly or indirectly, the use of [W-Drug] to achieve weight loss or treat obesity."

b. "[K-Corp.]'s promotional material and activities for [W-Drug] are

> consistent with the approved Prescribing Information and the supporting clinical data. All of the documentation and materials we have reviewed and provided to you during the course of this inquiry support this conclusion."

STEVENS' November 6, 2003 Letter

38. In or about September 2003, **STEVENS** learned that an employee of K-Corp. had reported K-Corp.'s promotion of W-Drug for unapproved uses to the FDA and had sent the FDA a copy of the promotional slide presentations used by Dr. H and a physician in California (hereinafter "Dr. F"). Both slide presentations contained information and claims about unapproved uses of W-Drug.

39. On or about November 6, 2003, **STEVENS** sent a letter to the FDA in which she stated that the issues raised by the sales representative "do not present any new issues." With the letter, **STEVENS** produced to the FDA only the Dr. H and Dr. F slide sets she knew the FDA had already received from the sales representative. **STEVENS** did not provide the FDA with other promotional slides that K-Corp. had gathered from Dr. H and others.

40. In her November 6, 2003 letter to the FDA, **STEVENS** further sought to mislead the FDA and deter further investigation or enforcement action by stating:

> "Although there were isolated deficiencies, the objective evidence clearly demonstrates that [K-Corp.] has not developed, maintained, or encouraged promotional plans or activities to promote, directly or indirectly, [W-Drug] for weight loss, the treatment of obesity, or any other unapproved indication."

41. By November 6, 2003, **STEVENS** knew that K-Corp. had held what was likely more than 1,000 programs that were led by speakers whose presentation materials included off-label information about W-Drug, and thus that these were not "isolated deficiencies."

COUNT ONE
(Obstruction of a Proceeding)

1. Paragraphs 1 through 41 of the Introductory Allegations are incorporated here.

2. From in or about October 2002 and continuing through at least in or about January 2004, in the District of Maryland and elsewhere, the defendant,

LAUREN STEVENS,

in a matter within the jurisdiction of the FDA, the Department of Health and Human Services (HHS), and the Department of Justice (DOJ), agencies of the executive branch of the government of the United States, attempted to and did corruptly obstruct, influence, and impede an official proceeding, by making false and misleading statements to the FDA, and by withholding and concealing documents and other information about promotional activities by K-Corp. for W-Drug, including for unapproved uses, while representing that she had completed the response to the FDA.

18 U.S.C. § 1512
18 U.S.C. § 2

COUNT TWO
(Falsification/Concealment of Documents)

1. Paragraphs 1 through 41 of the Introductory Allegations are incorporated here.

2. From in or about October 2002 through at least in or about January 2004, in the District of Maryland and elsewhere, the defendant,

LAUREN STEVENS,

in a matter within the jurisdiction of the FDA, HHS, and DOJ, agencies of the executive branch of the government of the United States, knowingly concealed, covered up, and falsified records, documents and tangible objects with the intent to impede, obstruct, and influence the investigation and proper administration of a matter within the jurisdiction of the FDA, HHS, and DOJ, agencies of the United States, and in relation to and contemplation of any such matter, in that she sent false letters, falsified and altered documents, and concealed and covered up evidence of promotional activities including gifts and entertainment by K-Corp. for W-Drug, including for unapproved uses.

18 U.S.C. § 1519
18 U.S.C. § 2

COUNT THREE
(False Statement)

1. Paragraphs 1 through 41 of the Introductory Allegations are incorporated here.

2. On or about February 28, 2003, in the District of Maryland and elsewhere, the defendant,

LAUREN STEVENS,

in a matter within the jurisdiction of the FDA, an agency of the executive branch of the government of the United States, knowingly and willfully falsified, concealed, and covered up by a trick, scheme, and device a material fact and made a materially false, fictitious, and fraudulent statement and representation, that is, she sent a letter to the FDA, which included the following statements regarding K-Corp.'s activities from January 1, 2001, through October 9, 2002:

> "[K-Corp.] has not developed, devised, established, or maintained any program or activity to promote or encourage, either directly or indirectly, the use of [W-Drug] as a means to achieve weight loss or treat obesity."
>
> * * *
>
> "[K-Corp.]'s promotional material and activities for [W-Drug] are consistent with the approved Prescribing Information and the supporting clinical data."
>
> * * *
>
> "As noted, [K-Corp.] has not developed or maintained promotional plans or activities to directly or indirectly promote W-Drug for weight loss or the treatment of obesity."
>
> * * *
>
> "[K-Corp.] has two types of advisory boards – National Advisory Boards and Local Advisory Boards. . . . [K-Corp.], through its field-based Market Development Managers, has established Local Advisory Boards in certain sales regions for the purpose of obtaining specific advice from health care professionals in that locale for [W-Drug] and/or issues relating to the therapeutic area of depression. Pursuant to [K-Corp.] policy, no sales region may have more than two Local Advisory Boards, and no such board may meet more than twice per year."

3. In fact, **STEVENS** knew that K-Corp. had maintained programs and activities that directly and indirectly promoted and encouraged the use of W-Drug as a means to achieve weight loss and treat obesity and that K-Corp.'s promotional activities for W-Drug were not consistent with the approved prescribing information.

4. In fact, **STEVENS** also knew that, in addition to national and local advisory boards, K-Corp. held another type of advisory board, known as "special issue boards," relating to W-Drug and that these special issue boards met significantly more than twice per year per sales region.

