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Top Legal Developments Life Sciences Companies Need to Watch

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June 15, 2016

Agenda

- **Day 1**
  - **Compliance with the FCPA and Anticorruption Laws for Life Sciences Companies**
    - Jacqueline Wolff
  - **False Claims Act Litigation**
    - Kimo Peluso
  - **Antitrust Issues**
    - Lisl Dunlop
- **Day 2**
  - **340-B Program**
    - Helen Pfister
  - **Emerging Environmental Regulations: Life Sciences**
    - Ted Wolff
  - **Wearables, Devices and Cybersecurity**
    - Helen Pfister, Kimo Peluso
  - **Advertising and Marketing: Communicating with Consumers**
    - Marc Roth

COMPLIANCE WITH THE FCPA AND ANTICORRUPTION LAWS FOR LIFE SCIENCES COMPANIES

Jacqueline Wolff
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Agenda

- FCPA 101
- Enforcement Landscape: DOJ and SEC Focus on Life Sciences
- DOJ FCPA Voluntary Disclosure Pilot Program
- Compliance Expectations

- Bribery Provisions
  - A “corrupt” offer, payment, promise, or gift of any money or thing of value
  - To any
    - Foreign Official or
    - Other person knowing that some or all of the payment will be passed on to a Foreign Official
  - For the purpose of obtaining or retaining business or obtaining any improper advantage (quid pro quo)

- Books and Records & Internal Control Violations
  - Failure of Issuer/Regulated Entity to Record Bribe “Accurately” and “In Reasonable Detail”
  - Failure of Issuer/Regulated Entity to Have Internal Controls that Provide Reasonable Assurances that Transactions Are Recorded as Necessary for Preparation of Financial Statements in Conformity with GAAP

– Defenses & Exceptions

- Payment Not Corrupt: Personal Non-Business Purpose or Legitimate Payment For Service Unrelated to Government Decision-Making
- "Grease" or "Facilitating" Payments: Necessary to Expedite Specified Routine Government Action (But...illegal in other countries; *e.g.,* U.K., China, Mexico and Brazil)
- Promotional Travel and Lodging Expenses
- Travel and Lodging in Connection with Carrying Out a Government Contract
- Written Law in Foreign Country Permits Conduct—Custom Is Not Good Enough

- Criminal & Civil Penalties
  - Bribery
    - Individuals: $100,000 and 5 Years in Prison
    - Corporations: $2 Million or Twice the Gain
  - Felony Books & Records/Internal Controls—Willful Failure
    - Individuals: $5 million and 20 Years
    - Corporations: $25 million or Twice the Gain
  - Civil Books and Records/Internal Controls
    - Disgorgement
    - Civil Penalties
    - Injunction
  - Other
    - Debarment & Exclusion
    - Lawsuits
    - Reputational Risk

On February 19, 2016, Kara Brockmeyer, chief of the SEC's Foreign Corrupt Practices Act unit, announced that, in terms of upcoming enforcement investigations, the Commission is "going back to the pharma industry after a break for a period of years," because the pharmaceutical industry was "having a difficult time addressing the risks."

– Practicing Law Institute's "SEC Speaks in 2016" Conference, Washington, D.C.

- Syncor (2002)
  - Medical Imaging Supplier
  - During Vendor/Business Partners Due Diligence, Potential FCPA Problem Uncovered by Entity Seeking to Acquire Subsidiary
  - Approximately $600,000 in "Payments" to Physicians Employed by State-owned Hospitals in Five Countries
    - Registration fees, travel, lodging, and meals to attend educational seminars
  - Gifts of computer equipment, digital cameras, wines, wristwatches, software and office furniture
  - Resolution
    - Criminal plea by subsidiary
    - $2 million criminal fine
    - $500,000 civil fine against parent
    - Installation of "independent consultant" to review controls and report to the government

Enforcement Landscape: The Distributors

- AGA Medical Group (2008)
  - Medical device manufacturer
  - 1997-2005 payments to Chinese doctors employed at state-run hospitals via local distributor
  - $460,000 in payments to have hospitals order products
  - Voluntarily disclosed bribes
  - DPA: Two Count Information; $2 million criminal penalty and 3-year monitor

