DMH BioPharm Advisors, LLC.

Late Breaking News:

Prosecutor Panel Discusses Current Enforcement Trends at April 2018 Compliance Congress

DMH BioPharm Advisors, LLC – Mary Holloway

At the 15th annual Pharmaceutical Compliance Congress, held April 23-25, 2018, a panel of past and present prosecutors discussed current enforcement trends, many which are new to the list and thus deserve attention by commercial and compliance colleagues.

1. Increased Focus on Smaller Companies:

It is clear based on recent trends (Big Pharma off-label cases abating) and recent enforcement actions that the Department of Justice focus is shifting toward smaller companies and manufacturers with niche or specialty products.

2. Start-Up Companies

The DOJ is aware that start-up companies, especially those that are venture capital backed, have high growth potential and a high propensity for risk. The belief that these types of companies are flying under FDA radar is false and is attested by the Advanced BioHealing/Shire settlement. Three high-level commercial executives of Advanced BioHealing along with several healthcare providers received criminal convictions including imprisonment for the Senior Vice-President of Sales.

SHIRE/ADVANCED BIOHEALING: THE SETTLEMENT

> **Shire Pharmaceuticals LLC** and other subsidiaries of Shire plc (Shire) will pay $350 million to settle federal and state False Claims Act allegations that Shire and the company it acquired in 2011, **Advanced BioHealing (ABH)**, employed kickbacks and other unlawful methods to induce clinics and physicians to use or overuse its product "Dermagraft," a bioengineered human skin substitute approved by the FDA for the treatment of diabetic foot ulcers.[1]
>
> **Kickbacks | Off-Label Promotion | Upcoding**
> The settlement resolves claims that ABH unlawfully induced the prescribing of Dermagraft to clinics and physicians with expensive meals, entertainment, travel, medical equipment and supplies. Additional incentives included unwarranted payments for speaking engagements, purported case studies as well as cash, credits and rebates to encourage Dermagraft prescribing. Additionally, the settlement resolved off-label marketing of Dermagraft and upcoding claims.
>
> The settlement represents the largest FCA recovery in a kickback case involving a medical device.

3. Patient Assistance Programs and Charitable Contributions

A passion for helping patients has led many manufacturers to support independent charitable foundations that help needy patients obtain their medications in the form of copay assistance. Manufacturers can give charitable contributions to patient assistance charities, as long as the money isn't tied to supporting a specific product.

UNITED THERAPEUTICS: THE SETTLEMENT

United Therapeutics Corporation (UT) paid $210 Million to resolve claims that it used a foundation, Caring Voice Coalition (CVC), as a channel to pay the copays of Medicare patients taking United Therapeutics' pulmonary arterial hypertension(PAH) drugs, a violation of the False Claims Act.[2]

Charitable Contribution as Violation of Anti-Kickback

The information alleges that CVC provided United Therapeutics with data on how many patients were taking UT's products and how much CVC had spent on those patients. DOJ further alleged that the charity paid the copay of Medicare patients on United Therapeutics' PAH drugs and UT considered this information when deciding how much to donate to the charity.

4. Orphan & Specialty Companies

Orphan drugs are those drugs and biologics intended for rare diseases or conditions that affect less than 200,000 people. Large shifts beyond market and revenue estimate are clear indicators that something is amiss.

A. AEGERION: THE SETTLEMENT

Aegerion Pharmaceuticals Inc., a Cambridge, Massachusetts-based subsidiary of Novelion Therapeutics Inc., has agreed to plead guilty to charges relating to its prescription drug, Juxtapid; Will pay more than $35 Million to resolved criminal charges and civil False Claims Allegations.[3]

Juxtapid was approved to treat homozygous familial hypercholesterolemia (HoFH), a rare familial disorder that cause high levels of circulating LDL-C, as an adjunct to a low-fat diet and other lipid-lowering treatments. The label had a black box warning for liver toxicity. As a result, Juxtapid was only available through a REMS program to ensure that the benefit of taking Juxtapid outweighed the toxicity risk.

Off-Label Promotion

The information asserts that Aegerion broadly promoted Juxtapid as appropriate for patients with high cholesterol regardless of clinical or lab diagnosis of HoFH and promoted Juxtapid for first line use, despite the indication as adjunctive therapy.

Moreover, sales personnel were trained to tell physicians that Juxtapid could prevent impending heart attacks or strokes, even though the effect on cardiovascular morbidity and mortality has not been determined.

