Aegerion Settles Criminal and Civil Probe of Promotional Practices, REMS and HIPAA Compliance, and Patient Assistance Programs

Skadden

09/28/17

If you have any questions regarding the matters discussed in this memorandum, please contact any of the attorneys listed or call your regular Skadden contacts.

Four Times Square
New York, NY 10036
212.735.3000

skadden.com

On September 22, 2017, Aegerion Pharmaceuticals resolved a wide-ranging probe by the Department of Justice (DOJ) regarding the company's U.S. commercial activities relating to Juxtapid, a lipid-lowering agent for the treatment of homozygous familial hypercholesterolemia (HoFH).[1] As detailed below, DOJ relied on a number of statutes and a complex web of agreements to address a wide array of alleged misconduct, including:

- two misdemeanor violations of the federal Food, Drug and Cosmetic Act (FDCA), with $7.2 million in criminal fines and forfeiture, to resolve alleged misbranding in the form of off-label promotion and noncompliance with an FDA-mandated Risk Evaluation and Mitigation Strategy (REMS);
- a deferred prosecution agreement (DPA) to resolve charges of conspiracy to violate the Health Insurance Portability and Accountability Act (HIPAA); and
- a $28.8 million civil False Claims Act settlement (and related settlements with various states) to resolve allegations relating to Aegerion's promotional and patient assistance program activities.

In addition, the company agreed to a series of forward-looking measures, including a corporate integrity agreement (CIA), an FDA consent decree of permanent injunction and extensive compliance obligations incorporated into the plea agreement and DPA.

Key Takeaways

- Criminal FDCA charges and imposition of a consent decree demonstrate that the government will still pursue criminal liability for off-label promotional activities and has expanded its focus to REMS compliance.
- The DPA for HIPAA violations highlights the risks for pharmaceutical companies that handle protected health information, while the DPA's compliance provisions provide guidance for establishing privacy controls within drug and device companies.
- The civil FCA resolution is the second one setting forth the government's theory that donations to a copay charity may violate the Anti-Kickback Statute (AKS) where the charity lacks independence from the manufacturer.
- The CIA represents the most recent government guidance regarding controls intended to ensure a manufacturer's charitable donations do not run afoul of the AKS, and also continues the trend of imposing demanding oversight requirements in recent CIAs involving pharmaceutical companies.
- Whistleblowers continue to be a primary catalyst for DOJ investigations, with the three relators in this case receiving a total of $4.7 million.[2]

[1] The company also resolved allegations by the Securities and Exchange Commission (SEC) relating to the company's disclosure practices. The SEC settlement is outside the scope of this client alert.

[2] *United States ex rel. Clarke, et al. v. Aegerion Pharmaceuticals, Inc., et al.*, No. 13-CV-11785 (D. Mass.).

Aegerion Settles Criminal and Civil Probe of Promotional Practices, REMS and HIPAA Compliance, and Patient Assistance Programs

FDCA Used to Impose Criminal Liability for Misbranding and REMS Noncompliance

Two components of the settlement — the criminal plea agreement and the FDA consent decree — resolve Aegerion's FDCA liability. The factual basis for that liability is set forth in an Information that charges two separate misdemeanor FDCA violations.

Promotion of Juxtapid for Unapproved Uses. The Information charges that Aegerion misbranded Juxtapid by promoting it for uses for which the drug's label lacked adequate directions for use, in violation of 21 U.S.C. § 352(f). The Information asserted that Aegerion:

- sought and received Orphan approval for Juxtapid because it was intended to treat HoFH, a malady expected to occur in approximately one in 1 million patients;
- nevertheless trained sales representatives to more broadly promote Juxtapid by intentionally failing to define HoFH, discouraging the use of genetic testing and established diagnostic criteria to identify HoFH patients, misleading prescribers regarding the clinical profiles of patients in the Juxtapid pivotal trial, and identifying patients whose clinical profiles did not meet established diagnostic criteria for HoFH;
- trained sales representatives to tell prescribers and patients that using Juxtapid would prevent "impending" heart attacks or strokes, although Aegerion did not have data showing Juxtapid had a meaningful effect on cardiovascular mortality or morbidity;[3] and
- promoted Juxtapid for use as monotherapy, despite the drug's indication as adjunctive therapy.

