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ASPEN, CO >> See Page 3
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LAS VEGAS, NV >> See Page 8
April 5-6, 2013 / NACDL & CACJ's "Making Sense of Science VI"

White Collar Crime Issue

- The SEC's Cooperation Initiative
- The Willfulness Element of a False Statement Charge
- Defense Strategies and Compliance Issues in the New Insider Trading Environment
- Jury Instructions: Key Topics in Federal White Collar Cases
- The Most Effective Opening Statement Ever Given?
- Overzealous Bankruptcy Practice Can Lead to a Prison Cell

The Most Effective Opening Statement Ever Given?

In January 2012, a team of defense attorneys treated white collar practitioners to what may have been the most effective opening statements ever given in the prosecution of a business organization.[1] The team — led by a cadre of former federal prosecutors — outlined their clients' defenses to a federal jury in *United States of America v. Stryker Biotech et al.* on Thursday, January 12th and Friday, January 13th. That weekend — before the government had finished examining its first witness — the U.S. Attorney for the District of Massachusetts had the wisdom and courage to dismiss all 13 felony counts against the company, and all counts against all individual defendants. As part of this accommodation, Styker Biotech pleaded guilty to one count of misdemeanor misbranding in violation of the Food Drug and Cosmetic Act and paid a $15 million fine. To put this in perspective, the company, if convicted, would have faced a nine-figure fine, exclusion from federal health programs (the so-called "corporate death penalty"), and a multi-year Corporate Integrity Agreement. The individuals had faced Sentencing Guidelines ranges as high as 10 years, hundreds of thousands of dollars in fines, and exclusion. Never before had the federal government reversed course so quickly and completely in a white collar prosecution.[2]

How did the defense team do it? What inspired them to deliver the knock-out opening statements in the manner they did? From the deconstructed transcript below, observers can see that an uncanny parallel emerges between the defense statements to the jury and the principles the Department of Justice itself applies when determining whether to charge a business organization.[3] These principles are set forth in the so-called "Filip Memorandum" issued by DOJ in 2008, and formally known as the "Principles of Federal Prosecution of Business Organizations."[4] It is more than a bit ironic that a defense team composed largely of former federal prosecutors appears to have hoisted the government on its own petard.

The beauty of this apparent strategy is that it can be applied to more than just the defense of the medical device and pharmaceutical industries. The DOJ Principles of Federal Prosecution govern prosecutions of all businesses. Defense counsel can use these principles to structure an opening statement — or to pitch for declination before indictment — in any case, whether it involves tax evasion, collusion, bribery, pollution, fraud, or a false claim.

The Product and the Charges In *USA v. Stryker Biotech*

The charges against Stryker Biotech and its senior executives arose from their sale of two products: OP-1, a biologic bone growth stimulant; and Calstrux, a "bone void filler." The FDA had approved their sale individual-

BY CHRISTOPHER R. HALL

ly, but not together.

The indictment alleged that Stryker Biotech and the charged executives had conspired to manipulate physicians to use the two products together, and that their illegal agreement had two goals or objects: to impede the FDA in its effort to protect the public from ineffective or unsafe medical devices, and to trick surgeons into using the two products together. The substantive counts alleged that the company had deliberately manipulated doctors and conveyed to them false and incomplete information about the combined use of OP-1 and Calstrux, all for the purpose of obtaining millions of dollars in sales. The substantive counts also alleged that the company had misbranded the OP-1 product by causing sales representatives to provide written instructions to surgeons for how to combine OP-1 and Calstrux. The FDA had not approved these instructions, and, the indictment alleged, Stryker Biotech distributed the instructions to defraud and deceive surgeons and hospitals into believing that the FDA had.

The Filip Memorandum: Cornerstone Principles

Before dissecting the transcript of the opening statement by Stryker's counsel — with an eye towards how to construct effective opening statements in future cases — it is important to begin with the Filip Memorandum, which the Stryker defense team appears to have exploited so well. The Memorandum is grounded in two overarching principles. The first elegantly fuses the role of federal prosecutors and corporate leaders. The principle states simply that the faithful execution by corporate leaders and federal prosecutors of their respective roles and responsibilities should guide them to agree on how best to proceed.[5]

"Respondeat Superior," or "Let the Master Answer" is the second of the two guiding principles.[6] The Department of Justice will not treat organizations leniently because of their artificial nature, and white collar practitioners should expect juries to adopt the same view. But a key limiting factor fairly applies. This sub-principle insulates corporations from liability for actions by employees "inimical" to the interests of the company. In short, DOJ (or a jury in the case of indictment and trial) should not punish a company for actions an employee takes solely to advance his or her interests.

