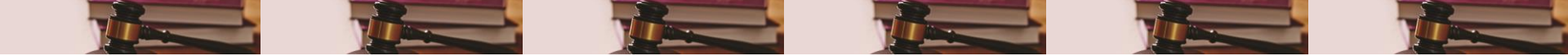

# Management Oversight and Control: How to Ensure Compliance and Limit Liability

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*"With the money we'll save by shutting down quality control, we can issue some truly spectacular apologies."*

# The Government Has Consistently Focused on Management Responsibility

- FDA has consistently required that individuals be named as defendants when it brings injunctive proceedings
- 2015 Yates Memo ("Individual Accountability for Corporate Wrongdoing") directs, among other things that "civil attorneys should consistently focus on individuals as well as the company…"
  - This underscored existing DOJ policy
- USAM was also updated in 2015 to "emphasize the primacy in any corporate case of holding individual wrongdoers accountable"
- Entry of Consent Decree does not preclude criminal liability and often invites derivative litigation

# The Ranbaxy Consent Decree

- Announced in 2012, it named the parent company, a U.S. subsidiary and three individuals
- Decree followed a 2008 import alert pertaining to dozens of drugs and which stopped all future approvals
- Decree Covers GMP issues at facilities in India and New York
- Includes data integrity requirements applicable to Indian facilities
- Ranbaxy agreed to relinquish 180-day marketing exclusivity rights for three pending generic drug applications; additional applications at risk if deadlines not met
- In 2017, FDA lifted the import alert against the Mohali manufacturing facility

# The Ranbaxy Consent Decree – The Named Individuals

- Named the Senior VP/Head of Global Quality of Ranbaxy Laboratories, Ltd. (RLL), which is the global parent company as the individual responsible for implementing drug quality at all of Ranbaxy's drug manufacturing sites
  - Entered the role in 2010, after the conduct in question had occurred
- In 2015, Adkisson petitioned the court for a partial release from the Decree, arguing that he is no longer employed by Ranbaxy
- The government opposed, noting that the SVP's current employer, Daiichi Sankyo, has an ownership interest in Sun Pharmaceuticals, the successor to RLL
- The Court denied the motion

# The Ranbaxy Consent Decree – The Named Individuals (continued)

- Named the CEO and Managing Director of RLL as the "highest ranking corporate official and the most responsible person at RLL…who also sits on RLL's Board of Directors"
  - Entered the role after the conduct in question had occurred
- "Responsible for and oversees all facets of Ranbaxy's business, including but not limited to: manufacturing, quality operations, regulatory affairs, purchasing, sales, marketing, business administration, and human resources"

# The Ranbaxy Consent Decree – The Named Individuals (continued)

- Named the Regional Director for the Americas for Ranbaxy, Inc. as the "most responsible person for all of the [subsidiary's] operations in the United States and Canada"
- "Oversees manufacturing, sales, and business development for all of Ranbaxy, Inc.'s U.S. operations, and has oversight over the regulatory affairs department, which is responsible for submitting annual reports to FDA for drug products manufactured in the United States and India"
- Had been in the position since 2007

# The Ranbaxy Consent Decree – Forward Looking Governance Provisions

- The Decree requires Ranbaxy to establish an office of Data Reliability, in the U.S., to audit and certify all data before it is submitted to FDA (*see* Consent Decree, Sec. IX.)
- The Office of Data Reliability will be headed by the Chief Reliability Officer, who reports to the Managing Director
- The Chief Reliability Officer also reports in person and in writing to the Board of Directors
- Requires the establishment of a disclosure program, to be headed by the Chief Reliability Officer, where employees can report issues or ask questions, and requires the maintenance of a disclosure log of all disclosures received, which is to be provided to FDA upon request

# The Philips Consent Decree (2017)

- Named Philips North America and Royal Philips Healthcare as defendants
- Suspended the manufacture and distribution of external defibrillators at two facilities, with certain exceptions
  - Another manufacturer of AEDs, Physio Control, entered into a Consent Decree in 2008
- Required Philips to pay an amount equal to 30% of net revenue associated with the excepted defibrillators and accessories (profit disgorgement payments)
- Required other business lines manufactured at the facilities to undergo a “comprehensive” review by an independent expert and are subject to enhanced FDA regulatory oversight, including the payment of liquidated damages for un-remediated deficiencies

# The Philips Consent Decree (continued)

- Although the 2017 Decree was most immediately preceded by inspections and 483s issued in 2015, FDA did not issue a Warning Letter following those inspections
  - FDA issued Warning Letters in 2009 and 2011
  - FDA met with Philips on multiple occasions, including in 2013 and 2015, to discuss FDA's concerns
- Philips estimated the injunction will have an EBITA impact of $23.2 million in 4Q 2017, and an EBITA impact of $70 million in CY2018, primarily due to the suspension of production, profit disgorgement payments, and incremental costs to prepare for and handle the regulatory inspections

# The Philips Consent Decree – The Named Individuals

- Two individuals were named as Defendants in the Decree, both of whom have authority over the quality of the Philips devices at issue
- Carla Kriwet, Business Group Leader for PCMS, has responsibility for, and authority over, the quality of Philips's devices at the two covered facilities
  - Kriwet assumed the position in February 2015 and reports to the Chief Executive Officer of Royal Philips
- Ojas Buch, VP & Head of Quality and Regulatory for PCMS, has responsibility for the quality of the PCMS devices at the two facilities, a position he assumed in March 2015
  - The Decree focuses on Philip's Emergency Care & Resuscitation (ECR) business unit, which falls within the Patient Care and Monitoring Solutions (PCMS) business group

# The Philips Consent Decree – Substitute Defendants

An individual Defendant shall notify FDA within twenty (20) days after said Defendant ceases to be employed or otherwise act for all of the Defendant Entities. Within thirty (30) days of the separation of the individual Defendant from Defendant PMS, PMS shall designate an individual of similar position and responsibilities to be substituted as an individual Defendant ("Substitute Individual Defendant") and notify FDA of the identity and nature of employment of the Substitute Individual Defendant. FDA and PMS shall submit a stipulation to the Court identifying the Substitute Individual Defendant and requesting that the Court effect the substitution by order. The Substitute Individual Defendant added to this Decree shall be bound by the Decree in the same manner as the Defendants originally named in the Decree.