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Chapter 3

Trust, but Verify? Inside Counsel, Outside Counsel, and *United States v. Lauren Stevens*

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I. INTRODUCTION

II. THE FACTS IN THE CASE

III. WHOM DO YOU TRUST? INSIDE COUNSEL, OUTSIDE COUNSEL, AND ETHICAL QUANDARIES

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[1]Grateful appreciation is expressed to Jeff Sconyers, Senior Vice President and General Counsel of Seattle Children's Hospital, for his helpful comments on an earlier version of this chapter. The views expressed, however, are solely those of the author, and any errors are likewise solely the responsibility of the author.

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I. INTRODUCTION

§ 3:1 Introduction: do you need a lawyer (and does your lawyer need you)?

Lawyers are, it may be said, a jaded bunch. Indeed, a certain worldly, seen-it-all air is arguably a sine qua non for a lawyer. One does not want one's client to think that one is just as shocked/perplexed/confused/frightened as the client is, after all. Oh, it takes something pretty big to get a lawyer's rapt attention.

Like the indictment of another lawyer. For doing legal work. Surrounded by still more lawyers.

In late 2010, lawyers sat up and took notice at the federal indictment of Lauren Stevens, formerly a Vice President and Associate General Counsel of GlaxoSmithKline (GSK), on a variety of obstruction and false statement charges relating to her alleged actions in connection with a Food and Drug

Administration (FDA) inquiry into GSK's alleged promotion of off-label use of one of its flagship drugs, Wellbutrin SR.[1] According to the government, Ms. Stevens had, in the course of responding on behalf of GSK to a voluntary request for information and documents by the FDA "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 would have shown the extent of GSK's alleged misconduct, all in violation of federal criminal laws.[2]

Taking the indictment at face value, it appeared that Ms. Stevens had engaged in plain, old-fashioned lying and was now being brought into the dock for it. As her defense began to emerge, however, it became clear that there was another version of the story: from the perspective of Ms. Stevens, she had not only responded appropriately to the FDA's inquiry but had done so with the advice and concurrence of a variety of other inside and outside counsel to GSK, including multiple former FDA staff attorneys.[3]

Ultimately, this duel of perspectives was resolved in favor of Ms. Stevens. After the close of the government's case in a jury trial, U.S. District Judge Roger W. Titus granted her motion for a judgment of acquittal, and she walked away a free lawyer, none the worse for wear if you ignore the legal fees, mental anguish, and reputational damage.[4] Judge Titus's decision to acquit Ms. Stevens without letting the case get to the jury was viewed in much of the legal trade press and the related blogosphere as a significant slapdown to the government, at least insofar as its strategy of pursu-

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[Section 3:1]

[1]*See* Indictment, U.S. v. Stevens, Case No. RWT-10-CR-0694 (D. Md.), filed Nov. 8, 2010 ("Original Indictment"). As discussed below, the Original Indictment was dismissed without prejudice, and Ms. Stevens was thereafter reindicted. *See* Indictment, U.S. v. Stevens, Case No. RWT-10-CR-0694 (D. Md.), filed Apr. 13, 2011 ("Second Indictment").

[2]Original Indictment at ¶ 25; Second Indictment at ¶ 26.

[3]*See* Lauren Stevens' Motion under Fed. R. Crim. P. 29 for Judgment of Acquittal, U.S. v. Stevens, Case No. RWT-10-CR-0694 (D. Md.), filed May 8, 2011, at 7–11 ("Motion for Acquittal").

[4]*See* Transcript, May 10, 2011, U.S. v. Stevens, Case No. RWT-10-CR-0694 (D. Md.), *available at* http://freepdfhosting.com/53b29eb9a9.pdf (order from the bench granting Motion for Acquittal) ("Acquittal Order").

ing individual corporate agents—especially lawyers—on criminal charges relating to alleged corporate misconduct was concerned.[5]

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[5]*See, e.g.,* John R. Fleder, *Black Tuesday for the Government: The Lauren Stevens Case is Dismissed*, FDA Law Blog, May 10, 2011, *available at* www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/05/black-tuesday-for-the-government-the-lauren-stevens-case-is-dismissed.html; David Stout, *Lauren Stevens: A Case the DOJ Would Probably Like to Forget*, Main Justice (blog), May 11, 2011, *available at* www.mainjustice.com/2011/05/11/lauren-stevens-a-case-the-doj-would-probably-like-to-forget/; Alicia Mundy & Brent Kendall, *U.S. Rebuffed in Glaxo Misconduct Case*, wsj.com, May 11, 2011, *available at* online.wsj.com/article/SB10001424052748703730804576315101670843340.html. In general, commentators like these viewed the case as both a proper rebuke to the government for an inappropriate prosecution and at least an implicit vindication of Ms. Stevens on the underlying facts. For somewhat contrary views, *cf.* Jim Edwards, *Acquittal of Glaxo Lawyer Suggests It's OK to Lie to the FDA*, cbsnews.com, May 10, 2011, *available at* www.cbsnews.com/8301-505123_162-42848276/acquittal-of-glaxo-lawyer-suggests-its-ok-to-lie-to-the-fda/; Ed Silverman, *The Judge & The Former Glaxo Lawyer: Patrick Explains*, pharmalot.com Pharma Blog, May 12, 2011, *available at* http://www.pharmalot.com/2011/05/a-judge-the-former-glaxo-lawyer-patrick-explains/ (in which a noninvolved lawyer argues that, at a minimum, Stevens should have been required to put on a defense before the judge took the case away from the jury). For fairly evenhanded, if brief, factual summaries of the case, *see* Sue Reisinger, *Crossing the Line: The Trial of GlaxoSmithKline Lawyer Lauren Stevens*, CORP. COUNS., June 23, 2011, *available at* www.law.com/jsp/cc/PubArticleCC.jsp?id=1202497750428&rss=cc; Virginia A. Gibson & Thomas J. Widor, *U.S. v. Lauren Stevens Case Dismissed: What Now for In-House Attorneys?*, 9 Pharm. L. & Industry Rep. at 622 (May 20, 2011); William F. Gould & Michael M. Gaba, United States v. Lauren Stevens: *How FDA's Questions about Off-Label Promotion Led to the Criminal Prosecution of a Company Lawyer*, FDLI UPDATE (Sept./Oct. 2011) at 7. Additional interesting background from lawyers involved in the trial may be found at Lisa Brennan, *Rajaratnam, Farkas, Stevens Lawyers Discuss Trial Hurdles*, Main Justice (blog), Mar. 7, 2012, *available at* www.mainjustice.com/2012/03/07/rajaratnam-farkas-stevens-lawyers-discuss-trial-hurdles/.

A bit over a year after her acquittal, Ms. Stevens told her own story at the 2012 annual meeting of the Association of Corporate Counsel. A summary of her presentation is contained in Sue Reisinger, *How Ex-GSK GC Lauren Stevens Fought the Law—and Won*, CORP. COUNS., Oct. 2, 2012, *available at* www.law.com/corporatecounsel/PubArticleCC.jsp?id=1202573330716&How_ExGSK_GC_Lauren_Stevens_Fought_the_Law151and_Won&slreturn=20120929231916 (note: the title of the article incorrectly suggests that Ms. Stevens was the general counsel of GSK; the text of the article correctly identifies her position). *See also* Jennifer Smith, *Ex-Glaxo VP on 'The Criminalization of the Practice of Law'*, WSJ Law

Notwithstanding this resolution, however, the case holds much of interest to students of legal ethics.[6] As will be discussed below, in *Stevens*, much of the government's cased hinged on what Ms. Stevens had told GSK's outside lawyers (and other inside lawyers) and on what those lawyers would say she had told them. In turn, those other lawyers presumably had to worry about whether, if they gave the wrong (or at least the unsatisfactory) answers, they might be accused of conspiring with Ms. Stevens in the alleged obstruction of the FDA investigation.

In many respects, the *Stevens* case raises fundamental questions about the relationship and interactions between inside counsel and outside counsel in the context of a government investigation, about the degree to which such counsel may rely on each other's good faith and professional judgment, and about the duty that members of a counsel "team" may have to go behind factual statements made, and legal advice given, by other members. In particular, the implications of some of the positions taken by prosecutors in *Stevens*—positions which were rebuffed by this judge in this case, but which might find a more comfortable reception before another tribunal—give rise to troubling questions concerning how lawyers who counsel clients under investigation meet their professional obligations and whether their representation may be inhibited by new fears of personal exposure. Such questions may be of particular interest to health care lawyers since, in these parlous times, "clients under investigation" and "healthcare clients" are phrases that have become disturbingly close to being synonyms.

This chapter will explore some of those questions, and the

Blog (Oct. 1, 2012), *available at* http://blogs.wsj.com/law/2012/10/01/former-glaxo-vp-the-criminalization-of-the-practice-of-law-is-here/.

[6]Not least because it is one of what must be a fairly small number of cases in which thousands of dollars in legal fees were spent in arguments over the admissibility and relevance of evidence regarding applicable rules of legal ethics and the amount and nature of ethics CLE training received by the defendant. *See* Letter re: Evidence Rules and Ethics Training, dated April 18, 2011, to the Honorable Roger W. Titus from Sara Miron Bloom and Patrick Jasperse and Letter re: Evidence Rules and Ethics Training, dated April 18, 2011, to the Honorable Roger W. Titus from Reid H. Weingarten, William T. Hassler and Brien T. O'Connor, Docket Entries 154 and 155, respectively, in U.S. v. Stevens, Case No. RWT-10-CR-0694 (D. Md.).

dynamics of the inside-outside counsel relationship in investigation situations, in the context of both the American Bar Association's Model Rules of Professional Conduct[7] and the publicly available information in the *Stevens* case. In particular, this chapter will focus on the ethical and professional responsibilities of inside counsel in working with outside counsel in such situations and on the degree to which inside and outside counsel may rely on each other without conspiring with each other. Beyond that, this chapter will also offer some thoughts on the larger implications of *Stevens* on the representation of clients by both inside and outside counsel.

II. THE FACTS IN THE CASE

§ 3:2 Truth and/or consequences: the file on Lauren Stevens[1]

In order to set the stage, it is helpful first to review the facts (admitted and alleged) of the *Stevens* case, many of which are undisputed (although the legal import of them is not).

In October 2002, the FDA sent a letter[2] to GSK requesting that GSK voluntarily provide extensive information relating to GSK's marketing of Wellbutrin SR to physicians, with a

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[7]MODEL RULES OF PROF'L CONDUCT (2012). The Model Rules currently form the basis of the rules of professional responsibility applicable in all U.S. jurisdictions other than California. However, there is significant variation among those jurisdictions as to the actual rules in effect; for example, some states have not adopted all of the amendments to the Model Rules, others have adopted the Model Rules but not the associated commentary, etc. This chapter will use the Model Rules as the touchstone for analysis, but the reader should bear in mind that his or her license is governed not by the Model Rules but by the specific rules in effect in the jurisdiction(s) that issued that license.

[Section 3:2]

[1]*Cf.* THE FILE ON THELMA JORDAN (Hal Wallis Productions 1950), a classic film noir in which Barbara Stanwyck and Wendell Corey have ethical issues of their own with which to grapple.

[2]The letters referred to in this and the succeeding paragraphs are attached as exhibits to Memorandum of Law in Support of Defendant's Corrected Motion in Limine to Exclude Evidence outside the Scope of the Allegations of the Indictment, U.S. v. Stevens, Case No. RWT-10-CR-0694 (D. Md.), filed March 31, 2011 ("Stevens MIL Memo"). In the interests of brevity, specific citations to individual letters are omitted here.

particular focus on GSK's financial and other relationships with physicians who made presentations to other physicians and professionals about the drug and on the slides, videos, and other documentation used in such presentations. The letter indicated that the FDA had received information indicating that GSK might have been promoting off-label use of Wellbutrin as a weight-loss aid, a use for which the drug had not been approved by the FDA.[3]

The requests for information were fairly sweeping in scope: 15 separate categories of information, including both requests for existing documents and requests for the creation of new documents, as well as requests for discrete items of factual information. The FDA requested a response within 10 days.

On October 29, Ms. Stevens responded with a letter recounting the results of two conference calls between the FDA and the GSK team and GSK's understanding of certain limitations on and priorities for the response agreed to by the FDA. In that letter, she noted that certain of the requested documents used at GSK-sponsored promotional programs were not created by, or under the custody or

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[3]As it eventually developed, GSK was apparently doing pretty much exactly that. In July 2012, GSK entered into a settlement agreement with the Department of Justice pursuant to which it agreed to plead guilty to criminal charges and pay a total of $3 billion in civil and criminal penalties relating to, among other things, illegal off-label marketing of Wellbutrin and other drugs. *See* U.S. Dep't of Justice Press Release, "GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data" (July 2, 2012), *available at* www.justice.gov/opa/pr/2012/July/12-civ-842.html; Katie Thomas & Michael S. Schmidt, *Glaxo Agrees to Pay $3 Billion in Fraud Settlement,* N.Y. TIMES, July 2, 2012, *online version available at* www.nytimes.com/2012/07/03/business/glaxosmithkline-agrees-to-pay-3-billion-in-fraud-settlement.html?pagewanted=all&__r=1& (print version published at page A1 of the July 2, 2012, edition, under the title *Drug Firm Guilty in Criminal Case*). See also Alexandra Sifferlin, *Breaking Down GlaxoSmithKline's Billion-Dollar Wrongdoing* (July 5, 2012), *available at* http://healthland.time.com/2012/07/05/breaking-down-glaxosmithklines-billion-dollar-wrongdoing/; Scott Hensley, *Glaxo Settlement Pulls Back Curtain on Drug Marketing* (July 3, 2012), *available at* http://www.npr.org/blogs/health/2012/07/03/156192227/glaxo-settlement-pull-back-curtain-on-drug-marketing. The New York Times reported that the $3 billion settlement represented only about half of GSK's revenues from Wellbutrin sales alone during the period in question, and not quite 11% of its combined revenues from the three primary drugs involved in the settlement. *See* Thomas & Schmidt.

control of, GSK and that there was a possibility that some individuals who did have custody or control of those materials might decline to provide them to GSK. The letter went on to state,

> You [i.e., the FDA] further confirmed that it is your expectation that GSK attempt to obtain and provide to you materials and documents presented at GSK-sponsored promotional programs, even if not created by, or under the custody or control of GSK. 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.

