Will Life Sciences Companies Face More Scrutiny In 2018?

By **John Bentivoglio and Jennifer Bragg**

John Bentivoglio

Jennifer Bragg

The pace of U.S. Department of Justice settlements with life sciences companies slowed in 2017, with eight companies resolving criminal or civil allegations under various federal health care fraud laws. While the lack of Senate-confirmed officials in key posts at DOJ headquarters and in numerous U.S. attorneys' offices likely contributed to the slowdown, a change in enforcement approach may also be at play. While the number of settlements was modest, three civil cases involved settlements exceeding $100 million and prosecutors continued to demand criminal pleas in cases involving serious misconduct. The question that remains is whether life sciences companies will face increased scrutiny in 2018 as Senate-confirmed U.S. attorneys in key districts (including Massachusetts) take the reins and address bipartisan concerns about drug pricing and improper sales and marketing practices.

Enforcement in 2017: By the Numbers

In 2017 the DOJ has reached settlements with nine pharmaceutical and medical device manufacturers, totaling approximately $1.4 billion in criminal and civil fines and penalties.. This is two fewer settlements than in 2016, and $200 million short of 2016 recoveries. Two cases results in criminal dispositions: one misdemeanor plea under the Federal Food, Drug and Cosmetic Act, while another involved both a misdemeanor Food, Drug and Cosmetic Act (FDCA) plea and a felony deferred prosecution agreement (DPA).

On the civil side, federal prosecutors achieved four nine-figure civil settlements: one involved an improper relationship with a charitable copay foundation ($210 million), another involved improper price reporting relating to Mylan's EpiPen ($465 million) and the remaining two resolved combinations of civil allegations of unlawful inducements and false and misleading promotional practices (Shire; $350 million) and Celgene ($280 million).

Major Areas of Enforcement Scrutiny

Company Financial Relationships with Physicians Continue to Draw Intense Scrutiny

Alleged kickbacks (primarily in the form of improper payments to physicians) and improper promotional practices were the most common activities giving rise to settlements in 2017 and remains unchanged in the past decade or more. Half of the civil settlements in 2017

involved allegations of unlawful kickbacks to prescribers under the False Claims Act (Shire, Celgene, Galena and Aegerion). Prosecutors have moved beyond merely scrutinizing whether speaker payments are consistent with fair market value and have begun to question the underlying legitimacy of programs by looking at program attendees, questioning the attendance of nonprescribers or attendance by physicians at multiple programs (which often involve the same or similar speaker decks). And for the first time, prosecutors used the aggravated identity theft statute (18 U.S.C. §1028A) to charge a former pharmaceutical company district manager and sales representative based upon allegations that they signed speaker program sign-in sheets on behalf of HCPs who did not actually attend programs.

Boston USAO-Led Investigation of Co-Pay Assistance, Reimbursement Support Activities Results in First Settlement in Industry-Wide Investigation

While kickbacks to health care providers was again the most common fact pattern for FCA and kickback settlements in 2017, the year also saw the first major settlement in the government's industry-wide investigation of potential kickbacks to Medicare patients through purportedly independent charitable foundation. On Dec. 20, 2017, the DOJ and United Therapeutics entered into a $210 million settlement to resolve FCA allegations that the company paid unlawful kickbacks in the form of copay assistance to Medicare patients through Caring Voices Coalition (CVC), a not-for-profit patient assistance foundation. The DOJ alleged that UT used a foundation, which claims 501(c)(3) status for tax purposes, as a conduit to pay the copay obligations of thousands of Medicare patients taking the company's drugs for pulmonary arterial hypertension. From February 2010 through January 2014, the government alleged, UT routinely obtained data from the foundation detailing how many patients on each UT PAH drug the foundation had assisted and how much the foundation had spent on those patients, and used this data to decide the amount to donate to the foundation. At the same time, UT had a policy of not permitting Medicare patients to participate in its free drug program (which was open to other financially needy patients) even if those Medicare patients could not afford their copays for UT drugs. In addition to the FCA settlement, the company entered into a five-year corporate integrity agreement with the U.S. Department of Health and Human Services, Office of Inspector General. More than 15 companies have publicly disclosed subpoenas from the U.S. Attorney's Office in Boston involving similar relationships with copay assistance foundations, and additional enforcement activity and settlements are likely in 2018.

Promotional Theories Evolve to Focus on False and Misleading Practices

Improper promotional practices were a continuing area of enforcement scrutiny in 2017, with four of the eight settlements involving alleged improper promotional practices. In recent years, the DOJ has faced headwinds in this areas thanks to a line of cases establishing that truthful and not misleading promotional speech enjoys First Amendment protection.[1] As a result, prosecutors have turned their attention to instances where companies have violated their obligations under FDA-mandated risk evaluation and mitigation strategies (REMS) (Aegerion and Novo-Nordisk) and instances where companies have provided allegedly false or misleading information about the risks of certain products (Celgene). In the Aegerion case, the company agreed to plead guilty to violating the FDCA by failing to give health care providers complete and accurate information about the condition for which the company's product was approved and how to properly diagnose it, and for filing a misleading REMS assessment report with FDA.

