### TUESDAY, DECEMBER 5TH, 2017

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>7:15 am</td>
<td>Breakfast and Registration in the Renaissance Foyer</td>
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<tr>
<td>8:00 am</td>
<td><strong>Informal Breakfast Roundtable Discussion</strong></td>
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<td><strong>Renaissance B</strong></td>
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<td></td>
<td>Matthew Might Ph.D., Director, Hugh Kaul Precision Medicine Institute, University of Alabama at Birmingham</td>
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<td></td>
<td>Sarfaraz K. Niazi, Ph.D, Adjunct Professor, Department of Biopharmaceutical Sciences, UIC College of Pharmacy</td>
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<td>Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, Food and Drug Administration</td>
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<tr>
<td>8:45 am</td>
<td><strong>Chairman's Opening Remarks</strong></td>
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<td></td>
<td><strong>Renaissance A</strong></td>
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<td></td>
<td>Nielsen Hobbs, Editor, The Pink Sheet</td>
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<tr>
<td>8:55 am</td>
<td><strong>Fireside Chat with FDA Commissioner</strong></td>
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<td><strong>Renaissance A</strong></td>
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<td></td>
<td>Scott Gottlieb, MD, Commissioner of Food and Drugs, The Food and Drug Administration (FDA)</td>
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<td>Nielsen Hobbs, Editor, The Pink Sheet</td>
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<tr>
<td>9:30 am</td>
<td><strong>Keynote Address: The Center for Drug Evaluation and Research in 2017 and the Year Ahead</strong></td>
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<td>Hear an update from CDER on current initiatives, challenges and accomplishments of 2017 and what's in store for the year ahead</td>
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<td>Janet Woodcock, MD - Director, Center for Drug Evaluation &amp; Research (CDER), U.S. Food and Drug Administration (FDA)</td>
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<tr>
<td>10:00 am</td>
<td><strong>CDER Office of New Drug Update</strong></td>
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<td>Hear an update on developments in OND and what is currently in the pipeline for 2018.</td>
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<td>Patrick Frey, Senior Advisor to the Director, Office of New Drugs, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA)</td>
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<td>10:30 am</td>
<td>Networking and Refreshment Break in the Renaissance Foyer</td>
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<td>11:00 am</td>
<td><strong>Update on Drug Safety and Post Market Surveillance</strong></td>
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<td>Gerald Dal Pan, MD, MHS - Director, Office of Surveillance and Epidemiology, U.S. Food and Drug Administration (FDA)</td>
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<tr>
<td>11:30 am</td>
<td><strong>Industry Panel Follow up on Office of New Drug Update</strong></td>
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<td><strong>Moderator:</strong> Meg Tirrell, Reporter Biotech and Pharma, CNBC</td>
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<td><strong>Confirmed Panelists:</strong></td>
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<td>Karen Hauda, Senior Director, Regulatory Policy, Novo Nordisk</td>
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<td>John Maraganore, Ph.D., Chief Executive Officer, Alnylam Pharmaceuticals, Inc</td>
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<td>Peter Honig, SVP, Worldwide Safety and Regulatory, Pfizer Inc</td>
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<td>12:30 pm</td>
<td>Networking Lunch in Fireview and Fifteen Squares Room on Lobby Level</td>
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<td>1:30 pm</td>
<td><strong>Understanding the Emerging Role of Patient Reported Outcomes (PRO) and FDA Use in Drug Programs</strong></td>
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<td><strong>Moderator:</strong> Kay Holcombe, (Fmr) Senior Vice President for Science Policy, Biotechnology Innovation Organization</td>
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<td><strong>Panelists:</strong></td>
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<td>Cynthia Grossman, Ph.D., Associate Director, Science of Patient Input, FasterCures, Milken Institute</td>
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<td>Christine McSherry, Executive Director, The Jett Foundation</td>
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<td>Carmen Bozic, Senior Vice President, Global Development, Biogen</td>
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<td>2:15 pm</td>
<td><strong>Update: Current Political and Regulatory Proposals and Developments Impacting Pharma and Healthcare</strong></td>
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<td>Hector De La Torre - Executive Director, Transamerica Center for Health Studies</td>
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<td>2:45 pm</td>
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### TUESDAY, DECEMBER 5<sup>th</sup>, 2017 (continued)

**3:15 pm**  **The Opportunities and Challenges of Expanded Access**  
*Moderator:* Jess Rabourn, Managing Director, **Wide Trials**  
*Panelists:*  
Jonathan Jarow, Senior Consultant Health Policy, Center For Drug Evaluation and Research, (CDER), **Food & Drug Administration (FDA)**  
Shimere Williams Sherwood, Ph.D, Associate Director, NIH and FDA Advocacy, Policy & Advocacy, **American Society of Clinical Oncology**  
Beth E. Roxland, J D., M.Bioethics, Senior Consultant on Law, Ethics and Policy  
Associate, Division of Medical Ethics, **NYU Langone Medical School**  
Martin Naley, General Manager, US, **My Tomorrows**

**4:00 pm**  **Keynote Fireside Chat: When Science Becomes Medicine**  
Sit in on a discussion on the intersection of ethics, innovation and precision medicine, from patient to pill  
Matthew Might Ph.D., Director, Hugh Kaul Precision Medicine Institute, **University of Alabama at Birmingham**; Strategist, **The White House**  
Nicole Fisher, Contributor, **Forbes Magazine**, founder & CEO, **HHR Strategies**