Thereafter, GSK provided a series of response letters, all signed by Ms. Stevens, describing in some detail GSK's promotional and training activities with respect to Wellbutrin, including the establishment of two "National Advisory Boards" and an unspecified number of "Local Advisory Boards" comprising physicians and other consultants engaged to provide GSK with feedback and advice on issues relating to Wellbutrin, as well as a "Speakers Bureau" authorized to make product-related presentations on behalf of GSK. The responses included spreadsheets, represented as having been created solely for purposes of the responses, containing certain information about Wellbutrin-related speaker events sponsored by GSK. They did not, however, include promotional presentation materials of the type described in the October 29 letter.

(As it transpired, Ms. Stevens allegedly undertook both to try to collect Wellbutrin-related materials from speakers and to discuss the issue with the FDA to the extent such collection efforts were unsuccessful. The legal team then allegedly identified some 2,000 persons who had given Wellbutrin-related promotional talks during 2001–2002. Ms. Stevens sent a letter to 550 of those speakers, advising them that the FDA had "requested that GSK provide all materials and documents presented at GSK-sponsored speaker programs for Wellbutrin SR during the years of 2001-2002" and that GSK intended to "cooperate fully" with the FDA's requests. Thereafter, some 40 of the speakers provided slides and other materials to Ms. Stevens. Ms. Stevens sent a follow-up letter

to 28 of the 40, advising them that she had identified material in the presentations promoting off-label uses of Wellbutrin and admonishing them that such promotion was inappropriate.[4] It does not appear that, in any of her correspondence with the FDA, Ms. Stevens described the number of speakers identified, the significantly smaller number of speakers who were contacted, the very small fraction of that number that actually provided materials, or the fact that over 70% of those who did provide materials in response to Ms. Stevens' request had apparently used presentations that were potentially tainted with off-label promotion.)

On May 21, 2003, GSK submitted a letter that it characterized as its "final supplemental response" to the FDA inquiry and its "last submission." The letter concluded, "With this final submission [GSK] complete[s its] production of information and documents" and requested the opportunity to "arrange a teleconference with [the FDA] to discuss any final questions that [the FDA] may have." And there, at least insofar as Ms. Stevens was concerned, the matter lay for a bit.[5]

Wheels had, however, commenced turning behind the scenes. In April 2003, the Department of Justice (DOJ) advised the FDA that the Department had commenced an investigation into GSK's promotional activities. Thereafter, the DOJ asked the FDA for copies of all documents provided by GSK in connection with the FDA investigation, and at

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[4]Second Indictment at ¶¶ 15–20; the Original Indictment had a slightly different version of these allegations, asserting that Ms. Stevens had undertaken to send a letter to "all health-care professionals who spoke on behalf of [GSK] regarding [Wellbutrin] within the specified time period" and that 2,700 such speakers had been identified. Original Indictment at ¶¶ 15–20.

[5]Actually, there was one further letter from Ms. Stevens, on behalf of GSK, to the FDA in November 2003. Apparently, GSK had become aware that a sales representative had provided to the FDA slide presentations used by two physicians allegedly promoting off-label use of Wellbutrin, and Ms. Stevens sent a letter to the FDA concluding that the sales representative's disclosures "[did] not present any new issues"—although, of course, they did present new *materials*, since GSK had not previously provided any of the slides. *See* Second Indictment at ¶¶ 39–42.

some point on or prior to June 30, 2003 (and unbeknownst to GSK), the FDA discontinued its own investigation.[6]

In late 2003 or early 2004, the DOJ began a grand jury investigation in Massachusetts "to conduct a wide-ranging investigation into alleged off-label promotion of prescription drugs by [GSK]".[7] As part of that investigation, DOJ initially interviewed Ms. Stevens in 2008, and in May 2009, she received a "target letter" from DOJ.[8] In addition, the grand jury apparently heard testimony from other inside and outside counsel who had been involved in GSK's response to the FDA.[9] The original indictment then issued in November 2010.[10]

The basic allegations of the indictment were fairly straightforward. According to the government, Ms. Stevens "made . . . false statements and withheld documents she recognized as incriminating with the goal of curtailing further FDA investigation [of GSK] and avoiding or minimizing any FDA regulatory action against [GSK] and any other potential government investigations or potential enforce-

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[6]*See* Letter, dated Jan. 26, 2011, from Patrick Jasperse to William T. Hassler, attached as Exhibit A to [Redacted] Reply in Support of Defendant's Motion to Compel Discovery and Disclosure of Material and/or Exculpatory Information, U.S. v. Stevens, Case No. RWT-10-CR-0694 (D. Md.), filed Mar. 31, 2011 ("Stevens Motion to Compel Reply").

[7]Stevens MIL Memo at 3.

[8]Declaration of Brien T. O'Connor ("O'Connor Decl."), filed as Exhibit 1 to [Redacted] Defendant's Memorandum of Law in Opposition to United States' Motion to Preclude Advice of Counsel Defense, U.S. v. Stevens, Case No. RWT-10-CR-0694 (D. Md.), filed Mar. 31, 2011 ("Stevens Advice of Counsel Opp.").

[9]*See* Peter D. Hardy & Matthew T. Necomer, *Obtaining Federal Grand Jury Materials: Lessons from the* Stevens *Decision*, THE LEGAL INTELLIGENCER, May 9. 2011.

[10]The indictment was issued by a federal grand jury in Maryland, notwithstanding that the investigation-in-chief was being conducted by a federal grand jury in Boston. The United States Attorney for the District of Maryland did not sign the indictment, a fact that excited considerable comment when it emerged after the conclusion of the case. *See, e.g.,* David Stout, *Maryland U.S. Attorney Wouldn't Sign Indictment of GSK Counsel*, Main Justice (blog), June 20, 2011, *available at* www.mainjustice.com/2011/06/20/maryland-u-s-attorney-wouldnt-sign-indictment-of-gsk-counsel/.

ment actions against [GSK]."[11] In particular, the government alleged that Ms. Stevens had obtained, but concealed, information tending to show that GSK was actively involved in promoting off-label use of Wellbutrin, both by making affirmative misrepresentations of fact concerning GSK's promotional activities and by failing to produce potentially incriminating documents. According to the indictment, Ms. Stevens knowingly withheld information about GSK's use of "special issue boards" (in addition to the disclosed National Advisory Boards and Local Advisory Boards) to promote off-label uses to physicians, knowingly misrepresented facts concerning whether attendees at promotional meetings were compensated by GSK, and knowingly withheld slide sets and presentation materials used by presenting physicians that may have indicated improper promotion of off-label uses. Of particular significance to the government was a memorandum to Ms. Stevens in March 2003 that was prepared by other lawyers on the GSK response team, outlining the supposed "pros and cons" of turning over the physician presentations to the FDA.[12] In any event, the presentations were not provided to the FDA, and, in the government's view, the statements in the May 21 letter that such letter was GSK's "final" response and that GSK had "complete[d its] production of information and documents" were intended to mislead the FDA and obstruct its investigation.[13]

Once the indictment had issued, the role of counsel—Ms. Stevens, GSK's other inside counsel, and GSK's outside counsel at the firm of King & Spalding—quickly became a central theme in the criminal case.[14] Early on in the process, it became apparent that Ms. Stevens intended to rely in part

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[11]Original Indictment at ¶ 26.

[12]Original Indictment at ¶¶ 27–35. Among the pros: "[r]esponds to FDA's request" and "[p]otentially garners credibility with the FDA." Among the cons: "[p]rovides incriminating evidence about potential off-label promotion . . . that may be used against [GSK] in this or in a future investigation". Original Indictment at ¶ 35. *See* Gould & Gabba at 9.

[13]Original Indictment at ¶¶ 36–37.

[14]*See, e.g., Law firm's advice could be key in Glaxo lawyer case*, Thomson Reuters News & Insight, Nov. 11, 2010, *available at* http://newsandinsight.thomsonreuters.com/Legal/news/2010/11__-__november/law__firm__s__advice__could__be__key__in__glaxo__lawyer__case/; *King & Spalding to be center of Glaxo lawyer's trial*, Thomson Reuters News & Insight, March 18, 2011, *available at* http://newsandinsight.thomsonreute

on the defense that, contrary to the government's apparent contention that she had unilaterally engaged in a pattern of obstruction and deceit, she had in fact been simply giving voice to the unanimous decisions of the entire GSK legal team with respect to how to respond to the FDA.[15] (In a 2012 presentation, Ms. Stevens stated that the outside lawyers had drafted the response letters, but "she signed them because GSK was afraid that if 'we fronted the law firm to the FDA, it would raise a red flag.' ")[16] According to Ms. Stevens, it was the shared conclusion of the entire legal team that GSK "had no centralized corporate strategy to promote Wellbutrin off-label to treat obesity."[17] Further,

> The legal team discussed at length whether to produce the [omitted physician] presentations to [the] FDA absent the

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rs.com/Legal/news/2011/03__-__march/king_____spalding__to__be__center__of__glaxo__lawyer__s__trial/.

[15]*Cf.* the Carl Reiner-Mel Brooks comedy recording about the (fictitious) pop singer Fabiola, who says of his fans, "I am them, they are me, we are all singing, I have the mouth." (Quoted in GARY GIDDINS, RIDING ON A BLUE NOTE: JAZZ AND AMERICAN POP (1981) (Da Capo Press edition, 2000), at 19.)

[16]Reisinger, *Fought the Law*. One of Ms. Stevens's defense counsel confirmed that "King & Spalding [produced] the first drafts of almost all the response letters before they were circulated to the other team members." O'Connor Decl. at 3. As a strategic matter, the decision to have inside counsel rather than outside counsel sign the response letters is plausible but somewhat curious; given the skepticism with which government regulators have sometimes been known to view in-house lawyers, one might have thought having the responses sent out over the name of a well-known law firm with FDA experience might have been viewed as enhancing the credibility of the conclusions (and the investigative process from which they resulted) with the FDA. However, given the "informal" nature of the FDA request, it would not have been unreasonable to conclude that a visible indication that GSK had "(outside) lawyered up" might have suggested to the FDA that its investigators were in fact on to something. Consistent with this approach, it does not appear from any of the response letters that GSK had made the FDA aware of King & Spalding's involvement, not that it was under any obligation to do so. *Cf.* Sarah E. Swank & William A. Roach, Jr., *Five Lessons Learned (the Hard Way?) for In House Counsel*, Ober Kaler Health Law Alert, 2011 Issue 6, at 2 ("In house [*sic*] counsel should make clear to government officials from the outset that they will be relying, in good faith, on the advice of outside counsel throughout the investigation, since it appears that their own guidance as in house counsel may not be enough in the eyes of government investigators.").

[17]Stevens Advice of Counsel Opp. at 4.

> context necessary to assess the presentations. The team was concerned that simply producing the presentations with no explanation could create a misleading impression. The team reached a consensus not to produce the presentations immediately but instead to seek a meeting with [the] FDA at which GSK would discuss the presentations. [Despite calls from Ms. Stevens in May and June 2003 to arrange such a meeting, no meeting occurred.] At no time did King & Spalding advise GSK that its nonproduction of the presentations was unlawful.[18]

In short, Ms. Stevens alleged, if she had done wrong, she had done so in reliance upon the advice of qualified inside and outside counsel, therefore lacking the *mens rea* to have committed the crimes of which she was accused.

The government sought to undercut that argument early in the proceedings through a motion to prohibit, or at least to strictly limit, the introduction of evidence supporting an advice-of-counsel defense.[19] Ignoring certain technical aspects of the motion relating to specific charges and procedural issues that are not relevant to this discussion,[20] the government offered three basic contentions:[21]

- That Ms. Stevens had not provided GSK's other counsel with all relevant facts known to her;
- That she had not sought the advice of counsel in good

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[18]Stevens Advice of Counsel Opp. at 5. The defense went on to note that "[n]o other members of the legal team have been charged."

[19]*See* United States' Motion to Preclude Advice of Counsel Defense to 18 U.S.C. § 1519 and for Hearing Regarding Applicability of the Defense to Other Charges, U.S. v. Stevens, Case No. RWT-10-CR-0694 (D. Md.), filed Dec. 17, 2010 ("Gov't Advice of Counsel Mot.")

[20]Parts of the motion dealt with whether 18 U.S.C. § 1519 constituted a specific-intent crime and whether the advice-of-counsel defense were available with respect to it and with procedural prerequisites for asserting the defense.

[21]*See* Gov't Advice of Counsel Mot. at 12–17. As pointed out by the defense, the last argument described below is highly questionable as a matter of law and ridiculous as a matter of policy; were that to be the law, no individual charged with committing a crime as a corporate agent could ever raise an advice-of-counsel defense unless that individual had engaged a personal lawyer to advise him or her with respect to acts or omissions on behalf of the corporation, even if the corporation had expressly directed corporate counsel to communicate with and/or through the individual agent, or if the individual agent were the instrument through which the corporation could take action in the matter. *See* Stevens Advice of Counsel Opp. at 14–16.

faith (and correlatively, that she could not have reasonably relied on such advice if, in essence, the advice was rendered by counsel who were conspiring with her to conceal documents and information from the FDA); and

- That she could not rely on the defense if the advice on which she purportedly relied were rendered by counsel for GSK who did not represent her personally.

