

# COVINGTON

## Medical Device & Digital Health Symposium

OCTOBER 22, 2024 | NEWPORT BEACH, CA

| Time                    | Session  | Description  |
|-------------------------|--|--|
| 8:30 a.m. – 9:10 a.m.   | Registration & Continental Breakfast   |  |
| 9:10 a.m. – 9:15 a.m.   | Opening Remarks  |  |
| 9:15 a.m. – 9:50 a.m.   | Insights from DC: A Fireside Chat on HHS Priorities  | With responsibility for important federal authorities that impact the device and digital health ecosystem, this panel will discuss recent and upcoming HHS efforts and priorities. To kick off our day, our guest speaker will provide insights from DC.   |
| 9:50 a.m. – 10:50 a.m.  | Plenary Session 1<br><b>Is Break Time Over? Emerging FDA and DOJ Enforcement Trends in the Medical Device and Digital Health Industries</b> <ul style="list-style-type: none"><li>▪ <a href="#">Matt O'Connor</a> (Moderator), Covington</li><li>▪ <a href="#">Pam Forrest</a>, Covington</li><li>▪ <a href="#">Dan Shallman</a>, Covington</li><li>▪ <a href="#">Aaron Lewis</a>, Covington</li></ul> | This panel will explore: <ul style="list-style-type: none"><li>▪ The recent uptick in FDA medical device enforcement, including specific areas of enforcement focus;</li><li>▪ What may lie ahead in FDA digital health enforcement; and</li><li>▪ Current DOJ enforcement priorities and their potential impact on medical device and digital health companies.</li></ul> |
| 10:50 a.m. – 11:05 a.m. | Morning Break  |  |

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| 11:05 a.m. – 12:05 p.m. | <p>Plenary Session 2</p> <p><b>Looking Ahead on AI: Regulatory and Transactional Considerations, Governance Strategies, and Opportunities for Uses of AI in Healthcare and Life Sciences</b></p> <ul style="list-style-type: none"><li>▪ <a href="#">Wade Ackerman</a> (Moderator), Covington</li><li>▪ <b>Joseph Fireman</b>, OpenAI</li><li>▪ <a href="#">Van Ellis</a>, Covington</li><li>▪ <a href="#">Christina Kuhn</a>, Covington</li></ul> | <p>Our expert panel will explore the evolving landscape and latest trends for AI in healthcare and life sciences, including the rapid adoption of generative AI. We will tackle key regulatory challenges and how to navigate uncertainty, address strategic considerations for transactions and collaborations, and explore best practices for deploying AI.</p> <p>Gain insights into how to operationalize effective governance frameworks that balance business growth and responsible innovation to help stay ahead of emerging opportunities in this rapidly evolving landscape.</p> |
| 12:05 p.m. – 12:35 p.m. | <b>Buffet Lunch</b>  |  |
| 12:35 p.m. – 1:20 p.m.  | <p>Luncheon Session</p> <p><b>Medical Device and Digital Health GC Perspectives</b></p> <ul style="list-style-type: none"><li>▪ <a href="#">Scott Danzis</a> (Moderator), Covington</li><li>▪ <b>Arnold (Arnie) Pinkston</b>, Edwards Lifesciences</li><li>▪ To be confirmed</li></ul>   | <p>Hear from the General Counsel and Chief Legal Officers of leading medical device and digital health 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?</p>   |
| 1:20 p.m. – 1:35 p.m.   | <b>Afternoon Break</b>   |  |

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| 1:35 p.m. – 2:05 p.m. | CovTalk Session 1<br><b>Top 5 ESG Considerations for Medical Devices &amp; Digital Health</b> <ul style="list-style-type: none"><li>▪ <a href="#">Jayni Hein</a>, Covington</li></ul>  | The program will include discussion of: <ul style="list-style-type: none"><li>▪ Climate reporting landscape (CA, federally, and EU);</li><li>▪ Environmental marketing;</li><li>▪ Equity and environmental justice;</li><li>▪ Energy use and sourcing; and</li><li>▪ End of life product issues.</li></ul>   |
| 2:05 p.m. – 2:10 p.m. | <b>Mini-Break</b>  |  |
| 2:10 p.m. – 2:40 p.m. | CovTalk Session 2<br><b>Current Issues in Asia Pacific Digital Health Regulation</b> <ul style="list-style-type: none"><li>▪ <a href="#">John Balzano</a>, Covington</li><li>▪ <a href="#">Helen Hwang</a>, Covington</li><li>▪ <b>Becky Hsiao</b>, Illumina</li></ul> | As digital health regulation has advanced in the rest of the world, countries in East and Southeast Asia have also advanced specialized medical device software, AI, and telehealth regulation. This panel will examine specific regulatory and compliance challenges that companies developing and marketing products in the Asia Pacific region encounter, particularly those in Mainland China. |
| 2:40 p.m. – 2:50 p.m. | <b>Mini-Break</b>  |  |

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| 2:50 p.m. – 3:50 p.m. | <p>Plenary Session 3</p> <p><b>The 2024 Election: Looking Ahead to Implications for the Medical Device and Digital Health Sectors</b></p> <ul style="list-style-type: none"><li>▪ <a href="#">Jayni Hein</a> (Moderator), Covington</li><li>▪ <a href="#">Gabe Neville</a>, Covington</li><li>▪ <a href="#">Matt Shapanka</a>, Covington</li></ul> | <p>Hear from experts on the state of the November election and the implications for the life sciences and digital health industries. With the election rapidly approaching, control of the White House and both chambers of Congress hang in the balance. How the election is decided could have dramatic implications on the next administration's leaders and policy agenda, as well as the likelihood of legislative action, all of which will impact medical device and digital health businesses.</p> <p>The speakers include former officials from both sides of the aisle that served in senior positions in the White House, Congress, and key congressional committees.</p> |
| 3:50 p.m. – 4:00 p.m. | <b>Closing Remarks</b>   |  |
| 4:00 p.m. – 5:30 p.m. | <b>Cocktail Reception</b>  |  |