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FCPA Enforcement in the Life Sciences Industry

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Agenda

- Refresher on the FCPA and FCPA Enforcement
- Why is the Life Sciences Industry High Risk?
- FCPA Enforcement in the Life Sciences Industry
- Recent FCPA Cases in the Life Sciences Industry
- Parting Thoughts

Refresher on the FCPA and FCPA Enforcement

Foreign Corrupt Practices Act Refresh

- Two Main Components:
  - Anti-bribery Provisions: Prohibit paying, promising, offering, or authorizing the payment, directly or indirectly, of money or anything of value to a foreign official in order to influence that official to obtain or retain a business benefit or any other improper advantage
  - Accounting Provisions: Require "issuers" and their subsidiaries (including foreign and domestic subsidiaries, consolidated joint ventures, and other consolidated entities) to meet certain standards regarding books, records, and internal controls
    - Books and Records Provisions – require issuers to make and keep accurate books, records, and accounts that, in reasonable detail, accurately and fairly reflect the issuer's transactions and disposition of assets
    - Internal Controls Provisions – require that issuers devise and maintain reasonable internal accounting controls aimed at preventing and detecting FCPA violations
- Penalties
  - Criminal or civil penalties can be imposed on individuals or companies.
  - Individuals can face prison sentences as well as monetary fines

FCPA Refresh

- Facilitating payment exception
  - Small payments to secure or expedite “routine governmental action”
  - Rarely used, as such payments almost always violate other laws
- Affirmative defenses
  - “Local Law” defense – lawful under the written laws and regulations of the official’s country
  - Promotional and Contract-Related Expenditures
    - Reasonable and bona fide expenditure
    - Directly related to:
      - The promotion, demonstration, or explanation of products or services; or
      - The execution or performance of a contract with a foreign government
- Enforcement
  - Department of Justice – Criminal
  - Securities and Exchange Commission - Civil

Growth of FCPA Enforcement

- Both the DOJ and the SEC have specialized units dedicated to investigating and prosecuting FCPA violations
- DOJ's FCPA Unit
  - Established in 2006.
  - More than 30 prosecutors dedicated fulltime to FCPA enforcement
    - In conjunction with the DOJ's growth, the FBI also established four new squads of special agents devoted to FCPA investigations and prosecutions
- SEC's FCPA Unit
  - Established in 2010
  - Nearly three dozen attorneys dedicated to FCPA enforcement
- DOJ/SEC Coordination with Foreign Counterparts re FCPA
  - DOJ's 2018 formal policy against "piling on" – now the DOJ considers fines/penalties imposed by foreign governments in order to achieve a total equitable result
  - The stated "aim" of the policy is to "enhance relationships with [DOJ's] law enforcement partners in the United States and abroad"

Increased Penalties Under the FCPA

- Increased FCPA enforcement has been accompanied by a steady increase in average penalties, despite same sentencing and penalty regime

Year	Average Penalty*
2015	$5,376,833
2016	$43,516,771
2017	$51,368,779
2018	$44,321,886
2019	$116,044,004

- Does not include data about other forms of monetary sanctions, such as disgorgement or restitution
- *Source:* http://fcpa.stanford.edu/chart-penalties.html

Why is the Life Sciences Industry High FCPA Risk?

Why is the Life Sciences Industry High FCPA Risk?

- Worldwide industry with global need and reach
- Highly regulated, each country with its own regulations
- Need for government approvals to sell products
- Need for vast geographic coverage requires third-party distribution channels
- Most countries have government-run healthcare, meaning most doctors outside the US will be affiliated with a government entity and considered "foreign officials" for purposes of the FCPA
- Marketing is done directly to doctors who prescribe or administer medicines or procedures rather than to one central procurement function, so there are many, many sales touchpoints
- Companies have legitimate needs to enter into business arrangements with doctors, often the same doctors to whom they market their products
  - Consulting, research studies, medical education, product development, etc.
- In some countries, doctors are not well paid, causing pressure to supplement their income through other means

