Life Sciences & Healthcare Industry Group

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Key Takeaways From the 5th Annual King & Spalding West Coast Pharmaceutical & Medical Device University

On June 20, King & Spalding held its 5th Annual West Coast Pharmaceutical & Medical Device University in San Francisco. More than 125 people attended—including representatives from drug, biologic, and medical device manufacturers, their in-house counsel, regulatory professionals, managers, and executives—to discuss emerging issues and hot topics for leaders in the life sciences industry. King & Spalding attorneys led two plenary sessions focused on the enforcement landscape and trends, followed by two tracks of in-depth presentations. Below are some key takeaways from selected sessions.

DOJ Enforcement Developments and Trends: Enforcement against the life sciences and healthcare industries through federal anti-kickback cases continued unabated in 2019, and the U.S. Department of Health and Human Services' inspector general warned companies late last year to watch for risks involving patient assistance programs and other arrangements with health care providers. The Department of Justice also reaffirmed the use of the 60-year-old federal Travel Act as part of its arsenal of statutes to go after alleged illegal kickbacks outside the purview of the federal anti-kickback statute. In addition, the use of data in opioid investigations and pursuit of managers, manufacturers, and distributors is providing a roadmap for investigations of other kinds of medical products. *Panelists: Partners Jade Lambert, Brandt Leibe and John Richter.*

Current Issues in Women's Health: Increased FDA Attention and a Greater National Focus: The market for women's health products is expected to grow to $200B by 2025. At the same time this sector is growing, it is attracting more scrutiny from the media, FDA, and plaintiffs' lawyers alike. In November of last year, FDA announced that it would strive to be the first among regulatory bodies to identify safety issues associated with medical devices, and that it would be particularly focused on devices that impact women's health. Since that time, FDA has held advisory committee meetings focusing on safety issues potentially associated with breast implants and transvaginal mesh for the repair of

pelvic organ prolapse. FDA has also taken steps to safeguard women's health in the pharmaceutical and the cosmetics space, and it recently issued a series of guidances aimed at ensuring that women are better represented in clinical trials. These guidances address, among other things, best practices for lactation and pregnancy studies. With the additional media and FDA scrutiny on women's health products and mass tort litigation involving these products on the rise, clients are increasingly reaching out to products liability and FDA practitioners at King & Spalding for pro-active risk assessments and strategies to stop or stem products liability litigation before it starts. These strategies include better understanding the factual record and identifying potential vulnerabilities, building the scientific record (e.g., through correspondence with FDA or post-market registries), and developing social media and public relations strategies—before the litigation has the opportunity to distort or corrupt the science. *Panelists: Partners Lisa Dwyer, Robert Friedman and Meredith Redwine. Download the presentation here.*

CFIUS – Regulatory Reform and Implications for Foreign Investment in Biotech, Life Sciences and Healthcare: Changes in the federal rules that govern foreign controlling and non-controlling investments in a U.S. business may now require a mandatory filing with the Committee on Foreign Investment in the United States (CFIUS) for deals involving "critical technology" owned by U.S. biotechnology, neurotechnology, nanobiology, synthetic biology, and genomic and genetic engineering businesses. Under the new rules, failure to make a mandatory filing can result in fines up to the value of the transaction for each party. CFIUS also can block or unwind deals, or require divestment of certain assets as a condition of approving the transaction. In 2019, CFIUS has required divestments in multiple transactions, and the Committee appears particularly concerned about foreign investors gaining access to the data of U.S. citizens, such as a Chinese company's minority investment in the U.S. patient health data company PatientsLikeMe. CFIUS deal risk and the mandatory filing requirement depend on the nature of the U.S. business involved in a transaction, the nature of the foreign buyer's business, and the transaction structure. Parties should consider CFIUS as a gating issue and should conduct diligence around CFIUS and structure the transaction accordingly, negotiate CFIUS-related terms into the deal agreements, and factor CFIUS approval processes into the timing of a deal's closing. *Panelists: Partners Laura Bushnell, Jack Capers and Christine Savage, along with senior associate Alexis Early. Download the presentation here.*

A World Without Pharmaceutical Rebates: Fraud & Abuse, Pricing and Commercial Implications: While both political parties list high drug prices as a concern, no easy solution has been offered by either side. One change proposed in January by the Department of Health and Human Services focused on eliminating traditional PDM/payor rebates and making that value available to patients at the point of sale. The proposed rule sought to achieve this by clarifying the scope of the federal Anti-Kickback Statute and limiting a safe harbor available for certain discounts, and proposing new safe harbors for discounts passed through to the point-of-sale and for certain pharmacy-benefit-manager service fees. *Panelists: Partners Seth Lundy and John Shakow, along with counsel Abigail Bortnick. Download the presentation here.*

Insider Trading: The Real Cost to Pharma and Device Companies and Their Employees: The Securities and Exchange Commission continues to bring cases against executives, as well as their friends and family members, who engage in insider trading. The life sciences industry represents an outsized shared of those insider trading cases. In recent years the SEC has brought a string of cases involving healthcare executives whose loved ones misappropriated non-public news about FDA approvals, pending mergers, and other important corporate news, then either made profits or avoided losses by trading ahead of the news. While the insider-executives may have escaped being named in an enforcement action, they were no doubt wrapped up in the SEC's costly and invasive investigations. Given the financial, familial, and career risks of being dragged into an investigation if a loved one trades, it is best to avoid divulging

nonpublic information when asked about sensitive developments at work. *Panelists: Partners Dixie Johnson and Aaron Lipson, along with senior associate Matt Hanson. Download the presentation here.*

Color Within the Lines: The Latest on FDA Advertising and Promotion Enforcement Trends: The FDA's Office of Prescription Drug Promotion (OPDP) is continuing to set policy through guidance documents, rather than through enforcement efforts. When FDA does take enforcement action, it can also set off separate inquiries by DOJ and various state attorneys general. Current areas of interest for OPDP include boxed warning products, opioid products, representations made at conference booths, risk disclosures, overpromotion of efficacy, and their continuing leverage of the "Bad Ad" program. On the medical device side, FDA remains focused on new intended uses, unapproved new devices, omission or minimization of risk information, inadequate support for claims, and significant changes to labeling or instructions for use. One area in the spotlight going forward will be the implications of healthcare professionals making social media posts about company products and the circumstances in which it may trigger FTC's spokesperson disclosure requirements. *Panelists: Partners Gary Messplay, Nikki Reeves and Elaine Tseng. Download the presentation here.*

Click here to see the full 5th Annual King & Spalding West Coast Pharmaceutical & Medical Device University 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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