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Pharmaceutical Company Lawyer Charged with Obstruction and Making False Statements

WASHINGTON – An attorney for a major pharmaceutical company was charged with obstruction and making false statements, the Justice Department announced today. Lauren Stevens of Durham, N.C., was charged with one count of obstructing an official proceeding, one count of concealing and falsifying documents to influence a federal agency, and four counts of making false statements to the Food and Drug Administration (FDA).

The indictment states that in October 2002, the FDA asked for information about the company's promotion of a prescription drug, as part of an inquiry into whether the drug was being promoted for uses that had not been approved by the FDA. Data demonstrating a drug's safety and efficacy for a particular use is required for FDA approval. Federal law prohibits the marketing or promotion of drugs for unapproved – or "off-label" – uses.

The indictment alleges that, in response to the FDA's inquiry, Stevens signed and sent a series of letters from the company to the FDA that falsely denied that the company had promoted the drug for off-label uses, even though she knew, among other things, that the company had sponsored numerous programs where the drug was promoted for unapproved uses. The indictment alleges that Stevens knew that the company had paid numerous physicians to give promotional talks to other physicians that included information about unapproved uses of the drug. According to the indictment, the company paid one such physician to speak at 511 promotional events in 2001-2002 and another physician to speak at 488 such events during that time period.

The indictment also alleges that Stevens did not provide the FDA with slide sets used by the physicians who were paid by the company to promote the drug, even though the FDA had asked for the slide sets and Stevens had previously promised to obtain and provide the FDA with such materials. The indictment

alleges that a legal memorandum was prepared for Stevens that set forth the "pros" and "cons" of producing the slide sets to the FDA. According to the indictment, one of the "cons" was that the slide sets would provide "incriminating evidence about potential off-label promotion of [the drug] that may be used against [the company] in this or in a future investigation." Instead of providing the requested slide sets to the government, Stevens represented that the company's responses to the FDA's requests was "final" and "complete."

"Where the facts and law allow, the Justice Department will pursue individuals responsible for illegal conduct just as vigorously as we pursue corporations," said Tony West, Assistant Attorney General for the Civil Division of the Department of Justice. "Criminal charges are appropriate when false statements such as those alleged here are made to the FDA."

"There is a difference between legal advocacy based on the facts and distorting the facts to cover up the truth," said Carmen Ortiz, U.S. Attorney for the District of Massachusetts. "Federal agencies such as the FDA cannot protect the public health if the entities and individuals they regulate provide false information and conceal the true facts."

The charges were filed in the District of Maryland, where the FDA is located. The case is being prosecuted by the Civil Division's Office of Consumer Litigation and U.S. Attorney's Office for the District of Massachusetts. The case is being investigated by agents from the Office of Inspector General of the Department of Health and Human Services, the FBI, the FDA's Office of Criminal Investigations and the Defense Criminal Investigative Service (DCIS).

"This indictment demonstrates that those who purposely subvert the regulatory functions of the FDA through false statements and misleading information will be held accountable for their deception," stated Dara Corrigan, FDA's Associate Commissioner for Regulatory Affairs. "We commend the efforts of the Department of Justice and the other law enforcement agencies that are vigorously pursuing the prosecution of this matter."

"Lauren Stevens allegedly misled investigators intentionally and failed to comply with our request for documents," said Susan J. Waddell, Special Agent in Charge of the Department of Health and Human Services Office of Inspector General's Boston region.

"This indictment shows that we will investigate those responsible for unlawful acts done on a company's behalf. When individual employees are identified, they will be held accountable for their illegal activity. Individual employees now know that concealing information from the government, obstructing investigative activity and making false statements to federal investigators will be investigated and prosecuted," said Richard DesLauriers, Special Agent in Charge, FBI, Boston Division.

"This indictment demonstrates that misleading federal officials is a serious offense that will not be tolerated," said Leigh-Alistair Barzey, DCIS Resident Agent in Charge. " DCIS will continue to partner with other federal agencies, such as the FDA, in an effort to protect the DoD's TRICARE health plan, which provides medical care for America's military members and their families."

Each of the obstruction charges carries a maximum penalty of 20 years in prison. Each of the false statement counts carry a maximum penalty of five years in prison. Charges contained in the indictment are simply accusations, and not evidence of guilt.

The pharmaceutical company for whom Stevens worked has not been charged with a crime and was not identified in the indictment.

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Civil Division