Insights in Enforcement, Litigation & Compliance for Pharmaceutical and Medical Device Manufacturers at FDLI's Enforcement, Litigation and Compliance Conference, December 12-13, 2012

By Thomas Sullivan, President, Rockpointe, Editor Policymed.com and Abraham Gitterman, Research Associate, Rockpointe

On December 12-13, FDLI hosted the annual Enforcement, Litigation & Compliance conference in Washington, DC. The two-day conference was packed with extremely informative topics, and included an astounding number of high-level government officials from the Food and Drug Administration (FDA), the Department of Health and Human Services (HHS) Office of the Inspector General (OIG), the Department of Justice (DOJ), and several other related offices.

Below is a summary of some of the panels, quotes from participants, and some overall analysis and commentary. It should be noted that all participants from the government spoke on their own behalf and were not speaking on behalf of their respective agencies.

New Faces of Enforcement

The first panel of the conference included some of the top officials in food and drug law and healthcare enforcement. The panel, moderated by **Eugene M. Thirolf**, former Director of the DOJ Consumer Protection Branch, consisted of:

- **Michael S. Blume**, Director**,** Consumer Protection Branch, U.S. Department of Justice
- **Gregory Demske**, Chief Counsel to the Inspector General, HHS-OIG
- **Joseph Rannazzisi**, Deputy Assistant Administrator, Office of Diversion Control, U.S. Drug Enforcement Administration (DEA)
- **John Roth,** Director, Office of Criminal Investigation, FDA

Greg Demske spoke first, noting that although OIG will not make any major changes to its enforcement priorities, there will be different approaches to the way OIG handles cases. He mentioned the need for change given the continuously large settlements, questioning whether OIG and healthcare law enforcement is doing enough. Demske assured the audience that OIG will continue to work closely with industry to engage in a productive dialogue, promote voluntary compliance, and to identify best practices for compliance and fighting healthcare fraud and waste. He noted that OIG will hopefully continue to engage industry like it has in the past year, with more industry roundtables.

Demske did emphasize that OIG will "focus on individuals and the decisions they are making," in reference to DOJ's more recent focus on the *Park* doctrine, and OIG's use of convictions under that doctrine to exclude individuals. In making this remark, he explained to the audience OIG's exclusion authority, the differences between mandatory and permissive exclusion, and discussed the Synthes and Purdue Pharma cases. Demske also discussed the use of corporate integrity agreements (CIAs), and how OIG decides whether to waive exclusion in order for the company or entity to enter into a CIA. In referencing the Purdue case, he noted how the D.C. Circuit court denied the executives request for a hearing *en banc* (all judges of the court), leaving executives with only the option of petitioning the Supreme Court for a writ of certiorari.

Finally, Demske discussed GlaxoSmithKline's (GSK) recent CIA with OIG, and the new provisions addressing the "Patient First Program" and the "claw back" provisions for executive compensation and bonuses.

Michael S. Blume, Director, Consumer Protection Branch, U.S. Department of Justice, engaged the audience during his address during the "New Faces of Enforcement" keynote.

Joseph Rannazzisi gave the next presentation, which focused primarily on the tremendous public health concern our country is facing regarding abuse of opioids and other pain killers. His animated presentation gave useful data and insight into the tremendous extent of this problem and the harmful effects it is having on our healthcare system as well as the costs. He gave an overview of how DEA operates and its legal authority and jurisdiction under the Controlled Substances Act (CSA), and the agency's work with DOJ, FBI, and other federal healthcare law enforcement. He also discussed several cases, including one in which individuals were driving all the way from Massachusetts to Florida to get opioids.

Next, John Roth gave a presentation on FDA's Office of Criminal Investigations (OCI). He gave a broad overview of OCI's mission, explained the nature of their work and gave some examples of recent actions and cases. OCI mainly deals with injunctions, seizures and criminal enforcement of the Food, Drug & Cosmetic Act. OCI works with DOJ and other law enforcement to protect the public health and has highly trained investigators that help carry out its work. OCI works closely with the centers at FDA (e.g. CDER, CDRH) to get information about where its enforcement priorities should be and where to investigate.

OCI handles cases involving counterfeit pharmaceuticals (such as the recent Avastin case) and is also responsible for investigating companies that may have committed clinical trial fraud or made misrepresentations to FDA in their product application or required post-market reporting.

Finally, Michael Blume discussed DOJ's enforcement priorities and how his office handles cases. The Consumer Protection Branch (CPB) is involved in all cases involving the FDCA and is largely involved in many of the off-label promotion cases. Blume noted that his office is working in an environment of limited resources, but nevertheless, uses data from various sources to help determine a proactive approach at pursuing cases. He said that CPB is reaching out more aggressively to stakeholders and consumers in the industry, and is looking for cases that will change the behavior of industry and have a larger impact on stakeholders, rather than just looking for big money settlements.

Blume noted that his office is being more transparent about the facts of each case and the unlawful conduct that occurred so

the office can send a message or signal to stakeholders. In other words, those facts and unlawful conduct made public are a warning for companies to know that they may get a knock on their door if similar conduct occurs in their business. Finally, Blume noted CPB's look into requiring more compliance, despite OIG's role. He noted that his office is working with OIG and having a discussion about ways to hold companies responsible and the right factual circumstances to include enhanced penalties such as required compliance that is separate and additional to a CIA. Blume also noted that CPB is seeing more medical device cases involving defects or failure to make required reporting, and that this may be a growth area for the office.

Mary A. Malarkey, Director, Office of Compliance and Biologics Quality, presented the notable compliance work done by CBER in 2012.