The issue then became a turning point in the case, as Judge Titus found not only that the advice-of-counsel defense was available to Ms. Stevens but that the prosecutors had, in response to a direct question from a grand juror, misinstructed the grand jury on the relevance of the defense at the charging stage and that such faulty instruction had tainted the original indictment. Accordingly, the court dismissed the indictment without prejudice, allowing the government to seek to reindict before a different grand jury.[22]

Which is exactly what happened, as a chastened but undaunted DOJ team obtained a substantially identical new indictment from a new grand jury, and the case proceeded to trial.[23] The government's case-in-chief took around two weeks to present, at which time Ms. Stevens filed a motion for judg-

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[22]*See* Memorandum Opinion, U.S. v. Stevens, Case No. RWT-10-CR-0694 (D. Md.), filed Mar. 23, 2011 ("Original Dismissal").

[23]The only substantive difference between the Original Indictment and the Second Indictment was the inclusion of a paragraph purporting to reproduce Ms. Stevens' handwritten notes relating to potential issues regarding the promotional activities of a specific physician, noting potential arguments that might be made by the FDA and by the Office of Inspector General of the Department of Health and Human Services. See Second Indictment at ¶ 22. As an observation, this and other documents in the case suggest that Ms. Stevens might have been rather more obsessive about making notes than would be ideal, at least if one is concerned about whether such notes might someday be discoverable; another note written by Ms. Stevens shortly after the original FDA inquiry reads, in the government's edited version, "N2S [presumably, "Note to Self"]: We already have probs w/ [three doctors paid by GSK to speak at promotional events]; FDA doesn't have to dig deeper & rather than open up everything, let's admit probs & take lump—reform practices." United States' Opposition to Defendant's Motion in Limine, U.S. v. Stevens, Case No. RWT-10-CR-0694 (D. Md.), filed Mar. 4, 2011, at 3. Other such notes are referenced in Motion for Acquittal at 9–10, indicating a particular habit of writing down pros and cons that, it might be suggested, would be a good habit to break. In hindsight, Ms. Stevens took a more sanguine perspective, stressing that her case "[wasn't] a lesson about don't take notes, but about take effective notes . . . Had we not had those notes I wouldn't have

ment of acquittal under Rule 29 of the Federal Rules of Criminal Procedure. In many respects, that motion seems driven by semantics: arguments that "not producing" something is not the legal equivalent of "concealing" that something, especially in the context of a voluntary response to a government inquiry that does not have the force of a subpoena behind it; arguments that the deletion of a column from a specially created spreadsheet (which column reflected entertainment expenditures by GSK in connection with physician programs) did not make the spreadsheet "false"; arguments that "gifts and entertainment" for speakers were not "compensation" to those speakers; arguments that GSK's knowledge of (what may fairly be characterized as pretty routine and recurring) violations of its policy concerning promotion of off-label usage did not support the inference that GSK had a "plan" to engage in such promotion.[24]

Amidst these somewhat precious arguments, however, were three recurrent major themes:[25]

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remembered all those [exculpatory] things we did back in 2003." Reisinger, *Fought the Law*.

[24]*See* Motion for Acquittal, *passim*. Note that referring to these arguments as semantic ones does not mean that they are per se invalid arguments; the law is a semantics-driven enterprise. In analyzing the specific portions of the response letters that the government identified as being false statements, one commentary noted that "[a] number of the statements sound very much like legal advocacy and careful factual characterization in the light most favorable to the client." Gibson & Widor, *U.S. v. Lauren Stevens Case Dismissed*, at 624. On the other hand, the "semantical" nature of the arguments does suggest that the defenses involved subtleties of the sort that might be challenging to a jury. In posttrial reflections, Ms. Steven herself noted that "her letters to the FDA contained 'a lot of advocacy and zealous representation. If I were to do it again, I think I would set a different tone in the letters.' " Reisinger, *Fought the Law*.

[25]The last of which brings up an interesting sidelight on the defense strategy. In many ways, the weak link in the defense is the language in the May 21 letter that seemed clearly to imply that GSK did not have further responsive materials to provide: "final response," "completes our production," etc. Although the letter requested a teleconference, that request indicated that the purpose of the teleconference would be "to discuss any final questions [the FDA] may have," not "to tell the FDA what we didn't produce and why" or something like that.

In pretrial filings, the defense suggested that it would offer evidence that, at a proposed meeting with the FDA, "Ms. Stevens and other members of the GSK legal team assumed that [the] FDA would question

GSK about why certain 'slide decks' had not yet been produced." [Redacted] Memorandum in Support of Defendant's Motion to Compel Discovery and Disclosure of Material and/or Exculpatory Information, U.S. v. Stevens, Case No. RWT-10-CR-0694 (D. Md.), filed March 31, 2011, at 5–6 ("Stevens Motion to Compel Memo"). More or less in so many words, the defense suggested that the GSK team believed that the FDA must have known that GSK had not handed over all relevant slide decks, that the burden was on the FDA to ask for them, and that the FDA's failure to ask for them was a (presumably welcome) surprise to GSK. U.S. v. Stevens, Case No. RWT-10-CR-0694 at 8. Only on the eve of trial, according to the defense, did Ms. Stevens become aware that the FDA had discontinued its investigation in favor of the DOJ investigation, which her defense team viewed as accounting for the FDA's apparent lack of interest in a meeting. U.S. v. Stevens, Case No. RWT-10-CR-0694 at 8. Running through this argument (which is amplified in Stevens Motion to Compel Reply, *passim*) seems to be a subliminal argument that someone in the FDA or the DOJ had an obligation to tell GSK that the FDA had discontinued its investigation by the summer of 2003 so that GSK would have been on notice that it should not rely on the FDA's silence as a justification for not producing the slide decks.

The government suggested that Ms. Stevens's arguments that she fully intended to discuss the slide decks had been retrofitted to the facts, citing

> . . . a meeting in mid-May 2003 [at which] Stevens and the other [GSK lawyers] discussed how to respond if the FDA asked about doctor-speaker slide sets. Stevens' own notes from that meeting say: "let them come back despite 10/29/02 stmt." The notes of another participant at the meeting state: "find a way to not provide." If Stevens truly wanted to discuss the slide sets with the FDA, she could have stated in one of her letters that GSK had collected off-label slide sets but did not want to produce them until it had a chance to discuss the materials with the FDA. Instead, Stevens concealed the off-label materials and called her May 2003 submission "final" and "complete."

[Redacted] Government's Opposition to Defendant's Motion to Compel, U.S. v. Stevens, Case No. RWT-10-CR-0694 (D. Md.), filed March 31, 2011, at 12. The government went on to note that "[o]ne may not make false statements to the government and obstruct a government investigation on the assumption that there will be a chance to take a different position later if the initial approach does not succeed." U.S. v. Stevens, Case No. RWT-10-CR-0694 at 15. Although that argument is logically flawed in that it assumes its premises, it is difficult not to have a least a bit of sympathy for the government on this point. Ms. Stevens and the rest of the GSK team may, in good faith, have planned to discuss the omitted materials at the meeting that never happened, but the May 21 letter seems, in substance and in literal language, to have been designed to minimize the importance of the requested "teleconference" and to discourage the FDA from pursuing additional production of documents. Certainly, it did not state or directly imply that there were additional documents that could be made available for the asking. At least one contemporaneous commentator expressed, rather colorfully, the notion that this was a bit of

- Other inside counsel at GSK and outside counsel at King & Spalding (including, in both camps, former in-house lawyers from the FDA) advised Ms. Stevens at every step of the way, and all of her actions were undertaken only after consensus was reached among the counsel team;
- Ms. Stevens did not knowingly and intentionally make false statements to, or conceal information from, the FDA; and
- Ms. Stevens would not have repeatedly requested to meet with the FDA after the May 21, 2003 if she had intended to conceal anything, and the FDA's failure to schedule such a meeting was the primary reason that it was not made aware of the information intentionally omitted from GSK's production.

The government's response was hurried and brief, basically asserting that it had introduced evidence sufficient to withstand a Rule 29 motion and that, in any event, the court should not rule on the motion until after the jury had deliberated and rendered its verdict.[26]

Judge Titus, however, was having none of it. In an order from the bench, he first noted that the government's case was largely predicated on information obtained from attorney-client privileged documents that a Massachusetts magistrate had determined were discoverable under the crime-fraud exception, a determination with which Judge Titus disagreed.[27] As a result of that determination, in Judge Titus's words, "the prosecutors were permitted to forage through confidential files to support an argument for criminality of the conduct of the defendant." However, in the judge's view, the privileged documents "show that [Ms. Stevens] was a client [*sic*; presumably "lawyer" was meant]

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a disingenuous approach. Jim Edwards, *Glaxo Lawyer Says Disclosing Illegal Activity Would Be "Misleading" to the FDA*, CBS Moneywatch, Apr. 22, 2011, available at http://www.cbsnews.com/8301-505123_162-42848074/glaxo-lawyer-says-disclosing-illegal-activity-would-be-misleading-to-the-fda ("A lawyer might conclude that a teleconference at which one can ask 'any final questions' is a suggestion that you have a box full of smoking guns, but it is hard to imagine 12 laypersons seeing it that way.").

[26]*See* United States' Initial Response to Defendant's Motion for Judgment of Acquittal, U.S. v. Stevens, Case No. RWT-10-CR-0694 (D. Md.), filed May 9, 2011.

[27]*See* Acquittal Order at 3, 5.

that was not engaged to assist a client to perpetrate a crime or fraud. Instead, the privileged documents . . . show a studied, thoughtful analysis of an extremely broad request from the [FDA] and an enormous effort to assemble information and respond on behalf of the client." Further, "[t]he responses that were given by the defendant may not have been perfect . . . . They were, however, sent to the FDA in the course of her bona fide legal representation of a client and in good faith reliance [on] both external and internal lawyers for [GSK]."[28]

After concluding that Ms. Stevens was entitled to acquittal on all counts as a matter of law, Judge Titus went on to summarize the basis for his holding:[29]

> [T]here are serious implications for the practice of law generated by this prosecution. Lawyers can never assist a client in the commission of a crime or a fraud . . . . [¶] However, a lawyer should never fear prosecution because of advice that he or she has given to a client who consults him or her, and a client should never fear that its confidences will be divulged unless its purpose in consulting the lawyer was for the purpose of committing a crime or a fraud. [¶] There is an enormous potential for abuse in allowing prosecution of an attorney for the giving of legal advice. I conclude that the defendant in this case should never have been prosecuted and she should be permitted to resume her career. [¶] The institutional problem that causes me a great concern is that while lawyers should not get a free pass, the Court should be vigilant to permit the practice of law to be carried on, to be engaged in, and to allow lawyers to do their job of zealously representing the interest of their client. Anything that interferes with that is something the court system should not countenance.

It is interesting, if not terribly productive, to speculate on why Judge Titus took what he acknowledged to be the highly rare step of taking this particular case from the jury and rendering a judgment of acquittal on what it must be said are somewhat dodgy facts. Admittedly, the prosecution had quite the air of a witch-hunt about it. Ms. Stevens was singled out from all the other lawyers involved in representing GSK and even from GSK itself. The prosecution developed much of its evidence through a grand jury investigation

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[28]Acquittal Order at 5.

[29]Acquittal Order at 9–10. Reportedly, "the jurors stood up and applauded" when Judge Titus announced his ruling. *See* Reisinger, *Crossing the Line*.

conducted in a different district from that of the grand jury issuing the indictment and was found by the court to have misled the indicting grand jury on a key question of law. Further, the prosecution made aggressive, and as to one aspect (the "she couldn't have relied on King & Spalding's advice because King & Spalding was not her personal counsel" argument) even specious, arguments as to why Ms. Stevens should not even have been allowed to argue that she was relying on the advice of (indisputably competent) counsel, essentially an absolute defense to the specific-intent crimes with which she was charged. It is not clear why the government sought to demonize this one lawyer out of all those involved, and one might also question the arguable attempts by the government to influence the testimony of those other lawyers with veiled threats of prosecution.

At the same time, even allowing for the 20/20 quality of hindsight, Ms. Stevens appears to have made some questionable calls, and aspects of her defense seem to have been based on somewhat retroactive justifications. It may be true that Ms. Stevens and the rest of the team intended to discuss with the FDA why they had not produced certain documents that, in their view, would have been misleading out of context. However, it seems disingenuous to suggest that the May 21 letter should have put the FDA on notice that it needed to have a meeting with the GSK team to obtain such documents or even that such documents might exist; the letter appears to have been clearly designed to suggest that GSK had nothing more to say (and, at least by reasonable implication, nothing else to provide).[30] Similarly, the defense seems to have relied fairly heavily on somewhat fine semantic distinctions to explain why various affirmative statements about GSK's involvement in the promotion of off-label use of Wellbutrin were accurate and not misleading; some of the statements made by Ms. Stevens in her letters were, if not misleading, not forthcoming either.

