The Last Two Years: A Summary of 2014 - 2015 Office of Prescription Drug Promotion (OPDP) Enforcement and Relevant FDA Guidance

March 1, 2016

By Jennifer A. Romanski and Kim C. Capone

The past two years have created a bit of uncertainty for life sciences promotional review professionals. With fewer enforcement letters, high-profile lawsuits, and a shift in marketing focus as a result of the Affordable Care Act, companies are struggling for a greater understanding of the Food and Drug Administration's ("FDA") enforcement objectives and some predictability to help with sales and marketing initiatives.

In 1998, FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC"), now the Office of Prescription Drug Promotion ("OPDP"), issued 158 enforcement letters. Over the years, the number of letters issued has decreased drastically. In stark contrast to the late 1990s, OPDP issued ten letters in 2014 and nine letters in 2015. Despite fewer letters, there is still much to be learned from the content of the communications and related FDA actions.

Also noteworthy, the past two years have demonstrated that OPDP enforcement is not reserved for larger pharmaceutical companies. In both years, a greater number of "small pharma" companies have received warning and untitled letters than "big pharma."

Please click here to read the full summary, published by Porzio Life Sciences.