DIA

Combination Products Conference: Innovation and New Frontiers

Short Course: October 24 | Conference: October 25-26
Bethesda North Marriott Hotel and Conference Center | North Bethesda, MD

PROGRAM CHAIR

Rachel SW Turow, JD, MPH
Executive Counsel, Regulatory Law
Teva Pharmaceuticals Ltd.

PROGRAM COMMITTEE

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

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

Kirsten Paulson, MS, RAC
Senior Director, Global CMC Medical Devices
Pfizer Inc

Kim M. Quaintance-Lunn
Vice President and Head, US Regulatory Policy
Bayer

John Barlow Weiner, JD
Associate Director, Policy and Product Classification Officer, OCP, OC
FDA

Overview

The *Combination Products Conference: Innovation and New Frontiers* will examine the current regulatory ecosystem for combination product development and approval, including provisions of the 21st Century Cures Act, proposed PDUFA VI commitments, the implementation of new decision-making models at FDA, US regulatory developments, global regulatory changes, and global alignment efforts. In-depth treatment of digital and eHealth issues, labeling for combination products and complex generics, and CGMPs for combination products will be featured.

Highlights

- **TWO** Keynote Addresses
- In-depth analysis of 21st Century Cures provisions
- FDA Leadership panel with OCP, OCE, CDER, CBER, and CDRH
- **NEW!** Professional Posters Session
- Approved for 12 RAC Credits

Who Should Attend

Professionals involved in:

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

Schedule At-A-Glance

SHORT COURSE | TUESDAY, OCTOBER 24		ROOM
12:00-4:30PM	Short Course Registration	
1:00-4:30PM	**Short Course:** Combination Product Advanced Case Studies	Glen Echo
DAY ONE | WEDNESDAY, OCTOBER 25		**ROOM**
7:00AM-4:45PM	**Registration**	
7:00-8:15AM	Continental Breakfast, Exhibits, and Networking	Salon H
8:15-8:30AM	**Welcome and Opening Remarks**	Salon F-G
8:30-9:00AM	**Keynote Address:** FDA's Strategic Vision for Combination Products	Salon F-G
9:00-10:00AM	**Session 1:** FDA News Feed: 2017	Salon F-G
10:00-10:30AM	Refreshment, Posters, Exhibits, and Networking Break	Salon H
10:30-11:30AM	**Session 2:** 21st Century Cures: Combination Products Implications	Salon F-G
11:30AM-1:15PM	Luncheon, Exhibits, and Networking	Salon H
1:15-2:15PM	**Session 3:** Appropriate GMPs for Combination Products	Salon F-G
2:15-3:15PM	**Session 4:** Words Matter: Labeling Challenges Unique to Combination Products	Salon F-G
3:15-3:45PM	Refreshments, Posters, Exhibits, and Networking Break	Salon H
3:45-4:45PM	**Session 5:** Generics for Combination Products: It's Complicated	Salon F-G
4:45-6:00PM	Networking, Posters, and Exhibits Reception	Salon H
DAY TWO | THURSDAY, OCTOBER 26		**ROOM**
7:00AM-3:15PM	**Registration**	
7:00-8:15AM	Continental Breakfast, Exhibits, and Networking	Salon H
8:15-8:30AM	**Opening Remarks**	Salon F-G
8:30-9:00AM	**Keynote Address:** Combination Product Regulation – A Combination Perspective	Salon F-G
9:00-10:30AM	**Session 6:** Navigating Global Combination Product Regulations	Salon F-G
10:30-11:00AM	Refreshment, Posters, Exhibits, and Networking Break	Salon H
11:00AM-12:30PM	**Session 7:** Digital Health Combination Products: What's Next?	Salon F-G
12:30-2:00PM	Luncheon, Exhibits, and Networking	Salon H
2:00-3:15PM	**The View from the Top: FDA Panel**	Salon F-G

Learning objectives

At the conclusion of this conference, participants should be able to:

- Examine recently issued guidelines and regulations, including FDA's latest implementation efforts for 21st Century Cures in the combination product space
- Discuss the FDA final guidance for combination product GMPs and identify appropriate mechanisms for resolving GMP-related questions for combination products
- Describe the challenges associated with global registration of combination products and regulatory strategies for navigating differing requirements in different countries
- Explain recent regulatory changes for digital health products and their impact on digital health drug/device combination products
- Identify challenges associated with establishing bioequivalence for generic products as well as for combination products

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Type of Activity: Knowledge

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Continuing Education Credit Allocation

Short Course:
IACET: .3 CEUs; Pharmacy: 3.25 Contact Hours or .325 CEUs, 0286-0000-17-080-L04-P

Conference:
IACET: 1.1 CEUs
Pharmacy: 11 contact hours or 1.1 CEUs, 0286-0000-17-079-L04-P

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This educational activity may include references to the use of products for indications not approved by the FDA. Opinions expressed with regard to unapproved uses of products are solely those of the faculty and are not endorsed by the DIA or any of the manufacturers of products mentioned herein. Faculty for this educational activity was asked to disclose any discussion of unlabeled or unapproved uses of drugs or medical devices.

