Viewpoints on FDA: Enforcement
I. Overview of FDA Enforcement Issues

By Jennifer Bragg and John Bentivoglio

The election and inauguration of President Barack Obama heralded the beginning of an era of change. Shortly after taking office, the President called for a “complete review” of the Food and Drug Administration’s (FDA’s) operations,¹ and his new FDA Commissioner, Dr. Margaret Hamburg, has moved promptly to bolster oversight and enforcement activity of FDA-regulated industries. The speed with which Dr. Hamburg has acted may reflect her knowledge and expertise from years of senior positions in federal and state governments. She served as New York City Commissioner of Health from 1991-1997, Assistant Secretary for Planning and Evaluation at the U.S. Department of Health and Human Services under President Clinton and since 2001, had served as the Vice President of Biological Programs at the Nuclear Threat Initiative’s Global Health and Security Initiative. Dr. Hamburg had also served as a member of the Board of Directors of a privately held medical device company.

Dr. Hamburg immediately assumed leadership of one of this country’s most influential and important agencies. FDA is vital to the economic health of the United States, regulating approximately $1 trillion in consumer products or 25 cents of every consumer dollar. The companies that FDA regulates are at the forefront of innovation and comprise an industry where the United States is still a dominant player vis-à-vis other countries.

The 21st century has provided FDA its share of challenges. It is sometimes hard to remember that 10 years ago, most of us did not know what Al Qaeda was, had never heard of Twitter or Facebook, and still saw the United States as the world’s most important consumer economy—the center of the universe. The world was not yet flat, and no one had yet unlocked the secret of what it takes for companies to go from good to great. Yes, we were still worried about the Y2K bug.

The world is a very different place than it was a decade ago, and FDA has sometimes struggled to keep pace with the scientific advances and growing global footprints of the companies that it regulates. This is reflected in the public’s confidence in FDA. A Harris Interactive poll conducted in April 2009 found that only 35 percent of Americans believe that FDA does a good job ensuring the safety and efficacy of new prescription drugs. This is down from 56 percent just five years ago.

FDA’s critics have come from a variety of sectors and were often diametrically opposed in their complaints—some thought that FDA was too slow and bureaucratic in its processes, while others bemoaned the lack of careful oversight by the agency. While some blamed lack of consistent leadership at the agency (interim commissioners have been at the helm for roughly four of the last eight years), others believed reduced funding was the cause. Although the highest levels of FDA have lacked stability, one thing has remained constant—the agency is staffed with many career personnel who are committed to fulfilling FDA’s simple yet compelling mission of protecting the public health.

FDA’s enforcement activities have not been spared from the chorus of criticism. Many in regulated industry believed that FDA has been heavy-handed and heartless in its demands. Others saw FDA as having become too cozy with those it regulated. As the data (taken from FDA’s Enforcement Story) demonstrate, FDA’s inspection activities have declined since 2004, with the agency performing approximately 25 percent fewer inspections in 2008 than it did in 2004. The number of warning letters issued by FDA has also declined by nearly 40 percent—from 725 in 2004 to 445 in 2008.² It is perhaps not surprising, then, that Commissioner Hamburg has modified agency policy to streamline the process for issuing warning letters.


GAO found:
FDA oversees drug promotion for off-label uses by reviewing promotional materials that drug companies submit to the agency. However, because FDA does not have separate oversight activities to specifically capture off-label promotion, its oversight occurs within a broader process that targets a variety of promotional violations. Furthermore, FDA reports it is unable to review all submissions because of the volume of materials it receives and prioritizes its reviews in order to examine those with the greatest potential impact on human health. However, FDA does not prioritize its reviews in a systematic manner but rather relies on its staff to sort through large volumes of material and select submissions for review. FDA is also hampered by the lack of a system that consistently tracks the receipt and review of submitted materials.
letters. Although this should result in more letters being issued by FDA, Commissioner Hamburg has also promised that the agency is prepared to take enforcement action in egregious situations without first issuing a warning letter.