That is not to say that these questionable calls constituted

[30]And while the government ultimately conceded that Ms. Stevens did contact the FDA on multiple occasions to discuss such a meeting, the defense does not seem to have suggested (and the government has not indicated) that in any of such calls did Ms. Stevens give any indication that GSK might provide or discuss additional documents at such a meeting.

crimes. Further, although the government repeatedly suggested that Ms. Stevens had culpable information that she did not share with the rest of the legal team, the public documents in the case do not seem to offer any evidence contradicting Ms. Stevens's assertion (through counsel) that everything she did (or omitted) was done with the knowledge, approval, and advice of the team. Even if the team were wrong, giving or believing bad legal advice is not a criminal act.[31]

On the other hand, giving bad legal advice does have

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[31]The reaction to the case in published commentary is somewhat polarized, although it appears that, at least by volume, most commentators believe that the decision to pursue the matter via criminal prosecution was clearly wrong and that the actions of Ms. Stevens and the GSK legal team were at, a minimum, appropriate in the context of the FDA inquiry. *See, e.g.,* JACK FERNANDEZ, AN ESSAY CONCERNING THE INDICTMENT OF LAWYERS FOR THEIR LEGAL ADVICE (2012) at 17–18 ("To its everlasting credit, King & Spalding, which had assisted Stevens in crafting her responses [to the FDA], stood by her at trial. (King & Spalding's conduct should form the basis for another article about honorable lawyering. The author hopes that this kind of lawyering is not in short supply.)"), 20 ("Certainly Stevens was entitled to treat the FDA lawyers requesting the documents as competent adversaries who could refine their document requests to obtain what they wanted. Stevens simply took a reasonably aggressive position and 'pushed back' on FDA document requests.") and 29 ("[T]he author applauds Ms. Stevens' courage because that is what it took to persist through trial in the face of what must have been very favorable plea offers."), *available at* http://lawprofessors.typepad.com/files/3533275__1-docx-3-3.pdf; Scott H. Greenfield, *Just Doing Her Job*, Simple Justice (blog), June 12, 2011, available at http://blog.simplejustice.us/2011/06/12/just-doing-her-job.aspx?ref=rss ("Lauren Stevens, former house counsel at [GSK], showed resolve. She did her due diligence and arrived at the conclusion that displeased the government. She said no. She conducted an in-house investigation and concluded that there was no smoking gun proving her employer a raging criminal enterprise. . . . Prosecutors[' faces] turned dark red. No one says no to them. No one. Time to send a message."); Walter Olsen, *A Case that 'Should Never Have Been Prosecuted'*, Cato @ Liberty (blog), June 10, 2011, *available at* http://www.cato-at-liberty.org/a-case-that-should-never-have-been-prosecuted/ ("Especially when it comes to defendants like Fortune 500 in-house counsel, the pressure and the risks of facing off against the federal government are so great that many or most will take a plea bargain, deferred-prosecution agreement, or some other kind of deal rather than resist the onslaught, even if they believe themselves to have done nothing wrong. Lauren Stevens and her colleagues stood up and fought back—for which they deserve our respect and even our gratitude."); David Mowry, *House Rules: When S**t Gets Real*, Above the Law (blog), Oct. 11, 2012, *available at* http://abovethelaw.com/2012/10/house-rules-when-st-gets-real/ ("So let's

review. [Ms. Stevens] responded positively and diligently to the inquiry. She put together a crack team of attorneys and outside counsel to assist in responding. She maintained open lines of communication with the agency. And when mistakes were discovered, they were disclosed, rectified, and steps were taken to avoid the same mistakes occurring. What happened next is not only frightening, but wrong and unjust."). Commentaries of this sort suggest what may be the dominant view, which is that Ms. Stevens was unfairly singled out by the government for acts or omissions that should be protected by sort of a lawyer's version of the "business judgment rule" applied in the corporate law setting—i.e., even if her decisions were not the best ones that could have been made, they were within the bounds of appropriate legal advice and representation.

On the other hand, some commentators were critical at least of Ms. Stevens's strategic decisions, particularly including her failure to provide any of the promotional slides after undertaking (in her original October 29, 2002 letter) to make "a good-faith effort" to do so. *See, e.g.,* Eric Esperne, *Inside Experts: Lessons Learned from Lauren Stevens*, available at www.insidecounsel.com/2011/08/05/inside-experts-lessons-learned-from-lauren-stevens (suggesting that Ms. Stevens's responses to the FDA had been inconsistent with the commitment that she had initially made, perhaps because of a lack of knowledge as to the level of off-label promotion actually being conducted by physicians under contract with GSK); Edwards, *Acquittal of Glaxo Lawyer* (implying in fairly harsh terms that evidence strongly supported the notion that Ms. Stevens affirmatively intended to mislead, if not to deceive, the FDA); Silverman, *The Judge & The Former Glaxo Lawyer* (suggesting that Ms. Stevens had violated "duty of candor" owed to the FDA); *see also* Edwards, *Glaxo Lawyer Says Disclosing Illegal Activity Would Be "Misleading."* With the possible exception of the later Edwards article, *Acquittal of Glaxo Lawyer*, these commentaries do not really suggest that Ms. Stevens engaged in criminal misconduct, but they do suggest to a greater or lesser degree that her actions may have been professionally inappropriate and potentially subject to noncriminal sanctions.

At the end of the day, Reid Weingarten, one of Ms. Steven's defense counsel, may have identified the single most offensive aspect of the prosecution:

> [Weingarten, speaking at an American Bar Association conference,] said his client should not have been singled out. Stevens closely worked with five lawyers at King & Spalding LLP, Glaxo's longtime outside counsel, yet only she had been charged. [Prosecutor Sara] Bloom[, speaking on the same panel,] said she sought to keep the case "narrowly focused" on those "most responsible."
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> "One of the more interesting things is why that case was brought," Weingarten said. "Lauren was head of a team. On the team were five other lawyers. Three of the other five had worked at the Food and Drug Administration. There's no question if you concluded she had criminal intent, the other five did too. How could it be the government decided she committed felonies and others didn't? It presented great opportunities for advocacy."

Brennan, *Rajaratnam, Farkas, Stevens Lawyers Discuss Trial Hurdles*. Fundamentally, whatever one thinks of the way in which Ms. Stevens

implications under the rules of professional responsibility, and the purpose of this chapter is not to second-guess the guilt, or ratify the innocence, of Ms. Stevens but instead to explore some of the professional responsibility challenges raised—or at least suggested—by the facts in *Stevens*. To do that, this chapter will identify some relevant ethics rules and then consider their application to those facts and to variations on those facts.

III. WHOM DO YOU TRUST? INSIDE COUNSEL, OUTSIDE COUNSEL, AND ETHICAL QUANDARIES

§ 3:3 Establishing the ground rules: relevant ethics principles

Before beginning the analysis, it is useful to consider and summarize some of the Model Rules that are most relevant in the context of a response to a government investigation.[1] These include:[2]

- Preamble, ¶ [9]: A lawyer must "zealously . . . protect and pursue a client's legitimate interests, within the bounds of the law, while maintaining a professional,

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handled the response to the FDA, there does not appear to be any material dispute that the strategy, right or wrong, was fully discussed among the inside counsel/outside counsel team, and there is no obvious reason why Ms. Stevens, alone among the six-member team, would be the only one perceived to have criminal culpability. Without question, this created the impression that Ms. Stevens had been singled out to be the in-house lawyer destined to be shot *pour l'encouragement des autres. Cf.* VOLTAIRE, CANDIDE, OU L'OPTIMISME (1759).

[Section 3:3]

[1]While the author believes he would have identified most of the Model Rules discussed in the succeeding paragraphs on his own, his thought process was greatly aided by reviewing the PowerPoint slides from Katy Meisel, William Gould & Patrick O'Brien, *United States v. Lauren Stevens: The Federal Prosecution of a Company Attorney* (May 11, 2011), an educational webcast presented by the Association of Corporate Counsel. Those slides are available, at least at the moment, at http://webcasts.acc.com/handouts/5.11.11_Webcast_Slides_ACC.pdf (ACC materials are generally available only to members, but this one does not seem to be behind a firewall, or at least not a very effective one).

[2]The following items are quoted, paraphrased or summarized from the 2012 edition of the Model Rules. In the interests of brevity, footnotes have been pretermitted, but were they present, they would all simply reference the indicated rules.

courteous and civil attitude toward all persons involved in the legal system."

- Rule 1.1: A lawyer must represent a client competently.
- Rule 1.2(a): A lawyer must "abide by a client's decisions as to the objectives of the representation" and consult with the client on the means of achieving those objectives.
- Rule 1.2(d): "A lawyer shall not counsel a client to engage, or assist a client, in conduct that the lawyer knows is criminal or fraudulent, but a lawyer may discuss the legal consequences of any proposed course of conduct with a client and may counsel or assist a client to make a good faith effort to determine the validity, scope, meaning or application of the law."
- Rule 1.3: A lawyer must represent a client with "reasonable diligence and promptness."
- Rule 1.6: In general, a lawyer may not reveal confidential information about a client obtained in the course of representing that client (whether from the client or from other sources) without the client's consent. However, a lawyer may reveal information without the client's consent, inter alia, "to prevent the client from committing a crime or fraud that is reasonably certain to result in substantial injury to the financial interests or property of another and in furtherance of which the client has used or is using the lawyer's services" or "to prevent, mitigate or rectify substantial injury to the financial interests or property of another that is reasonably certain to result or has resulted from the client's commission of a crime or fraud in furtherance of which the client has used the lawyer's services." In addition, a lawyer may reveal such information "to establish a claim or defense on behalf of the lawyer in a controversy between the lawyer and the client, to establish a defense to a criminal charge or civil claim against the lawyer based upon conduct in which the client was involved, or to respond to allegations in any proceeding concerning the lawyer's representation of the client."
- Rule 1.13: A lawyer representing an organization represents the entity, and not individual officers, directors, shareholders, or other constituents of the entity. "If a lawyer for an organization knows that an officer, employee or other person associated with the organiza-

tion is engaged in action, intends to act or refuses to act in a matter related to the representation that is a violation of a legal obligation to the organization, or a violation of law that reasonably might be imputed to the organization, and that is likely to result in substantial injury to the organization, then the lawyer shall proceed as is reasonably necessary in the best interest of the organization," including reporting the matter up the ladder to higher authority within the organization. If the highest authority that can act on the organization's behalf fails or refuses to do so, and "the lawyer reasonably believes that the violation is reasonably certain to result in substantial injury to the organization," then the lawyer may make a disclosure outside the organization (even if not permitted under Rule 1.6), "but only if and to the extent the lawyer reasonably believes necessary to prevent substantial injury to the organization." However, that "reporting out" right does not apply "with respect to information relating to a lawyer's representation of an organization to investigate an alleged violation of law, or to defend the organization or an officer, employee or other constituent associated with the organization against a claim arising out of an alleged violation of law."

- Rule 3.4: A lawyer has a duty of fairness toward opposing parties and their counsel, including a duty not to "unlawfully obstruct another party's access to evidence or unlawfully alter, destroy or conceal a document or other material having potential evidentiary value . . . [or] counsel or assist another person to do any such act," and a duty not to "falsify evidence, counsel or assist a witness to testify falsely."
- Rule 4.1: "In the course of representing a client a lawyer shall not knowingly: (a) make a false statement of material fact or law to a third person; or (b) fail to disclose a material fact to a third person when disclosure is necessary to avoid assisting a criminal or fraudulent act by a client, unless disclosure is prohibited by Rule 1.6."
- Rule 8.3: "A lawyer who knows that another lawyer has committed a violation of the Rules of Professional Conduct that raises a substantial question as to that lawyer's honesty, trustworthiness or fitness as a lawyer in other respects, shall inform the appropriate profes-

sional authority," but not if disclosure is prohibited by Rule 1.6.

- Rule 8.4: It is an ethical violation for a lawyer to, inter alia, "violate or attempt to violate the Rules of Professional Conduct, knowingly assist or induce another to do so, or do so through the acts of another" or "engage in conduct involving dishonesty, fraud, deceit or misrepresentation."

"Whew! That sure is a lot of rules!" one might reasonably think. "And whose responsibility is it to follow them when you have a whole team of lawyers involved?" Good questions, those. Some potential answers may be suggested by applying those rules to fact patterns present in *Stevens* and some hypothetical variations suggested by *Stevens*.

(In that regard, note that the purpose of this exercise is not to suggest a conclusion that Ms. Stevens or any other member of the GSK legal team acted otherwise than ethically. Rather, the purpose is to use the case as something of a "living hypothetical." In that regard, some of the illustrations below are phrased to suggest that Ms. Stevens, or sometimes another member of the legal team, made a decision or took an action unilaterally. The defense asserted that all actions of the legal team were done by consensus, and there appears to be no reason to assume that not to be the case. However, some of the issues are easier to see if the decisions are "individualized" and ascribed to a single person, usually Ms. Stevens, and so artistic license has been taken below.)

§ 3:4 The rules in context: some thoughts on professional responsibility issues in *Stevens*—Preamble, Rule 1.1 and Rule 1.3: the duties of zealousness, competence, and diligence

There appears to be little reason to question the zealousness, competence, and diligence of the inside or outside lawyers on the facts of *Stevens* even if (as discussed below) there may be reason to question some of the judgments they made. Both the inside and outside teams appear to have been quite competent by reason of experience and industry and agency knowledge. The process by which responsive information was assembled and reviewed seems appropriately diligent, and whatever else may be said, the team appears to

have worked together assiduously to formulate a response that they believed served GSK's interest.

In the context of this type of investigation, though, one might also consider different circumstances where the "diligence" duty might come into play. In pursuing Ms. Stevens, the government alleged that she withheld information from outside counsel (and perhaps from other inside counsel), thereby undercutting her ability to raise an advice-of-counsel defense (which is predicated on providing such counsel with full and complete information). Judge Titus did not bite at that, but it is fairly easy to construct a hypothetical where the duty of diligence might come into play based on the government's argument.

