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Life Sciences Governance, Risk Management, and Compliance

Key Compliance Guidance and Enforcement Actions since the COVID-19 Lockdown

COVID-19 and the ensuing lockdown did little to slow the workload faced by Ethics and Compliance Departments at life sciences companies. Over the past several months, Compliance professionals have had to quickly react to new risks and ways of working and provide guidance to their organizations – often via video conference from the home office.

In the months since the pandemic hit, several government agencies and industry organizations have released modified rules or guidances to reflect these unique times. In addition, the U.S. Department of Justice (DOJ) and other enforcement agencies have remained diligent in combatting fraud in the life sciences industry, as evidenced through a continued stream of enforcement actions and settlements.

The below is a summary of key guidance and enforcement actions released since March.

Open Payments Program

- The U.S. Centers for Medicare and Medicaid Services (CMS) released a **COVID-19 announcement** stating it will exercise enforcement discretion with respect to submissions completed after the statutory deadline due to circumstances beyond the reporting entity's control associated with the pandemic. CMS states that organizations may explain reporting methodologies or reasons for unusual or partial submissions in their assumptions document.
- CMS also published a **resource page** for the new 2021 reporting requirements that provides guidance on the expanded covered recipient requirements, the updated nature of payment categories, and the new device reporting requirements. CMS added **new FAQs** on these reporting requirements as well.

FDA Drug Samples Policy

- In June, the U.S. Food and Drug Administration (FDA) **released the document**, "Samples: Temporary Policy on Prescription Drug Marketing Act Requirements for Distribution of Drug Samples During the COVID-19 Public Health Emergency." In it, FDA outlines the agency's temporary policy regarding certain requirements under the Prescription Drug Marketing Act (PDMA) for distribution of drug samples during COVID-19. FDA provides flexibility on the requirement to collect a physical signature upon delivery of drug samples, and offers guidance on the ability of licensed providers to request drug samples be delivered to their homes.

OIG FAQs on Application of Enforcement Authority During COVID-19

- The Office of Inspector General (OIG) is **accepting inquiries** from the health care community regarding the application of OIG's administrative enforcement authorities, including the Federal Anti-Kickback Statute and civil monetary penalty (CMP) provision prohibiting inducements to beneficiaries. Thus far, FAQs have focused on inquiries from healthcare providers, but are helpful in understanding OIG's position on certain COVID-related practices.

PhRMA Code on Interactions with Healthcare Professionals

- The Pharmaceutical Research and Manufacturers of America (PhRMA) released **guidance on providing meals to healthcare providers (HCPS) during COVID-19**. The guidance specifies that company representatives who are virtually detailing an HCP may still provide a meal to the HCP's office if the representative remains virtually "present" throughout the informational presentation, and where there is reasonable expectation the HCP will remain present as well. PhRMA reiterates its policy that field sales representatives and their immediate managers should limit provision of meals to in-office settings.

AdvaMed Code of Ethics Compliance Guidance

- The Advanced Medical Technology Association (AdvaMed) released the "**Code of Ethics Compliance Guidance Related to the COVID-19 Response**." The guidance specifically addresses the provision of monetary or in-kind donations in response to COVID-19 as well as standards for virtual education events. Regarding the provision of meals, AdvaMed states that companies should create a process to continue to ensure meals are not used as an inappropriate inducement and to track attendance to ensure only appropriate recipients of training/education receive meals. AdvaMed also states that companies should specify that no home delivery of meals will be permitted.

DOJ's Updated Guidance on "Evaluation of Corporate Compliance Programs"

- While not directly spurred by the challenges brought by COVID-19, the June 2020 updates to DOJ's "**Evaluation of Corporate Compliance Programs**" are especially noteworthy in the current period where compliance resources are stretched thin and new business risks have materialized. Key additions to the 2019 document focus on whether the corporate compliance program is "adequately resourced and empowered to function effectively." Another new section, "Data Resources and Access," asks whether compliance personnel have sufficient access to the data needed to allow for timely and effective monitoring, and, if there are impediments to accessing that data, what the company is doing to address them. The document encourages companies to incorporate data-driven reviews into ongoing risk assessments.

