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ALERT

Executive Summary of Recent Food and Drug Enforcement, Litigation, and Compliance Conference

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Members of Wiley Rein's Food, Drug, and Medical Device Law (FDMDL) and White Collar Defense & Government Investigations (WCDGI) practices attended the FDLI Enforcement, Litigation, and Compliance Conference in Washington, DC. Kevin Muhlendorf, a partner in the WCDGI practice and former federal prosecutor, was a featured speaker on how the U.S. Department of Justice (DOJ) approaches strict liability based on U.S. Food and Drug Administration (FDA or Administration) violations. Sonali Gunawardhana, of counsel in the FDMDL practice, was one of the conference organizers.

Representatives from the FDA emphasized that 2017 should see an increase in foreign inspections, particularly in India and China. This follows a trend the FDA is seeing in an increase in import alerts in India and China. The FDA's compliance priorities for 2017 include improvements in data integrity and data assurance, monitoring of the compounding industry, and an overall improvement in quality and safety of products. In particular, the FDA is concerned that organizations are failing to apply robust systems that inhibit data risks and/or investigate and address root causes when failures do arise. The most common data integrity problem that the FDA has witnessed is improper access to Current Good Manufacturing Practice (CGMP) computer systems.

Regarding companies that compound human drugs in accordance with Section 503A of the Food, Drug, and Cosmetic Act (FDCA), the FDA noted that the compounding industry is rapidly growing and needs to be monitored more closely. The 2012 fungal meningitis

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outbreak which spread from a New England compounding pharmacy focused the FDA on the potential risks to public health within this sector. FDA has seen an increase in warning letters reflecting problems with data integrity and quality assurance issues for compounders.

The FDA's recent "Guidance for Industry, Contract Manufacturing Arrangements for Drugs: Quality Agreements," was thoroughly discussed at the conference by directors and deputy directors within the Administration. Although "quality agreements" are not required under the FDCA, the FDA strongly feels that organizations need them in order to have quality, CGMP-compliant products. Indeed, the failure to have a written quality agreement raises immediate questions and concerns for the FDA during an investigation.

A large focus of the conference was on FDA enforcement actions once the DOJ gets involved. Given the potential of strict liability under the FDCA, and the DOJ's renewed focus on individual accountability (the "Yates memo" policy), recent food and drug prosecutions demonstrate how companies and executives are more exposed than ever. The new DOJ requirement that companies produce all relevant evidence of individual wrongdoing before receiving any cooperation credit is changing how FDCA prosecutions are conducted and defended, and how companies relate to their executives in those investigations. Nonetheless, the best defense continues to be a C-Suite level focus on the proper development, implementation, and evaluation of compliance programs.

Please contact the author listed on this alert for more information.