Suppose, for example, that inside counsel attempted—in the friendliest and most reasonable way—to limit the scope of outside counsel's review by restricting outside counsel's access to files or personnel likely to have responsive information: "I've already personally reviewed the files of our Director of Physician Education and these 17 pages are the only relevant documents; no need to waste your time there." Would outside counsel have satisfied his or her duty to represent the client diligently if he or she accepted that position, or should outside counsel insist on his or her own, potentially duplicative, review of those files? What if outside counsel took some action to note this limitation for the record—e.g., through a qualification in a report of investigation ("We have relied upon internal counsel for the review of the following files and have not independently reviewed those files") or a "memo to file"?

Conversely, what if inside counsel believes that outside counsel has (by reason of negligence, limitations of time or resources, lack of knowledge of the client's organizational structure, or whatever) failed to conduct certain interviews or review certain files that make outside counsel's conclusions suspect? May inside counsel simply say, "Oh, well, we're paying them to be the experts and if they didn't want to look at the XYZ files, who am I to question them?," or does inside counsel have a duty under Model Rule 1.3 to go behind the work of outside counsel?

Obviously, there are no perfect answers to these questions even on the oversimplified hypothetical fact patterns outlined above. However, it seems clear that part of the duty of dili-

gence must include taking reasonable steps to verify that the legal conclusions and strategies reached take into account all relevant information and that any response to the government is accurate and complete in accordance with its terms. This does not suggest that one set of counsel needs to duplicate the work of another, but it does suggest that part of the duty of diligence is to ensure that obvious gaps or apparent errors do not go unquestioned.

§ 3:5 The rules in context: some thoughts on professional responsibility issues in *Stevens*—Rule 1.2(d): the duty to walk the tightrope

Rule 1.2(d) is, in some respects, the most significant ethics rule for health care law practitioners, for the simple reason that most things in the health care world that make business sense are also arguably illegal. Under Rule 1.2(d), a lawyer may not counsel a client to engage in illegal acts—at least those that are criminal or fraudulent—or assist the client in so doing, but a lawyer may help the client to make good faith efforts to determine where the boundary between "legal" and "illegal" may be.

In the ordinary course, the application of this rule in the health care setting is fairly easily understood in principle, if not always easy to follow in practice. If the client says, "We need to pay our referring physicians $100 for every patient they send us, and you need to dummy up some sort of contract to make it look legal," the lawyer's obligation is to say no. If the client says, "We need to enter into a business arrangement that does not fit within a safe harbor, and we need you to help us figure out how to do it so we don't get in trouble with the law," the lawyer is free to accept that engagement, and even if the arrangement is ultimately found to be a problem, the lawyer still does not have an ethical issue as long as the client's inquiry and the lawyer's work were in good faith.[1]

The application of this rule to the *Stevens* facts is a bit

[Section 3:5]

[1]For more elaboration of this point*, see generally, e.g.,* William W. Horton, *In the Eye of the Beholder: Physician Transactions, Professional Responsibility, and the Winding Road from* Anderson *to* Tuomey, in HEALTH LAW HANDBOOK (Alice G. Gosfield, ed.) (West 23rd ed. 2011).

less straightforward. Here, the GSK legal team withheld information from a voluntary production. So far as was alleged, the information was not destroyed, mutilated, etc., nor was it withheld in response to a subpoena or other compulsory disclosure order. Unless the GSK correspondence contained false statements about the existence or production of such information (as the government alleged), simply withholding that information would not appear to be a violation of the law.[2]

On the other hand, as will be discussed further below, the available facts make it difficult to say that GSK did not at least skirt around the edges of misleading the FDA, its primary regulatory agency, about the existence of responsive information that was not being provided. Ms. Stevens's defense indicated that the decision to draft the GSK response letters in that fashion was one made by the entire legal team. Under prevailing circumstances, presumably the team consensus was that there was not a clear legal obligation to either provide the missing information or more clearly disclose that it had been withheld. However, if some members of the team had concluded that there were such an obligation, then Rule 1.2(d) would constrain their actions. This can be a delicate line to walk.

§ 3:6 The rules in context: some thoughts on professional responsibility issues in *Stevens*—Rule 3.4: the duty to play fair

Rule 3.4 essentially imposes a duty to preserve evidence, a duty not to obstruct other parties' lawful access to evidence, and a duty not to falsify evidence (or to counsel or assist someone else to do any of those things). There are a couple of important factors to bear in mind in analyzing the rule:

- Rule 3.4 is not a disclosure obligation; it is a nonobstruction obligation. It does not impose upon a lawyer a duty to come forward with information, a duty to create in-

[2]Destroying or otherwise spoliating it might have been a violation under the "anticipatory obstruction of justice" provisions of 18 U.S.C. § 1519, which, among other things, catches "obstruction activities" that are undertaken "in relation to or in contemplation of" a government investigation. *See generally, e.g.,* T. Markus Funk, *'Honey Laundering,' a Toilet Flush, and a Governor's Yahoo Account: The New Age of Anticipatory Obstruction of Justice*, THE CHAMPION (May 2011) 22–26.

formation, or even a duty to make information available in a form more user-friendly than its natural state. Rather, it is in the nature of a duty not to tilt the playing field by concealment, spoliation, or just plain lying.

- More or less explicitly, Rule 3.4 assumes the existence of an adversary proceeding with an opposing party or at least a foreseeably imminent adversary proceeding; it is not a general obligation that prohibits the lawyer from assisting the client to manage potentially damaging information as to which there is no known pending or threatened proceeding (although some activities aimed at managing such information may implicate other applicable ethics rules).

How could Rule 3.4 apply to the facts in *Stevens*? The threshold question is whether it applies at all, given that the FDA's inquiry had not even reached the subpoena stage. However, in light of the fact that the FDA's original request for information clearly specified that it was concerned about potential violations of the FDA statute and regulations and that, logically speaking, the FDA's conclusion that such violations existed could lead to an adversary proceeding, it appears that the spirit of Rule 3.4 would apply to the situation even if there were an argument that it were not literally applicable.

Assuming the rule did apply, the next question is whether the acts of Ms. Stevens or others on the legal team were consistent with the rule. That question is most clearly applicable to two aspects of the GSK response: the decision not to turn over the physician presentations (and not to make any affirmative disclosure that they had not been disclosed)[1] and the decision to delete from the spreadsheet showing physician

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[Section 3:6]

[1]Although it does not seem to have been raised as a particular issue in the case, one might also point out that there was no disclosure concerning the fact that only 40 physicians, out of 2,000 identified and 550 contacted, had produced presentations in response to the request from Ms. Stevens and that 28 of the 40 presentations provided apparently raised compliance issues (or, for that matter, that the GSK had not even contacted nearly three-quarters of the identified physicians). The absence of any disclosure at all about the presentations made this something of a moot point. If, however, the presentations had been turned over as part of the correspondence with the FDA, it might have posed an interesting question as to how the disclosure might have been couched. "We identified

relationships and compensation the column showing what GSK had spent on "entertainment" for the physicians.

The defense addressed those issues in the criminal law context, if not the ethics context, in its Motion for Acquittal. As to the physician presentations, the defense argued (successfully, obviously) that they were not "concealed" from the FDA—that the FDA knew or should have known they existed, that Ms. Stevens did not represent to the FDA that she was providing all of the physician presentations, and that "[m]ere nonproduction" was not the same thing as concealment.[2] As to the spreadsheet, the essence of the defense's argument was that the spreadsheet was not falsified because (i) the information on the spreadsheet was accurate, and (ii) GSK had not represented that the spreadsheet would contain information other than that which it contained.[3] Put another way, the document was not preexisting "evidence" but was created for the purpose of responding to the FDA and did not need to do anything except contain accurate information of the type it said it contained.

From a professional responsibility standpoint, the spreadsheet argument appears consistent with Rule 3.4; that is, Rule 3.4 does not impose a duty to create evidence, but only to preserve it, and the creation of a document that is accurate as far as it goes does not imply a duty to make it go

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2,000 physicians who had made Wellbutrin presentations, and we only got 28 presentations that had any problems" would obviously have been misleading. On the other hand, "We identified 2,000 physicians who had made Wellbutrin presentations, and 70% of the presentations we received presented problems" would have likewise been misleading, aside from being somewhat damaging to the story the home team was trying to present. The obvious answer would have been to simply recount the numbers, which are outlined in § 3:2 above, but that in itself would have opened the door to a variety of uncomfortable questions from the government, such as why only about 25% of the physicians identified were actually sent letters, and why the GSK team did not follow up further when less than 10% of the physicians who were sent letters responded by providing copies of their presentations.

[2]Motion for Acquittal at 5–7. The defense also argued that there could be no concealment absent a duty to disclose, that a voluntary request for production, as opposed to a subpoena, created no such duty, Motion for Acquittal at 6–7, and that Ms. Stevens's multiple attempts to schedule a meeting with the FDA at which the presentations would purportedly be discussed showed the absence of an intent to conceal them, Motion for Acquittal at 10–11.

[3]Motion for Acquittal at 11–14.

farther absent an express undertaking to do so. The physician presentations argument appears to be more tenuous. Under the circumstances, there would not seem to be any duty to turn over the presentations as part of a voluntary submission; in other words, it would be a legitimate legal call not to produce the presentations if, in the lawyers' judgment, there were good and sound reasons not to turn them over in the absence of compulsory process. However, a reasonable person might conclude that the completes-our-production language of the May 21 response letter, along with its extensive summary of why GSK believed there was no FDA violation, was designed to induce the FDA not to ask to see anything else, if not to mislead the FDA into thinking that nothing else existed. Under the literal terms of Rule 3.4, that may still not be "concealment," but it may dance rather closer to the precipice of concealment than one would normally like.[4]

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[4]Paradoxically, one's view of the application of Model Rule 3.4 to the letter may depend on whether one believes that, at the time the letter was written, the GSK team actually intended to produce, or at least discuss, the omitted presentations at the to-be-scheduled meeting with the FDA. This was the version of the facts suggested by the defense. However, if one thinks that was the case, the letter seems more misleading because the letter seems to have been designed to discourage the FDA from thinking any such meeting was necessary or that it would be productive. On the other hand, if one believes that this rationale—"We were going to give them the presentations at the meeting, and we were shocked that they didn't ever agree to have a meeting with us"—was retroactively created as a part of the defense strategy and was not the team's intent when the letter was written, the letter seems less misleading because it simply says, in effect, "We've given you what we're going to give you and we're not giving you anything else," without affirmatively representing that what has been produced was all the relevant materials there were. In other words, if one does not believe that the GSK team really planned to produce the presentations, it is easier to read the letter as simply drawing a line in the sand rather than an attempt to gull the FDA into thinking that no meeting was necessary.

§ 3:7 The rules in context: some thoughts on professional responsibility issues in *Stevens*—Rules 1.2(a), 1.6, 1.13, and 4.1: the duty of deference, the duty not to disclose, the duty to disclose up-the-ladder, the right (but not the duty) to disclose, and the duty not to fail to disclose (unless disclosure is forbidden)

Taken together, these rules really present some of the most difficult questions in a *Stevens*-type situation. For example, suppose that other members of the legal team had recommended that the physician presentations be turned over to the FDA and Ms. Stevens had declined to follow that recommendation. Assuming that they were unsuccessful in persuading her of the error of her ways, what recourse would the other members of the team have?

Assuming (as seems to be the case) that the client, GSK, had delegated to Ms. Stevens the authority to make the final decision on the response to the FDA, Rule 1.2(a) would suggest that the team would have to defer to her decisions even if they believed her to be a walking fool as long as they did not believe that carrying out those decisions would be unlawful.

But suppose they genuinely believed that Ms. Stevens were making a horrible error, e.g., by withholding information that GSK was not under a legal compulsion to disclose but that would severely impair GSK's negotiating position with the FDA if the FDA were to discover it. Could the legal team go around Ms. Stevens and disclose it anyway? Well, not under Rule 1.6; not unless the team determined that such disclosure were necessary "to prevent the client from committing a crime or fraud that is reasonably certain to result in substantial injury to the financial interests or property of another and in furtherance of which the client has used or is using the lawyer's services" or "to prevent, mitigate or rectify substantial injury to the financial interests or property of another that is reasonably certain to result or has resulted from the client's commission of a crime or fraud in furtherance of which the client has used the lawyer's services."

This is a demanding standard. In the first place, there are lots of bad ideas that are not crimes or frauds, and then one gets into all that stuff about "reasonably certain to result in

substantial injury" on top of that. It is not enough to say, "Gee, we have a duty to protect the client, and the client is going to get whacked by the FDA if they figure out we didn't give them the slide decks"; if the decision, e.g., not to give the FDA the slide decks is not a crime or a fraud, then the Rule 1.6 loopho—sorry, exceptions—do not provide any flexibility.

"Okay, but does that mean we have to stand around and do nothing?" the legal team might ask. Not necessarily; indeed, Rule 1.13 might mean that that is not even an option. Under that Rule, if the legal team believed that Ms. Stevens's decision would likely lead to "a violation of a legal obligation to the organization, or a violation of law that reasonably might be imputed to the organization, and that is likely to result in substantial injury to the organization," then the lawyers have a duty to take it up the ladder within GSK—including, if necessary, to the highest authority that can act on behalf of GSK—unless they reasonably believe it is not in the best interests of GSK to do so. Note that this standard for "up the ladder" reporting is lower than the Rule 1.6 standard for external disclosures: a "violation of a legal obligation to the organization" presumably includes a violation of a fiduciary duty, or even a violation of a compliance plan or employee handbook, and a "violation of law" is a much lower threshold than the "crime or fraud" of Rule 1.6. There is still a "likely to result in substantial injury" threshold, but Rule 1.13 essentially errs in favor of not only permitting, but compelling, internal disclosure.