Noncompliance With Juxtapid REMS. The Information also alleges that Aegerion failed to comply with the Juxtapid REMS, which was designed to ensure that Juxtapid's benefits outweighed the drug's risk of liver toxicity by educating prescribers about that risk and restricting access to Juxtapid to patients with a diagnosis consistent with HoFH. The Information asserts that Aegerion was responsible for implementing, maintaining, monitoring and evaluating the REMS but violated 21 U.S.C. § 352(f) when:

- sales representatives advised prescribers that they could sign required REMS attestations for patients whose clinical profiles did not meet established diagnostic criteria for HoFH, completed attestations without prescribers' knowledge, and included false and misleading information in statements of medical necessity to make patients appear to be HoFH patients on forms submitted to FDA about the REMS program;
- Aegerion failed to conduct REMS training for physicians who supervised nurse practitioners who were prescribing Juxtapid; and
- Aegerion provided misleading information regarding who was being prescribed Juxtapid to FDA in a required REMS assessment report.

Plea Agreement. In addition to pleading guilty to the two-count Information, Aegerion agreed to pay a $6.2 million criminal fine and $1 million in restitution. The plea agreement also requires that for three years, Aegerion, its president and its parent company's board of directors annually review and certify compliance with the plea agreement and consent decree.

Consent Decree. The consent decree requires Aegerion to comply with the Juxtapid REMS, retain an independent auditor to annually audit and monitor its REMS compliance for a period of five years and remediate any noncompliance within specified time frames. If FDA determines that Aegerion has failed to comply with the consent decree or FDCA, it may take various administrative actions (including ordering Aegerion to cease selling, detailing or distributing Juxtapid), pursue further civil or criminal penalties, or impose stipulated financial penalties.

Analysis of FDCA Resolutions. The theories of FDCA liability and the resulting resolutions in the Aegerion case are notable for a number of reasons. First, in recent years, many industry observers have noted a marked decline in criminal cases based on alleged off-label promotion.[4] The resolution in Aegerion, however, shows that DOJ and FDA will still pursue criminal charges in off-label promotion cases, particularly where certain "aggravating factors" are present. In the case of Aegerion, those factors appear to have been (1) flouting FDA's regulatory authority — the Information asserts that Aegerion repeatedly represented to FDA that it would not promote the drug beyond the narrow HoFH indication; and (2) identified patient harm — the Information specifically alleges that numerous patients, including elderly and pediatric patients, suffered significant adverse events due to unapproved use of Juxtapid. In short, while the government has primarily pursued off-label cases through civil

[3] Notably, in November 2013, FDA issued a warning letter to Aegerion regarding public statements the company's CEO had made that FDA determined misleadingly suggested Juxtapid was safe and effective in decreasing the occurrence of cardiovascular events including heart attacks and strokes. The letter noted the limitation of use in Juxtapid's prescribing information stating that the effect of the drug on cardiovascular morbidity and mortality had not been determined.

[4] DOJ has pursued few criminal off-label promotion cases since the U.S. C ourt of Appeals for the Second Circuit's 2012 ruling in *United States v. Caronia* that the FDCA neither prohibits nor criminalizes truthful, nonmisleading speech that may constitute off-label promotion of an approved prescription drug. 703 F.3d 149 (2d Cir. 2012). At the same time, however, DOJ and state attorneys general have continued to pursue off-label promotion through civil settlements and, in the past 19 months, have recovered more than $716.5 million in four settlements based, at least in part, on improper promotional claims. *See* "Recent Settlements Suggest Off-Label Cases Aren't Extinct," John Bentivoglio, Jennifer Bragg, Avia Dunn and Elizabeth Berry, Law360 (August 30, 2017).