18 U.S.C. § 1001
18 U.S.C. § 2

COUNT FOUR
(False Statement)

1. Paragraphs 1 through 41 of the Introductory Allegations are incorporated here.

2. On or about March 28, 2003, in the District of Maryland and elsewhere, the defendant,

LAUREN STEVENS,

in a matter within the jurisdiction of the FDA, an agency of the executive branch of the government of the United States, knowingly and willfully falsified, concealed, and covered up by a trick, scheme, and device a material fact and made a materially false, fictitious, and fraudulent statement and representation, that is, she sent a letter to the FDA which included the following statement regarding K-Corp.'s speaker program activities from January 1, 2001, through October 9, 2002:

> "Attendees were not paid, reimbursed, or otherwise compensated to attend these events, with the exception of reimbursement for parking fees in some cases."

3. In fact, **STEVENS** knew that K-Corp. had provided gifts and entertainment to the attendees of these programs and had removed this information from a portion of the "Event Spreadsheet" that she provided as an Appendix to this letter.

18 U.S.C. § 1001
18 U.S.C. § 2

COUNT FIVE
(False Statement)

1. Paragraphs 1 through 41 of the Introductory Allegations are incorporated here.

2. On or about May 21, 2003, in the District of Maryland and elsewhere, the defendant,

LAUREN STEVENS,

in a matter within the jurisdiction of the FDA, an agency of the executive branch of the government of the United States, knowingly and willfully falsified, concealed, and covered up by a trick, scheme and device a material fact and made a materially false, fictitious, and fraudulent statement and representation, that is, she sent a letter to the FDA which included the following statements regarding K-Corp.'s activities from January 1, 2001, through October 9, 2002:

> "[W]e systematically and carefully collected, reviewed and provided you with extensive information and supporting documentation regarding [K-Corp.]'s promotional and non-promotional activities relating to [W-Drug] and weight loss. . . . In the final analysis, all of the information consistently and clearly points to the same conclusion – [K-Corp.] has not developed, devised, established, or maintained any program or activity to promote, either directly or indirectly, the use of [W-Drug] to achieve weight loss or treat obesity."
>
> * * *
>
> "[K-Corp.]'s promotional material and activities for [W-Drug] are consistent with the approved Prescribing Information and the supporting clinical data."
>
> * * *
>
> "The extensive information that we have provided . . . objectively demonstrates that [K-Corp.] has not engaged in the promotion of [W-Drug] for weight loss."
>
> * * *
>
> "With this final submission, we complete our production of information and documents in response to the requests in your letter dated October 9, 2002 and additional requests raised in your teleconference with [K-Corp.] on January 21, 2003 concerning [W-Drug]."

3. In fact, **STEVENS** knew that K-Corp. had collected information which showed that K-Corp.'s paid speakers for W-Drug were presenting materials about unapproved uses of W-Drug during promotional events sponsored by K-Corp. and that K-Corp. had maintained programs and activities that directly and indirectly promoted W-Drug for weight loss and to treat obesity.

4. **STEVENS** also knew that a substantial number of W-Drug promotional programs and activities sponsored by K-Corp. from January 1, 2001, through October 9, 2002, contained information that was not consistent with the approved prescribing information and supporting clinical data.

5. **STEVENS** knew that K-Corp. had engaged in the promotion of W-Drug for weight loss and that she had not provided to the FDA materials that showed that K-Corp.'s top speakers for W-Drug were promoting W-Drug for weight loss and other unapproved uses, even though the FDA had specifically requested such information and **STEVENS** had promised to produce such information to the FDA.

18 U.S.C. § 1001
18 U.S.C. § 2

COUNT SIX
(False Statement)

1. Paragraphs 1 through 41 of the Introductory Allegations are incorporated here.

2. On or about November 6, 2003, in the District of Maryland and elsewhere, the defendant,

LAUREN STEVENS,

in a matter within the jurisdiction of the FDA, an agency of the executive branch of the government of the United States, knowingly and willfully falsified, concealed, and covered up by a trick, scheme, and device a material fact and made a materially false, fictitious, and fraudulent statement and representation, that is, she sent a letter to the FDA, which included the following statement regarding K-Corp.'s activities from January 1, 2001, through October 9, 2002:

> "Although there were isolated deficiencies, the objective evidence clearly demonstrates that [K-Corp.] has not developed, maintained, or encouraged promotional plans or activities to promote, directly or indirectly, [W-Drug] for weight loss, the treatment of obesity, or any other unapproved indication."

3. In fact, **STEVENS** knew that K-Corp.'s deficiencies were not isolated, but rather that K-Corp. had maintained extensive promotional plans and activities that directly and indirectly promoted W-Drug for weight loss, the treatment of obesity, and other unapproved indications, and that she had not provided to the FDA information that showed that K-Corp.'s top speakers for W-Drug were promoting W-Drug for weight loss, the treatment of obesity, and other unapproved indications, even though the FDA had specifically requested such information and **STEVENS** had promised to produce the information to the FDA.

18 U.S.C. § 1001
18 U.S.C. § 2

A TRUE BILL:

SIGNATURE REDACTED

Foreperson of the Grand Jury

CARMEN MILAGROS ORTIW
UNITED STATES ATTORNEY
DISTRICT OF MASSACHUSETTS

SARA MIRON BLOOM
ASSISTANT UNITED STATES
ATTORNEY

TONY WEST
ASSISTANT ATTORNEY GENERAL
U.S. DEPARTMENT OF JUSTICE

PATRICK JASPERSE
TRIAL ATTORNEY
OFFICE OF CONSUMER LITIGATION

Date: November 8, 2010