But what if the board of directors says, "Ms. Stevens is our lawyer, and we're sticking with her call?" Rule 1.13 permits (but does not require) external disclosure, "but only if and to the extent the lawyer reasonably believes necessary to prevent substantial injury to the organization." Further, such permissive disclosure is not available where it relates to information obtained by the lawyer in the course of investigating (or defending against charges of) an alleged violation of law by the organization—no defense-team whistleblowers here!—so the legal team will likely have to abide by the board's decision or withdraw from the engagement.

But what about Rule 4.1? That rule forbids a lawyer from knowingly making a false statement of material fact or law to a third person (presumably including a regulatory agency

like the FDA) and from failing to disclose a material fact where disclosure is necessary to avoid assisting a criminal or fraudulent act by the client. Would that protect a member of the legal team if he or she unilaterally decided to, say, produce the physician presentations to the FDA? Not really, for a couple of reasons. First, there is the "criminal or fraudulent act" threshold. It is certainly not clear that GSK's failure to disclose information was a criminal violation; indeed, Judge Titus said it was not, at least insofar as Ms. Stevens was concerned. Beyond that, Rule 4.1 has a sort of clawback clause: it is not a violation of Rule 4.1 to fail to disclose a material fact if such disclosure would not be permitted under Rule 1.6, and as has already been observed, the Rule 1.6 exceptions really set a pretty high bar for permissible disclosures.

On the other hand, there is another Rule 1.6 exception that may be relevant in this type of case. Ms. Stevens, remember, is a lawyer too, bound by the same ethics rules. Suppose that Ms. Stevens had actually proposed to turn over the physician presentations, produce the unexpurgated spreadsheet, etc., but the powers that be at GSK had overruled her, based on the advice of the other members of the legal team that such disclosures were not required. Ms. Stevens shrugs her shoulders, says "You win some, you lose some", and goes back to work, where she is busily engaged right up until the point where the FBI comes in and arrests her on charges of obstruction and making false statements on the same basis as in the actual indictment. How can Ms. Stevens defend herself, given that all of the internal decision-making that lead to the nondisclosure is confidential client information subject to Rule 1.6?

Fortuitously, the good folks at the ABA House of Delegates thought of that. Rule 1.6 permits a lawyer to disclose confidential information without the client's consent

> . . . to establish a claim or defense on behalf of the lawyer in a controversy between the lawyer and the client, to establish a defense to a criminal charge or civil claim against the lawyer based upon conduct in which the client was involved, or to re-

spond to allegations in any proceeding concerning the lawyer's representation of the client.[1]

Thus, a lawyer in the position of Ms. Stevens can do just as the defense did in the actual case and unburden herself of such confidential information as is necessary to defend herself and keep out of jail.

§ 3:8 The rules in context: some thoughts on professional responsibility issues in *Stevens*—Rules 8.3 and 8.4: the duty to be your sibling's keeper (unless it's confidential) and the duty to emulate Johnny Cash (by walking the line)

These final two rules will be dealt with in cursory fashion and are included as a reminder that, in addition to the analysis of one's obligations under "specific detail" rules like the ones cited above, which can sometimes be a counting-the-angels-on-the-head-of-the-pin exercise, one must always be mindful of the "über-rules." Under Rule 8.3, lawyers have a duty to police each other and to disclose to the appropriate licensing/disciplinary authorities ethical violations by other lawyers that "raise[ ] a substantial question as to the [violator's] honesty, trustworthiness or fitness as a lawyer." However, such reporting is not required or permitted if it would in itself violate Rule 1.6.

Rule 8.4 is, in disciplinary terms, the "rule di tutti rules": it is an ethical violation to commit, or attempt to commit, another ethical violation or to facilitate someone else's ethical violation and likewise it is an ethical violation to "engage in conduct involving dishonesty, fraud, deceit or misrepresentation." Aside from a sort of existential issue (violating Rule 8.4(c) is in turn a violation of Rule 8.4(a), which is in turn another violation of Rule 8.4(a), and so on until the mirrors grow dim in the distance), this presents another potential problem for a defendant like Ms. Stevens. One may hypothetically be acquitted on a criminal charge relating to fraud or misrepresentation—even acquitted on the merits, as was Ms. Stevens; Judge Titus seems to have concluded she was affirmatively innocent of the charges, not simply that the government did not meet its burden of

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[Section 3:7]

[1]Model Rules of Prof'l Conduct R. 1.6(b)(5).

proof—but then find oneself facing bar disciplinary action because the threshold is lower ("dishonesty" is not a very demanding standard, when you get right down to it) and the burden of proof is lower.[1] That provides something of a sobering thought for consideration.

IV. THE BIGGER PICTURE: THE SIGNIFICANCE OF *STEVENS* FOR INSIDE COUNSEL/OUTSIDE COUNSEL/CLIENT RELATIONSHIPS

§ 3:9 The broader implications of *Stevens*

The discussion above uses the facts in *Stevens* (and hypothetical variations thereon) as a springboard for consideration of what may seem somewhat precise and arcane, if (it is to be hoped) still practical, issues under the rules of professional responsibility. Such ethical issues were rather closer to the surface in *Stevens* than they often are. At the same time, the case drew more prominent attention from commentators for what it had to say about issues that are arguably more of a big-picture nature, issues relating to the approaches inside and outside counsel take in responding to government investigations, the allocation of authority and responsibility between inside counsel and outside counsel, and the perception that the case illustrated an expansion in the government's much-discussed efforts to pursue lawyers personally in the course of pursuing their clients.[1] Those issues came to the fore again when Ms. Stevens began speaking publicly about the case in 2012. This section will briefly analyze three important themes raised in the ongoing professional dialogue on the case, with a view toward assessing the validity of what has been presented, at least to some degree, as the conventional wisdom on the morals to be derived from the case.

[Section 3:8]

[1]Just to be perfectly clear, the author is not aware that any disciplinary actions have been brought or threatened against Ms. Stevens and does not suggest—indeed, for what it is worth, would affirmatively deny—that any basis for such action exists.

[Section 3:9]

[1]For general discussion of that phenomenon, *see generally, e.g.,* William W. Horton, *Target-at-Law: Instructive Moral Lessons from the New Lawyer Wars*, in HEALTH LAW HANDBOOK (Alice G. Gosfield, ed.) (West 21st ed. 2009).

§ 3:10 The broader implications of *Stevens*—Notes and correspondence: *Stevens* and the written word

As mentioned earlier, Ms. Stevens was featured at the 2012 annual meeting of the Association of Corporate Counsel, the principal bar organization focusing on in-house counsel. In this presentation, given just over a year after her acquittal, Ms. Stevens reflected on what she saw as major lessons to be learned from the case. Two of those lessons had to do with written communications—the notes that she took herself and that she received from outside counsel in the course of responding to the FDA inquiry, and the response letters themselves.

The prosecution, as previously observed, based a fair amount of its argument that Ms. Stevens was knowingly withholding information from the FDA and/or misleading the FDA about the existence of information on notes taken by Ms. Stevens or by other lawyers with respect to meetings at which Ms. Stevens was a participant.[1] An objective observer might conclude that some of those notes, which seem to reflect a good bit of deliberation as to whether the government might go away relatively quietly if GSK did not disclose certain potentially damaging information, illustrate the dangers of committing too much of one's thought process to paper.[2] Ms. Stevens, however, apparently drew a different conclusion:

> Among the lessons [Ms. Stevens] stressed for other in-house counsel [in her ACC presentation]: . . . Take careful notes of meetings, and be careful with emails because they may get admitted into evidence one day. "This isn't a lesson about don't take notes, but about take effective notes . . . Had we

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[Section 3:10]

[1]*See* discussion in § 3:2, above.

[2]Of course, an alternative argument might be that a lawyer who was actively planning to mislead government investigators would be unlikely to write memos that might as well have been captioned "Pros and Cons of Misleading Government Investigators," and thus that the simple act of writing such memos would imply a lack of *mens rea*—i.e., that only someone who did not see anything wrongful in what she planned to do would actually write down the arguments that would tend to contradict that perception.

not had those notes I wouldn't have remembered all those [exculpatory] things we did back in 2003."[3]

Certainly, taking good notes is a salutary goal, and Ms. Stevens makes the increasingly relevant point that a lawyer should never place too much reliance on the assumption that his or her notes will never see the light of day. As a practical matter, in any circumstance where a lawyer is representing an organizational client in a matter which may draw regulatory scrutiny—and most definitely if the lawyer is representing such a client in a matter which has already drawn regulatory scrutiny—there is a nontrivial risk that the lawyer's written notes, analyses, and emails may be ultimately be seen by regulators and prosecutors; in many cases, the client will waive applicable privileges either to show cooperation with an investigation or to support an advice-of-counsel defense or else the client will be shown to have involuntarily lost such privileges through disclosures made to persons not within the scope of the privileges.

On the other hand, Ms. Stevens's conclusion indicates one of the real perils to the lawyer-client relationship that arises when lawyers must fear what have been referred to as "pretextual prosecutions"—prosecutions based not on the underlying substantive offense about which the government is concerned but rather on "process" claims such as obstruction of justice or the making of false statements in connection with the government's investigation of such substantive offense, or even with characteristics or actions of the target that are not directly related to the substantive offense at all but that are relatively easier to prove to a jury.[4] Ideally, one wants one's lawyer to be concerned with taking notes—and taking other actions—in such a way as is most likely to fur-

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[3]Reisinger, *Fought the Law*. *See also* Smith, *Ex-Glaxo VP* (Ms. Stevens: "I wouldn't put in [attorney notes] any personal musings or statements that could be subject to interpretation.").

[4]*See generally* Harry Litman, *Pretextual Prosecution*, 92 GEO. L.J. 1135 (2004). Professor Litman offers up the prosecution of Al Capone for income tax evasion instead of for his numerous more colorful (and more bloody) alleged crimes as a prototype of pretextual prosecution, which he defines as "target[ing] persons for conduct or characteristics of the defendant other than the conduct involved in the charged offense". 92 Geo. L.J. at 1137. The pretextual prosecution analysis is applied to the *Stevens* case in Katrice Bridges Copeland, *In-House Counsel Beware!*, 39 FORDHAM URB. L.J. 391 (2011).

ther the client's interest. If instead the lawyer must focus on memorializing conversations and documenting analyses in such a way as is most likely to minimize the risk that the lawyer will be accused of personal wrongdoing or to support the lawyer in distancing himself or herself from any claim that he or she had been given culpable information by the client, will the lawyer's advocacy and advice still be as effective? Will the client still be as willing to provide full and accurate information to the lawyer?

Somewhat related concerns arise from another observation by Ms. Stevens, involving another set of writings:

> Don't make your legal arguments in your letters to agencies[, Ms. Stevens advised the ACC audience]. She recalled that her letters to the FDA contained "a lot of advocacy and zealous representation. If I were to do it again, I think I would set a different tone in the letters."[5]

A review of the letters does indicate that, on a spectrum ranging from "Enclosed are the information and documents you asked for. Please let us know if you need anything further, as we'd be happy to provide it" to "As you can easily see from what we've told you, we've done nothing wrong, and why don't you go chase some real criminals anyway?," the tone is a bit closer to the latter than to the former. On the other hand, an objective reader familiar with these types of communications would be unlikely to say that the GSK letters crossed any line of propriety or were especially inflammatory. Indeed, much of the basis for Judge Titus's opinion seemed to be his desire to ensure that the threat of prosecution would not deter lawyers from zealous advocacy ("the Court should be vigilant . . . to allow lawyers to do their job of zealously representing the interest of their client"),[6] and many of those commentators who criticized the

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[5]Reisinger, *Fought the Law*. *See also* Smith, *Ex-Glaxo VP* (Ms. Stevens: "[W]hen you're zealous in a letter, the statements get taken out of context. The better practice is to tell them what you're giving them, and then follow up where you can have that robust conversation.").

[6]Acquittal Order at 5.

prosecution spoke approvingly of the letters as appropriately zealous advocacy.[7]

Nonetheless, in hindsight Ms. Stevens apparently questioned her strategy and, at least implicitly, suggested that she might have modified it to reduce her personal exposure had she realized at the time that she in fact had any personal exposure. (In fairness, she also advised her listeners to "go back and defend your client zealously and don't back away because you are afraid of my experience.")[8] To the extent that was her conclusion, it is not an unreasonable one. Had the GSK letters been confined to factual responses to the FDA's inquiries (with some identification of the limits on those responses, such as a straightforward discussion of what physician presentations had been obtained, why they were not being provided, and under what circumstances GSK would be willing to provide them), it seems unlikely that even an aggressive prosecutor would have sought the indictment of Ms. Stevens, even if that prosecutor were convinced that GSK itself had engaged in criminal behavior. The correspondence could have concluded with a clear request for a meeting at which GSK's representatives could have raised their arguments about the legal implications of the information. That would certainly have been one valid approach to the response, and one which would have been highly unlikely to result in the prosecution of Ms. Stevens or any other lawyer involved based on the process of the response itself (as opposed to any substantive involvement in any underlying alleged misconduct, such as encouraging or supporting the alleged off-label marketing activities in the first place).