Flesh on the Bone: The Filip Memorandum's Nine Factors

With the two cornerstone principles in mind, the Filip Memorandum outlines nine factors federal prosecutors should consider when assessing whether to charge an organization.[7] Practitioners can deliver an effective opening statement on behalf of a corporation by infusing their argument with most if not all of the nine factors:

1. The nature and seriousness of the offense, including the risk of harm to the public;
2. The pervasiveness of wrongdoing within the corporation, including whether management condoned the bad conduct;
3. Any history of similar misconduct;
4. Timely and voluntary disclosure of wrongdoing, and the corporation's willingness to cooperate in the investigation of its employees;
5. The existence and effectiveness of a pre-existing compliance program;
6. The company's remedial steps, including action to implement an effective compliance program or to improve an existing one, to replace responsible management, to discipline or terminate wrongdoers, to pay restitution, and to cooperate with relevant agencies;
7. The collateral consequences that may flow from conviction, including disproportionate harm to shareholders, employees, and others not personally culpable;
8. The adequacy of the prosecution of individuals who undertook the bad conduct; and
9. The adequacy of civil or regulatory enforcement actions.

As seen below, some of these factors serve to structure neat, contained components of an opening statement. For example, the first factor — which requires an assessment of the nature and seriousness of the offense — implicates the elements of the crime alleged and the sufficiency of the evidence. An effective opening statement on behalf of a corporation likely should devote substantial time and attention to these issues as a stand-alone topic. Other factors blend with one another and overlap elegantly. For example, practitioners can easily link the factors of pervasiveness of bad conduct and the question whether a history of similar conduct exists. Defense counsel can also combine the factors of cooperation and remedial actions. In short, while the factors that give life to the principles of federal prosecution provide a useful scaffold from which to construct an opening statement, the defense team in *Stryker* presented some as stand-alone grounds for acquittal, and used others simply to paint the prosecution as generally flawed.

The Tale of the Tape

The focus below is on the opening statement developed by Brien O'Connor, Joshua Levy, Cori Lable, and Aaron Katz from Ropes & Gray, and delivered by Mr. O'Connor. The transcript reveals that the defense team drew heavily from the two overarching principles of federal prosecution, and infused these principles with the nine factors that prosecutors are also supposed to consider. The effect of this tactic was withering. Over the course of a mere 45 pages of transcript, the defense held the federal prosecutors accountable for the very DOJ standards that they should have applied, but did not. Starting with the defense's opening salvo, the paragraphs below deconstruct the transcript.

Begin With the End: The Ninth Factor of Federal Prosecution

The defense began with the ninth and last factor that prosecutors are supposed to consider when deciding whether to prosecute a business organization: the adequacy of alternative civil or regulatory remedies. Defense counsel highlighted this factor and explained to the jury that "criminal cases are different."

> *This, ladies and gentlemen, is a criminal case. Over my more than 25 years as a lawyer, more than a decade in each of the public and private sectors, I've learned that criminal cases are different and more important than regulatory actions, commercial litigation, and every other type of case. Criminal cases involve the most serious kind of government action and core individual rights and liberties.*

There's just more at stake, ladies and gentlemen, in a criminal case, so the process is really important. … This is a federal felony criminal case. Not a civil enforcement action, not a regulatory action and not even a misdemeanor criminal case. In the spectrum of legal proceedings, a federal felony criminal case is up here, and everything else is somewhere down here.

