

**U.S. Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Patient Engagement Advisory Committee (PEAC) Meeting
Holiday Inn Gaithersburg**

AGENDA

September 10, 2019

Tuesday, September 10, 2019

8:00 AM – 5:30 PM

- 8:00 AM **Patient Engagement Advisory Committee (PEAC) Call to Order**
Paul T. Conway, Chairperson, PEAC
- 8:20 AM **Welcome and Opening Remarks**
Norman “Ned” Sharpless, M.D., Acting Commissioner, FDA
- 8:35 AM **Updates from the Patient Science & Engagement Program**
Michelle Tarver, M.D., Ph.D., Director, Patient Science & Engagement Program, FDA
- 8:45 AM **Medical Device Cybersecurity: A Total Product Lifecycle Approach**
Seth Carmody, PhD, Cybersecurity Program Lead, Office of Strategic Partnerships & Technology Innovation, CDRH, FDA
- 8:55 AM **Cybersecurity and Medical Device Updates**
Kevin Fu, PhD, Associate Professor, The University of Michigan
- 9:05 AM **Physician Perspective on Cybersecurity**
Christian Dameff, M.D., University of California San Diego
- 9:15 AM **Cybersecurity Vulnerabilities**
Jay Radcliffe, Thermo Fischer Scientific
- 9:25 AM **CDRH Communication of Medical Device Vulnerabilities and Safety Concerns**
Jodi Duckhorn, Acting Deputy Director, Office of Communication and Education, CDRH, FDA

- 9:35 AM **Cybersecurity Vulnerability Communication**
Catina O'Leary, PhD, LMSW, President/CEO, Health Literacy Media
- 9:45 AM **Industry Perspective on Cybersecurity Communication**
Nastassia Tamari, Associate Director, Cybersecurity Incident Response, Becton Dickinson (BD)
- 9:55 AM **Patient Perspective on Cybersecurity Communication**
Karen McChesney, Juvenile Diabetes Research Foundation (JDRF)
- 10:05 AM **Open Committee Discussion**
- 10:35 AM **BREAK**
- 10:45 AM **Open Public Hearing**
- 12:15 PM **LUNCH**
- 1:00 PM **Roundtable Discussions**
- 2:00 PM **Roundtable Summations**
- 2:30 PM **Open Public Comment**
- 2:45 PM **Open Committee Discussion**
- 3:00 PM **BREAK**
- 3:15 PM **Committee Discussion of FDA Questions**
- 5:15 PM **Closing Remarks**
- 5:30 PM **Adjourn**