FCPA Enforcement in the Life Sciences Industry

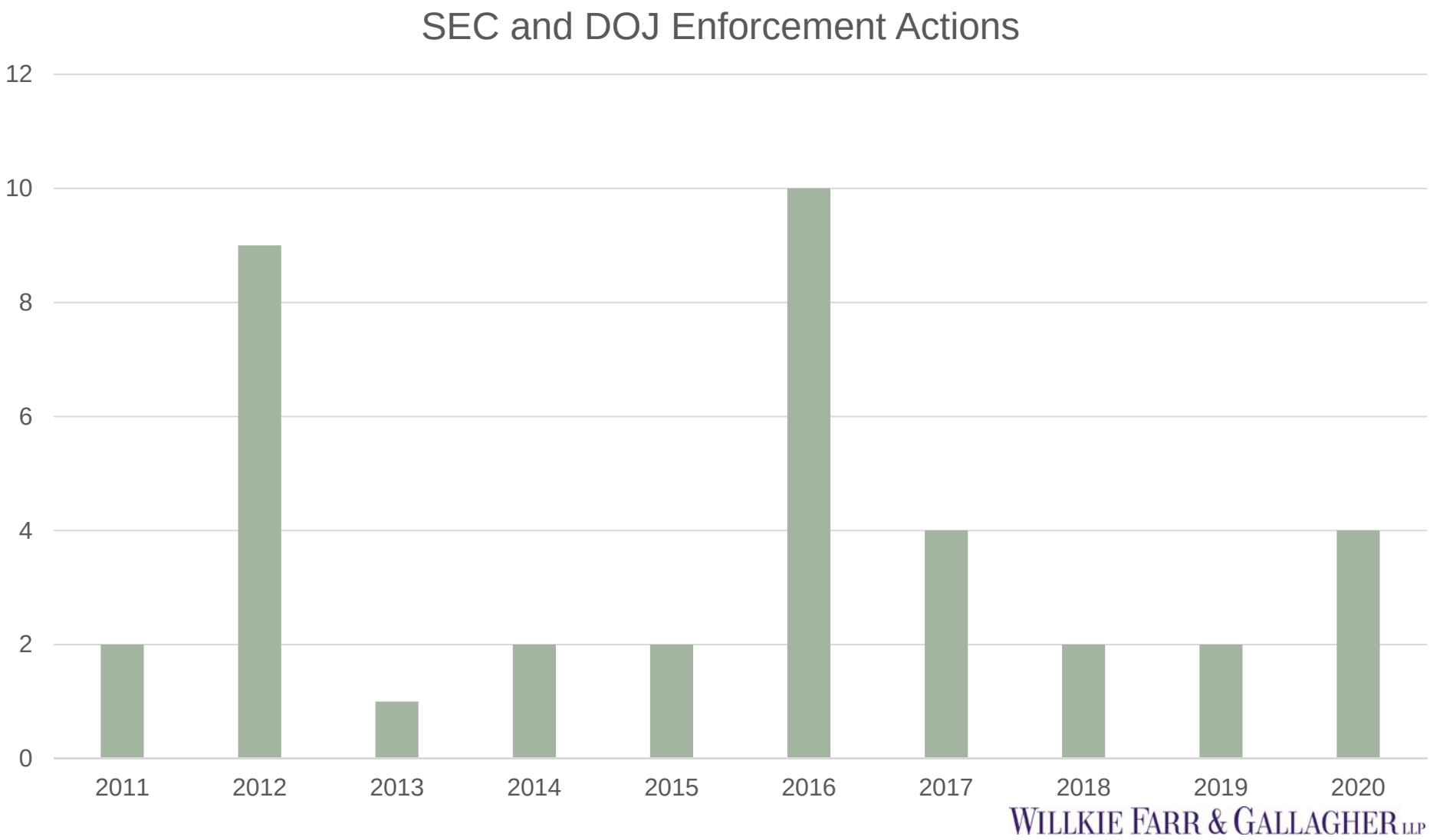
FCPA Enforcement in the Life Sciences Industry: What the Enforcers Say