The notion that alternative remedies exist — and that the government had chosen to pursue a route that would lead to the harshest possible sanction — dovetailed perfectly with preliminary instructions that Judge George A. O'Toole Jr. had given to the jury just before the opening statements began. Judge O'Toole had emphasized the importance of the case to both sides, and had explained that he would follow formal procedures to ensure a fair process. He also reiterated that the government bore the burden of proving the charges beyond a reasonable doubt. In sum, the ninth factor of federal prosecution of business organizations — which directs prosecutors to consider whether less draconian alternatives to a felony charge adequately serve the public's interest — parallels the considerations of due process that judges follow. This factor offered a perfect way for Stryker Biotech to align its interests with those of the court (and, derivatively, the jury) in its opening statement.

The Nature and Seriousness Of the Offense Alleged: Deceit of Doctors, Hospitals, and the FDA

Having established that "criminal cases are different" — and having impressed the jury with the gravity of the moment and the heavy burden the federal prosecutors bore — the defense moved quickly from the ninth factor of federal prosecution to the first. Defense counsel explained in simple terms the nature and seriousness of the offense alleged, and flatly rejected the government's claim of fraud:

The prosecutors … say that Biotech … manipulated, lied to, cheated and deceived brilliant and experienced neurosurgeons and spinal surgeons into using Biotech's OP-1 and Calstrux together. … The evidence in this case, ladies and gentlemen … will prove no such thing. … Surgeons were not tricked into using the OP-1/Calstrux combination; they chose to use it because it worked.

The defense weaved this theme — the absence of a serious offense — repeatedly into the balance of the opening statement. The defense was quick to challenge the assertion made by the federal prosecutor in her opening that the company's sale of the combined products caused multiple "adverse events" that threatened the health and safety of patients. The prosecutor had told the jury that the combination caused "localized induration, swelling, inflammation, wound drainage, infection, and device migration. That's where it moves out of the place where it was set." The prosecutor had also told the jury that the company had withheld information about the adverse events from doctors and hospital Internal Review Boards, or "IRBs," and that one doctor had warned the company that the rate of adverse events was "higher than the norm" and that the combination of the two products did not work. If true, this evidence would have established the first factor for federal prosecution — that the company had committed a serious offense.

When the opportunity came for the defense team to speak, it met the prosecutor's charge head on, declaring that the prosecutor had misled the jury. The evidence would in fact show that the rate of adverse events was only one half of one percent — 63 adverse events out of over 10,000 surgeries. The defense then proceeded to demystify the term "adverse event," which had sounded foreboding but was not at all. It was "a specialized medical term," that referred to "anything that goes wrong in a surgery no matter how minor. …" And, contrary to the suggestion by the prosecutor, the characterization of an incident as an "adverse event" did not mean that the surgeon had thought "that the device caused the event." The defense made these comments toward the beginning of its statement, and by so doing, immediately put into play the question whether the company had in fact committed a serious crime. This technique — to swiftly push the government off its proffered definition of a technical regulatory term — is essential to any white collar defense.

The defense then proceeded to address the allegation of serious fraud through the lens of common sense. It parried the prosecutor's allegation of a sinister financial motive and offered a credible alternative business strategy. The long-term financial health of the corporation, the defense observed, depended on its relationships with respected surgeons, who made the decision to buy, and the FDA, which had the power to approve or reject all devices. Why would the company compromise the trust of these two constituencies, especially where OP-1 was approved for sale only pursuant to a special "Humanitarian Device Exemption"? This exemption limited the sale of OP-1 to 4,000 patients per year, hardly blockbuster. The government's depiction of the financial motives made "no sense and did not happen."

But the most effective method the defense used to address the government's allegation of a serious offense involved a discussion of the direct evidence. The defense told the jury that they would hear from witnesses who would directly contradict the government's claim:

The indictment specifically identifies only seven surgeons: Drs. H, P, C, D, M, I, and R. Now you would think that before bringing these very serious criminal charges [and] bringing us all together, the prosecutors would have taken the time to interview these seven surgeon victims, right? They would have wanted to confirm that the supposed victims were actually victimized, right?

Well, apparently not. Incredibly, before hauling these defendants into court on criminal charges, the prosecutors and their hefty corps of investigative agents never interviewed even one of these supposed victim surgeons. They … had no time to ask the surgeon victims: "Were you tricked?"

