



Enforcement,
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Preparing for and Responding to FDA Enforcement Actions – Advance Topics: Food and Dietary Supplements

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United States v. Lauren Stevens

Federal Charges against Ms. Stevens:

- **Count 1: Obstructing an Official Proceeding**
 - 18 U.S.C. § 1512; maximum sentence of 20 years and \$250K fine.
- **Count 2: Concealing and Falsifying Documents to Influence the FDA**
 - 18 U.S.C. § 1519; maximum sentence of 20 years and \$250K fine.
- **Counts 3-6: Making False Statements to the FDA**
 - 18 U.S.C. § 1001; maximum sentence of 5 years and \$250K fine.

Government's Allegations

- Post Dec. 12, 2002 follow up letter to physicians who submitted slides.
- Stevens wrote that she had “reviewed the content of your presentation and determined they contained material relating to GSK products (e.g. Wellbutrin SR) and uses that are not currently FDA-Approved indications for products. Any affirmative presentation in a GSK-sponsored non-independent program suggesting that a GSK product is effective in conditions that are not approved indications is inconsistent with FDA requirements, GSK policy and your contract with GSK.”

Government's Allegations

- “Dr. P” spoke at 488 GSK promotional events in 2001-2002 and promoted Wellbutrin for unapproved uses. Stevens makes handwritten notes about “Dr P” in 2002:
 - “det’d that he has been discussing WBSR at GSK-sponsored events & using off label info-”
 - “What is risk to Co. w/ respect to the rel. w/ [Dr. P.] – Is he someone we have invested a great deal of \$ in, liking what he says; providing him opps for \$”
 - “Govt might say: FDA: off-label – Co. liked it/condoned it as evid’d by proliferation of prez. OIG: payment to [Dr. P] at issue -- pay to Rx?”

Government's Allegations

March 18, 2003 Memorandum from GSK outside counsel to Stevens on pros and cons of submitting physician presentations on Wellbutrin:

Pros

- Responds to FDA's request 5(a) for copies of all materials presented by individuals identified in response to item 3 and relating to Wellbutrin.
- Potentially garners credibility with FDA.

Cons

- Provides information that appears to promote off-label uses of Wellbutrin for weight loss.
- Potentially demonstrates GSK's lack of control over GSK sales reps.
- Potentially demonstrates GSK's lack of control over physician speakers.
- Provides incriminating evidence about potential off label promotion.