Enforcement Landscape: The Customs Brokers

- Nature's Sunshine (2009)
  - Bribes to customs brokers to allow unregistered vitamins to be imported and sold in Brazil
  - COO (current CEO) of U.S. parent did not participate or have knowledge of conduct
  - SEC complaint vs. COO and CFO charged both as "control persons" for "failure to adequately supervise" personnel who were directly responsible for internal controls regarding registration of product in Brazil
  - No admission by COO, but payment of $25,000 to settle SEC books & records/internal control charges

Enforcement Landscape: The Freight Forwarders

- Panalpina, Inc. (2010)
  - Freight forwarder—U.S. Sub of Foreign Parent
  - Neither U.S. Sub nor Foreign Parent Traded on the U.S. Exchanges
  - Alleged bribes were to assist "issuer customers" in overcoming customs delays or seeking to avoid customs duties
  - Charged by SEC for aiding and abetting customers to violate the books and records and internal control provisions
  - Charged by DOJ under bribery provisions
  - Resolution: DPA with DOJ; Final judgment with SEC; disgorgement of over $11 million and criminal penalty of $70 million

Enforcement Landscape: The Joint Venture Partners

- RAE Systems, Inc. (2010)
  - Trades on the U.S. Exchanges
  - Pre-formation due diligence on KLH, Chinese JV partner, owned by Beijing Academy of Sciences, reveals:
    - Significant government client base
    - Cash advances used to bribe Foreign Officials to obtain business
    - False government-issued tax receipts (fapiao) submitted to Accounting
    - Accounting aware receipts are false
    - Accounting uses fapiao to justify T&E expense deductions
  - Upon formation, RAE has significant majority ownership of JV; increased in 2006 to 96%
  - Following JV formation, RAE instructs JV personnel to revise business practices to conform with major multinationals regarding commissions, consultants, etc.
  - RAE verbally informs JV officers bribery must stop
  - A month later, RAE CFO informs RAE HQ that bribery continues at JV
  - Each JV employee required to take FCPA compliance training