Ladies and gentlemen, they may not have talked to the surgeons, but we did. And because of that, you're going to get to hear the surgeons' side of the story. Let's stop and think about this for a second. The defendants in this criminal fraud case who, as the court will tell you, have no burden to do anything at all and are entitled to just look the prosecutors in the eye and say, "Prove it," are the ones who will bring the supposed victims of this fraud here to testify.

Why will that testimony be important? Well, because these surgeons . . . who are going to take that witness stand will tell you three things: The defendants did not lie to them; the defendants did not deceive them; the defendants did not defraud them in any way.

In four short paragraphs, the defense described direct evidence that would confront head-on the government's allegation that the company had committed a serious fraud. The first principle of federal prosecution — that the DOJ should only charge corporations where the evidence showed a serious offense — had been completely undercut.

It does seem remarkable that the government failed to interview the alleged victims of the company's fraud. But the defense did not limit its attack to this somewhat glaring omission by the federal prosecutors. It further undercut the allegation of serious fraud by pivoting to the chemical components of the products at issue: OP-1 and Calstrux. "So what's Calstrux?" defense counsel asked the jury. It is a bone void filler made with tricalcium phosphate, a mineral "that exists naturally in our bodies," and is "an ingredient in milk, in cheese, in toothpaste. …" Defense counsel then used a humorous analogy that vividly depicted the product as harmless and called into question the allegation of a serious threat to patient health: "[It is] even in Gerber baby food. So we've got some bananas, we've got some apples, we've got tricalcium phosphate right here."

Overarching Principle: *Respondeat Superior*

The defense did not stop with the concept that "criminal cases are different" or the fact that the case before the jury did not involve an especially serious offense. The opening statement also embraced the key principle of *respondeat superior*, and the company figuratively wrapped its arms around the employees on trial. Counsel for Stryker Biotech identified each executive by name and described their character in ways that made them likeable and, though perhaps a bit flawed, human, just like the jurors.

- Co-defendant Bill Heppner had been at the company for 10 years; he had "earned" the respect of his surgeon clients and peers; he served as a "positive motivator," "a leader," and "a champion" of the sales team. He was "outspoken and supportive" of the sales effort. "He's a great athlete; he's competitive. … He was a warm-blooded participant. …"

- Co-defendant Dave Ard had joined the company seven years earlier and served as a regional sales director. Dave was "excited" about the "healing powers" of OP-1. He already had a "strong reputation" in the industry when he joined the company, and the surgeons in his territory regarded him as a "straight shooter."

- Co-defendant Jeff Whitaker, the final executive on trial, had a "beautiful family." He had come to Stryker with more than 15 years of experience in the medical field. He was a "hard-working" sales rep who fostered "long-term relationships" with surgeons.

The company had appointed him as a regional sales director in 2005.

These descriptions of Heppner, Ard, and Whitaker served to undercut the inferences that the government had drawn from their emails — that they had deceived doctors and defrauded hospitals and the FDA. The adjectives and anecdotes the attorney for Stryker used provided the jury with a forgiving lens through which to view the employees — and their employer.

After embracing the three individuals who stood for trial with the company, counsel for Stryker Biotech drew a line in the sand and drove the point home. The company completely and unequivocally stood by its employees. They had done nothing wrong, and by inference, neither had the company:

> *Let me say this about Bill, Dave and Jeff: never in a million years did any of them consider even remotely possible that anyone would point the finger at them and tell them they were criminals, accuse them of lying to or cheating the very surgeons they were trying most to help.*

In one short sentence, the defense flipped the overarching principle of *respondeat superior* on its head, turning the government's sword into the company's shield. Rather than weighing the question whether it should hold a company responsible for the misdeeds of its employees, the jury suddenly found itself considering the question how it could possibly convict a corporation where its employees had done nothing wrong.