Notable Enforcement Activity

Despite some flexibility offered for business practices in the COVID-19-era, the DOJ and other agencies have continued enforcement activity with numerous high-dollar settlements and other actions.

1. **Novartis Settles for $642 Million over Speaker Program and Co-Pay Foundation Activities**
   - On July 1, **Novartis settled allegations** that its speaker programs were used as illegal inducements via speaker fees to high prescribers and via lavish meals to attendees at sham speaker programs. The government highlighted consistent violations of company meal limits, attendees repeatedly attending identical programs, the minimal medical discussion that would often take place, and the fact that the Compliance department was not adequately resourced to monitor speaker program compliance. Of note in the settlement agreement are limitations on Novartis Speaker Programs going forward, including that programs may only be conducted within 18 months after launch/approval of a new indication, that programs must be conducted only in virtual formats, and that total fees for all speakers on a particular product/indication are capped at $100,000 (with a $10,000 cap per individual speaker).
   - The settlement also addressed conduct related to allegations that Novartis violated the Anti-Kickback Statute by giving money to foundations to cover the co-pays of Medicare patients taking Novartis drugs. This portion of the settlement reflects similar allegations to other recent foundation-related enforcement, and focuses on Novartis' coordination with foundations to ensure only Novartis patients received co-pay coverage and requiring foundations to narrow eligibility criteria to cover more Novartis patients.

2. **Indivior Entities Involved in DOJ's Largest Opioid Resolution; CEO Pleads Guilty to FDCA Violations**
   - On July 24, the DOJ announced that Indivior Solutions **agreed to pay $600 million** to resolve criminal and civil liability associated with marketing of opioid addiction treatment, Suboxone. The agreement came after the parent company Reckitt Benckiser was indicted in April 2019. The indictment alleged Indivior deceived HCPs and benefit programs into believing the film version of Suboxone, which has an opioid component, was safer and less susceptible to diversion and abuse than other opioids. Prosecutors said the scheme began before Reckitt Benckiser spun off Indivior. Last year, Reckitt Benckiser agreed to pay $1.4 billion to resolve related claims.
   - This settlement follows the June 30 news that former Indivior CEO Shaun Thaxter pleaded guilty to causing the introduction into interstate commerce of Suboxone, which was misbranded in violation of the Federal Food, Drug, and Cosmetic Act (FDCA). Under the terms of the plea, Thaxter agreed to pay $600,000 and faces up to one year in prison. According to the criminal information, Thaxter asked Indivior employees under his direction to devise a strategy to win preferred drug status for Suboxone Film over a non-opioid competitor that the Massachusetts Medicaid agency, MassHealth, was considering for treating opioid-addiction. Certain Indivior employees subsequently shared false and misleading safety information with MassHealth about Suboxone Film's risk of accidental pediatric exposure. Two months later, MassHealth announced it would provide access to Suboxone Film for Medicaid patients with children under the age of six.

3. **AbbVie Pays $24 Million to Settle California's Nurse Educator-Related Investigation**
   - On August 6, the California Department of Insurance announced a **settlement agreement** with AbbVie Inc. to resolve alleged violations of the California Insurance Frauds Prevention Act involving the marketing of Humira. The Department alleged that nurse ambassadors ("AbbVie Ambassadors") provided misleading information to patients and "interfered with the flow of doctor-patient communications". The Department also alleged that certain AbbVie activities constituted kickbacks, including, for example, the provision of meals and drinks to providers outside the context of speaker programs.

- The Department states that while AbbVie continues to deny the allegations, AbbVie agreed to certain reforms, including requirements that AbbVie Ambassadors disclose to patients that they are provided by AbbVie and do not work under the direction of the patient's healthcare provider, and that Ambassadors must not have patient-specific discussions with providers. Additionally, AbbVie employees are prohibited from describing Ambassadors to providers as "extensions of their offices". AbbVie employees and Ambassadors also must not actively participate in conversations between patients and insurance companies.
- Notably, this action by California follows a **2018 decision by the DOJ to dismiss** nurse educator- / ambassador-related actions brought against 11 pharmaceutical manufacturers. In particular, DOJ stated that these patient support programs were in the public interest because, "given the vast sums the government spends on the medications at issue, federal healthcare programs have a strong interest in ensuring that…patients have access to basic product support." The California settlement terms, however, may indicate certain better practices in how companies utilize their nurse educators.

