AdvaMed Innovation Summit:
Diving Into the Ever-Changing Health Care Landscape and the New Digital Frontier

Sidley Austin LLP | 1501 K Street NW | Washington, DC
April 11-12, 2017

April 11, 2017

8:30 – 9:00 am **Registration Check-In and Continental Breakfast**

9:00 – 9:05 am **Welcome and Introductions**

9:05 – 9:45 am **Enabling Self-Care Through MedTech: Future Trends in Healthcare**
Corinna E. Lathan, Board Chair and CEO, AnthroTronix, Inc.

9:45 – 10:30 am **3D Printing from Tooling, Prototyping, Production, & Customizable Implants and the Impact on MedTech for the Future**
Vijay Iyer, Vice President, Business Development, BioEnterprise

From tooling, prototyping, production and customizable implants, additive manufacturing is impacting how biomedical products are created. As Northeast Ohio is poised to become a national leader in additive manufacturing, Vijay Iyer, Vice President of Medical Devices for Cleveland-based BioEnterprise, is prepared to discuss this transformative, time-saving and cost-effective approach to biomedical design and development.

10:30 – 11:45 am **Designing Clinical Studies to Meet Regulatory and Reimbursement Stakeholders Needs**
***Moderator**: Seth Goldenberg, Director, Product Development Strategy, NAMSA*
***Panelists**:*
Michael Branagan-Harris, CEO, Device Access UK Ltd
Kathy Sherwood, Director, Global Market Access, Boston Scientific
Ken Skodacek, Policy Analyst, FDA/CDRH
Richard Tuson, CEO, Health Analytical Solutions Ltd
Tom Clutton-Brock, Chair of NICE Interventional Procedures Advisory Committee

Patient access for safe and effective medical devices is key for all medical device companies. It can be challenging from regulatory approval to payer coverage. Increasing price pressure demonstrates the need to collect clinical data to strengthen reimbursement claims. It is essential that clinical leaders collaborate with payer, reimbursement teams and market access teams to incorporate data collection that will support product goals from conception to post-market. There are several global initiatives and opportunities to address this concern. This session will focus on trying to help device developers to understand the strategies for gaining access to both regulators and payers for their products early enough so that they can design clinical studies to address those concerns.

11:45 – 12:45 pm **Networking Lunch**

12:45 – 2:00 pm **Innovation in Clinical Evidence Generation, Synthesis and Appraisal to Advance Regulatory Science for the Total Product Life Cycle**

***Moderator**: Dan Schwartz, Medical Device Innovation Consortium (MDIC)*

***Panelists**:*

Jing Xie, Medical Device Innovation Consortium (MDIC)
Telba Irony, Deputy Director, Office of Biostatistics and Epidemiology, FDA
Owen Faris, Clinical Trial Director, FDA
Danica Marinac-Dabic, Director of Epidemiology, FDA

- MDIC Mission and Initiatives in Advancing Regulatory Science
- Virtual Patient
- Role of Real World Evidence (RWE) in supporting Premarket Clinical Trials and Regulatory Decision Process: Current State and Opportunities
- Capitalizing on Robust NEST Infrastructure and Novel Methodologies to Shift Premarket Data Collection to Post-Market

2:00 – 3:15 pm **21st Century Cures Act Panel Discussion**

***Moderator**: Elizabeth Pika Sharp, Senior Vice President and Managing Director, Federal Government Affairs, AdvaMed*

***Panelists**:*

Diane Johnson, Senior Director, North America Regulatory Affairs Policy and Intelligence, Medical Devices, Johnson & Johnson
Robert Horne, Senior Vice President, Horizon Government Affairs
Stephanie Hales, Partner, Healthcare and Government Strategies, Sidley Austin

- Overview and walkthrough of the act
  - Patient experience
  - Breakthrough devices
- How the act will affect the medical device industry
- Implications for the future

3:15 – 3:30 pm **Break**

3:30 – 4:45 pm **Advancing the Art and Science of Regulatory Patient Preference Assessment**

***Moderator**: Stephanie Christopher, Program Director, Medical Device Innovation Consortium (MDIC)*

Panelists:

Kathryn O'Callaghan, CDRH Assistant Director for Strategic Programs, FDA
William Murray, President/CEO, Medical Device Innovation Consortium (MDIC)
Lauren McLaughlin, The Michael J. Fox Foundation for Parkinson's Research
Kara L. Haas, Global Regulatory Affairs Policy and Intelligence, Medical Device Evidence and Outcomes, Johnson & Johnson

The 2015 release of draft guidance on the inclusion of patient preference information in the regulatory review of medical technology, as well as the CDRH 2016-17 strategic priority to partner with patients, confirm CDRH's commitment to engagement with patients across the device product lifecycle. The Medical Device Innovation Consortium (MDIC), a leading voice in the integration of patient preferences into benefit-risk analysis, along with CDRH and device company sponsors recognize that there are a number of

opportunities to advance the science of patient preference assessment and encourage medical device companies to undertake patient preference studies. In order for sponsors to submit patient preference information, and for regulators to consider that information in their benefit-risk analysis, both the sponsors and the regulators must have confidence that the patient preference data is valid and collected by scientifically rigorous methods. This panel will feature perspectives from CDRH and MDIC about the opportunities to continue to advance the science of patient preference assessment and encourage medical device companies to consider undertaking their own patient preference studies, including advances in methodology and factors sponsors should consider when selecting a patient preference assessment method and undertaking patient preference studies.

4:45 – 6:00 pm **Networking Reception**

April 12, 2017

8:30 – 9:00 am **Continental Breakfast**

9:00 – 10:15 am **Three Issues You Need to Know Concerning 'Connected' Medical Devices**
***Moderator**: Elizabeth Shah; Attorney; Bookoff McAndrews, PLLC*
***Panelists**:*
Jeffrey K. Shapiro; Director; Hyman, Phelps & McNamara, P.C.
Amy Mushahwar; Counsel & Chief Information Security Officer; ZwillGen PLLC
Christopher Agrawal; Partner; Bookoff McAndrews, PLLC

As internet connected medical devices grow in popularity, medical device companies now find themselves contending with a slew of new issues. Medical device companies need to consider the management of patient data within a device and across platforms, including issues of data encryption, security, and HIPAA concerns. The regulatory landscape is changing as the Food and Drug Administration regulates healthcare-related applications for users and provides recommendations for mitigating and managing cybersecurity threats. Additionally, medical device companies need to reassess how to patent and protect medical devices that interact with a larger network and may work in cooperation with other, separate components. This panel will address three of the major topics that medical device companies need to be aware of when developing and releasing connected medical devices.

10:15 – 10:30 am **Break**

10:30 – 11:45 am **Medical Software Post-21st Century Cures: Fostering Innovation or Confusion**
***Moderator**: Zach Rothstein, Associate Vice President, Technology & Regulatory Affairs, AdvaMed*
***Panelists**:*
Pat Baird, Head of Global Software Standards, Philips
Michelle Jump, Principal Regulatory Affairs Specialist, Stryker
Nathan Brown, Partner, Akin Gump Strauss Hauer & Feld LLP

11:45 am **Adjournment**