Reasonable accommodations will be made available to persons with disabilities who attend an educational activity. Contact the DIA office in writing at least 15 days prior to event to indicate your needs.

SHORT COURSE | TUESDAY, OCTOBER 24

12:30-4:30PM	**Short Course Registration**
1:00-4:30PM	**Short Course** Combination Product Advanced Case Studies The short course will explore a series of case studies of complex combination products legal and regulatory issues. This will cover areas such as digital health, primary modes of action, drug delivery systems, biologic-device issues, and complex generics. This dynamic and interactive course will allow you the chance to engage with instructors and your peers to assess and analyze the regulatory challenges posed in both hypothetical and real-life case studies. At the conclusion of this short course, participants should be able to: • Describe the more complex combination products issues arising at FDA • Evaluate the FDA's position on complex combination products regulatory issues • Apply concepts learned to resolve challenges in the work setting with complex combination products **Instructors** **Nancy K. Stade, JD** Partner Sidley Austin LLP **Rachel SW Turow, JD, MPH** Executive Counsel, Regulatory Law Teva Pharmaceuticals Ltd.

DAY ONE | WEDNESDAY, OCTOBER 25

7:00AM-4:45PM	**Registration**
7:00-8:15AM	Continental Breakfast, Exhibits, and Networking
8:15-8:30AM	**Welcome and Opening Remarks**
8:30-9:00AM	**Keynote Address** FDA's Strategic Vision for Combination Products **Keynote Speaker** **Thinh X. Nguyen** Director, Office of Combination Products, OSMP, OCFDA
9:00-10:00AM	**Session 1** FDA News Feed: 2017 **Session Chair** **Rachel SW Turow, JD, MPH** Executive Counsel, Regulatory Law Teva Pharmaceuticals Ltd. FDA regulation of combination products has seen huge advances in recent years. Both PDUFA VI and 21st Century Cures have included programmatic changes for combination products, and FDA has been busy issuing guidance and regulations as well as implementing organizational changes to aid in the review of combination products. The Office of Combination Products will give an update on all of these aspects and forecast some future issues we might see addressed under the new FDA Commissioner. **John Barlow Weiner, JD** Associate Director, Policy and Product Classification Officer, Office of Combination Products, Office of the Commissioner FDA
10:00-10:30AM	**Refreshment, Posters, Exhibits, and Networking Break**

DAY ONE | WEDNESDAY, OCTOBER 25

10:30-11:30AM

Session 2
21st Century Cures: Combination Products Implications

Session Chair
Carla Cartwright, JD, LLM
Director, Federal Affairs
Johnson & Johnson

Explore how the combination product provisions of 21st Century Cures are being implemented by FDA and industry, looking at what is currently in place at FDA and what remains to be done. We will look at how reforms that were already underway, such as the CP Policy Council overlay with the 21st Century Cures requirements and PDUFA VI commitments for FDA. Exploring this from the vantage points of FDA, industry, and those with insights on the legislative intent will help us consider what more needs to be done moving forward and possibly define "success."

21st Century Cures from Three Sides: Hill, Agency, and Industry Perspectives

Kalah Auchincloss, JD, MPH
Senior Vice President, Regulatory Compliance
Greenleaf Health, Inc.

E. Cartier Esham, PhD
Executive Vice President, Emerging Companies Section; Vice President, Science amd Regulatory Affairs
Biotechnology Innovation Organization

11:30AM-1:15PM

Luncheon, Exhibits, and Networking

1:15-2:15PM

Session 3
Appropriate GMPs for Combination Products

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

The issues surrounding Good Manufacturing Practices (GMPs) for combination products can be complex. This session will review the FDA final guidance, Current GMP requirements for combination products, on streamlined GMPs for combination products. Common GMP issues and approaches for addressing questions or concerns will be discussed. The session will also explore how the 21st Century Cures combination product provisions can be leveraged to resolve GMP issues.