Compliance Central with FDA Center Compliance Directors

This panel included the top officials from all of FDA's Centers, including drugs, devices, biologics, foods, tobacco and veterinary medicine. A significant amount of discussion from CDER focused on the new authorities under the Food and Drug Administration Safety and Innovation Act (FDASIA) regarding the drug supply chain. Douglas Stearn, Deputy Director for Policy and Analysis, Office of Compliance, CDER, discussed the new office in CDER that deals with drug supply chain issues and counterfeiting as well as a new trend in enforcement letters from FDA dealing with current good manufacturing practices (cGMP) violations.

In response to a question about why FDA sent a cGMP warning letter directly to a CEO or senior level officials, Stearn noted that the agency did so because quality control is a corporate commitment that FDA believes needs to be taken seriously by senior management. He noted how quality control is now an aspect of the company that is integrated, so it is important that someone is held accountable.

The CDRH presentation also included a very interesting discussion of new programs the center is working on such as the Single Audit Program and the Case for Quality Initiative.

Brien T. O'Connor, Partner, Ropes & Gray LLP, discussed considerations when deciding whether to negotiate a pre-filing resolution or to contest the government's case in a trial.

Advanced Applications Panel

This panel consisted of Jill Furman (Deputy Director, Consumer Protection Branch (CPB), U.S. Department of Justice), Christopher B. Mead (Attorney, London & Mead) and Brien T. O'Connor (Partner, Ropes & Gray LLP). The panel traced some of the steps the government goes through in deciding whether to bring a case for an alleged FDCA violation. First, Ms. Furman noted that a large number of cases that CPB handles come from *qui tam* relators or "whistleblowers." Under the Qui Tam

The Second Circuit decision vacated the conviction of Alfred Caronia for promoting a drug for off-label use on First Amendment grounds. During the "Hot Topics in Enforcement: 2012 Review, 2013 Preview", John Fleder lead a discussion on what this means for the food and drug law community.

statute, the government must review each qui tam; however, the discretion and process for such review varies by office and agency, thus there is not necessarily a statutory outline for what factors and considerations the government will look at.

Instead, Furman noted that CPB looks at whether there have been any regulatory actions against the alleged company or products by FDA or a specific center; whether there is a public health concern; whether there have been a large number of warning letters; and several other factors. She also noted the importance of a company's initial response to an inquiry, including, where the response came from, the perspective of fixing the problem, and who was hurt. In general, she noted that the focus of CPB is the harm to patients/consumers caused by the product. She also discussed where the product fits in at the company, the regulatory and/or enforcement history of the company, any communications between the agency and the company about the product, and the pervasiveness of the conduct or actions.

Another important factor Furman mentioned was how the alleged conduct affects the regulatory approval process or oversight of the agency. Consequently, she noted that her office decides on pursuing cases, issuing subpoenas, looking at documents, etc., when the basic fact and factors noted above show that a likely result will be restitution that is worth the resources put into it. Nevertheless, she noted that cases brought to CPB require a lot of resources, sometimes 2-3 agents and 2-3 lawyers, which can be full-time and has consequences when those government actors are unable to pursue other cases or work.

There was also a brief discussion about when DOJ Criminal decides to get involved in FDCA violation cases. It was noted that DOJ Criminal, CPB, FDA, and other enforcement agencies work together to share information about a particular case and based on that work make a decision whether to pursue criminal charges. This raised concerns from some criminal defense attorneys because many companies and executives have a distrust about DOJ coming back after the civil case is resolved bringing criminal charges. They expressed their preference of resolving cases "globally," to avoid this problem.

Chris Mead, the attorney who represented Mark Hermelin, the former KV Pharmaceutical CEO who was excluded from federal health programs last year, discussed several aspects of the case and made a recommendation based on his experience. He said that CEOs should not be more involved in clinical and quality decisions then they need to be. In the case of Hermelin, he was heavily involved in the decision making that led to the company using improper machines that resulted in the creation of adulterated products. This involvement was the primary

Howard R. Sklamberg, Deputy Associate Commissioner for Regulatory Affairs, ORA, FDA, outlined challenges faced by FDA in protecting public health while maintaining international and federal-state relations.

conduct that led to his convictions and eventual exclusions. Because it appeared based on his role as CEO that these decisions were made out of greed and a total disregard for public health and patient safety, Mead said that other executives should take a hands-off approach in manufacturing and clinical decisions. Doing so may ensure that the company's decisions are being made in an unbiased and impartial way that prioritizes public health and patient safety over profits.

Hot Topics and U.S. v. Caronia

The last panel of the first day included a healthy discussion of the recent 2nd Circuit Opinion in *U.S. v. Caronia*. The various panel members discussed their viewpoints and made predictions about the future of the case and its potential implications. Several interesting points were made.

First, one commentator noted that for many of the companies that are involved in off-label promotion cases, the company usually communicated with FDA about pursuing an off-label indication. Consequently, the panel noted that if FDA expressly denies a company's claim about another use or the company submits additional data about pursuing an off-label indication, with which FDA disputes, and then a company goes and promotes it off-label—*Caronia* makes it uncertain what the outcome would be if FDA prosecuted such conduct. It was noted, however, that under such facts, a company may be misleading or making false statements about its product given FDA's rejection or dispute regarding the off-label use.

The panel also noted that given this opinion, the calculation and negotiation of damages with the government, particularly when false claims are involved, may be affected. For example, in calculating damages and false claims, the government typically tries to quantify the amount of prescriptions or the "market" for off-label use. In making this calculation, they may consider a certain percentage of doctors who were prescribing off-label without the effect of detailing or sales reps. Now with *Caronia*, as long as a sales rep's speech is truthful and non-misleading, then the claims being submitted for them may no longer be "false."