

# Enforcement in Life Sciences Series

Key Cases in 2020 Reflect Emerging DOJ Focus for Pharmaceutical and Medical Device Makers

If you have any questions regarding the matters discussed in this memorandum, please contact the following attorneys or call your regular Skadden contact.

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## About the Enforcement in Life Sciences Series

Recent settlements between the U.S. Department of Justice (DOJ) and a range of FDA-regulated drug and medical device manufacturers provide a snapshot of the DOJ's enforcement focus. These settlements involve new DOJ theories of liability or new ways of evaluating long-standing industry practices and may be harbingers of future DOJ enforcement activity. In this six-part series of client alerts, we take an in-depth look at the facts and legal theories in each case or set of cases, discuss what makes each novel and consider the compliance implications for each. You can [find copies of all the client alerts in the series here](#).

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## DOJ and FDA Target Companies That Undermine FDA Oversight

Recent government enforcement actions underscore regulators' focus on efforts by companies to frustrate government inspections of their manufacturing facilities. In particular, a February 2021 criminal settlement highlights the perils of company conduct during a regulatory inspection that impedes or obstructs Food & Drug Administration (FDA) oversight.<sup>1</sup> Under a global settlement, Fresenius Kabi Oncology Limited (FKOL) agreed to plead guilty to concealing and destroying records prior to a 2013 FDA facility inspection and to pay \$50 million in fines and forfeiture. The company also agreed to implement a comprehensive ethics and compliance program.

According to court documents, the company owned and operated a plant in West Bengal, India, that manufactured active pharmaceutical ingredients (APIs) used in various cancer drug products and distributed to the United States. The DOJ charged that, after receiving notice from FDA of its intention to conduct a facility inspection and prior to commencement of the inspection, plant management directed employees to remove certain records from the premises and delete other records from computers that would have revealed that the company was manufacturing APIs in contravention of FDA requirements. Plant employees removed computers, hard copy documents and other materials from the premises and deleted spreadsheets that contained evidence of the plant's violative practices.

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<sup>1</sup> U.S. Attorney's Office, District of Nevada, "[Indian Cancer Drug Manufacturer Agrees To Plead Guilty and Pay \\$50 Million for Concealing and Destroying Records in Advance of FDA Inspection](#)," February 9, 2021.

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The settlement followed Warning Letters issued by FDA about the plant's operations in 2013 and again in 2017. The 2013 Warning Letter called out some of the specific conduct that gave rise to the new settlement.

At the time of settlement, the company stated that it notified FDA when it discovered that some of its employees had hindered the inspection. It highlighted also that the products manufactured at the plant were within specifications and that it took corrective actions soon after the misconduct came to light. Nevertheless, at the time of settlement and at sentencing, senior DOJ and FDA officials emphasized their concerns about the obstruction of FDA oversight activities in a manner that could pose a risk to patient health and safety.

### Compliance Implications

Facility inspections are FDA's primary tool for assessing the quality of the products that it regulates. Given the importance of facility inspections in ensuring both manufacturer compliance and ultimate product quality, the law provides FDA with broad latitude to inspect regulated facilities and strong enforcement remedies if companies flout its oversight in connection with inspections. The refusal to permit an inspection is a crime in itself under Section 301(f) of the Federal Food, Drug, and

Cosmetic Act (FDCA), and in 2012, Congress amended Section 501(j) of the FDCA to deem adulterated any drug manufactured, processed, packed or held in an establishment that delays, denies or limits an inspection, or refuses to permit entry or inspection. Concerns related to data integrity violations have become a growing focus of FDA inspectors in recent years, especially in certain parts of the world, and FDA's increasingly forensic review of these issues has uncovered suspicious behavior in some cases. FDA has cited companies for attempting to delay or obstruct inspections in a string of Warning Letters issued between 2011 and 2021 to companies such as Wockhardt, Pan Drugs, Xiamen Origin, Baoying County Fukang Medical Appliance and Zhejiang Hisoar. The FKOL prosecution represents in many ways a culmination of tensions related to data integrity and inspection misconduct that have been brewing for years, and the lessons from the settlement are relatively straightforward. FDA-regulated companies need to establish and enforce procedures for handling FDA inspections, including strict prohibitions on efforts to conceal information from inspectors. Where such misconduct is discovered, companies need to act promptly to identify the extent of the problem, remedy the deficiencies, consider whether self-disclosure is appropriate, and hold accountable those individuals (particularly supervisors) who were involved in or had knowledge of the misconduct.