National Academy of Science
Biomedical Engineering Materials Applications Roundtable (BEMA) Winter 2019 Meeting
March 25, 2019

Topic: Law and Medical Devices: The Complex, Interdigitated, Essential and Evolving World
An Opportunity for Understanding, Clarity and the Path Forward

Sunday March 24, 2019
Working Dinner (Carmines Restaurant, 425 7th St., NW. Washington D.C.
Seating @ 6:00 p.m.)

Dinner Talk – Tag team

1. Law and Medical Device 101: An Introduction for the Non-Lawyer - setting the stage for the Next Day - US Law, Natural Hx of Law - Medical Device Interface, Law In/for Innovation
   Marv Slepian MD Prof Med/ BME, Director – ACABI AZ Center for Accel Biomed Innovation – UA
2. How do we educate the next generation of Device/Tech-savvy Lawyers?
   Marc L. Miller JD – Dean, Rogers College of Law - UA

Monday March 25, 2019
8:00 a.m. Breakfast

8:30 a.m. Welcome and Introductions Becky Bergman, Art Coury, BEMA Co-Chairs

8:40. a.m. Materials Regulation – "Fuel in the Tank" - How do we Keep the Medical Device Industry Engine Running?
Topics covered: sourcing, auditing, maintaining supply chain (in evolving world view), substitute materials, new materials, US/OUS, liability, case example - P4HB polymers
David Martin PhD – Chief Scientific Officer and SVP R&D, Tepha Medical Devices, Lexington, MA
Stephen Rhodes, MS = Streamline Regulatory, Former Director, IDE, and HDE Programs – FDA

9:40 a.m. Intellectual Property – Evolution in the IP world - Where are we? What is coming?
Topics covered: IP process 2019, New Laws, Major cases to consider as examples
Rivka Monheit, JD – Pabst Patent Group, Atlanta GA

10:30 a.m. Break

10:45 a.m. FDA perspective – Evolution of CFR 21 – The "Looking in the Mirror View"
2 speakers to provide inside vs outside view
Inside view - FDA *Nancy K. Stade JD, Sidley Austin LLP (fmr Dep. Dir. Policy FDA CDRH)*
Outside view – *Peter Barton Hutt JD*, Harvard Law/Covington & Burling LLP
(Former Chief Counsel of FDA "71 – '75)
Topics: Evolving devices, hybrids, FDASIA device-related provisions, MDUFA IV, AI and modeling, rapidity of approval and similar current topics

12:00 p.m. Working LUNCH (12:00 – 12:15 Grab Lunch for working session)

12:15 p.m. Big Data, Artificial Intelligence, Medical Devices and Health Care: Emerging Legal and Ethical Issues *I. Glenn Cohen, JD*, Director – Petrie-Flom Center for Health Law Policy, Harvard Law, Cambridge, MA

1:00 p.m. Clinical Trial Issues – Design, Bias, Consent; Privacy; and Cybersecurity
Chris Robertson PhD, JD - Professor of Law, Assoc. Dean for Research & Innovation - Arizona
Tara Sklar JD - Professor of Health Law & Dir. of Graduate Health Sciences Program – Arizona
Ronald D. Lee JD – Arnold and Porter, Washington DC

2:15 p.m. Medical Device Liability – A Case Perspective – Syntheses
Jeff Miller JD, Mng. Dir. – Asterion Consulting, Chief Compliance Officer (rtrd.) – DePuy Synthes (JNJ)

3:10 p.m. Break

3:25 p.m. Medical Device Liability –How Do We Prevent Claims From the Get-Go?
Topics: Liability Law, Torts, Damages, Remuneration Case ex. Of consequences
Evan C. Holden JD - Greenberg Traurig, Atlanta, GA
Sean K. Burke JD – Duane Morris, Washington, DC

4:15 p.m. Rapporteur Report – Peter McFadden PhD, 2L, University of Arizona

4:45 p.m. Future Meeting Planning

5:00 p.m. Adjourn