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

Allison Fulton, Partner, Sidley Austin LLP

Leslie T. Krasny, Partner, Keller and Heckman LLP

Alan G. Minsk, Partner, Arnall Golden Gregory LLP

Moderated by: Stuart M. Pape, Shareholder, Polsinelli PC
United States v. Lauren Stevens

Federal Charges against Ms. Stevens:
• Count 1: Obstructing an Official Proceeding
• Count 2: Concealing and Falsifying Documents to Influence the FDA
• 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?”
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.