On the other hand, it is impossible to say that one of these approaches would have been objectively more likely to be successful than the other as far as dissuading the FDA from taking action against GSK. This raises the larger consideration suggested by Ms. Stevens's "Don't make your legal arguments in your letters to agencies" conclusion: is it desirable for counsel advising a client to make strategic decisions on behalf of that client that are influenced by the lawyer's

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[7]*See* Gibson & Widor, *U.S. v. Lauren Stevens Case Dismissed*, at 624, and the numerous sources cited in the first paragraph of the last footnote of § 3:2, above.

[8]Reisinger, *Fought the Law*.

assessment of which decision is least likely to expose him or her to personal liability? And is it socially desirable for prosecutors to exercise their discretion in such a way as to compel that result?

As some (including the author) have argued before, a lawyer who represents a client that is faced with a government investigation cannot prudently be oblivious to the risk that the lawyer himself or herself may become a target of the investigation, particularly if the lawyer had been involved in the substantive matters underlying the investigation. At the same time, it is not consistent with a lawyer's ethical obligations for that lawyer to let personal considerations change the advice he or she gives the client, and it is not socially useful for clients to have to fear that the legal advice they receive will be muted by the lawyer's fear of potential prosecution or disciplinary action. Clients that believe that to be the case will be unlikely to be open and forthcoming with their lawyers, and that is simply contrary to society's best interests.

Ms. Stevens's observations raise the specter that a lawyer's representation of a client might be constrained or influenced by the concern that, if things do not work out well, the lawyer may face prosecution—not for substantive wrongdoing but for the professional choices made by the lawyer in the course of representation. It is an imperfect world, and that may be true more often than one would like to think. Nonetheless, one might hope, even if naively, that prosecutors evaluating the possibility of bringing the next *Stevens*-type case might pause to consider the broader social consequences of that decision.

§ 3:11 The broader implications of *Stevens*—Oh no, that's okay, you just sign it: *Stevens* and inside/outside relationships

According to a published report, Ms. Stevens drew laughter from the Association of Corporate Counsel (ACC) annual meeting audience when she observed that the first lesson she had learned from her prosecution was "If you're going to write letters to agencies, have your outside counsel sign

them."[1] That throwaway line, however, illustrates one of the more significant dangers that may result from the *Stevens* case—the prospect that personal-liability risk management may assume too dominant a role in the working relationship between in-house counsel and outside counsel, to the detriment of effective representation.

In an ideal world, where internal and external lawyers jointly represent a client in handling a matter, they should ordinarily function as a single legal team. That does not mean that they must always present a unified front—there are often cases where a good cop/bad cop approach can be useful in dealing with a recalcitrant adversary (or even a recalcitrant client), and in the context of government investigations it may sometimes be useful for outside counsel to display independence from inside counsel in order to enhance the credibility of an argument or presentation. However, absent some substantive reason that the two components must act unilaterally (e.g., the circumstance where the issue at hand may be perceived to involve potential conflicts for inside counsel), inside counsel and outside counsel should be able to communicate freely, resolve any differences, and generally get to a stage where both factions are comfortable in whatever boat they may have found themselves in.

Stevens may be seen to represent, at least in some ways, a fundamental attack by the prosecutors on that basic unity of purpose. This is made clear by several distinctive factors present in the case:

- As was repeatedly noted by commentators before and after the trial, although there seemed to be no question that Ms. Stevens was part of a unified legal team involving multiple inside and outside counsel, she alone was singled out for prosecution. Indeed, there was not even much of an overt suggestion that others on the legal team might have conspired with her in the wrongdoing she was alleged to have committed.[2]
- At least some of the other members of the GSK legal

[Section 3:11]

[1]Reisinger, *Fought the Law*.

[2]The defense suggested that the government had "allud[ed] to the possible existence of unindicted co-conspirators" without actually using

team apparently testified before the Massachusetts grand jury. Although there does not appear to be evidence in the public record to confirm what actually occurred in that regard, human experience would suggest that, as part of that process, those persons called to testify may have come to have some sense (whether or not grounded in fact) that it would be in their best interests if their testimony tended to support the government's position on the culpability of Ms. Stevens.

- The prosecution made significant attempts to prevent Ms. Stevens from having any meaningful opportunity to introduce evidence either of her reliance on the advice of other counsel or of the opinions of other involved counsel as to the propriety of her actions.[3]
- Throughout its arguments on the subject, the prosecution suggested that Ms. Stevens had not sought the advice of other counsel in good faith and/or that she did not provide full information concerning relevant facts to such counsel.[4] What evidentiary support the govern-

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that term by "suggest[ing] in a court filing . . . that unidentified individuals who advised Ms. Stevens may somehow be complicit in the crimes charged." Defendant's Memorandum Regarding Disclosure of Alleged Co-Conspirators, U.S. v. Stevens, Case No. RWT-10-CR-0694 (D. Md.), filed Feb. 23, 2011, at 2. The reference is apparently to Gov't Advice of Counsel Mot. at 17 ("The advice of counsel defense is . . . not available where the counsel participates in the crime. . . . Thus, the defense is not available if the evidence shows that some other counsel agreed with Stevens to conceal the 'incriminating' documents and information from the FDA . . . .").

[3]*See* Gov't Advice of Counsel Mot., *passim*; United States' Motion in Limine Regarding Opinion Testimony, U.S. v. Stevens, Case No. RWT-10-CR-0694 (D. Md.), filed Feb. 4, 2011, *passim*.

[4]*See, e.g.,* Gov't Advice of Counsel Mot. at 16. The government's argument on the good faith issue seems particularly circular and, from a philosophical standpoint, particularly troublesome:

> [T]he defendant also must establish that she in good faith sought the advice of counsel about whether she could legally make . . . knowingly false representations, and that she reasonably relied upon counsel's advice to believe that it was legal and appropriate to make false statements to the FDA and to conceal promised documents and information from the FDA while representing that her response to the FDA was final and complete. Stevens knew the representations she was making were not true. It cannot be reasonable for someone to rely upon an attorney to advise him or her to knowingly make false statements.

Gov't Advice of Counsel Mot. at 16. Once again, the government relies on a logically flawed argument—*petitio principii*, or "begging the question."

ment planned to offer for such propositions was not clear from the government's arguments.

As the case ultimately turned out, of course, this attack was unsuccessful, and the publicly available information does not even indicate that the prosecution had much luck in rebutting the proposition that the responses to the FDA were, for better or for worse, the joint work product of a team of inside and outside counsel as to which Ms. Stevens was not a lone ranger. Nonetheless, one logical reaction of an inside lawyer to the prosecution of the case would be, "Okay, what do I need to do to make sure my outside counsel can't throw me under the bus and ride off in their limousines if the government says we've done something wrong?" An equally logical reaction of an outside lawyer would be, "How do we protect ourselves if it turns out this avaricious general counsel has been lying to us to prop up her stock options?" That way lies discord.

Some commentary on the case suggests strategies that might lead to that discordant result if taken to their logical conclusions. A client advisory from a knowledgeable and experienced law firm offered these suggestions, among others:[5]

- "In house counsel should make clear to government officials from the outset [of an investigation] that they will be relying, in good faith, on the advice of outside counsel throughout the investigation, since it appears that their own guidance as in house counsel may not be enough in the eyes of government investigators"; and
- "[I]n house counsel should ensure that the engagement letter with outside counsel defines the scope of the bona fide representation. Make sure to state explicitly in the letter the extent to which in house counsel will rely on the advice of outside counsel. For example, the letter should clearly state whether outside counsel will submit documents to the government on the client's behalf."

At first glance, these suggestions make considerable sense, at least if priority is placed on insulating inside counsel from

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In this case, the questions are whether the statements in question were in fact false, and if so, whether Ms. Stevens did in fact know them to be so. Or, to put it another way, when did Ms. Stevens consult an attorney about whether to stop beating her husband . . . ?

[5]Swank & Roach, *Five Lessons Learned*, at 2 and 3.

exposure. As a practical matter, though, implementing them could have unintended and perhaps pernicious consequences in terms of both the inside/outside counsel relationship and the effective representation of the client.

Taking the second point first, it is not at all clear how far it is possible or helpful to go in "stat[ing] explicitly in the [engagement] letter the extent to which in house counsel will rely on the advice of outside counsel." Certainly, to some extent it may be possible to set out an allocation of responsibility, such as whether outside counsel will be the point of contact for the government in the course of investigation. On the other hand, it is difficult to imagine an engagement letter in which inside counsel says, in essence, "You outside guys are the pros from Dover,[6] and even if I don't think you're right, I'm going to rely on your expertise. (And, of course, I'll claim that I was just a babe in the woods dependent on you if the government ever says we made false statements or anything. You have malpractice insurance, right?)."

Carrying the thought forward, the logical response of any thoughtful outside counsel in such a circumstance would be to insist that the engagement letter also contain language expressly requiring inside counsel to acknowledge that all advice rendered by outside counsel would be based on factual representations made (or vouched for) by inside counsel and that outside counsel disclaimed any responsibility for such advice if it turned out that the information provided by inside counsel were inaccurate or incomplete—perhaps even requiring that inside counsel acknowledge that outside counsel might be relying in part on legal analyses developed by inside counsel and that outside counsel would not be responsible for bad things that happened as a result of inside

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[6]"Pros from Dover: An American slang term for outside consultants who are brought into a business to troubleshoot and solve problems. The term comes from the 1968 book M*A*S*H by Richard Hooker. In the book, the character Hawkeye is described as using the guise of being the pro from Dover to obtain free entrance to golf courses: 'Hawkeye would walk confidently into a pro shop, smile, comment upon the nice condition of the course, explain that he was just passing through and that he was Joe, Dave or Jack Somebody, the pro from Dover. This resulted, about eight times out of ten, in an invitation to play for free. If forced into conversation, he became the pro from Dover, New Hampshire, Massachusetts, New Jersey, England, Ohio, Delaware, Tennessee, or Dover-Foxcroft, Maine, whichever seemed safest.' " www.urbandictionary.com/define.php?term=pros%20from%20dover&defid=1969915.

counsel's inadequate lawyering.[7] Aside from the amount of time (and legal fees, or at least opportunity costs) that would be spent on negotiating such engagement letters, the end result seems likely to be that communication between inside and outside counsel would be chilled, as each side structured its interactions to ensure that responsibility (and blame) could be shifted to the other side if the government started accusing lawyers of misconduct.

This would not be a good thing. Obviously, there are many cases—and *Stevens* appears to be one of them—where inside counsel should be able to say, "Even if what I did was wrong, I did it in good faith based on the advice received from outside counsel (or consistent with a consensus reached among inside and outside counsel). I may have been wrong, but I am not a crook." Likewise, there are certainly cases where outside counsel may have been affirmatively misled or even deceived by inside counsel with knowledge of wrongdoing, and such outside counsel should be able to assert that as a defense, to the extent relevant, against claims of misconduct asserted against them.

Nonetheless, it is not at all clear that the ability of a lawyer on either side of the counsel team to assert those sorts of defenses is going to be materially affected by self-serving language in an engagement letter. In *Stevens*, the government was bent on asserting that Ms. Stevens could not appropriately assert an advice-of-counsel defense and, in support of that proposition, argued (among other things) that she had not sought such advice in good faith and that she had not provided all relevant information to outside counsel. It appears unlikely that the government would have been dissuaded from making those arguments had Ms. Stevens been able to point to an engagement letter and say, "See? See? It says right here that I am going to rely on what they tell me and that I will defer to them if we disagree." The government's argument would doubtless remain that Ms. Stevens knew that she was giving GSK's outside counsel bad information that would lead to erroneous advice and

[7] In short, one could end up with an engagement letter which looked much like those used by outside auditors, which some would say are written almost entirely for the protection of the audit firm. *See, e.g.,* the sample audit engagement letter at www.naplia.com/resources/engagement%20letters/Example%20Audit%20engagement%200109.DOC.

thus that she could not rely on such advice. Similarly, had the government decided to come after King & Spalding instead, the lawyers from that firm would likely have had difficulty asserting blind reliance on information provided by Ms. Stevens if the government believed they should have gone further in conducting their own factual investigation.

In other words, while it is always appropriate and useful to have an engagement letter that accurately describes the parameters of the engagement, it seems over-optimistic to assume that government prosecutors, on the scent of alleged wrongdoing, will give deference to what amounts to a contractual allocation of risk among inside and outside counsel. On the other hand, negotiating over such an allocation of risk does have the potential to undercut the relationship of trust and teamwork that should exist between inside and outside counsel as it focuses each part of the team not on the most effective means of accomplishing the client's goals but on the most effective way to assure that if the strategy blows up, it does so on someone else. On balance, it does not seem clear that any incremental benefit in protecting one group (or even both groups) of counsel from allegations of personal liability outweighs the potential loss of "working trust" among the entire counsel team.

Returning to the first point above, it is likewise not clear that an assertion by inside counsel that he or she will be "relying, in good faith, on the advice of outside counsel throughout the investigation" serves much of a purpose as far as insulating inside counsel from liability, and it does have some potential detriment. Realistically speaking, it is not as if the government were unaware that Ms. Stevens had received advice from GSK's outside counsel until after she had been indicted. If the original GSK correspondence had been signed by a King & Spalding lawyer or if it had been more forthcoming about the role of King & Spalding in the response, would that have caused the prosecutors to question their case against Ms. Stevens? Perhaps, but it does not seem all that likely. Again, much of the government's argument was based on the position that Ms. Stevens had determined to make false statements to the FDA and that she had either deceived the outside lawyers or, perhaps, enlisted them as coconspirators. This effort to separate her from the rest of the team gives the impression of having been reverse-engineered to neutralize her defenses; if that

were in fact the case, then it would have been only a small stretch to argue that any front-end communication saying, "I'm relying on King & Spalding every step of the way" was just part of the cover-up.

