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Key Takeaways From the 13th Annual King & Spalding Medical Device Summit

King & Spalding held its 13th Annual Medical Device Summit on Nov. 10-11, 2020, in a virtual format for the first time. This year's theme was "Beyond Viral: Turning the Corner on COVID-19," and our program brought together over 400 life sciences leaders from around the world. Attendees could choose from 21 interactive panel discussions, and four separate tracks of content, featuring issues of critical importance to the medical device and diagnostics industry. The recorded program is still available for viewing, and eligible for CLE credit. Please contact Monique Wharton at mwharton@kslaw.com to obtain access if you are not already registered for the program.

Below are some key takeaways from selected sessions.

COVID-19 Diagnostics and Testing: FDA's Regulatory Approach Creates New Opportunities and New Risks for Medical Device Companies: The FDA's vague requirements and backlog in authorizing serology tests has created a two-tier system wherein those antibody tests lucky enough to receive an Emergency Use Authorization (EUA) dominate the market, while the others languish as second-class citizens on the notification list, often for months. The U.S. Department of Health and Human Services announcement that FDA now must engage in notice and comment rulemaking to establish authority to conduct premarket review of Laboratory Developed Tests may also have implications for other FDA-regulated technologies. U.S. Attorneys from across the country have brought an array of enforcement actions focusing on small business assistance, PPE fraud, price-gouging, and other pandemic-related activity—EUAs may offer some degree of protection from these enforcement actions. *Presenters: associate Kate Armstrong; partners Lisa Dwyer, Pete Leininger, and Elaine Tseng.*

DOJ Enforcement Priorities & Compliance Trends in the COVID-19 Era: What Medical Device Companies Need to Know: DOJ remains active and aggressive, including in the medical device space. We anticipate seeing an increased focus from DOJ on False Claims Act cases involving stimulus funds from the CARES Act, as well as cases alleging

kickbacks, and cases raising safety issues (e.g., failing to file medical device reports). With the upcoming change in presidential administrations, we would expect DOJ to continue its active enforcement and prosecution of cases. To limit risk and prepare for the eventual post-COVID world, compliance programs should be tailored to the company's specific risks and consider current enforcement trends. Companies are expected to have a living compliance program that not only addresses issues, but also identifies potential compliance concerns proactively. *Presenters: partners Ethan Davis, Mark Jensen and Brandt Leibe.*

PREP Act Immunity and Other Risk Minimization Strategies for COVID-19 Product Manufacturers: While HHS has been clear that the PREP Act should be interpreted broadly to provide immunity from tort liability, no court has addressed the Act's scope in the context of a lawsuit brought against a manufacturer of a COVID-related countermeasure. It is important for manufacturers to monitor FDA's COVID-19 policies because they are often changing, as has been the case for FDA's policies regarding KN95 respirators, hand sanitizers, and serology tests since the start of the pandemic. FDA, and specifically the Center for Devices and Radiological Health, is beginning to consider a transition plan for 2021, and manufacturers operating under COVID-19 related guidance's and EUAs should begin developing an exit strategy, or a transition to full regulatory compliance. *Presenters: partners Geoffrey Drake and Amanda Klingler; counsel Jessica Ringel; senior associate Mark Sentenac.*

EU Medical Devices Regulation: Opportunities for Medical Device Companies in Clinical Trials and eHealth: The EU Medical Device Regulation (MDR) changed slightly during the COVID-19 pandemic, and this provides opportunities for device companies. Until May 26, 2021, the Medical Devices Directive (MDD) continues to apply, and companies can certify a medical device under the MDD rather than the MDR. Regarding clinical investigations, the MDR imposes a stricter system of clinical evaluation based on tightened requirements and provides new challenges. While clinical evaluation is required for all classes of devices, clinical investigations are only mandatory for Class III and implantable medical devices, with an exception for devices equivalent to a currently available medical device (but evidence of equivalence is difficult to bring). Overall, more clinical investigations will be conducted in the EU. *Presenters*: *partners Ulf Grundmann and Geneviève Michaux; senior associate Elisabeth Kohoutek.*

Inspections After the Pandemic: Are You Prepared for What's Next?: The FDA is planning to launch a voluntary pilot program that will allow the agency's investigators to inspect medical device facilities virtually, as a response to the COVID-19 pandemic. The virtual inspection program is in a very preliminary stage at this point, but FDA understands the necessity of such a program. FDA has been minimally active in conducting in-person inspections since March, due to COVID-19. Until inspections resume in a regular form, it is recommended that industry conduct gap assessments, practice inspections, train specialized staff, and track and monitor known deficiencies to prepare for future audits. *Presenters: senior quality systems and compliance advisor Eric Henry; lead quality systems and compliance consultant Steven Niedelman; partner Kyle Sampson.*

The iPad Will See You Now: Fraud and Abuse Risks Related to EHRs and Telemedicine: The Anti-Kickback Statute (AKS) makes it illegal to pay (or offer) or accept anything of value to induce the purchase, referral, or recommendation of items and/or services reimbursed by a federal health care program (e.g., Medicare, Medicaid and Tricare). There is no COVID-19 exception for the AKS, so common manufacturer activities involving electronic health records (EHR) and telemedicine could implicate the statute, thus requiring a risk analysis. Any form of "remuneration" to healthcare providers and patients (even indirect) should be carefully scrutinized, as well as relationships with any third parties who are in a position to impact whether or in what circumstances your products will be used. *Presenters: partners Brian Bohnenkamp and Gina Cavalier; associate Jarred Reiling.*

Let's Get Back to Work! Considerations for Sales Force Re-Engagement in the Field: Medical device companies continue to face numerous challenges arising from navigating a return to work strategy in the context of the pandemic. This can be particularly difficult when considering the challenges related to field-based personnel returning to the field. In developing a return-to-work strategy, one should develop a Task Force. The Task Force should develop company principles to guide the development of flexible protocol. In considering protocols, the Task Force should cover COVID-19 specific issues (e.g., testing protocols, sick leave) and reexamine topics likely already covered in your existing policies. As part of that effort, companies should avoid including restrictions or parameters in documented policies and procedures without considering whether the organization can satisfy the standards it sets; generally, you want to avoid instituting written policies and procedures with which the company cannot reasonably comply. *Presenters: partners Brian Bohnenkamp, Edward Holzwanger, Michael Johnston, and Cheryl Sabnis.*

Shareholder Lawsuits Against Medical Device Companies: Legal Update and Steps to Limit Exposure: COVID-19 has disrupted supply chains, shifted product demands and created product shortages—it also has threatened to cause an uptick in shareholder lawsuits, creating new challenges for officers and directors of public companies, particularly those developing or manufacturing medical devices related to COVID-19, including ventilators or PPE. In the current environment, shareholders (and plaintiffs' attorneys) may scrutinize with particular care a company's disclosures, projections or business plans connected to COVID-19-related products. Twenty-four percent of total securities class action lawsuits in 2019 (97) cases were against life sciences and medical device companies, a 12.8% increase over 2018, and 148.7% increase from five years prior. Part of the reason for this growth is cannabis. There were nine lawsuits against cannabis companies in 2019. *Presenters: partners Paul Bessette, Mike Biles and Lisa Dwyer; associate Rebecca Matsumura.*

Click here to see the full 13th Annual King & Spalding Medical Device Summit agenda. If you would like to be included on our regular pharmaceutical manufacturers, medical device manufacturers or healthcare provider mailing lists to receive notices of other events and written updates, sign up here.

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