OCT. 4, 2021

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Key Takeaways From the 14th Annual King & Spalding Medical Device Summit

King & Spalding held its 14th Annual Medical Device Summit on Sept. 9-10 in an all-virtual format. This year's theme, "Beyond Viral: Navigating the Post-Pandemic Crossroads," explored the effects of the COVID-19 pandemic on the medical device and diagnostics industry, regulatory compliance, and government enforcement priorities. The two-day event attracted over 250 life sciences leaders from around the world and featured 21 unique panel discussions across four themed tracks. 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 have not already registered for the program.

Below are some key takeaways from selected sessions.

Turning the Corner on COVID-19: What Does It Mean for EUAs?: Since the COVID-19 pandemic took hold, the U.S. Food and Drug Administration has been highly active in issuing hundreds of Emergency Use Authorizations for vaccines and medical devices. We have seen that FDA's strategy is continually evolving, particularly in the example of KN95 respirators. On June 30, 2021, FDA revoked EUAs for: decontamination and bioburden reduction systems for personal protective equipment, and non-NIOSH approved filtering facepiece respirators (either manufactured in China or otherwise imported). These revocations were either effective immediately, or with just one week of notice. To prepare, medical device companies with EUAs can develop an exit strategy now—whether that is withdrawal of the product from the market or seeking another method of permanent FDA authorization outside of the EUA pathway. Such an exit strategy can also account for other regulatory considerations, such as inspections, clinical trials, workforce constraints, and a focus on digital health and telemedicine. *Presenters: partners Amanda Klingler, Jessica Ringel and Kyle Sampson; associate Jarred Reiling.*

Emerging From the Pandemic With New Compliance Risks: The COVID-19 public health emergency fueled the transition to a virtual environment and altered the ways in which device manufacturers interact with healthcare providers and market and sell their products. New activities and operations, including virtual interactions with meals, and relationships with telemedicine providers, give rise to new types of risks under the federal Anti-Kickback Statute, False Claims Act and

industry codes of conduct. These new areas also converge with growing enforcement areas of focus, including those around demos and loaners, educational/speaker programs, and Open Payments compliance, to create a particularly potent mix of compliance risks facing device manufacturers coming out of the pandemic. Device manufacturers should recognize that compliance processes and policies are now even more critically important to help substantiate the legitimate purposes underlying their activities and to help reduce the chances that otherwise legitimate activities create material compliance risks in execution. *Presenters: partners Brian Bohnenkamp and Seth Lundy; senior associate Caitlyn Ozier.*

Digital Health and the Healthcare Revolution: The digital healthcare revolution has yielded more precise diagnostics and therapeutics, and has expanded access to healthcare. However, this is a heavily regulated space, and it is important that—before launching digital health offerings—companies assess which laws apply, and plan accordingly. Often the manner in which a digital health offering is regulated depends on whether it is presented as a product or as a service. For example, FDA's regulatory framework often applies if digital health offerings are presented as products; whereas state professional licensing laws and state laws involving the corporate practice of medicine often play a more central role for services. In addition, other laws, including the Anti-Kickback Statute, HIPAA, and Medicare and Medicaid apply to both product and service business models. *Presenters: partners Lisa Dwyer, Juliet McBride, Kyle Sampson and Rick Zall.*

The Biden Administration's Impact on the Value of My Intellectual Property: With the transition to the new Biden administration coupled with recent U.S. Supreme Court decisions regarding the Patent Trial and Appeal Board, the open question for device manufacturers is how such changes will impact the value of their intellectual property. Companies are looking at early actions by the Biden administration to determine whether we will see a continuation of the pro-patent approach of the Trump administration or a swing back to the Obama-era policies that substantially reformed patent law. Early indicators seem to point toward an increasing focus on protecting American IP, including, among others, the proposal of a Buy American Rule for government procurements, the introduction in the U.S. Senate of the SECRETS Act that would seek to stop and exclude Chinese rip-offs and exports, and recent prosecutions by DOJ of trade secret theft abroad. These actions are further impacted by a recent executive order from the Biden administration to enforce antitrust restrictions against big tech, as well as the *U.S. v. Arthrex* Supreme Court decision that puts IPRs in the hands of the PTO Director. *Presenters: partners Chris Campbell and Brit Davis; senior associate Abby Parsons.*

Unique Issues and Strategic Considerations for Development of Drug-Device "Ecosystems": A drug-device "ecosystem" refers to a system that includes a software component that is used in conjunction with a drug or drug-device combination product. The components of an ecosystem include a drug product, sometimes a drug-delivery device, and a software application (such as drug adherence and dose-tracking software and dose-recommending software). This session discussed the product IP lifecycle—from development to litigation—the applicable FDA regulatory framework, and issues in reimbursement. From the IP perspective, companies should consider protecting those aspects of the product that are regulated by FDA, appear on the label, or are otherwise important to obtaining FDA approval. Patent protection may be sought for the software in addition to the drug and the device, and competitors seeking to enter the market should be aware that not all such patents may be listed in the Orange or Purple Books. On the FDA regulatory front, companies will want to consider whether the software will be regulated as a medical device and, separately, whether the software output may be regulated as prescription drug-use-related software, or PDURS. Companies should: bring the entire team together (including from clinical, regulatory, reimbursement, marketing and R&D) early in the development process to discuss goals and objectives; consider the intended patient population and the payer mix for the product; structure clinical trials to maximize reimbursement and with an eye to the regulatory frameworks; choose an FDA pathway with coverage, coding, and payment in mind; build broad support for the product;

and consider the changing payer landscape. *Presenters: partners David Farber, Preeya Noronha Pinto and Eva Temkin; senior associate Andrew Cochran.*

Privacy & Security Risk Assessments: A New Dawn: The most difficult part of managing privacy and security risks is identifying the threat. Medical devices have evolved largely from analogue, non-networked, and isolated hardware to networked devices incorporating remote access, wireless technology, and complex software. Increasing levels of interconnection and data exchange between medical devices can have significant benefits to both patients and the healthcare system but can also leave devices vulnerable to unauthorized access. These vulnerabilities can negatively impact safety by causing diagnostic or therapeutic errors, or by affecting clinical operations. Global privacy laws require robust technical and organizational security protections to be in place to protect the device and data stored on it. Many global privacy laws, including GDPR, require higher standards of protection for sensitive personal data, including health -data—the level of risk involved in processing the type of data dictates how robust the security measures must be. Failure to protect the device and data held on it can lead to data breaches, regulatory enforcement actions, and (in some jurisdictions) claims from individuals about the loss of their data and consequential damage. Risk assessments are a necessary tool to be implemented on a regular cadence. They must be appropriate and scalable to the risks, and must be periodically revisited to ensure they are robust and relevant for your organization. *Presenters: partners Sumon Dantiki and Robert Hudock; counsel Kim Roberts.*

Click here to see the full 14th Annual King & Spalding Medical Device Summit agenda. If you would like to be included on our regular pharmaceutical manufacturers, medical device manufacturers, or health provider mailing lists to receive notices of other events and written updates, sign up here.

This article was authored by Caitlyn Ozier, Jarred Reiling, Cassie Rasmussen, Rebecca Paradis, and Jonathan Trinh, Washington, D.C.-based attorneys on King & Spalding's FDA & Life Sciences team, and Ben Torres, an Atlanta-based associate on King & Spalding's Trial and Global Disputes practice group.

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