In October 2003, Ranbaxy hired Lachman Consultant Services to audit the company. The investigation found that Ranbaxy's Patient Safety Department did not seriously investigate patient reports of ineffectiveness or harmful side effects, much less report such claims to the Food and Drug Administration (FDA). Lachman also identified poor record-keeping in Ranbaxy's manufacturing plants. In October 2004, Rajinder Kumar resigned as director of Ranbaxy's research and development after the board of directors refused to recall drugs that he had shown were approved using fraudulent testing.[19] Dinesh Thakur, who had compiled the fraudulent data as Ranbaxy's director of Research Information & Portfolio Management, also resigned after the company tried planting pornography on his computer to initiate a for-cause firing.[20] Kumar and Thakur's whistleblower reports prompted the FDA to issue an Import Alert for generic drugs produced from two of Ranbaxy's manufacturing plants in September 2008.[21] In February 2009, the FDA halted reviews of all Ranbaxy drug applications after finding that its manufacturing plant in Paonta Sahib frequently falsified data in approved and pending drug applications.[22] When Ranbaxy sought approval of its Batamandi plant only 2.5 miles (4.0 km) away from the Paonta Sahib plant the prior year, FDA investigators proved that the company was merely pretending that products developed in Paonta Sahib were produced at this cleaner facility.[23] On 8 February 2012, three batches of the proton-pump inhibitor pantoprazole were recalled in the Netherlands due to the presence of impurities.[24] On 9 November 2012, Ranbaxy halted production and recalled 41 lots of atorvastatin due to glass particles being found in some bottles.[25][26] Also in 2012, an apparent dosage mistake was reported in which 20 mg tablets were found in a bottle of atorvastatin labeled as containing 10 mg tablets; this led in 2014 to the voluntary recall in the United States of some 64,000 bottles.[27] In May 2013, Ranbaxy pleaded guilty and paid $500 million in fines, for felony charges relating to the manufacture and distribution of certain adulterated drugs made at two of Ranbaxy's manufacturing facilities in India, and misrepresenting clinical generic drug data.[28][29][30] Ranbaxy pleaded guilty to three felony violations of the Federal Food, Drug, and Cosmetic Act of 1938 and another four felony counts of knowingly making false statements to the FDA. Included in the adulterated products were antiretroviral (ARV) drugs destined for treatment of HIV/AIDS in Africa.[20] In September 2013, further problems were reported, including apparent human hair in a tablet, oil spots on other tablets, toilet facilities without running water, and a failure to instruct employees to wash their hands after using the toilet.[31][32] Ranbaxy was prohibited from manufacturing FDA-regulated drugs at the Mohali facility until it complied with United States drug manufacturing requirements.[33] In 2014, the FDA notified Ranbaxy Laboratories, that it was prohibited from manufacturing and distributing active pharmaceutical ingredients (APIs) from its facility in Toansa, India, for FDA-regulated drug products. The FDA's inspection of the Toansa facility, which concluded on 11 January 2014, identified significant cGMP violations. These included Toansa staff retesting raw materials, intermediate drug products, and finished API after those items failed analytical testing and specifications, in order to produce acceptable findings, and subsequently not reporting or investigating these failures.[34][35] In 2019, investigative journalist Katherine Eban published Bottle of Lies, an in-depth investigation of generic drug manufactures. Aside from recounting the Ranbaxy scandals described above, Eban noted that FDA leaders suppressed internal awareness of Ranbaxy's fraud to maintain the supply of cheap generic

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drugs.[36]

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