MINTZ

Health Care Enforcement Review and 2017 Outlook: FDA's Wide-Ranging Activities

January 04, 2017 | Blog | By **Joanne S. Hawana**, **Benjamin M. Zegarelli**

VIEWPOINT TOPICS

- Health Care

RELATED PRACTICES

RELATED INDUSTRIES

Over the past year, clear trends have emerged in FDA's enforcement activities. Enforcement arising from alleged violations of the Federal Food, Drug, and Cosmetic Act (FFDCA) can take many forms, including FDA advisory actions such as warning letters, adverse inspectional observations that can lead to specific administrative actions like product recalls or import detentions, and the pursuit of product seizures using express judicial tools, criminal convictions, or civil settlements in cooperation with DOJ. Structurally, individual compliance offices within the FDA centers and regional offices can initiate enforcement activity against regulated industries, while the FDA Office of Criminal Investigations (OCI) has primary responsibility for criminal investigations conducted by the FDA and works closely with DOJ in setting enforcement priorities for new cases.

In 2016, FDA focused on technical compliance issues that can pose risks to the safety of regulated products, such as data integrity within drug and device manufacturing facilities and unsanitary conditions in compounding pharmacies. FDA issued 14 data integrity warning letters to drug companies, continuing a trend from 2013-2015, during which FDA issued 24 warning letters citing the same issue. This spike coincides with FDA's release in April 2016 of the draft guidance ***Data Integrity and Compliance with cGMP***. Specifically, on August 25th, FDA issued a warning letter to Pan Drugs Ltd requesting a comprehensive report on the firm's data integrity problems, a risk assessment, and a management plan for remediation. In another emerging trend, FDA issued 22 warning letters to compounding pharmacies across the U.S. citing insanitary preparation and storage conditions leading to adulterated product, including Fallon Wellness Pharmacy LLC in the New York District (February 1), Custom Compounding Center in the Dallas District (March 16), Eagle Pharmacy, Inc. in the New Orleans District (October 13), and College Pharmacy Inc. in the Denver District (August 15).

FDA's inspection observation statistics reveal significant differences in the types of observations issued to device manufacturers versus drug manufacturers. On the device side, the top three inspectional observations for 2016 were inadequate CAPA procedures (344 observations), inadequate complaint handling procedures (264 observations), and lack of written MDR procedures (146 observations). The top three observations for drug companies were lack of quality control procedures (147 observations), lack of scientifically sound laboratory controls (133 observations), and failure to investigate discrepancies and failures (126 observations). The top observations for biologics firms and food establishments were failure to establish manufacturing SOPs (39 observations) and lack of effective pest exclusion measures (314 observations), respectively. The trend in recent years of FDA inspectors documenting deficiencies in procedural systems rather than focusing on specific product or systems deficiencies certainly continues.

Following the **settlement** between FDA and Amarin Pharma in March 2016, the courts extended First Amendment commercial speech protections to appropriate off-label communications while law enforcement officials seem to be attempting to apply creative theories of liability in cases involving individuals. Examples of DOJ's expanded efforts include the misdemeanor **convictions of former Acclarent executives** for misbranding of a medical device and the **prosecution of Vascular Solutions and its CEO**, in which the government contended that the company failed to seek an expanded indication and failed to provide revised labeling to account for a particular use of the device as part of a conspiracy (thus avoiding *Amarin's* settlement constraints). We await the outcome of FDA's two-day public hearing on off-label communications to provide an indication of FDA's own policy on these matters. Originally expecting some progress in early 2017, the FDA recently announced an extension of the comment period through April 2017, delaying any policy announcement until at least late 2017.

The number of significant settlements involving alleged violations of the FFDCA continued to increase and in some cases those settlements were made with downstream players in an increasingly complex global supply chain for regulated products. Most recently, on December 7th, the **government announced** that it had entered into a "wide-ranging agreement" with GNC Holdings Inc., the largest retailer of dietary supplement products, "to reform its practices related to potentially unlawful dietary ingredients and dietary supplements, and … to embark on a series of voluntary initiatives designed to improve the quality and

purity of dietary supplements." The non-prosecution agreement resolves GNC's liability for selling certain dietary supplements produced by a firm currently under indictment, includes GNC's agreement to pay $2.25 million to the U.S., and requires GNC to cooperate in ongoing dietary supplement investigations.

And in November, DOJ and OCI **settled a civil and criminal case** involving medical device manufacturer Biocompatibles Inc., which pleaded guilty to misbranding its embolic device used to treat liver cancer, LC Bead, and to allegations under the False Claims Act that the company caused false claims to be submitted to government health care programs for procedures in which LC Bead was loaded with chemotherapy drugs and used as a drug-delivery device, which was not an FDA-approved or cleared use for the product.

Finally, in December, Congress passed the 21st Century Cures Act, which mandated various changes to drug and device programs at FDA. Although we cannot yet predict the ultimate effect of the Cures Act on FDA's pattern of enforcement actions, the Agency's compliance priorities typically track with the planned focus areas of CDER and CDRH for the next fiscal year. Regardless of legislative changes, we expect to see continued wrangling between FDA and other government agencies over how to deal with off-label communications and other statements by executives in 2017. We will be monitoring regulatory changes and new trends at FDA and their possible effects on regulated industry stake-holders in 2017.

Please refer to our Health Care Enforcement Review and 2017 Outlook blog post series for additional insights on key government policies, regulations, and enforcement actions from 2016 and their expected impact on health care enforcement in the year ahead. We also encourage you to sign up for our annual webinar, *Health Care Enforcement Review & 2017 Outlook*, which will take place on Wednesday, January 25 at 1:00 p.m. ET.

Authors

Joanne S. Hawana, Member

Joanne counsels global clients on the regulatory and distribution-related implications when bringing a new FDA-regulated product to market and how to ensure continued compliance after a product is commercialized.

Benjamin M. Zegarelli, Of Counsel

Benjamin advises pharmaceutical, medical device and biotech companies on the FDA regulatory process to identify the correct regulatory pathway, assisting with FDA communications and strategy.