DIA Combination Products:

Current, Evolving, and Future Pathways

Short Course: October 24 | Conference: October 25-26 | Renaissance Washington DC Dupont Circle Hotel | Washington, DC

PROGRAM COMMITTEE

Steven B. Binion, PhD, MBA
Director, Policy, Technology and Communication, Corporate Regulatory Affairs
Becton Dickinson

David E. Paul, JD
Consultant, US Regulatory Affairs, Policy and Strategy
Eli Lilly and Company

Kim Quaintance-Lunn
Head, US Regulatory Policy
Bayer

Rachel SW Turow, JD, MPH
Director, Regulatory Policy
Novo Nordisk Inc.

John Barlow Weiner, JD
Associate Director, Policy and Product Classification Officer, Office of Combination Products, Office of the Commissioner
FDA

Target Audience

Senior Level Professionals and Decision-Makers Involved in:

- Biopharmaceutical, Device, and Combination Product R&D and Development
- Policy
- Regulatory Affairs
- Clinical Research
- Consulting, Legal, Government Affairs
- Quality Assurance and Control
- CMC
- Business Development

Overview

The increasing use of and interest in innovative combination products—products combining a drug, device, and/or biologic—is raising significant challenges both for regulators and the industries they regulate. To bring these promising new therapies to market, innovators must often overcome challenges resulting from differences in policies, development processes, and review pathways. *Combination Products: Current, Evolving, and Future Pathways* examines examines the impacts on the combination product lifecycle of recent and coming changes in policy, regulation, FDA organizational, and FDA review processes. The evolving potential of convergence across FDA's centers, as piloted by the Oncology Center of Excellence, will be discussed as a model for innovation and how it may relate to combination product regulation.

Highlights

- Short Course: Digital Health Technologies for CombinationProducts: Development and Regulation
  October 24 | 1:30-5:00PM
- Discuss policy and regulation supporting medical product innovation and what they mean for combination products
- Examine digital health technologies, including mobile medical apps and clinical decision apps - when and how they are regulated as combination products
- FDA Oncology Center of Excellence and its potential as a model for other therapeutic areas
- Explore the future of inter-center collaboration at FDA and its implications for medical product innnovation

Schedule At-A-Glance

SHORT COURSES | MONDAY OCTOBER 24	
7:30AM-5:00PM	Short Course Registration
1:30-5:00PM	**Short Course 1:** Digital Health Technologies for Combination Products: Development and Regulation

DAY ONE | TUESDAY, OCTOBER 25	
7:15AM-5:30PM	Registration
7:15-8:15AM	Continental Breakfast and Networking
8:15-8:30AM	Welcome and Opening Remarks
8:30-9:00AM	**Keynote Address:** Innovation in Medical Product Development: A Regulatory Perspective
9:00-10:30AM	**Session 1:** US and EU Combination Products Regulatory Updates
10:30-11:00AM	Refreshment and Networking Break
11:00AM-12:30PM	**Session 2:** FDA Combination Product Review Process Improvements and Organizational Changes
12:30-2:00PM	Luncheon and Networking
2:00-3:30PM	**Session 3:** FDA Oncology Center of Excellence: Implications for Intercenter Coordination
3:30-4:00PM	Refreshment and Networking Break
4:00-5:30PM	**Session 4:** Combination Products on Capitol Hill
5:00-6:00PM	Networking Reception

DAY TWO | WEDNESDAY, OCTOBER 26	
7:30AM-3:30PM	Registration
7:30-8:30AM	Continental Breakfast and Networking
8:30-9:00AM	**Keynote Address:** Innovation in Medical Product Development: An Industry Perspective
9:00-10:30AM	**Session 5:** Challenges and Opportunities of Differing Regulatory Paradigms for Drugs and Devices
10:30-11:00AM	**Refreshment and Networking Break**
11:00AM-12:30PM	**Session 6:** Digital Health Technologies: Are They Combination Products? Does it Matter?
12:30-2:00PM	**Luncheon and Networking**
2:00-3:30PM	**Session 7:** The Future of the Inter-Center Collaboration at FDA
3:30-4:30PM	**"Sweet Treats" Networking Reception**

Learning Objectives

At The Conclusion Of This Activity, Participants Should Be Able To:

- Describe legislative and regulatory developments pertaining to combination products in the US and EU
- Understand and discuss differing perspectives and approaches of drug and device development and regulation, and implications and opportunities for combination product regulatory practice and policy
- Discuss developments and opportunities for facilitating innovations in medical product development through collaborative regulatory approaches such as the FDA Oncology Center of Excellence

Continuing Education Credit

Appropriate Accreditation and Credit Designation Statements

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program (short course and conference) is designated for 14.75 contact hours or 1.475 continuing education units (CEU's).

