Introduction to Drug and Device Law and Regulation for Patient Organizations

November 18–19 & December 2–3, 2020
Virtual Event
Agenda

WEDNESDAY, NOVEMBER 18, 2020

12:00–12:15 PM **Welcome and Announcements**

12:15–1:15 PM **Introduction to FDA Organization and Other Agencies**

David L. Chesney, Principal and General Manager, DL Chesney Consulting

- The U.S. Drug Regulatory Process
- FDA Organization
- Types of FDA Regulatory Requirements and Pronouncements
- Congressional Oversight
- The FDA's Relationship with Other Agencies

1:15–2:00 PM **FDA in the Headlines and the Impact to Your Communities**

Remy L. Brim, Vice President, Regulatory Policy and Strategy, BGR Group
Ryan Hohman, Vice President - Public Affairs, Friends of Cancer Research

- Overview of FDA's Jurisdiction and Its Role During the Pandemic
- Relationship Between HHS, FDA, White House Task Force
- Impacts on Patient Organizations

2:00–2:15 PM **Break**

2:15–3:15 PM **New Drug Development Under an Investigational New Drug Application (IND)**

Heidi Gertner, Partner, Hogan Lovells US LLP

- What is a "Drug"?
- What is a "New Drug"?
- Other Drug-Like Products
- Who Decides Whether a Product is a "New Drug"?
- The IND Process and Application

3:15–3:30 PM **Break**

3:30–5:00 PM **The FDA Approval Process for Drugs**

Lee H. Rosebush, Partner, BakerHostetler

- Submission & Filing of NDAs/BLAs
- Approval Standards
- The Review Process
- Expedited Review

5:00–5:30 PM **Networking Session: "Applying the Law to My Organization"**

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THURSDAY, NOVEMBER 19, 2020

12:00–1:00 PM **Approval and Clearance Pathways for Medical Devices—Part 1**

Allyson B. Mullen, Director, Hyman, Phelps & McNamara, PC
Ami E. Simunovich, Executive Vice President, Chief Regulatory Officer, Becton Dickinson (BD)

- What is a "Device"?
- Medical Device Amendments of 1976
- Predicate Devices and Substantial Equivalence
- Who Decides Whether a Device Needs Premarket Approval (PMA) or a 510(k) Clearance?
- Laboratory-Developed Tests and In-Vitro Diagnostics
- De Novo Requests for Classification
- Medical Devices, Combination Products, and EUAs
- Real World Examples and Practical Applications

1:00–1:10 PM **Break**

1:10–2:00 PM **Approval and Clearance Pathways for Medical Devices—Part 2**

2:00–2:15 PM **Break**

2:15–3:30 PM **Post-Market Considerations for Drugs and Devices**

Elizabeth Mulkey, Associate, Goodwin Procter, LLP
Steven Tjoe, Associate, Goodwin Procter, LLP

- Recalls / Safety Communications
- Post Market Surveillance
- Post Approval Changes and Supplements to NDA, ANDA, PMA—And When a New 510(k) Must be Filed
- Risk/Benefit Health Risk Assessments

3:30–3:45 PM **Break**

3:45–4:45 PM **Expanded Access to Investigational Therapies for Drugs and Medical Devices**

Richard Klein, Director, Expanded Access Programs & Policy, GE2P2 Global Foundation

- Expanded Access
- Federal Right-to-Try Legislation and Effect on Current FDA Expanded Access Framework

4:45–5:15 PM **Networking Session: "Applying the Law to My Organization"**

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WEDNESDAY, DECEMBER 2, 2020

1:00–2:00 PM	**Conduct of Clinical Trials for Drugs and Medical Devices and Human Subjects Protections**

Pamela Tenaerts, Executive Director, Clinical Trials Transformation Initiative

- Clinical Testing/Investigation and "Good Clinical Practice" (GCP)
- Clinical Trials Registration and Results Reporting (clinicaltrials.gov)
- Human Subjects Research Protection
- Bioresearch Monitoring (BIMO)
- Investigational Device Exemptions
- Adverse Event Reporting

2:00–2:30 PM	**Break**

2:30–3:30 PM	**Calculating the Benefit/Risk Assessment for Your Organization**

James E. Valentine, Associate, Hyman, Phelps & McNamara, P.C.
Melissa Goetz, Co-Founder, FCS Foundation

3:30–4:00 PM	**Networking Session: "Applying the Law to My Organization"**

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THURSDAY, DECEMBER 3, 2020

12:00–1:00 PM **Intellecutal Property and Regulatory Incentives to Protect Innovation**

Ryan Kaat, Senior Director, Law, PhRMA

- Patent Term Restoration/Extension
- Five- and Three-Year Exclusivity
- 180-Day Exclusivity
- Pediatric Exclusivity
- Orphan Drugs
- Priority Review Vouchers (PRVs) (Tropical Disease, Rare Pediatric Disease, and Medical Countermeasures)
- Biosimilars: Intersection of Regulatory Exclusivity and Patent Exclusivity

1:15–2:15 PM **Stakeholder Interactions in the Drug Development Community**

David R. Zook, Chair, Faegre Drinker Consulting

- Sponsor-Patient Group Engagement
- Payor Communications Post-Cures Act
- Ways Non-Profit Patient Groups Can Effectively Engage with FDA
- The Role of PRO Data and How Can Patient Advocacy Groups Influence the Use of PRO Data in FDA Decision Making

2:15–2:30 PM **Break**

2:30–3:30 PM **Engaging with FDA: Opportunities and Boundaries**

Tracy Gray, Patient Engagement Lead, Patient Science & Engagement Program, Center for Devices and Radiological Health (CDRH), FDA
Sadhna Khatri, Associate Director of Operations, Professional Affairs and Stakeholder Engagement, Center for Drug Evaluation and Research (CDER), FDA
Susan Chittooran, Patient Engagement Project Manager, Patient Affairs Staff, Office of the Commissioner, FDA

- FDA's Patient Engagement Offices
- FDA's Patient Engagement Programs
- Participating in FDA Policymaking

3:30–4:00 PM **Networking Session: "Applying the Law to My Organization"**

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