The Second Overarching Principle: Duties of Corporate Leaders

Having embraced the employees with whom the company stood for trial, the defense swiftly moved to the other overarching principle of federal prosecution — the duties of corporate leaders. The defense deftly combined this bedrock principle with two of the factors the government considers when weighing whether to prosecute a business organization: the corporation's timely and voluntary disclosure of wrongdoing and its remedial actions. As they had with the principle of *respondeat superior*, the defense attorneys turned these principles against the government, arguing that the company had acted in an exemplary fashion that did not warrant federal prosecution:

> *Now, you may be wondering how this case got started. Why are we here for so long, right? Was it triggered by these adverse events or patient deaths? No, not at all.*

Defense counsel then proceeded to explain that the company had discovered misconduct by one of its sales representatives — an individual who was not on trial. The bad conduct violated an FDA requirement for the Humanitarian Device Exemption that governed the sale of OP-1. Because OP-1 was still considered experimental in nature, the FDA required the company to secure the advance written approval of hospital Internal Review Boards before surgeons could use it. Stryker learned in 2007 — right in the middle of the alleged conspiracy — that one of its sales representatives had forged an IRB approval. The company immediately conducted a thorough internal investigation, discovered that a few other sales representatives had also forged IRB approvals, fired the employees, and self-reported to the FDA. That was how the case started.

This picture painted Styker executives as exemplary leaders despite shocking behavior by subordinates. Defense counsel then characterized the company's response as completely inconsistent with the government's allegation of fraud and deceit:

> *So the point is the case didn't begin with surgeon or patient complaints about adverse events. But also, think about this for a minute. Think about Biotech's disclosure of the IRB misconduct in the middle of the supposed conspiracy to target and defeat the FDA. The notion that at the same time the company was reporting violations of its policies to the FDA it was also participating in a criminal conspiracy against the FDA makes no sense at all.*

To underscore the important point that the company would never seek to undermine the FDA, the defense then offered a live demonstrative aid. Defense counsel introduced a corporate leader the jury would meet during the trial — the person responsible for compliance with FDA rules:

> *Now, at this point, it's high time, I want to introduce Stryker Biotech's corporate representative, Beth Staub. I'll ask Beth to stand. Beth has been at Stryker Corporation for over 20 years. Since 2005, she's been the vice president of regulatory affairs and quality assurance. Beth chairs a steering committee of the regulatory leaders of all the Stryker businesses which oversee Stryker's compliance with FDA rules.*

While there were many important moments in the Stryker opening, this surely was one. The Filip Memorandum gives great weight to the manner by which corporate executives carry out their duties for good reason. The quality of a company's leadership goes to the very heart of the question whether federal prosecutors — serving as a proxy for a future jury — should seek to indict on felony charges. By meeting this issue head on, and by producing a qualified, credible, and responsible corporate leader — in the flesh for all the jury to see and hear — the Ropes & Gray team shook the very foundation of the government's case.

But the defense was not finished. During the minutes that followed, defense counsel (1) acknowledged the evidence of fraud cited by the government, (2) provided important regulatory context, (3) lavished praise on the FDA, (4) embraced the FDA's mission of promoting public health (which the company shared), and (5) showed that the company's leaders had responded responsibly to the information about adverse events.

The defense then ended its opening statement with a twist. As noted above, the Filip Memorandum does not discuss the principle of corporate leadership in a vacuum. It describes this concept as a "common cause" — a double helix of sorts — with the duty of federal prosecutors to promote trust and confidence. "Prosecutors," the memorandum notes, "should also be mindful that confidence in the Department is affected both by the results we achieve and by the real and perceived ways in which we achieve them."[8] Stryker had embraced the common cause of public trust and confidence, but the government had not:

> *Remember I told you how this case got started, when Stryker Biotech went to the FDA during the height of the supposed con-*

spiracy and said, "We have a problem we want to report to you"? …

In addition to the FDA disclosures, in early 2008 Biotech gave statements it took from employees about their IRB forgeries to these prosecutors. The prosecutors had suggested to the company that they wanted the statements and that it would help the company to give them. Shortly thereafter, the prosecutors threatened the former employees — the ones we reported, or the conduct of whom we reported to the FDA — with criminal charges. Ultimately, the former employees cut deals with the prosecutors, agreeing to plead guilty to criminal charges and cooperate against the company. …

When they cut their deals, these former employees knew that they would get no credit for talking about misconduct the prosecutors already knew about from our client, from Biotech, forging of IRB signatures. They knew they had to help the prosecutors make a new case, so here we are.