- 2009 – DOJ AAG: *"[O]ne area of focus will be overseas sales in the pharmaceutical industry. In some foreign countries . . . nearly every aspect of the approval, manufacture, import, export, pricing, sale and marketing of a drug product may involve a 'foreign official' within the meaning of the FCPA."*
- 2009 – DOJ AAG*: "Our focus and resolve in the FCPA area will not abate, and we will be intensely focused on rooting out foreign bribery in your [pharmaceutical] industry."*
- 2015 – SEC Director, Division of Enforcement: *"[T]he pharma industry is one which we have been particularly focused in recent years."*
- 2016 – SEC FCPA Unit Chief: The SEC is *"going back to the pharma industry after a break for a period of years."*
- 2018 – SEC FCPA Unit Chief: *"Bribery in connection with pharmaceutical sales remains a significant problem despite numerous prior enforcement actions involving the industry and life sciences more generally."*
- 2019 – DOJ AAG: *"[G]ood corporate citizens within the pharmaceutical and medical device industries invest heavily in their compliance programs. And they need to do so. Most of you operate in a heavily regulated space, and the risks of non-compliance are high."*

FCPA Enforcement in the Life Sciences Industry: By The Numbers

- **23** life sciences companies have settled FCPA enforcement actions since 2011
  - **17** US companies
  - **6** Non-US companies
- **8** of **10** largest pharmaceutical companies have settled or been investigated for FCPA violations
- **8** of **10** largest medical device companies have settled or been investigated for FCPA violations
- $**1.7 billion** total fines, penalties and disgorgement since 2011
- **45** countries involved in the conduct
- **4** life sciences companies have been prosecuted for FCPA violations twice

Life Science FCPA Cases: 2011-2020



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FCPA Industry "Sweep"

- An industry "sweep" is a series of investigations focused on one industry based on a common practice or intermediary that regulators suspect may reflect an industry-wide improper practice
- Led by the SEC, whose mandate and powers as a regulator are broader than a prosecutor's
- Sweeps have occurred in the oil and gas, life sciences, financial services, and entertainment industries
- Life sciences industry sweep began in 2010
  - NYT Aug. 13, 2010*: "At least a dozen major drug and device makers are under investigation by federal prosecutors and securities regulators in a broadening inquiry into whether the companies made illegal payments to doctors and health officials in foreign countries."*
- From 2011 to 2016, 17 life sciences companies settled FCPA enforcement actions for total fines and penalties of almost $1 billion
- In 2016 alone, 10 of the 39 FCPA cases resolved across all industries were against life sciences companies

Recent Life Sciences FCPA Cases

Alexion Pharmaceuticals, Inc. (July 2020)

- Alexion paid $21.5 million to settle SEC books and records and internal controls charges
- Turkey, Russia, Brazil, Colombia
- Turkey – Named Patient Sales (NPS) program required approval from HCPs on MOH commissions
  - Paid a consultant $1.3 million over 6 years, some of it passed to HCPs with approval authority
  - Paid the consultant by having a vendor pay and over-invoice Alexion
- Russia – Paid HCPs to influence regional healthcare budgets to favor Alexion's product
  - Honoraria and research payments totaling $100k to a HCP to influence the allocation of rare disease funds in the region
  - Honoraria, research, and education expenses totaling $85k to two HCPs who were advisors to the MOH on rare diseases, including approved drug lists

Novartis AG (June 2020)