REMS Non-Compliance

The information alleges that Aegerion failed to give physicians complete and accurate information about HoFH and how to properly diagnosis it. Aegerion also filed a misleading REMS assessment report to the FDA failing to disclose that it was distributing Juxtapid using a definition of HoFH that was not consistent with its label and did not correspond to any peer-reviewed clinical standard for diagnosing HoFH.

Aegerion sales representatives are also alleged to have provided physicians with false information to include in statements of medical necessity and at times have altered or falsified prior authorization forms and letters of medical necessity.

Charitable Contribution as Violation of Anti-Kickback

To eliminate price sensitivity of physicians and patients, Aegerion paid for patient's co-payment of Juxtapid through a charitable fund, created at Aegerion's request, to a third-party vendor PSI. Aegerion established the patient eligibility criteria for the fund.

HIPAA DPA

Aegerion has entered into a deferred prosecution agreement to resolve a felony charge that Aegerion conspired to violate HIPAA privacy provisions by obtaining patients personally identifiable health information without patient authorization for commercial gain.

B. CELGENE: THE SETTLEMENT

Celgene Agrees to Pay $280 Million to Resolve Fraud Allegations Related to Promotion of Cancer Drugs for Uses Not Approved by FDA.[4]

Off-Label Promotion | Pre-Approval Promotion

The information alleges that Celgene made false and misleading statements in promoting two cancer drugs – Thalomid and Revlimid for off-label uses that were not approved by the FDA for some or all the time-periods during which Celgene promoted the drugs for these uses.

Anti-Kickback Violations

Moreover, Celgene allegedly offered illegal kickbacks to physicians who had influence over the content of published drug compendia, medical literature, clinical studies, and NCCN guidelines entries for Thalomid and Revlimid.

Celgene was alleged to have paid physicians who prescribed Thalomid or Revlimid to conduct speaker programs, attend advisory boards and were given monetary support to conduct clinical trials or be listed authors on medical publications.

5. Speaker Events as Kickbacks

Speaker Events, especially when used as a kickback to a prescribing physician continues to trend, Other violations noted include reutilization of a sign-in sheet for multiple programs and repeat attendees at speaker programs that had the same topic, presenter and slide deck.

6. Cell Phone Texts to Doctors

This may be the first shot across the bow for this. No additional information was provided on this trend.

7. Individual Liability

The potential for individual liability continues to trend. The ABH/Shire case reflects this.

SUMMARY

The idea that smaller companies, start-up companies, and oncology companies are immune from prosecution has been dispelled. The FDA's current focus reinforces the need for Manufacturers to continually evaluate their commercial compliance training programs and implement controls to ensure that arrangements with third-party patient assistance programs are independent and compliant with the law.

About DMH BioPharm Advisors, LLC

DMH BioPharm Advisors is a boutique compliance-training firm with proven proficiency in creating and delivering highly effective and personally impactful compliance training curriculums and learning strategies for commercial, medical, and access employees in the biopharmaceutical and device industries. http://www.dmhbiopharm.com

Foot Notes:

[1] See Press Release, U.S. Department of Justice. January 11, 2017. "Shire PLC Subsidiaries to Pay $350 Million to Settle False Claims Act Allegations." Retrieved from: https://www.justice.gov/opa/pr/shire-plc-subsidiaries-pay-350-million-settle-false-claims-act-allegations

[2] See Press Release, U.S. Department of Justice. December 20, 2017. "Drug Maker United Therapeutics Agrees to Pay $210 Million to Resolve False Claims Act Liability for Paying Kickbacks." Retrieved from: https://www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability

[3] See Press Release, U.S. Department of Justice. September 22, 2017. "Drug Maker Aegerion Agrees to Plead Guilty; Will Pay More Than $35 Million to Resolve Criminal Charges and Civil False Claims Allegations." Retrieved from: https://www.justice.gov/opa/pr/drug-maker-aegerion-agrees-plead-guilty-will-pay-more-35-million-resolve-criminal-charges-and

[4] See Press Release , U.S. Department of Justice. July 24, 2017. "Celgene Agrees to Pay $280 Million to Resolve Fraud Allegations Related to Promotion of Cancer Drugs for Uses Not Approved by FDA." Retrieved from: https://www.justice.gov/usao-cdca/pr/celgene-agrees-pay-280-million-resolve-fraud-allegations-related-promotion-cancer-drugs

[5] See Corporate Integrity Agreement, Aegerion Pharmaceuticals
Retrieved from: https://oig.hhs.gov/fraud/cia/agreements/Aegerion_Pharmaceuticals_Inc_09222017.pdf