Short Course: 0286-0000-16-118-L04-P; 3.25 Contact Hours or .325 CEUs
Day 1: 0286-0000-16-116-L04-P; 6.5 Contact Hours or 0.65 CEUs
Day 2: 0286-0000-16-117-L04-P; 5 Contact Hours or 0.5 CEUs

Type of Activity: Knowledge

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MONDAY, OCTOBER 24

7:30AM-5:00PM — **Registration**

1:30-5:00PM

Short Course: Digital Health Technologies for Combination Products: Development and Regulation

Instructors

Rachel Turow, JD, MPH
Director, Regulatory Policy
Novo Nordisk Inc.

Wade Ackerman, JD
Partner
Covington & Burling LLP

Scott Danzis, MD, JD
Partner
Covington & Burling LLP

Pat Baird, MBA, MSc
Head of Global Software Standards
Philips

This short course will focus on how digital health technologies are being developed and regulated in the pharmaceutical/combination products space. Although many digital health technologies follow a fairly straightforward regulatory path as devices, those that interact with drug products often encounter more regulatory uncertainty. FDA's policy on how mobile medical apps, clinical decision support software, and wearables can be combined with pharmaceutical use is still in development, so it is often difficult to navigate the regulatory path to market for these products. The course will look at currently available FDA guidances and what they mean for digital health products that combine both a drug and device. In addition, participants will explore how to work with FDA when developing digital health technologies that may veer outside of established regulatory pathways. What it means to validate software and considerations for cybersecurity and risk management around cybersecurity will be addressed.

Learning Objectives:
At the conclusion of this short course, participants should be able to:

- Describe how digital health technologies are being regulated by FDA through a discussion of current FDA guidances and their effect on the development and approval of digital health products, some of which combine both a drug and device
- Identify how to work with FDA when developing digital health technologies via established regulatory pathways and what to do when those technologies veer outside of established regulatory pathways
- Review specific software validation requirements, cGMPs, risk management, and cybersecurity as well as identify techniques that innovators use to address them

TUESDAY, OCTOBER 25

7:15AM-5:30PM — **Registration**

7:15-8:15AM — **Continental Breakfast and Networking**

8:15-8:30AM — **Welcome and Opening Remarks**

Sudip Parikh, PhD
Senior Vice President and Managing Director, DIA Americas

8:30-9:00AM — **Keynote Address: Innovation in Medical Product Development: A Regulatory Perspective**

Session Chair
John Barlow Weiner, JD
Associate Director, Policy and Product Classification Officer, Office of Combination Products, Office of the Commissioner
FDA

Keynote Speaker
Nina Hunter, PhD
Associate Director for Science Policy, Office of Medical Products and Tobacco
FDA

FDA has been taking a close look at how it regulates combination products and regulatory considerations for other combined uses of medical products. Dr. Hunter will be offering remarks on the agency's vision in this area and efforts FDA is pursuing to break down silos and ensure a consistent, risk-based approach to regulation of combination products and other combined uses of medical products.

9:00-10:30AM — **Session 1: US and EU Combination Products Regulatory Updates**

Session Chair
Steven B. Binion, PhD, MBA
Director, Policy, Technology and Communication, Corporate Regulatory Affairs
Becton Dickinson

Speakers
John Barlow Weiner, JD
Associate Director, Policy and Product Classification Officer, Office of Combination Products, Office of the Commissioner
FDA

Elizabeth Baker
Licensing Division
Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom

In recent months, regulatory authorities have made numerous changes aimed at clarifying the complexities of combination product requirements. In this session, US and EU regulators will discuss the most recent and pending updates on guidances and rules for combination product review and life cycle management.