4. U.S. Files Complaint against Regeneron for Alleged Kickbacks through Co-Pay Foundation

- On June 24, the U.S. Attorney's Office of Massachusetts **announced the filing of a complaint** against Regeneron Pharmaceuticals, Inc. alleging the company paid "tens of millions of dollars in kickbacks for its macular degeneration drug Eylea, using a foundation as a conduit to cover co-pays for Eylea." The government allegations include evidence that Regeneron employees repeatedly contacted a co-pay foundation to learn the amount of donations the foundation would need to cover the co-pays of Eylea payments only, and evidence that Regeneron calculated return on investment analyses on the Medicare revenue that the company would derive from those patients. The complaint also alleges Regeneron management lied to company auditors regarding the nature of the data they were receiving from the foundation.

5. Pacira Pays $3.5 Million To Resolve False Claims Act Case Related to Research Grants

- Pacira Pharmaceuticals Inc. **agreed to pay $3.5 million** to resolve allegations it paid kickbacks to doctors in the form of "bogus research grants" to induce them to prescribe its analgesic EXPAREL. The government contended that from 2012-2015, Pacira paid kickbacks in the form of 28 grants to healthcare providers and/or institutions. According to the allegations, Pacira sales representatives or marketing executives typically initiated the grants, which were conditioned upon acceptance of EXPAREL onto the institution's formulary. Certain Pacira executives allegedly coached grant recipients on how to avoid internal scrutiny of the grant payments. Prosecutors contended that Pacira approved and funded the grants despite receiving little or no documented description of the proposed research, and that Pacira did not document a reasonable commercial need or a fair market value assessment for the grants. Prosecutors further contended that after awarding the grants, Pacira personnel conducted little or no follow-up on the proposed research, which certain grant recipients did not carry out according to the original proposal, and sometimes did not perform at all. These grant payments allegedly caused sales of EXPAREL at the recipient institutions to increase during the time relevant 2012-2015 period.

6. Novartis and Alexion Involved in FCPA Actions

- The past few months also saw Foreign Corrupt Practices Act (FCPA) enforcement actions focused on bribery by Novartis and Alexion subsidiaries.
- On June 25, the **DOJ announced** that Novartis Hellas S.A.C.I. (Novartis Greece), a subsidiary of Novartis AG, and Alcon Pte Ltd, a former subsidiary of Novartis AG and current subsidiary of Alcon Inc., agreed to pay a combined total of more than $233 million in criminal monetary penalties to resolve the department's investigation into violations of the FCPA. The resolutions arise out of a Novartis Greece scheme to bribe employees of state-owned and state-controlled hospitals and clinics in Greece, and to falsely record improper payments relating to the corrupt scheme and similar conduct, as well as an Alcon Pte Ltd scheme to make and falsely record improper payments in Vietnam. Novartis AG also agreed to pay over $112 million to the U.S. Securities and Exchange Commission (SEC) in a related matter.
- On July 2, the **SEC announced** that Alexion Pharmaceuticals Inc. agreed to pay more than $21 million to resolve FCPA-related charges. According to SEC's order, Alexion subsidiaries in Turkey and Russia made payments to foreign government officials to secure favorable treatment for Alexion's primary drug, Soliris. Alexion Russia and Alexion Turkey maintained false books and records of these improper payments, which Alexion's internal accounting controls were not sufficient to detect or prevent. The SEC further stated that Alexion's subsidiaries in Brazil and Colombia failed to maintain accurate books and records, including by creating or directing third parties to create inaccurate financial records concerning payments to patient advocacy organizations.

If you have any questions regarding these recent announcements and enforcement actions, Guidehouse has numerous resources to help. Our Life Science Governance, Risk Management, and Compliance Practice provides consulting and advisory services to life sciences companies across the globe on compliance related matters. This includes specific resources for **Risk and Compliance**, as well as our **Transparency Center of Excellence**.

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