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DELVACCA 2008 * 2010 Chapter of the Year

DELVACCA presents: "Avoiding Pitfalls When Responding to Government Regulators"

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Presented by:

Nicholas J. Nastasi, Jr., Esquire
Saul Ewing LLP

Amy Kurland, Inspector General
City of Philadelphia

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U.S. v. LAUREN STEVENS

- Lauren Stevens is 61 Years Old
- Born and Raised in Ohio
- Educated at Ohio State
- Graduated Law School
- Small Law Practice in Raleigh, NC
- In-house at GSK for 20 years
- Lives with her family, two college-age daughters, in Durham, NC

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- Vice President and Assoc. G.C.
- Received FDA Letter October 9, 2002

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- October 9, 2002 Letter states:
  - FDA aware of information suggesting GSK promoting Wellbutrin for an unapproved use – specifically for weight loss.

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- October 9, 2002 Letter asks:
  - GSK to provide materials relating to promotional programs, including copies of all slides, videos, handouts, and other materials.
  - GSK to identify any compensation provided to speakers.

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- October 29, 2002 Stevens Letter:
  - "We have committed to making a good-faith effort to obtain additional presentation materials, and to provide them to you . . . ."

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- Stevens knew of 2,000 GSK Speakers
- Dec. 12, 2002 wrote to 550 of the 2,000 requesting materials
- 40 of the 550 Physicians provided Stevens with materials

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- Stevens' internal review of the 40 responses revealed that 28 of them contained information about unapproved uses.

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- February 28, 2003 Letter:
  - "GSK has not developed, devised, established, or maintained any program or activity to promote or encourage, either directly or indirectly, the use of Wellbutrin SR as a means to achieve weight loss or treat obesity . . . . GSK's promotional material and activities for Wellbutrin SR are consistent with the approved Prescribing Information and the supporting clinical data"

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- March 18 pros/cons memo
  - prepared by King & Spalding
  - listed the potential pros and cons to producing the 40 slide sets and presentation materials gathered from the physicians.

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"As you have requested, we are providing a list of the pros and cons of submitting physician presentations on Wellbutrin SR to FDA . . . .

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 SR
- Potential garners credibility with FDA.

Cons

- Provides information that appears to promote off-label uses of Wellbutrin for weight loss as well as ADHD, sexual dysfunction, and other unapproved uses.
- Potentially demonstrates GSK's lack of control over GSK sales representatives.
- Potentially demonstrates GSK's lack of control over physician speakers.
- Provides incriminating evidence about potential off-label promotion of Wellbutrin SR that may be used against GSK in this or in a future investigation.

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- May 21, 2003 Letter:
- "With this final submission, we complete our production of information and documents in response to the requests in your letter dated October 9, 2002 . . ."

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- March 28, 2003 Letter:
  - "Attendees were not paid, reimbursed, or otherwise compensated to attend these events, with the exception of reimbursement for parking fees in some cases"

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- March 28, 2003 Letter:
  - Deleted "entertainment" column from speaker program spreadsheet attached to letter. Column described events where speaker programs were presented – sporting events, spas, skiing trips, rock concerts etc.

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- THE RESULT
  - 6-Count Indictment
  - Obstruction of Justice and Making False Statements
  - Faced Possible Jail Sentence and Heavy Fines.

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- THE RESULT
  - At the close of prosecution case, Defense Moved for Acquittal Under Rule 29
  - Almost Never Granted
  - Judge Granted Motion and Acquitted Lauren Stevens on all 6 counts.

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- COURT'S DECISION
  - the evidence in this case can only support one conclusion, and that is that the defendant sought and obtained the advice and counsel of numerous lawyers. She made full disclosure to them. Every decision that she made and every letter she wrote was done by a consensus. Now, even if some of these statements were not literally true, it is clear that they were made in good faith which would negate the requisite element required for all six of the crimes charged in this case.

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