The DOJ made similar assertions in connection with its September 2017 civil FCA settlement with Novo Nordisk. The DOJ alleged that Novo Nordisk sales representatives gave information to physicians that created the false or misleading impression that the REMS-required message was erroneous, irrelevant or unimportant and led some physicians to be unaware of the potential risks when prescribing the company's product. In response to a modification of the original REMS, the DOJ alleged that Novo Nordisk instructed its

sales force to provide statements to doctors that obscured the risk information and failed to comply with the REMS modification. The DOJ's Ethan Davis acknowledged this new prosecution theory, noting that the DOJ is evaluating compliance with the opioid REMS in connection with its efforts to tackle the opioid crisis.

HIPAA Risk: Not Just for Covered Entities

Prosecutors also took aim at the activities of sales representatives and their access to patient health information. The Aegerion DPA involved a felony charge that Aegerion conspired to violate HIPAA, 42 U.S.C. §§ 1320d-6(a) and 1320-6(b)(3) by admitting that its offices and sales reps knowingly obtained access to patients' personally identifiable health information, without patient authorization, in order to market the company's product directly to physicians and patients. The DPA further states the Aegerion personnel used improperly obtained PHI to complete statements of medical necessity. This is at least the second case (the other being Warner-Chilcott) in which the DOJ has charged a drug manufacturer for HIPAA violations involving improper sales rep access to PHI in connection with patient and reimbursement support activities.

Aegerion Isn't Settled

While the complex Aegerion settlement (involving a criminal plea, DPA, FDA consent decree, FCA civil settlement and CIA) provides important insights into the DOJ's enforcement focus and on the controls companies should consider about key risk areas (e.g., the PAP-related obligations in the CIA), the Aegerion settlement is not settled. On Nov. 20, 2017, U.S. District Court Judge William Young, D-Mass., rejected the plea on the grounds that the particular provision of the Federal Rules of Criminal Procedure (11©(1)©)) provides no discretion for the court to review and/or alter the terms of the plea. Rather, so-called © pleas require give the court one of two options: accept the terms of the plea (and proposed punishment) as a whole or reject the plea outright. Judge Young reviewed the serious misconduct contained in the factual recitation in support of the plea and found it raised too many questions about the adequacy of the proposed plea and fine in light of such conduct.

At the present time, Judge Young's view is in the minority — numerous courts recently have accepted "C" pleas. Nevertheless, his decision may resonate with other judges (in the district of Massachusetts and beyond), raising the stakes for companies that are willing to acknowledge some level of criminal culpability but seek the certainty of an agreed-to plea bargain. Going forward, the court's decision may make it significantly more difficult for prosecutors and defense counsel to reach criminal pleas and may put renewed pressure on other forms of resolution (including greater use of deferred prosecution agreements).

Developments in Corporate Integrity Agreements

Only two of the eight settlements in 2017 (Mylan and Aegerion) resulted in new corporate integrity agreement, continuing a trend away from the OIG seeking a CIA in every major health care fraud settlement. This is consistent with the OIG's April 2016 guidance, which formalized the agency's risk-based approach on its use of its (b)(7) permissive exclusion authority. One of the companies, Shire, already was operating under a CIA at the time of its January 2017 settlement. Given that the Shire case largely focused on the pre-acquisition conduct of a company that Shire purchased, it appears the OIG did not push for a new or amended CIA for Shire.

Perhaps the most important development on the compliance front in 2017 is the package of controls in the Aegerion governing relationships with and donations to independent copay charities. Unlike the controls in HHS OIG advisory opinions, which largely focus on controls for foundations seeking such opinions, the controls in the Aegerion CIA are those for a drug make-donor. Specifically, if Aegerion decides to resume any activities involving

independent charities, the company is required to:

- Vest sole and exclusive responsibility for all such activities (e.g., budgeting, communications, fund allocation, etc.) to a group within the company that operates independently from the commercial business units (the charity oversight group)
- Ensure the commercial business units do not receive information regarding the charities or otherwise have any involvement in, or influence over, the company's charity-related activities. Of note, the CIA prohibits sales reps from discussing specific charities or disease state funds at those charities with either HCPs or patients.
- Create an annual budget for charitable donations that is (i) developed and managed by the charity oversight group and (ii) approved "at a level above the commercial organization (e.g., at the executive level)"
- Develop standardized, objective criteria that govern the annual budgeting process, supplemental funding requests and fund disbursement and allocation
- Execute written agreements with the charities that include compliance representations regarding the charities independence and the company's lack of influence, including a representation that the company does not provide donations to a single-drug fund or a company-product only fund
- Require legal and compliance involvement in (i) developing guidelines and objective criteria for establishing a budget, assessing supplemental funding requests and allocating funds within the budget; (ii) the review and approval of donation agreements and (iii) the review and approval of supplemental funding requests