**5:00 pm**  Cocktail Reception in the Renaissance Foyer

### WEDNESDAY, DECEMBER 6<sup>th</sup>, 2017

**7:15 am**  Breakfast and Registration in the Renaissance Foyer

**7:45 am - 8:30 am**  **Breakfast RoundTable Discussion: The Sustainability of Healthcare Funding**  
*Moderator:* William Looney, Executive Editor, **Informa Pharma Intelligence**  
*Panelists:*  
Kenneth I Kaitin, PhD, Prof of Medicine and Dir, **Tufts Center for Drug Development**  
Jay Roberts, Chief Operating Officer and EVP, **Cancer Genetics Inc.**  
Sudeep S Parikh, PhD, SVP and MD, **DIA Americas**  
Indranil Bagchi, PhD, VP and Franchise Head, **Novartis Oncology**

**8:40 am**  **Chairman's Opening Remarks**  
Nielsen Hobbs, Editor, **The Pink Sheet**

**8:45 am**  **Opening Keynote Address: Partnering Opportunities with Industry to Solve Market Challenges**  
Seema Verma, Administrator, **Center for Medicare and Medicaid Services (CMS)**

**9:05 am**  **Fireside Chat: Question and Answer Session with the Administrator, CMS**  
Seema Verma, Administrator, **Center for Medicare and Medicaid Services (CMS)**  
*Moderator:* Nielsen Hobbs, **The Pink Sheet**

**9:30 am**  **Pricing, Value and Leverage: Addressing the Ever-Growing Cost of Drugs Through New Channels**  
*Moderator:* Meg Alexander, Head, Reputation & Risk Management Practice, **InVentiv Health**  
*Panelists:* Hervé Hoppenot, Chairman, President, and Chief Executive Officer, **Incyte**  
Jonathan Jarow, Senior Consultant Health Policy, Center for Drug Evaluation and Research, (CDER), **Food & Drug Administration (FDA)**  
Lindsay A. Rosenwald, MD, Chairman, President and CEO, **Fortress Biotech**

**10:15 am**  Networking and Refreshment Break in the Renaissance Foyer

**10:45 am**  **Obstacles, Reimbursement, and Leverage Opportunities for Boosting Competition and Adoption of Biosimilars in US Markets**  
*Moderator:* Nicholas Florko, Associate Editor, **Inside Health Policy**  
Aaron Hakim - Researcher, **Yale School of Medicine**  
Sarfaraz K. Niazi, Ph.D., Adjunct Professor, Department of Biopharmaceutical Sciences, **UIC College of Pharmacy**  
Joe Franklin JD, PhD, Associate Director for Policy, Therapeutic Biologics and Biosimilars Staff (TBBS), Office of New Drugs, **CDER, FDA**  
*Speaker TBD, The Biosimilars Forum*
### Wednesday, December 6th, 2017

#### 11:30 am

**Fast Track vs Breakthrough Therapy Designation - Small Business Perspective**

Catherine Melfi, Chief Regulatory Officer, **Omeros Corporation**

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#### 12:00 pm

**Networking Lunch, Renaissance East**

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#### 1:00 pm

**Rare Diseases: Trends, Developments, and PRVs**

*Moderator: InVentiv Health*

*Panelists:*
- Ron Cooper, President and CEO, **Albireo Pharma**
- Michael Spector, President and CEO, **Caelum BioSciences**
- Jonathan Goldsmith MD, Associate Director Rare Disease Program, Center for Drug Evaluation and Research (CDER) **Food and Drug Administration (FDA)**

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#### 1:45 pm

**Off-Label Developments: The Future of Product Communications**

*Moderator: Nielsen Hobbs, Editor, The Pink Sheet*

*Panelists:*
- Peter Marchesini, COO, **Alamo Pharma Services**
- Kevin Ryan, Senior Director, Ethics & Compliance Department, **Novo Nordisk Inc**
- *Panelists to be added*

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#### 2:30 pm

**The Impact and Implications of the “Right to Try” Movement**

*Moderator: Meg Tirrell, Reporter Biotech and Pharma, CNBC*

*Panelists:*
- Alison Bateman-House, Ph.D., Division of Medical Ethics, **NYU Langone Health**
- Christina Sandefur, Executive Vice President, **Goldwater Institute**
- Tom Watson, Executive Director, **TW Consulting Group**
- Chris Garabedian, Chairman, **Xontogeny LLC**
- *Panelists to be added*

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#### 3:15 pm

**Conference Concludes**

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### Wednesday, December 6th, 2017 • Concurrent Half-Day Workshop

**Innovations in the Science of Patient Input**

Hosted by **FasterCures, a center of the Milken Institute**

1:00pm - 4:00pm, Renaissance B

*Workshop Speakers:*
- Kim Mccleary, Managing Director, Acting Executive Director, **FasterCures**
- Gregory Daniel Ph.D., Deputy Director and Clinical Professor, **Duke-Margolis Center for Health Policy**
- Jeff Shuren, MD, Director at Center for Devices and Radiological Health, **Food and Drug Administration (FDA)**
- M. Suzanne Schrandt, Director, Patient Engagement, **Arthritis Foundation**
- Josh Seidman, Senior Vice President, **Avalere Health**
- Anindita Saha, Director, External Expertise and Partnerships, Center for Devices and Radiological Health, Office of the Center Director, **U.S. Food and Drug Administration**
- Josh Seidman, Senior Vice President, **Avalere Health**
- Sonya Dumanis PhD, Senior Director of Innovation, **Epilepsy Foundation**
- Erin Holve Ph.D., Director, Health Care Reform and Innovation Administration, Department of Health Care Finance, **Government of the District of Columbia**
- Stephanie Christopher, Program Director, Science of Patient Input, **Medical Device Innovation Consortium**
- Jamie Hamilton, Associate Director, Research Programs, **The Michael J Fox Foundation for Parkinson's Research**
- Jamie Sullivan, Vice President, Public Policy & Outcomes, **COPD Foundation**