On the other hand, if the strategic decision has been made that inside counsel is going to be the point person for communications, then it would seem unwise to diminish inside counsel's perceived authority by having inside counsel minimize his or her role. This does not mean that it would be unwise to let the government know up front that credible outside counsel was on the team and would be actively engaged in responding on behalf of the client. Indeed, in hindsight it appears that GSK might have been better served by letting the FDA know that its internal review had been conducted with the assistance of King & Spalding and that the firm was in agreement with the conclusions set forth in the response letters. Again, however, the value of self-serving statements the apparent purpose of which is to insulate inside counsel seems questionable. Instead, inside and outside counsel should agree on how to couch the responses to investigators' questions in such a way as to ensure that the credibility of those responses is maximized, and there is no one-size-fits-all way to accomplish that goal.

§ 3:12 The broader implications of *Stevens*—The scalded cat fears the hot stove, and the cold stove too: *Stevens* and the future

Those who write about professional responsibility issues for lawyers[1] can have a bit of a vulture-like aspect. When a lawyer's misfortune hits the news, there is a great temptation to extrapolate from the specific facts (or allegations) in the case and find trends—or at least common elements—that can be made into the next lesson for other lawyers.

Stevens proved ripe fodder for such extrapolation. It followed in the wake of a significant number of civil and criminal enforcement actions against lawyers and a significant number of pronouncements by prosecutors and regulatory enforcement officials about their intent to pursue lawyers (especially in-house lawyers) who were involved in facilitat-

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[1]Including the present author.

ing, perpetrating, or covering up client fraud.[2] Much like the now-legendary *Anderson* case, in which two health care lawyers were prosecuted (and acquitted) based on legal advice they gave their client in a complex, rapidly evolving area of the law,[3] *Stevens* lent itself to a "there but for fortune go I" reading.

As a result, at least in part, of these factors, much of the published discussion of *Stevens* has been couched in terms that suggest that such indictments may well become a recurring phenomenon and that in-house counsel should organize their lives around the risk that they themselves will be targeted.[4] In particular, as alluded to above, the case has been held up as something that either will or should, depending on one's point of view, lead to significant changes in the ways in which (i) in-house counsel participate in responding to government investigations of their employer/clients and (ii) inside and outside counsel relate and interact in the course of such investigations. A final question that must be asked is whether these predictions are accurate—whether *Stevens* will continue to resonate over the years to come, or whether the case will be viewed as an outlier, a rogue prosecution with limited application to other fact situations.

In trying to answer that question, one must consider why the case was brought in the first instance. Of course, it is impossible to know what motivated the government to indict Ms. Stevens and to indict her alone (i.e., without indicting either GSK or other members of the legal team). In their pleadings and afterward, the prosecutors insisted that Ms.

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[2]*See generally, e.g.,* Horton, *Target-at-Law, passim*.

[3]*See* U.S. v. Anderson, 85 F. Supp. 2d 1047, 1052–1061, 67 Soc. Sec. Rep. Serv. 350, 53 Fed. R. Evid. Serv. 1255 (D. Kan. 1999), rev'd, 217 F.3d 823 (10th Cir. 2000) and aff'd, 254 F.3d 900 (10th Cir. 2001), withdrawn from bound volume and opinion amended and superseded on denial of reh'g, 261 F.3d 993, 57 Fed. R. Evid. Serv. 254 (10th Cir. 2001) and aff'd, 261 F.3d 993, 57 Fed. R. Evid. Serv. 254 (10th Cir. 2001) (affirming convictions of three nonlawyer defendants). The case is described at some length in Horton, *In the Eye of the Beholder*, § 7.2.

[4]*See, e.g.,* Copeland, *In-House Counsel Beware!, passim*; E. Norman Veasey & Christine T. Di Guglielemo, *General Counsel Buffeted by Compliance Demands and Client Pressures May Face Personal Peril*, in 44TH ANN. INST. ON SEC. REG. (Practising Law Institute 2012) 689, 715–719 (internal pages 26–31); Gibson & Widor, *U.S. v. Lauren Stevens Case Dismissed*; Swank & Roach, *Five Lessons Learned*.

Stevens was targeted solely because she had, in their view, made false statements to the FDA and obstructed the FDA's investigation. Perhaps that is so, but if so, bringing the case as it was brought seems like an odd decision. Not only did the government fail to indict any of the other internal or external lawyers involved in the response; it did not (at the time) indict GSK or any employee or agent of GSK who was actually implicated in the alleged off-label marketing scheme. Pursuing Ms. Stevens for an alleged cover-up crime while forgoing, or at least postponing, pursuit of those allegedly involved in the underlying substantive crime seems unfair at a fundamental level and ill-thought-out at a strategic level (since it gave the defense a prime opportunity to argue that the prosecutors were abusing their discretion).

One logical conclusion would be that Ms. Stevens was targeted because the prosecutors viewed her as a weak link, a way to get into the larger conspiracy they believed was going on at GSK. Under this theory, indicting Ms. Stevens would pressure her to blow the whistle on others at GSK who were more directly culpable. In that case, pursuing her to the exclusion of the other lawyers might make some strategic sense in that it focused attention (and pressure) directly on her and that it gave the government a sword to attempt to hold over the other lawyers' heads (i.e., that they might be next if they did not turn on Ms. Stevens). (Note, however, that saying that such an approach might make some strategic sense is not the same as saying that it was an appropriate exercise of prosecutorial discretion.)

Unless someone from the prosecution team decides to break the party line, it is impossible to know the true rationale behind the prosecution if in fact there is a rationale other than the stated one. However, based on what is known from the public record, it seems premature to extrapolate from *Stevens* a sea change in the way that regulators and prosecutors will deal with private lawyers assisting their clients in responding to investigations, from a personal liability standpoint.

In the first place, the decision to prosecute based on facts in *Stevens* is just pretty weird, when one boils it right down. There is no suggestion in the record that Ms. Stevens was involved in an underlying primary offense—no suggestion that she devised or implemented GSK's alleged off-label marketing scheme, or even that she was vulnerable under

the FDA's strict-liability "responsible corporate officer" doctrine. There is no suggestion that she destroyed or spoliated evidence, counseled other employees of GSK not to cooperate, or otherwise engaged in "traditional" obstruction-of-justice activities. Further, although (as suggested above) one might take the position that some of the GSK responses over her signature were close to the borderline of being misleading, there is still a difference between "misleading" and "false," especially where criminal culpability is involved. This was simply an odd case in which to pursue criminal prosecution, and there does not yet seem to be any real reason to think that the government, as a matter of policy, intends to ramp up the number of odd cases it brings—especially given what can only be described as a comprehensive lack of success in *Stevens*.

In the second place, it is a bit of an oversimplification to characterize *Stevens* as (to quote the title of a monograph dealing, in part, with the case) "the indictment of [a] lawyer[ ] for [her] legal advice."[5] The charge against Ms. Stevens was not that she gave erroneous advice to her client GSK as to how to respond to the FDA inquiry or even that she gave erroneous advice to GSK on the legality of particular off-label marketing activities; the charge—however ill-founded—was that she personally made false statements and concealed evidence in responding to the FDA inquiry. Obviously, that is a fine distinction to be drawn; advising the client on the response and implementing that advice are actions that converge rather quickly, especially for the in-house lawyer. However, it is an overly aggressive reading of the case to view it as being truly analogous to the indictment of the lawyers in *Anderson*. In that case, the entire substance of the prosecution was that the legal advice given by the indicted lawyers had been tainted, that the lawyers were conspiring with their client to "paper up" a series of deliberate violations of a criminal statute.[6] In other words, the case was a direct attack on the professional actions of the

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[5]The reference is to the Fernandez monograph cited in the last footnote of § 3:2.

[6]For example, the prosecution argued that a letter from a lawyer to her hospital client stressing that certain physician contracts could not reflect any intention to pay the physicians for referrals was evidence that the lawyer knew that the hospital intended to do exactly that and was

lawyers in rendering everyday advice to their client as to structuring certain contractual relationships.

By contrast, *Stevens* is conceptually not much different from a conventional obstruction/false statement case, albeit a singularly aggressive and, one might reasonably conclude, ill-conceived one. The prosecution's claim was that Ms. Stevens had concealed evidence and lied to the FDA. Leaving aside the (serious) question of evidentiary support for that claim, the case is analytically no different than an allegation that Ms. Stevens had run through the GSK headquarters shredding off-label marketing presentations and then told the government that no such presentations had ever existed. This is not a case in which, for example, the prosecutors alleged that a lawyer had committed a criminal violation by, say, erroneously advising a client that a hospital-physician contract was commercially reasonable or fit within an Anti-Kickback Statute safe harbor. It is, instead, a case about a lawyer's acts and omissions in responding to an investigation. That obviously entails legal advice, but it is also obviously closer to the potential line of prosecutorial fire than garden-variety legal advice in the absence of a known investigation.

Now, this should not be understood as a defense of the decision to prosecute Ms. Stevens in the first place. Even if one can reasonably disagree with some, or even many, of the judgment calls made by the GSK legal team, it is very difficult to see how those decisions reach a level of culpability that can or should be punished under the criminal law. As noted above, on a theoretical level the indictment alleges a basic false statement/obstruction case. When that theoretical structure is applied to the particular facts, though, it is simply a weak case, and the social utility of bringing the charges in the first place is just not clear.

However, the analysis above does suggest that it is not necessary to be quite so apocalyptic about the implications of *Stevens* as some of the commentary—particularly the early commentary—might suggest. It is a disturbing case, and it certainly does raise issues that could be disruptive of an effective working relationship between inside and outside counsel, and between such counsel and their clients. Judge

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advising the hospital on how best to conceal its crime. *See* Horton, *In the Eye of the Beholder*, § 7.2.

Titus's admonitions to the government about the impropriety of using the threat of prosecution to deter zealous representation are well taken. However, given the somewhat strange prosecutorial decisions made in bringing the case, the singular lack of success the prosecution's effort enjoyed, and the fact that, on an analytical/theoretical level, the case is not all that dissimilar to a conventional obstruction case (as opposed to being *Anderson II*), it does not seem overly likely that *Stevens* should yet be seen as a precursor of prosecutions to come. Its lessons should be borne in mind by inside and outside counsel, and it should not be ignored, but the case does not seem to be quite the chunk of falling sky that it might have first appeared.

V. CONCLUSION

§ 3:13 Conclusion

What, then, are the professional responsibility lessons from *Stevens*? On the one hand, it is possible to read the case as a resounding victory for the general principle that lawyers should not be prosecuted for representing their clients to the best of their ability or for rendering legal advice even if the result is less than perfect. Certainly, no one can rationally fail to applaud any decision that pushes back against any perceived movement to criminalize differences in judgment or even bad judgment. The practice of law, especially in a regulated industry like health care, involves the delicate balancing of many different factors, and society ought to approach with caution any law enforcement initiative that might reasonably have the effect of discouraging lawyers from deploying their full skills on behalf of their clients because of fear of personal criminal liability.[1]

Certainly this is true in the health care industry, even (especially?) in that part which is not primarily regulated by

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[1]*See, e.g.,* Esperne, *Lessons Learned from Lauren Stevens* ("The attempt by the Department of Justice to prosecute a company lawyer for not voluntarily turning herself into a pseudo-government investigator, initiating a companywide search for internal documents and then handing over anything that turned up regardless of the consequences—all in response to a mere inquiry letter—will damage cooperation between in-house lawyers and regulators for years to come.").

the FDA. Lawyers who counsel clients on fraud and abuse and Stark matters deal more-or-less constantly with situations as to which reasonable people could differ on the appropriate legal analysis. If such lawyers become excessively conservative for fear that their professional judgments will be scrutinized from the perspective of criminal law, at least two bad results are likely to occur. First, clients may be discouraged from pursuing socially useful ventures that may increase access to care, lower costs, increase patient safety, etc., because their lawyers have induced them to be overly risk-averse. Second, clients may abandon lawyers who are perceived as being deal-killers and turn instead to less competent lawyers, who simply do not have the expertise to recognize the issues facing those clients and thus do not focus those clients on conducting their affairs in a compliant way.

At the same time, an objective observer might say that the legal team representing GSK, of which Ms. Stevens was at least the public face (or public signature), did not do itself a lot of favors. At a minimum, the GSK team seems to have taken a rather aggressive stance on some of its nondisclosure positions; certainly, it is much less likely that there would be a "Stevens case" at all if the May 21 response letter had simply concluded, "We would like to meet with you to discuss certainly potentially responsive documents that we have not provided to you, because we determined that those documents would not be clearly understood without further discussion of their context" instead of, effectively, "We've completed our production, but we could be available for a conference call if you *still* [sigh!] have any questions." Some of the defense's arguments—the arguments that suggested, in essence, that the burden was on the FDA to figure out that it did not have everything it expected and then ask questions about what was missing—seem like slim, reverse-engineered reeds on which to hang a defendant's guilt or innocence. It would have been much better to have addressed the issue head-on, or at least to have cut back on the "final," "complete," etc., etc., references.

The bar—at least, that part of the bar that does not work for the FDA or the Department of Justice—can breathe a sigh of relief and drink a toast to the wisdom of Judge Titus. Further, as noted above, the application of *Stevens* may not be as broad as it first appeared to be, and thus it need not be

perceived as quite the precursor of future prosecutions as some may have thought. However, when it is analyzed, *Stevens* still stands as a sobering reminder of the need for lawyers to remain constantly aware of their professional responsibility obligations and to seek out appropriate counsel on those obligations when the going gets complicated.