While the CIA does not go into detail regarding what the HHS OIG might consider as objective budgeting criteria, the CIA is, nevertheless, the most recent and definitive guidance from the government regarding the controls it believes are necessary to ensure a pharma company's charitable donations do not run afoul of the healthcare fraud and abuse laws.

Implications for Drug and Device Makers

The question of whether the pace of DOJ enforcement activity will pick up in 2018 is an open one. Senate-confirmed U.S. attorneys in the District of Massachusetts and other offices with aggressive health care fraud units will have an impact. These offices are likely to continue the focus on kickbacks, promotional practices (particularly those in which the government believes the improper activities are a risk to patient health and safety) and patient assistance and reimbursement support activities, the latter category of enforcement scrutiny is likely to grow as the pharma / biotech model continues to move in the direction of specialized, high-cost therapies where individual patients and prescriptions involve a material amount of revenue to companies and incentive compensation to sales reps and other commercial personnel. The days of drug companies taking comfort in the fact that HIPAA doesn't apply because they are not covered entities is (or should be) over, and companies should assess their overall HIPAA controls in light of his new area of scrutiny.

At the same time, the DOJ's enforcement efforts under the FDCA is likely to change. A senior DOJ official recently questioned the use of departmental resources to pursue "one-off technical regulatory violations where no one was hurt of defrauded, and where there was no clear risk of consumer harm, does not promote consumer health, safety, or economic security."[1] This official went on to say that the department's resources, particularly in criminal cases under the FDCA, will focus on whether there was a clear threat of patient harm or whether the target of the investigation acted knowingly or recklessly. U.S. Food and Drug Administration officials have also made important comments on the need to exercise restraint in pursuing prosecutions under the Park

doctrine (allowing strict liability misdemeanor convictions in the absence of any knowledge or willfulness on the part of the defendant). It remains to be seen whether the FDA will take this one step further and issue formal guidance on Park doctrine prosecutions as the authors have been calling for since 2010.[2]

While the political environment in Washington, D.C., and beyond is likely to remain unsettled, with sharp differences between and among the major political parties, the crackdown on fraud and abuse in the U.S. healthcare system enjoys rare bipartisan support, and companies are likely to face continued whistleblower suits under the False Claims Act and increased scrutiny by criminal and civil enforcement personnel.

Company	Date	Amount (millions)	Criminal	Civil	Allegations
Shire	Jan. 2017	350.0		X	FCA allegations of kickbacks and other inducements at subsidiary purchased by Shire, promotional violations, and false statements involving pricing and coding of product claims
Baxter Healthcare	Jan. 2017	18.2	X	X	cGMP violations (DPA) and related FCA allegations involving manufacture of sterile products
Sanofi-Pasteur	Apr. 2017	19.9		X	FCA allegations involving overcharging for VA products
Celgene	July 2017	280.0		X	FCA allegations involving promotional practices, kickbacks, PAP issues
Mylan	Aug. 2017	465.0		X	FCA allegations involving overcharging for EpiPen by classifying as a generic drug
Novo-Nordisk	Sept. 2017	58.6		X	FCA allegations of failing to comply with FDA-mandated REMS requirements
Galena	Sept. 2017	7.5		X	FCA allegations of inducements to HCPs for speakers, ad boards, rebate agreements
Aegerion	Sept. 2017	36.0	X	X	Criminal, civil settlement re kickbacks, promotional violations, HIPAA
United Therapeutics	Dec. 2017	210.0		X	FCA violation for paying kickbacks to Medicare patients through a charitable co-pay foundation
Totals	9	1,445.2	2	9	FDCA (criminal) – 1; Kickbacks (civil) – 5; Promotional (civil) – 3; HIPAA (criminal) 1)

John T. Bentivoglio and Jennifer L. Bragg are partners with Skadden Arps Slate Meagher & Flom LLP in Washington, D.C.

[1] Remarks by Deputy Assistant Attorney General for the Consumer Protection Branch Ethan P. Davis at the Food and Drug Law Institute's Enforcement Conference on December 7, 2017.

[2] Onus of Responsibility: The Changing Responsible Corporate Officer Doctrine," 65 Food and Drug Law Journal 525-538, Jennifer Bragg, John Bentivoglio & Andrew Collins, 2010