Aegerion Settles Criminal and Civil Probe of Promotional Practices, REMS and HIPAA Compliance, and Patient Assistance Programs

resolutions in recent years, companies should not assume that criminal off-label liability is off the table in appropriate cases.

Second, Aegerion is the second settlement *this month* to involve allegations that a pharmaceutical company failed to comply with its obligations under an FDA-mandated REMS program. On September 5, 2017, DOJ announced a $58 million civil settlement with Novo Nordisk that, among other things, resolved allegations that Novo Nordisk provided sales representatives with tactics to counter and neutralize the risk message required by the REMS for its Type II diabetes drug, Victoza. Following on the heels of the Novo Nordisk settlement, the Aegerion plea agreement and consent decree make clear that failure to comply with obligations under a REMS program creates both criminal and civil liability for companies subject to such programs. It also represents a novel use of the consent decree to address REMS compliance requirements, as historically, consent decrees have more often been imposed to address chronic manufacturing process deficiencies.

HIPAA Violations by Sales Personnel Result in Deferred Prosecution Agreement

Aegerion entered into a three-year DPA to resolve a charge that it conspired to violate HIPAA's patient privacy provisions. According to the DPA's agreed statement of facts, from January 2013 through 2015, Aegerion sales personnel obtained access to patients' protected health information without the requisite patient authorization in order to market Juxtapid to physicians and patients. Aegerion acknowledged that at the direction of and with the approval of senior management, Aegerion sales employees violated HIPAA by (1) gaining access to physicians' electronic medical record systems to identify potential patients for Juxtapid; (2) completing or assisting with completion of statements of medical necessity or prior authorizations for insurance coverage; (3) contacting patients directly to convince them to use Juxtapid or to obtain authorization to allow Aegerion customer service personnel to access their protected health information; (4) forging signatures on patient authorization forms; (5) obtaining patient signatures on HIPAA authorizations in English from non-English speaking patients who did not understand the nature of the HIPAA release; and (6) providing gifts or benefits to medical staff in exchange for access to patient data. The DPA also states that Aegerion sales managers and executives instructed sales employees to wear surgical scrubs in order to blend in with the office staff to facilitate access to HIPAA-protected information and implemented incentive compensation programs that motivated sales personnel to improperly access protected health information.

Under the terms of the DPA, Aegerion agreed to institute and maintain a compliance and ethics program designed to prevent, detect and correct HIPAA violations. The DPA imposes several certification and reporting obligations for Aegerion and its parent company's board of directors as part of that compliance program. For example, the DPA requires Aegerion to maintain a log of all reports of questionable HIPAA-related practices by Aegerion employees, and Aegerion's compliance officer is required to annually certify that the company maintained that log and report the number of log entries that relate to HIPAA. Aegerion's president is required to annually certify the effectiveness of the company's compliance program in detecting and preventing HIPAA violations, and the board of directors for Aegerion's parent company (or any future parent company) must conduct a review of the effectiveness of the HIPAA compliance program and submit a resolution to the government as to its findings of that review. Finally, Aegerion must provide the government with quarterly reports of any reportable events that a reasonable person would consider a probable violation of HIPAA.

The Aegerion settlement follows the 2015 Warner Chilcott settlement, which also included a manufacturer's plea to violations of HIPAA. These resolutions suggest that the government will pursue HIPAA charges even in instances where the target is not a covered entity under HIPAA. Both settlements involved allegations that sales personnel accessed patient files containing HIPAA-protected information, without permission, for commercial purposes. These settlements highlight the risk posed by having sales personnel involved in activities that give them access to protected health information.