In a few short paragraphs, the defense melded the concept of witness credibility with the core, overarching principle of the duty of federal prosecutors to join corporate leaders in the common cause of fairness and due process. Stryker had stood by this principle, while the government had not. Styker had self-disclosed in the reasonable expectation of fair accommodation, and the government had responded with a felony indictment.

The Final Pitch

The defense concluded by reiterating the theme of good corporate leadership. Stryker Biotech was a "good and honorable company" that had tried "to help patients, not hurt them." Defense counsel challenged the nature and seriousness of the offense as characterized by the government. "Biotech would never have put its business at risk by defrauding surgeons or the FDA." Counsel then ended by again embracing the concept of *respondeat superior*: "The defendants are not criminals. They did not lie, cheat or steal."

Devastating Effect — Another Shot From Boston Heard Around the World

The opening statements by the attorneys for the company and the individual defendants had a fast and furious effect. In less than 24 hours — before the government finished with the direct examination of its first witness — the government folded its tent, dropped all 13 felony charges against the company, accepted a meager fine by contemporary enforcement standards and a misdemeanor plea by the company, and set all of the individuals free.

Thoughts for the Future

The lessons from the *Stryker Biotech* opening statements are many. White collar practitioners who represent corporations — regardless of the regulatory milieu — should ground their statements to the jury in the principles of the Filip Memorandum. Presentations should include examples of good corporate leadership, a warm embrace of senior managers in keeping with the precept of *respondeat superior*, a challenge to the government's assertion of serious crime, and a fight for the true meaning of the regulations that apply.

The most important lesson, however, appears (somewhat ironically) to be that the government got it right: the Principles of Federal Prosecution of Business Organizations fairly balance the considerations that should determine the proper disposition of alleged corporate misconduct. The joint defense team in *Stryker* exploited these factors to tremendous effect — securing an about-face by the Department of Justice before the government's first witness left the stand. In future cases, if the Department brings an indictment without heeding its own policies first, there is now reason to hope that a well-crafted opening statement by the defense will convince a jury (or perhaps even the government) to nullify the bill.

Notes

1. Brien T. O'Connor, Joshua S. Levy, Cori A. Lable, and Aaron M. Katz from Ropes & Gray represented Styker Biotech; Robert L. Ullmann and Maya L. Sethi from Nutter, McClennen & Fish represented William Heppner; Brent J. Gurney and Miranda Hooker from WilmerHale represented David Ard; and Frank A. Libby Jr. and Alathea E. Porter from Libby Hoopes represented Jeffrey Whitaker. Stephen G. Huggard and Hilary B. Dudley of Edwards Angell Palmer & Dodge represented Mark Philip, who had been severed for trial and for whom the government also dismissed all charges.

2. By way of context, medical manufacturer Synthes Inc. agreed in October 2011 to resolve felony and misdemeanor allegations filed against it, a subsidiary called Norian Corporation, and four of its executives. Synthes agreed to divest Norian Corporation as part of the settlement; Norian, in turn, agreed to pay $22,500,000 in fines and penalties, the maximum allowed by law; and the four executives charged pleaded guilty to misdemeanor counts and were sentenced to prison terms ranging from five to nine months and fined $100,000 each.

3. Mr. O'Connor credits the winning strategy to his able team at Ropes & Gray: veteran former federal prosecutor Joshua Levy, and talented associates Cori Lable and Aaron Katz.

4. Mark R. Filip served as the Deputy Attorney General between 2008 and 2009, and issued his memorandum in that capacity. He currently practices law as a partner at Kirkland & Ellis in its Chicago and Washington offices.

5. United States Attorneys' Manual (USAM) 9-28.100.

6. USAM 9-28:200.

7. USAM 9-28:300.

8. USAM 9-28:100. ■

About the Author

Christopher Hall represents corporations and individuals during internal investigations, government criminal investigations, government civil enforcement actions, and related civil proceedings such as False Claims Act and securities fraud proceedings. He places particular emphasis on the healthcare, financial service, defense, and government contract industries.

Christopher R. Hall
Saul Ewing LLP
1500 Market Street
Centre Square West, 38th Floor
Philadelphia, PA 19102
215-972-7180
Fax 215-972-1917
E-MAIL chall@saul.com