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Health Care Enforcement Review And 2017 Outlook: Part 1

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Law360, New York (January 13, 2017, 12:43 PM EST) -- In 2016, the government demonstrated through both civil and criminal actions that health care fraud enforcement remains a top priority. In this four-part series, Mintz Levin Cohn Ferris Glovsky and Popeo PC's health care enforcement defense team will review the key government policies, regulations and enforcement actions from 2016, and the likely impact of these trends on enforcement in 2017.

FDA's Wide-Ranging Activities

Over the past year, clear trends have emerged in the U.S. Food and Drug Administration'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 the U.S. Department of Justice. 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 the DOJ in setting enforcement priorities for new cases.

In 2016, the 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. The FDA issued 14 data integrity warning letters to drug companies, continuing a trend from 2013 to 2015, during which the FDA issued 24 warning letters citing the same issue. This spike coincides with the FDA's release in April 2016 of the draft guidance Data Integrity and Compliance with cGMP (current good manufacturing practice). Specifically, on Aug. 25th, the 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, the 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 (Feb. 1), Custom Compounding Center in the Dallas district (March 16), Eagle Pharmacy, Inc. in the New Orleans district (Oct. 13), and College Pharmacy Inc. in the Denver district (Aug. 15).

The 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 the 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 the 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 the FDA's two-day public hearing on off-label communications to provide an indication of the 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 Dec. 7, 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 nonprosecution 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, the 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 the FDA. Although we cannot yet predict the ultimate effect of the Cures Act on the FDA's pattern of enforcement actions, the agency's compliance priorities typically track with the planned focus areas of Center for Drug Evaluation and Research (CDER) and Center for Devices and Radiological Health (CDRH) for the next fiscal year. Regardless of legislative changes, we expect to see continued wrangling between the 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 the FDA and their possible effects on regulated industry stake-holders in 2017.

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