10:30-11:00AM — **Refreshment and Networking Break**

11:00AM-12:30PM — **Session 2: FDA Combination Product Review Process Improvements and Organizational Changes**

Session Chair
Rachel Turow, JD, MPH
Director, Regulatory Policy
Novo Nordisk Inc.

Speakers
Melissa B. Burns, MS
Senior Program Manager, Office of Combination Products
FDA

Nina Hunter, PhD
Associate Director for Science Policy, Office of Medical Products and Tobacco
FDA

Cartier Esham, PhD, MSc
Executive Vice President, Emerging Companies, Vice President, Science and Regulatory Affairs
Biotechnology Industry Organization

Under the leadership of Commissioner Robert Califf, FDA has embarked on a series of significant process changes aimed at improving combination product regulation. These changes may have the greatest impact on the regulation of combination products since FDA began formally regulating combination products. During this session, FDA will give updates on the internal changes it has made to address issues in the combination products review process, including: establishment of a new Combination Products Policy Council, lean process mapping, a formalized inter-center consult process, and new goals for combination product review under the Prescription Drug User Fee Act.

TUESDAY, OCTOBER 25

12:30-2:00PM — **Luncheon and Networking**

2:00-3:30PM — **Session 3: FDA Oncology Center of Excellence: Implications for Intercenter Coordination**

Session Chair
Nathan Brown, JD
Health Care and Life Sciences Partner
Akin Gump Strauss Hauer & Feld LLP

Speakers

Paul J. Seligman, MD, MPH
Executive Director, Global Regulatory and R&D Policy
Amgen Inc.

Dr. Jeff Allen
President and Chief Executive Officer
Friends of Cancer Research

Michael J Doherty
Head, Strategic Innovation, Pharma Dev; Exec Advisor, Foundation Medicine Inc.
Hoffmann-La Roche Ltd.

Part of the National Cancer Moonshot Initiative, the recently announced Oncology Center of Excellence (OCE) calls on the FDA to leverage the combined skills of regulatory scientists and reviewers with expertise in drugs, biologics, and devices, and to formalize an innovative, yet seamless cross-center regulatory approach to enhance the coordination of clinical review across oncology-related drugs, biologics, and medical devices. While OCE is focused on a single therapeutic area, this approach may eventually benefit other therapeutic areas, such as cardiovascular, neurodegenerative, and infectious diseases. This session will discuss OCE and the implications, and possibilities, related to the review of combination products. Our esteemed panel will discuss the reasons behind the formation of OCE, including the perceived benefits of a matrix organizational structure on the development and review of combination products and companion diagnostics. The current status of OCE, including the goals around collaboration with the other Centers, and next steps in the implementation will be discussed.

3:30-4:00PM — **Refreshment and Networking Break**

4:00-5:30PM — **Session 4: Combination Products on Capitol Hill**

Session Chair
David E. Paul, JD
US Regulatory Affairs, Policy and Strategy
Eli Lilly and Company

Speakers
Wade Ackerman, JD
Partner
Covington & Burling LLP

Grace Stuntz
FDA Policy Advisor
Senate HELP Committee
Republican Staff

Carla Cartwright, JD, LLM
Director, Global Regulatory Policy and Intelligence
Johnson & Johnson

Diane Macculloch Johnson, MS
Senior Director, North American Regulatory Affairs Policy and Intelligence
Johnson & Johnson

The past year has been a time of almost unprecedented congressional attention to improving the combination product development and review processes. Provisions addressing these matters have been included in both House and Senate bills ("21st Century Cures Act," and "The Combination Products Regulatory Fairness Act," respectively). In addition to these bills, there has been some discussion of interest in legislation for a potential "third-pathway;" and in 2017 Congress will consider PDUFA VI, the Technical Letter of which also addresses combination product development and review processes. The panel will overview these bills from the perspectives of industry, agency, and congressional staffers; discuss the Hill's interests in legislation; and explore the possible fates of these bills or their provisions.