While declines have taken place in the administrative and civil enforcement arena (injunctions dropped from 13 in 2004 to five in 2008), FDA’s criminal enforcement activity has been robust and increasing. Perhaps the greatest apparent change in FDA enforcement policy is the agency’s use of its criminal investigative powers. The number of convictions by FDA’s Office of Criminal Investigations has almost doubled in the past five years, moving from 196 convictions in 2004 to 369 in 2008. Thus, there appears to be strong support for the notion that FDA’s enforcement priorities have shifted to the criminal arena.

FDA Office of Criminal Investigations
Fiscal Years 2004 – 2008
(Reported on 11/13/2009)

While the threat of FDA’s direct criminal investigative authority is real, the greatest risks from FDA enforcement action often involve the interplay between the agency’s administrative oversight authorities and the prosecutorial tools of federal and state prosecutors and the plaintiff’s bar. FDA inspections and warning letters, for example, have figured prominently in criminal and civil prosecutions by federal prosecutors\(^3\) and consumer protection suits by state Attorneys General\(^4\). Likewise, plaintiff’s attorneys have used warning letters and other FDA regulatory actions against manufacturers in product liability and related civil lawsuits.

The role that FDA administrative action plays in government and private litigation gives added import to the August 6, 2009, speech by Commissioner Hamburg outlining the agency’s enforcement priorities. In her speech, the Commissioner outlined a number of initiatives that FDA believes will improve its enforcement efforts. The most significant element of Commissioner Hamburg’s speech was her description of six policies that FDA has either put into effect, or that it will implement shortly. These include:

1. **483 Response Deadlines.** Manufacturers will be expected to respond to 483 observations within 15 working days of the conclusion of the inspection. FDA will make enforcement decisions as soon as 15 working days after the inspection is completed.

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\(^3\) See, e.g., US v. Norian Corporation, et al. Indictment at ¶93 (June 16, 2009) (“In order to further lull the FDA … and to avoid FDA scrutiny into the three deaths that occurred during the illegal ‘test market’ [certain defendants] knowingly made false statements to the FDA in response to the FDA’s observations concerning the inspection the FDA conducted in May and June 2004”). An indictment is an accusation and is not itself proof or evidence of wrongdoing.

2. **Swift and Aggressive Enforcement Action.** In certain situations, FDA may take immediate action against a noncompliant manufacturer without first issuing a warning letter. Additionally, FDA will no longer issue multiple warning letters to a company for the same compliance violations.

3. ** Expedited Issuance of Warning Letters.** FDA will no longer send all warning letters to its Office of Chief Counsel (OCC) for review prior to issuance. Instead, in an effort to narrow the time between the described conduct and the issuance of the warning letter, only those letters that give rise to significant legal issues will continue to be reviewed by OCC.

4. **Timely Inspection Follow-Up.** In an instance where FDA has issued a warning letter, or a major product recall occurred, FDA will make it a priority to follow up promptly with appropriate action, such as an inspection or investigation to assess whether the company has made required changes in its practices.

5. **Warning Letter Close-out Process.** If FDA determines that a company has fully corrected the violations raised in a warning letter, FDA will issue a “close-out” letter, indicating that the issues in the warning letter have been successfully addressed. The existence of the “close-out” letter will be published on FDA’s website. Not all warning letters will be eligible for a “close-out” letter.

6. **Collaboration with Regulatory Partners.** FDA will work more closely with its regulatory partners to develop effective risk control and enforcement strategies. At times, local, state, and international officials have authority to take action more quickly than FDA. In those instances, FDA will reach out to others to take rapid action.

The sweeping changes promised by President Obama will have a major impact on companies regulated by FDA. The agency’s new enforcement priorities, coupled with federal and state prosecutorial efforts and private litigation, will affect how companies develop and implement regulatory compliance efforts, interact with and respond to agency oversight efforts and defend themselves in court. These effects are likely to be felt for many years to come.