Kirsten Paulson, MS, RAC
Senior Director, Global CMC Medical Devices
Pfizer Inc

Diana Salditt
Senior Director, Regulatory Advocacy Policy
Medtronic

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

2:15-3:15PM

Session 4
Words Matter: Labeling Challenges Unique to Combination Products

Session Chair
Kirsten Paulson, MS, RAC
Senior Director, Global CMC Medical Devices
Pfizer Inc

Cross-labeled combination types range from companion therapeutics with diagnostic tests that must be used together, to loosely structured labeling references to use with a class of medical products. Can a new device recommend use with a marketed drug without changing the drug label? What happens when one of the cross-labeled products changes? This session will include discussion of challenges with legally labeling these related products and how to avoid pitfalls both pre and postmarket.

Heidi Gertner
Partner
Hogan Lovells US LLP

Ryan McGowan
Associate Director, Combination Products
AstraZeneca

Representative Invited
FDA

3:15-3:45PM

Refreshment, Posters, Exhibits, and Networking Break

3:45-4:45PM

Session 5
Generics for Combination Products: It's Complicated

Session Chair
Kim M. Quaintance-Lunn
Vice President and Head, US Regulatory Policy
Bayer

FDA Commissioner Gottlieb has made the approval of generics including complex generics, especially drug-device combinations, a top priority for the agency. This session will focus on the challenges associated with generics for combination products, ongoing regulatory science initiatives at CDER, and legislative changes designed to accelerate the availability of these products.

Kurt R. Karst, JD
Director, Prescription Drugs and Biologics, Corporate Transactions, Enforcement
Hyman, Phelps & McNamara, PC

Robert A. Lionberger, PhD
Director, Office of Research and Standards, Office of Generic Drugs
CDER, FDA

Cory A. Wohlbach
Senior Director, Regulatory Affairs
TEVA Pharmaceuticals United States of America Inc.

4:45-6:00PM

Networking, Posters, and Exhibits Reception

DAY TWO | THURSDAY, OCTOBER 26

7:00AM-3:15PM — **Registration**

7:00-8:15AM — **Continental Breakfast, Exhibits, and Networking**

8:15-8:30AM — **Opening Remarks**

8:30-9:00AM — **Keynote Address**

Combination Product Regulation – A Combination Perspective

Keynote Speaker

Kate Cook
Executive Vice President, Drugs and Biological Products
Greenleaf Health

Discuss FDA's assignment and regulation of combination products from a unique perspective – that of someone who helped develop key combination product regulations and policies while at FDA, and who now works as a consultant on behalf of sponsors seeking to develop combination products.

9:00-10:30AM — **Session 6**

Navigating Global Combination Product Regulations

Session Co-Chairs

Carla Cartwright, JD, LLM
Director, Federal Affairs
Johnson & Johnson

Kim M. Quaintance-Lunn
Vice President and Head, US Regulatory Policy
Bayer

Global regulatory requirements for combination products continue to evolve. This session will provide insight into how to navigate the disparate requirements, and a look to future developments in this space, including opportunities for greater harmonization and convergence.

Demetra S. Macheras, MBA
Director, Regulatory Policy and Intelligence
AbbVie, Inc.

Nicole Smith
Senior Director, Global Regulatory Affairs Policy and Intelligence Medical Devices
Johnson & Johnson

Elizabeth Baker
Group Manager Licensing Division Medicines and Healthcare products Regulatory Agency (MHRA),
United Kingdom

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

11:00AM-12:30PM — **Session 7**

Digital Health Combination Products: What's Next?

Session Co-Chairs

Rachel SW Turow, JD, MPH
Executive Counsel, Regulatory Law
Teva Pharmaceuticals Ltd.

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

While FDA regulation of digital health products has become increasingly clear for medical devices, the regulation of these products as combination products is still coming into focus. Especially for products that are not regulated at all as pure medical devices, once they are attached to a drug, the questions remain unanswered and the regulatory pathway is challenging to define. This session will give an update on many of the recent regulatory changes for digital health products and will seek answers to some of the more difficult regulatory questions through the use of hypotheticals.

21st Century Cures Act and Beyond — Implications for Digital Health

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

Case-Study: BetaConnect and MyBetaApp

Resmi John
Associate Director, Regulatory Affairs
Bayer Healthcare

Panelists

Mike Koenig
Deputy Director, CMC Regulatory Affairs
Bayer

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

Representative Invited
FDA

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

2:00-3:15PM — **The View from the Top: FDA Panel**

Session Chair

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

Medical Product Center, Office of Combination Products, and Oncology Center of Excellence leadership will discuss plans, priorities and challenges for combination products, enhancing coordination and collaboration more broadly, and the future face of FDA as the Agency addresses increasingly complex, cross-cutting medical products.

Panelists

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

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

Diane Maloney, JD
Associate Director for Policy
CBER, FDA

Angela C. Krueger
Acting Deputy Director, Office of Device Evaluation, CDRH
FDA

3:15PM — **Conference Adjourned**