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POST-MARKET SURVEILLANCE: HOW FDA REGULATES YOUR MEDICAL PRODUCT AFTER LAUNCH

WHAT YOU NEED TO DO TO COMPLY WITH AGENCY RULES, AVOID LIABILITY, AND IMPLEMENT BEST PRACTICES

JUNE 28, 2019

LAW OFFICES OF COVINGTON & BURLING • WASHINGTON, DC

Agenda

8:00 a.m. – 8:30 a.m. **Registration**

8:30 a.m. – 8:45 a.m. **Welcoming Remarks**

Kristin Davenport
Of Counsel, Covington & Burling

8:45 a.m. – 10:00 a.m. **Drug Pharmacovigilance Under CDER**

One of CDER's top missions is to monitor the safety and effectiveness of drugs that are currently available to the American public. To meet this goal, the FDA has implemented postmarketing programs that monitor marketed human medical products for unexpected adverse events. These programs alert the Agency to potential threats to the public health. Agency experts then identify the need for preventive actions, such as changes in product labeling information and, rarely, re-evaluation of an approval decision. This panel will help drug manufacturers, and their regulatory advisers, understand the scope of these programs, how they currently operate, and the process in the event additional substantiation or changes in exiting approval parameters are requested.

This session will cover all aspects of post-market drug regulation, including:

- Structure and function of post-market offices within CDER
- Use of registries and Phase IV Data

- Post-market field alerts, adverse drug reports, and Medwatch benefits and best practices of post-market monitoring
- Submission of post-marketing reports and process analysis
- FDA's Adverse Event Reporting System (FAERS)
- Safety signal detection
- Use of data mining
- Regulatory actions: warnings, precautions and adverse reactions
- Sentinel System Five Year Strategy: 2019-2023
- FDA's new efforts to address drug shortages
- Increasing role of social media in post-market surveillance
- Communicating safety issues that are effective and compliant
- Product liability litigation and how to avoid it

Moderator: **Paula Katz, Special Counsel, Covington & Burling**

Panelist: **Cynthia Schnedar, Executive Vice President, Regulatory Compliance, Greenleaf Health**

Panelist: **Brian Malkin, Of Counsel, Arent Fox**

10:00 a.m. – 10:15 a.m. **Networking Break**

10:15 a.m. – 12:00 p.m. **Device Post-Market Surveillance Under CDRH & §522**

This session will cover all aspects of post-market device regulation, including what you need to know about the FDA's current requirements following its issuance of guidance in 2016. That guidance concerned implementation of Section 522 FDCA that granted FDA the power to require post-market surveillance for devices that are implantable, life-supporting, used in children or reasonably likely to have a serious adverse health consequence. Topics addressed by panelists will include:

- Definitions and authorities affecting your device
- What is a serious adverse health consequence
- When a §522 order is issued
- What happens if manufacturers fail to comply?
- Post-market surveillance plans and best practices

- Preparation of interim and final reports
- Requesting proposed changes to surveillance plans
- Public disclosure of summary results
- Recalls, corrections and market withdrawals
- Compliance tips and liability avoidance

Moderator: **Christina Kuhn, Associate, Covington & Burling**

Panelist: **Sal Elmi, Senior Regulatory Counsel, Stryker**

Panelist: **Dr. Susan Alpert, Principal, SFA Regulatory, LLC**

12:00 p.m. – 1:00 p.m. **Luncheon**

1:00 p.m. – 1:45 p.m. **Surveillance Using Sentinel and iMEDS Program**

The FDA continues to strengthen systems that access and consolidate powerful government and private healthcare databases to evaluate safety issues. This panel will discuss the status of the current Sentinel Initiative, how it operates and how it can be accessed and used by product stakeholders. This panel also will also take a deep dive into a complementary big data sharing program administered by the Reagan-Udall Foundation between the FDA and industry to evaluate the use of these consolidated databases to flag potential adverse events at earlier stages in product development or postmarket utilization.

Moderator: **Julie Post, Associate, Coving & Burling**

Speaker: **Diana Zuckerman, President, National Center for Health Research, Cancer Prevention and Treatment Fund**

1:45 p.m. – 2:30 p.m. **Current FDA Initiatives and Opportunities Under 21st Century Cures & PDUFA VI**

The vast increase in the amount of electronic data captured during routine care, or by patients themselves, creates an unprecedented opportunity to modernize and augment clinical trials and improve the

postmarket monitoring process. Both Congress and the Administration have taken steps to improve the level of research and development efficiency by authorizing regulators to modernize drug and device discovery, development and approval using confirmatory of data beyond conventional controlled clinical trials. This presentation will evaluate the new tools provided to FDA under recent legislation and how those tools are being used currently in product preapproval applications.

Moderator: **Gary Heimberg, Of Counsel, Covington & Burling**

Panelist: **Krista Carver, Partner, Covington & Burling**

Panelist: **Remy Brim, Vice President Regulatory Policy and Strategy. BCG Government Affairs, LLC**

2:30 p.m. – 3:15 p.m. **How Real World Evidence is Really Being Used in the Real World**

Data gathered form sources outside of randomized controlled trials reflecting the actual experiences of patients during routine patient case is often referred to as real-world data. It entails a significant increase in physician electronic health records combined with a record increase in the number of Americans recording health information through devices and information-sharing applications. This session covers the FDA's enhanced powers and mandates to consider the actual use of medical products to reduce clinical substantiation and post-approval use in medical treatment.

- What RWE is and where you can find it
- How much RWE is premarket v. post-market?
- How RWE might be used to obtain an IND/IDE
- How RWE can reduce preapproval clinical data requirements
- How RWE can be used with CMS and insurer reimbursement decisions

Moderator: **Matthew Hegreness, Associate, Covington & Burling**

Panelist: **Megan O'Boyle, Principal Investigator for PCORnet's Phelan-McDermid Syndrome Data Network (PMS_DN) and the Phelan-McDermid Syndrome International Registry**

3:15 p.m. – 3:30 p.m. **Networking Break**

3:30 p.m. – 4:00 p.m. **Drug and Device Post-Market Surveillance Horror Stories, and Hypotheticals & Q&A with Audience**

This session covers situations you need to consider to make sure you are making the right decisions about your medical product in post-market surveillance. Real-world hypotheticals will test your knowledge and judgment on issues your company might face in 2019 and beyond.

Moderator: **Kristin Davenport, Of Counsel, Covington & Burling**

Panelist: **Sal Elmi, Senior Regulatory Counsel, Stryker**

Panelist: **Dr. Susan Alpert, Principal, SFA Regulatory, LLC**

Panelist: **Remy Brim, Vice President Regulatory Policy and Strategy. BCG Government Affairs, LLC**

4:00 p.m. **Adjournment & Reception**