Medical Device & Digital Health Symposium

OCTOBER 26, 2023 | MANDARIN ORIENTAL | BOSTON, MA

Time Slot | Location	Session	Description
8:00 a.m.– 9:15 a.m. *Bangkok Room*	*Women in MedTech Networking Breakfast*	
9:00 a.m. – 9:30 a.m. *Foyer & Oriental Gallery*	*Registration & Networking*	
9:30 a.m. – 9:35 a.m. *Oriental Ballroom*	**Opening Remarks** ▪ Megan Gates, Covington	
9:35 a.m. – 10:25 a.m. *Oriental Ballroom*	**Plenary Session One:** *Is Break Time Over? Emerging FDA and DOJ Enforcement Trends in the Medical Device and Digital Health Industries* Speakers: ▪ Pam Forrest (Moderator), Covington ▪ Shanya Dingle, Head of Government and Internal Investigations, Kenvue ▪ Geoff Hobart, Covington ▪ Jessica Zeller, Vice President, Quality, Regulatory & Public Affairs Counsel, Edwards Lifesciences	This panel will explore: ▪ The recent uptick in FDA medical device enforcement, including specific areas of enforcement focus; ▪ What may lie ahead in FDA digital health enforcement; ▪ Current DOJ enforcement priorities and their potential impact on medical device and digital health companies.

Time Slot | Location	Session	Description
10:25 a.m. – 10:35 a.m.	*Mini Break*	
10:35 a.m. – 11:25 a.m. *Oriental Ballroom*	**Plenary Session Two:** *MedTech M&A: The Current Environment and Deal Management* Speakers: ▪ Kristin Davenport (Co-Moderator), Covington ▪ Andrew Ment (Co-Moderator), Covington ▪ Paul Laurino, Head of Legal, Connected Care, Philips ▪ Anil Ranganath, Senior Vice President, General Counsel and Corporate Secretary, TransMedics ▪ Larry Weiss, Former Chief Legal Officer, Butterfly Network and Analog Devices	This panel will explore a variety of considerations affecting mergers and acquisitions in the MedTech industry, from the standpoints of both acquirers and acquirees, including: ▪ Practical tactics for streamlining the process; ▪ Risk mitigation and potential value creation strategies; ▪ Best practices for handling integration challenges; ▪ Regulatory due diligence considerations.
11:25 a.m. – 11:35 a.m.	*Breakout Transition*	

11:35 a.m. – 12:20 p.m. *Bangkok Room*	**Morning Breakouts** ***Breakout 1:*** *Recent Challenges and Opportunities in China* Speakers: ▪ John Balzano, Covington ▪ Weishi Li, Covington ▪ Jessica Zeller, Vice President, Quality, Regulatory & Public Affairs Counsel, Edwards Lifesciences	This session will be a panel discussion of recent challenges and opportunities facing medical device companies in China, including shifting global dynamics and continuing medical device reform in the device and the healthcare regulatory areas.
11:35 a.m. – 12:20 p.m. *Oriental Ballroom*	**Morning Breakouts** ***Breakout 2:*** *Covington Digital Health Survey Results - A Read-Out on Client Approaches, Challenges & Lessons* Speakers: ▪ Sarah Cowlishaw, Covington ▪ Van Ellis, Covington	Covington has surveyed a cross-section of leading companies in the medical device and MedTech industries on their internal approaches to, and experiences in, digital health. This session will explore: ▪ How these companies structure their digital health teams, ▪ Key challenges these companies face in the digital health space, and ▪ Practical approaches that the surveyed companies are adopting to navigate these challenges.
12:25 p.m. – 1:10 p.m. *Oriental Gallery & Ballroom*	*Buffet Lunch*	

1:10 p.m. – 2:00 p.m. *Oriental Ballroom*	**Lunch Panel:** *Medical Device and Digital Health Industry Perspectives - GC and CLO Dialogue* Speakers: ▪ Megan Gates (Moderator), Covington ▪ Esther Bleicher, General Counsel, Hello Heart ▪ Robert Blood, Executive Vice President, Chief Legal Officer and General Counsel, Candela Medical ▪ Rob Spadafora, Head of Legal, Philips North America	Hear from the General Counsels and Chief Legal Officers of leading medical device companies in the region on the challenges and opportunities they see for the sector. What keeps them up at night? What industry changes do they see on the horizon? How do they balance the multitude of evolving and time-sensitive demands on their time, while remaining current on legal issues affecting their internal clients?
2:00 p.m. – 2:15 p.m.	*Breakout Transition*	
2:15 p.m. – 3:00 p.m. *Oriental Ballroom*	**Afternoon Breakouts** **Breakout 1:** *Assessing the Legal Landscape for Diagnostics* Speakers: ▪ Scott Danzis (Moderator), Covington ▪ Sarah Cowlishaw, Covington ▪ Mary Lynne Kupchella, Vice President, Deputy General Counsel, Foundation Medicine ▪ Amy Leiser, Covington	This session will focus on diagnostic testing and discuss key developments. In the US, the FDA is poised to begin regulating laboratory developed tests as medical devices, while rolling out a new program for companion diagnostics. In the EU, the In Vitro Diagnostic Regulation (IVDR) is now in force but substantial challenges remain. Further, we have seen significant growth in digital diagnostics over the past several years. This panel will explore those challenges and offer strategic insights for companies developing diagnostics or partnering with diagnostic companies.

2:15 p.m. – 3:00 p.m. *Bangkok Room*	**Afternoon Breakouts** **Breakout 2:** *"Out-of-Network": Cyber Trends in Digital Health* Speakers: ▪ Ashden Fein, Covington ▪ Web Leslie, Covington	Experts from Covington will discuss growing cyber risks, best practices, and the latest regulatory movement in the ever-expanding ecosystem of connected medical devices and digital health services.
3:05 p.m. – 4:00 p.m. *Oriental Ballroom*	**Plenary Session Three:** *Artificial Intelligence in Healthcare and Life Sciences - Regulatory and Commercial Trends, Risk and Opportunities* Speakers: ▪ Wade Ackerman (Moderator), Covington ▪ Van Ellis, Covington ▪ Christina Kuhn, Covington ▪ Jean Liu, Associate General Counsel, Microsoft	This panel will explore the evolving regulatory and commercial landscape for AI in healthcare, including emerging trends and new challenges presented by the rapidly advancing technology, including the rise of generative AI. ▪ What considerations should be top of mind when entering into collaborations or other transactions for AI development or deployment in healthcare? ▪ How can regulatory challenges and risks be addressed? ▪ What are current best practices and what's around the corner?
4:00 p.m. – 4:10 p.m. *Oriental Ballroom*	*Closing Remarks* ▪ Megan Gates*, Covington*	
4:10 p.m. – 5:30 p.m. *Oriental Gallery & Ballroom*	*Happy Hour/Cocktail Reception*	