- Novartis paid $347 million to settle FCPA charges with the DOJ and SEC
  - DOJ – 2 DPAs – Novartis Hellas (Greece) and Alcon (Vietnam) - $234 million
  - SEC – Greece, Vietnam, and South Korea - $113 million
- International congresses – Novartis Greece paid for high potential prescribers, calling the sponsorships “investments”
- Clinical trials – Novartis Greece paid HCPs related to an epidemiological study in order to increase sales of Novartis drugs
- In Vietnam, Alcon had a “consultancy program” in which it made payments to a distributor to fund payments to HCPs to influence the purchase of surgical equipment and medical devices
- Novartis’s second FCPA enforcement action
  - In 2016, Novartis paid $25 million to settle with the SEC FCPA charges related to China

Cardinal Health, Inc. (February 2020)

- Cardinal Health paid $8.8 million to settle SEC books and records and internal controls charges
- In 2010, Cardinal acquired Chinese subsidiaries of a pharmaceutical distribution company, which became Cardinal China
  - In addition to acting as a distributor, Cardinal China, Cardinal China maintained on its books financial accounts used for fund its distribution customer's operations and marketing in China
  - After the acquisition, Cardinal China terminated most of the marketing accounts due to known FCPA risks
- Cardinal also formally employed 2,400 employees for a European dermocosmetic company, though it did not train or supervise the employees
- Cardinal China employees used marketing account funds to make payments to HCPs and state-owned retailer employees to promote the dermocosmetic company's products for which Cardinal China was the exclusive distributor
  - Improper payments included cash, luxury goods, gift cards, and travel

Fresenius Medical Care AG (March 2019)

- Fresenius, the world's largest provider of dialysis equipment, settled FCPA charges with the DOJ and SEC for total penalties of $232 million
  - The DOJ NPA with a monetary penalty of $84.7 million
  - The SEC settled for $147.7 million in disgorgement and prejudgment interest.
  - Fresenius agreed to retain an independent compliance monitor for 2 years and self-report for a third year.
- Fresenius allegedly made $30 million of bribe payments to HCPs and other government officials in 16 countries
  - Saudi Arabia, Morocco, Angola, Turkey, Spain, China, Serbia, Bosnia, Mexico, and eight countries in West Africa
- The company used cash payments through distributors, sham consulting arrangements, charitable contributions, gifts and travel, and entertainment to convey corrupt benefits to officials
- In Angola and Turkey, provided HCPs and government officials with a "free" ownership stake in Fresenius's local JV
- Fresenius voluntarily disclosed the conduct, but the DOJ did not issue a declination because the bribery was widespread and the company "did not timely respond to certain requests" by the DOJ

Sanofi (September 2018)

- Sanofi paid more than $25.2 million to settle SEC books and records and internal controls charges related to improper payments to procurement officials and HCPs in Kazakhstan and the Middle East
- Kazakhstan – used discounts and credit notes to distributors, kicked back to Sanofi employees, to bribe officials to influence tenders
  - Tracked kickbacks in internal spreadsheets with the code “marzipans”
- Middle East - paid foreign officials through product samples, consulting agreements, gifts, donations, clinical studies, and grants, to increase Sanofi sales
  - Request by an HCP of a large public hospital in Jordan for product samples – corporate policy required a medical justification for product samples
  - No justification was given but samples were provided that constituted nearly 20% of the hospital’s annual purchases
- Sales managers and medical representatives used the proceeds of sham travel and entertaining to fund bribes to HCPs
  - Medical representatives submitted doctored receipts for round tables that never occurred

Zimmer Biomet Holdings, Inc. (January 2017)

- Zimmer Biomet paid $30.5 million to settle FCPA charges with the DOJ and SEC
  - DOJ – subsidiary JERDS Luxembourg Holdings pled guilty to criminal books and records charges and was fined $17.5 million and a 3 year monitorship
  - SEC – $13 million
- Biomet had settled FCPA charges related to Brazil, Argentina, and China in 2012 for $23 million with a DPA and monitor
  - More improper conduct, in Brazil and Mexico, surfaced in 2013
  - Extended monitorship; in 2016, DOJ claimed Biomet breached the DPA
- Zimmer acquired Biomet in 2015
  - Zimmer subpoenaed in the SEC sweep; DOJ and SEC declinations in 2012
- In August 2020, the 3 year monitorship ended
- Mexico – Used a customs broker whose subagents bribed Mexican customs officials to allow Biomet to export mislabeled products to Mexico.
- Brazil – Even after the 2012 DPA, Biomet continued to use a distributor known to have paid bribes on Biomet's behalf