Civil False Claims Act Settlement Resolves Allegations Regarding Inducements to Patients Through Donations to Copay Charity, Promotional Practices

Aegerion entered into a civil False Claims Act settlement (and related state settlements) and agreed to pay $28.8 million to resolve four discrete categories of covered conduct: (1) unlawfully inducing patients to purchase Juxtapid by channeling donations to a charitable patient assistance organization where Aegerion participated in the creation of the fund and in establishing the criteria for coverage to facilitate copays for Juxtapid; (2) distributing Juxtapid for uses beyond "medically accepted indication[s]" that were thus not reimbursable by federal health care programs; (3) making false and misleading statements about the safe and effective use of Juxtapid, which circumvented the FDA-required REMS; and (4) providing (and instructing physicians to provide) false information in prior authorization forms and letters of medical necessity that were provided to health insurers.

Although much of this alleged conduct is addressed through other components of the resolution, only the civil settlement addresses Aegerion's donations to third-party charitable organizations. This part of the settlement is notable because patient

Aegerion Settles Criminal and Civil Probe of Promotional Practices, REMS and HIPAA Compliance, and Patient Assistance Programs

assistance programs are an area of intense government scrutiny. The Aegerion resolution represents the second time that DOJ has publicly articulated a theory that manufacturer donations to a patient assistance organization may violate the AKS when the charity does not operate with sufficient independence from the manufacturer and the manufacturer's donations disproportionately benefit its patients.

CIA Establishes Rigorous Oversight Requirements and Includes New Controls for Relationships With Independent Copay Charities

Aegerion's five-year CIA incorporates many of the most rigorous oversight provisions found in recent pharmaceutical company CIAs. Some noteworthy provisions of Aegerion's CIA include:

- The compliance obligations imposed on the board of directors apply to the board of Novelion Therapeutics, Aegerion's foreign-based parent.
- The chief compliance officer must report to the president of Aegerion and the global chief compliance officer at Novelion.
- Management certifications are required by officers of both Novelion and Aegerion.
- A financial recoupment program must be implemented that puts up to three years of annual performance pay at risk for specific covered executives if certain types of misconduct occur.
- An annual risk assessment and mitigation process must be implemented.
- Aegerion must conduct field force monitoring activities.

In addition, the Aegerion CIA is the first to include reasonably specific compliance controls focused on a drug manufacturer's relationship with and donations to an independent patient assistance charity. These controls include strict separation of patient assistance program decision-making from commercial personnel, limits on interactions with copay charities and internal rules regarding the budgeting process for donations to copay charities.

Implications for Drug and Device Manufacturers

The Aegerion global settlement is sweeping in its scope and detail. The settlement addresses alleged misconduct in several emerging risk areas, including compliance with FDA-mandated REMS requirements, access to protected health information under HIPAA, the accuracy and completeness of prior authorization and letters of medical necessity provided by companies to insurers, and relationships with and donations to charitable copay foundations.

The collection of documents generated by the settlement provides companies with an opportunity to assess their existing compliance programs and controls against those found in the Aegerion settlement materials, particularly in areas where government guidance has not been forthcoming. In addition, the Aegerion case reinforces the importance of assessing the drivers of behaviors (including but not limited to incentive compensation) and the role such drivers might play in encouraging or incentivizing improper conduct.

Contacts

John T. Bentivoglio
Partner / Washington, D.C.
202.371.7560
john.bentivoglio@skadden.com

Jennifer L. Bragg
Partner / Washington, D.C.
202.371.7980
jennifer.bragg@skadden.com

Michael K. Loucks
Partner / Boston
617.573.4840
michael.loucks@skadden.com

Gregory M. Luce
Partner / Washington, D.C.
202.371.7310
greg.luce@skadden.com

Avia M. Dunn
Counsel / Washington, D.C.
202.371.7174
avia.dunn@skadden.com

Maya P. Florence
Counsel / Boston
617.573.4805
maya.florence@skadden.com

Alexandra M. Gorman
Counsel / Boston
617.573.4852
alexandra.gorman@skadden.com