5:30-6:30PM — **Networking Reception**

WEDNESDAY, OCTOBER 26

7:30AM-3:30PM	**Registration**
7:30-8:30AM	**Continental Breakfast and Networking**
8:30-9:00AM	**Keynote Address: Innovation in Medical Product Development: An Industry Perspective** **Session Chair** **John Barlow Weiner, JD** Associate Director Policy and Product Classification Officer, Office of Combination Products, Office of the Commissioner FDA **Keynote Speaker** **Jay P. Siegel, MD** Chief Biotechnology Officer and Head, Scientific Strategy and Policy Johnson & Johnson
9:00-10:30AM	**Session 5: Challenges and Opportunities of Differing Regulatory Paradigms for Drugs and Devices** **Session Chair** **John Towns, PhD** Senior Research Fellow, Regulatory, Devices, Director, Global CMC Regulatory Affairs Eli Lilly and Company **Speakers** **Steven B. Binion, PhD, MBA** Director - Policy, Technology and Communication, Corporate Regulatory Affairs Becton Dickinson **Nancy Stade, JD** Partner Sidley Austin LLP **Patricia Love, MD, MBA** Deputy Director, Office of Combination Products, OSPM, OMPT FDA **Robert Kelly** Senior Director, Regulatory CMC and Marketed Products Bayer Healthcare Pharmaceuticals **Diane Macculloch Johnson, MS** Senior Director, North American Regulatory Affairs Policy and Intelligence Johnson & Johnson Drugs and Devices are regulated by different FDA centers and are subject to different statutory laws and regulations. Combination products precipitate these differences by requiring both a sponsor and the agency to work across these regulatory demarcations to advance development of a single regulated product having either a drug or a device primary mode of action. In this session, a panel of experts from the FDA, the medical device industry, and the biopharmaceutical industry will discuss their perspectives on the impact of bringing two products with different independent regulatory requirements together into one combination product—on product development and review and, importantly, on innovation.
10:30-11:00AM	**Refreshment Break and Networking**

WEDNESDAY, OCTOBER 26

11:00AM-12:30PM

Session 6: Digital Health Technologies: Are They Combination Products? Does It Matter?

Session Chair
Rachel Turow, JD, MPH
Director, Regulatory Policy
Novo Nordisk Inc.

Moderator
Zach Rothstein, JD
Associate Vice President
AdvaMed

Speakers
Douglas C. Throckmorton, MD
Deputy Director, Regulatory Programs, OCD
CDER, FDA

Bakul Patel, MD
Associate Director for Digital Health, Office of the Center Director, CDRH
FDA

Danelle R. Miller, JD
Vice President, US Regulatory Policy and Intelligence
Roche Diagnostics

Rachel Turow, JD, MPH
Director, Regulatory Policy
Novo Nordisk Inc.

The application of digital technology to health care has exploded in recent years. FDA has made huge strides in clarifying how certain digital technologies may be regulated as medical devices, but questions remain regarding digital health technologies that fall into the category of combination products. This panel will discuss the challenges of regulating digital health technologies that touch on both the drug and device paradigms as well as the challenges of innovating in this space without a clear regulatory path or guidelines.

12:30-2:00PM

Luncheon and Networking

2:00-3:30PM

SESSION 7: The Future of the Inter-Center Collaboration at FDA

Session Chair
John Barlow Weiner, JD
Associate Director, Policy and Product Classification Officer, Office of Combination Products, Office of the Commissioner
FDA

Speakers
William Maisel, MD, MPH
Deputy Director for Science and Chief Scientist, Director, Office of Device Evaluation (Acting), Center for Devices and Radiological Health
FDA

Thinh X. Nguyen
Director, Office of Combination Products, OSMP, OC
FDA

Douglas C. Throckmorton, MD
Deputy Director, Regulatory Programs, OCD
CDER, FDA

Sheryl L. Lard Whiteford, PhD
Associate Director for Quality Assurance, Ombudsman
CBER, FDA

This session presents the forward-looking views of key FDA thought leaders about the future of innovative product development and how it may be supported by an evolving holistic approach characterized by collaboration across centers. Our panelists will discuss the vision for such collaboration, challenges in achieving it, and its potential benefits and impact on innovative therapies.

3:30-4:30PM

"Sweet Treats" Networking Reception