Charitable Contributions

- Beginning with Schering-Plough in 2004, enforcement authorities have taken the view that contributions to a bona fide charity can violate the FCPA
  - Schering-Plough's Polish subsidiary made contributions to a local charity, the Chudow Castle Foundation; no allegation of personal financial benefit
  - The foundation's founder and president was the director of a regional health authority in Poland
  - Charged as a books and records and internal controls case – recorded as charitable donations but viewed as "dues" for the director's assistance
- In 2012, Eli Lilly resolved FCPA charges based on conduct that included payments to the same Chudow Castle Foundation
- In 2013, Stryker Corp. settled FCPA charges that included a $200,000 donation to a public university in Greece to fund a laboratory that was a "pet project" of a HCP in exchange for business
- In 2016, Nu Skin Enterprises, Inc. settled with the SEC based solely on a charitable contribution to a charity founded by a member of the Chinese Communist Party to secure his assistance with an AIC investigation
- Fresenius Medical in 2019

Parting Thoughts

COVID-19's Impact on FCPA Enforcement

- Supply shifts will lead to reliance on new third parties, and an increasing need to conduct due diligence on them
- New government controls/regulation may increase interactions with foreign officials, especially in countries with state-run healthcare
- Revenue pressures, logistical limitations, and travel and work restrictions may create perverse incentives for non-compliant behavior such as bribery
- Inability or difficulty in conducting on-site oversight may require a pivot toward increased compliance surveillance and monitoring; this may require technological investments (i.e., data analytics)
- Employment pressures may lead to increases in employee compliance risks and a likely increase in whistleblowers

Recent FCPA Guidance from DOJ and SEC

- June 2020 – DOJ issued a revised version of its Evaluation of Corporate Compliance Programs
- July 2020 – DOJ and SEC issued the second edition of *A Resource Guide to the Foreign Corrupt Practices Act*
- Key takeaways for life sciences companies:
  - A continued emphasis on devoting resources to compliance - the second of three "fundamental questions" changed from "is the program implemented effectively" to "is the program *adequately resourced and empowered* to function effectively"
  - A meaningful shift in the DOJ's approach to third parties from onboarding to "third party management" for the life of the relationship
    - *"Does the company engage in risk management of third parties throughout the lifespan of the relationship, or primarily during the onboarding process?"*
  - More emphasis on data analytics
    - *"Do compliance and control personnel have sufficient direct or indirect access to relevant sources of data to allow for timely and effective monitoring and/or testing of policies, controls, and transactions?"*

Questions?

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Jeffrey D. Clark is a partner in the Litigation Department and is a member of the Compliance, Investigations & Enforcement Practice Group. Jeffrey represents corporations and individuals in a wide variety of criminal and civil investigations and enforcement matters, including DOJ and SEC enforcement actions. His practice includes conducting complex, worldwide internal corporate investigations and providing advice to corporate management and directors regarding compliance and enforcement matters. He also counsels companies on designing and implementing corporate compliance programs. Jeffrey focuses on Foreign Corrupt Practices Act matters, and also has substantial experience in other types of international business and white collar litigation.

Chambers USA describes Jeffrey as “a top-notch lawyer” and “unquestionably an FCPA expert” who is “incredibly steady and really comforting to a client.” Jeffrey is co-author of The Foreign Corrupt Practices Act: Compliance, Investigations and Enforcement, a comprehensive book covering all aspects of FCPA compliance and enforcement.