Medical Devices: FDA Regulation in the Era of Technology and Innovation

June 6, 2019
South San Francisco, CA

Conference Agenda

8:15–8:55 AM	**Registration and Continental Breakfast**
8:55–9:00 AM	**FDLI Welcome** **Laura Brown**, Director of Educational Programs, FDLI **Jeffrey Shapiro**, Director, Hyman, Phelps & McNamara, PC and Chair, Medical Devices: FDA Regulation in the Era of Technology and Innovation Conference
9:00–9:45 AM	**Keynote Address** **Bakul Patel**, Director, Division of Digital Health, CDRH, FDA
9:45–10:45 AM	**The Promise of Digital Health: How Is FDA Adapting Its Regulatory Approach to This Exploding New Technology?** This session will cover recent vast technological advancements in digital health, including incorporation of wearable technologies, robotics, and virtual reality, to name just a few. These technologies aim to dramatically improve patient care. Panelists will discuss FDA's approach to regulating these new technologies, including the impact of the 21st Century Cures Act, 510(k) reform, combination products, and the Software Precertification Pilot Program (Pre-Cert). **Carla Cartwright**, Director, Global Regulatory Policy, Johnson & Johnson **Christina Kuhn**, Associate, Covington & Burling LLP **Randall Ortman**, Product Counsel, Verily Life Sciences LLC *Moderated by* **Ian Pearson**, Senior Associate, Jones Day
10:45–11:00 AM	**Coffee and Networking Break**
11:00–12:00 PM	**De Novo Clearance is Increasingly Important as a Pathway to Market for New Technologies: How Is the Program Working Now, and What Does the Future Look Like?** FDA's original device regulations were based on 1970s technology. More than 40 years later, developers are creating completely new device types that could not even have been envisioned in the 1970s. In order to reconcile these new device types with the classification regulations and the 510(k) program,

sponsors are increasingly pursuing the de novo process. This panel will discuss FDA's streamlining of the de novo process and the recently proposed de novo regulation, which, when finalized, will codify the pathway in existence since 1997. What is the process? Does it work? Is it proving a practical success in integrating new technologies? When is it most likely to be required? Speakers will also cover FDA's decision to leverage the de novo pathway to include the Pre-Cert program, recent de novo requests that were granted, and special controls.

Sergio de del Castillo, De Novo Program Lead, CDRH, FDA
Paul Gadiock, Counsel, Wilson Sonsini Goodrich & Rosati
Ankur Kaushal, Senior Manager, Regulatory Affairs, Roche Sequencing Solutions
Moderated by **Kristin Davenport**, Of Counsel, Covington & Burling LLP

12:00–1:00 PM **Networking Luncheon**

1:00–2:00 PM **The Unique Regulatory, Legal and Practical Challenges of Artificial Intelligence/Machine Learning**

The ever-evolving nature of artificial intelligence/machine learning offers vast opportunities in digital health care. A key regulatory challenge is that FDA normally requires premarket review of significant product modifications. One of the key features of AI/ML, however, is the potential for the software to modify its performance in the field based on real-world learning and adaptation. FDA has recently released a discussion paper that proposes a new regulatory framework to enable efficient approval of AI/ML-based software while still protecting patients. During this panel we will explain FDA's new framework and discuss how it might work and/or be improved. We will also address other practical questions related to development of AI/ML based software such as product liability concerns.

Alex Cadotte, Biomedical Engineer, CDRH, FDA
Carmine Jabri, President and CEO, E.M.M.A. International Consulting Group, Inc.
Ajit Narang, Senior Legal Director, Advanced Insulin Management, Medtronic
Moderated by **Jeffrey Shapiro**, Director, Hyman, Phelps & McNamara, PC Chair, Medical Devices: FDA Regulation in the Era of Technology and Innovation Conference

2:00–2:45 PM **How is 3D Printing Revolutionizing the Medical Device Industry?**

3D printing is providing exciting technological possibilities for industry by creating the concept of personalized medical devices, models for clinical trials, and other possibilities. How is FDA's regulation of 3D printers and printed medical devices both similar and different from that of other devices? The panel

will discuss how companies can successfully navigate FDA regulation of this technology, as well as address the all-important reimbursement issues.

Mark Levy, Partner, Eckert Seamans Cherin & Mellott, LLC
Farah Tabibkhoei, Senior Litigation Associate, Reed Smith
Richard Underwood, Managing Engineer, Exponent, Inc.
Moderated by **Janet Rozovics Gottlieb,** Executive Director, Global Medical Promotional Review, Allergan, Inc.

2:45–3:00 PM **Coffee and Networking Break**

3:00–3:45 PM **Human Factors in Digital Health**

A medical device user must be able to operate the device safely and as intended. FDA requires manufacturers to consider human factors in the design of medical device software, i.e., to consider human behavior, abilities, limitations, and other user characteristics, as well as to include potential user hazards in risk management assessments and validation testing. What do these potential hazards entail? How can manufacturers determine these interactions? What kind of testing and clinical human factor studies does FDA require?

Kimberly Kontson, Biomedical Engineer, CDRH, FDA
Yarmela Pavlovic, Partner, Hogan Lovells US LLP
Kimberly Snyder, Senior Partner, Validant
Moderated by **Karen Corallo**, Of Counsel, Skadden, Arps, Slate, Meagher & Flom LLP

3:45–4:30 PM **Overcoming Potential Regulatory and Practical Pitfalls**

This panel will discuss FDA requirements to protect against side effects of technological innovation, such as safeguards against cyber-attacks and hacking. Speakers will also discuss practical considerations associated with technology, including patient data and privacy protection, reimbursement, and electronic signatures.

Michael Gaba, Shareholder, Polsinelli PC
Tyrone Heggins, Senior Manager Quality – Product Security, BD
Vernessa Pollard, Partner, McDermott Will & Emery

4:30 PM **Closing Remarks and Adjournment**