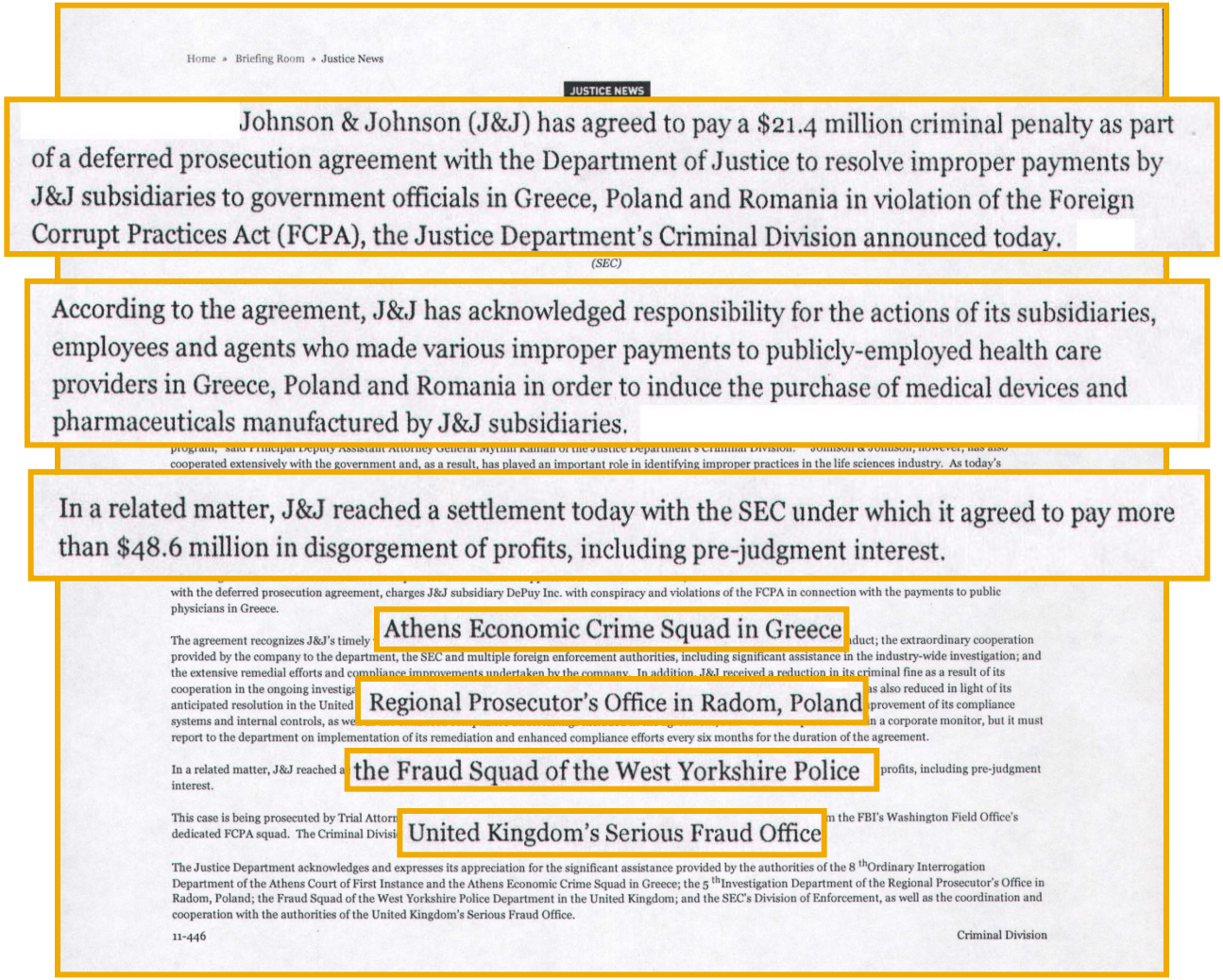
- RAE Systems, Inc. (2010)
  - Internal controls regarding cash advances, receipts and accounting are not revised
  - Bribery and accounting issues continue
  - Third-party consultants hired by JV; fees used as bribes to obtain contract
  - Whistleblower informs HQ of money laundering issue at JV which suggests potential bribery
  - RAE investigates and resolves money laundering issue – no inquiry into potential bribery and still no revisions to cash advance system
  - Second JV in China—no pre-acquisition due diligence and similar issues. RAE takes 70% interest in JV. JV partner is Liaoning Coal Industry Group Co.
  - Total bribes: $400,000 for $3 million in revenue and $1.1 million in profit
  - New CFO advises Audit Committee
  - Several months' internal investigation
  - Voluntary disclosure to SEC and DOJ

Enforcement Landscape: The Joint Venture Partners (cont'd)

- RAE Systems, Inc. (2010)
  - Full reporting to the SEC and DOJ on processes and results of internal investigation
  - $1.7 million criminal penalty
  - $1.2 million disgorged to SEC
  - Over $4 million in professional and legal fees for two years of investigation and remediation
  - Non-prosecution agreement with DOJ
  - Neither admit nor deny consent with SEC
  - Full cooperation regarding employees
  - Periodic reporting to DOJ

Enforcement Landscape: The Sales Agents and the Distributors

- Johnson & Johnson (2011)



Home » Briefing Room » Justice News

JUSTICE NEWS

Johnson & Johnson (J&J) has agreed to pay a $21.4 million criminal penalty as part of a deferred prosecution agreement with the Department of Justice to resolve improper payments by J&J subsidiaries to government officials in Greece, Poland and Romania in violation of the Foreign Corrupt Practices Act (FCPA), the Justice Department's Criminal Division announced today.

(SEC)

According to the agreement, J&J has acknowledged responsibility for the actions of its subsidiaries, employees and agents who made various improper payments to publicly-employed health care providers in Greece, Poland and Romania in order to induce the purchase of medical devices and pharmaceuticals manufactured by J&J subsidiaries.

cooperated extensively with the government and, as a result, has played an important role in identifying improper practices in the life sciences industry. As today's

In a related matter, J&J reached a settlement today with the SEC under which it agreed to pay more than $48.6 million in disgorgement of profits, including pre-judgment interest.

with the deferred prosecution agreement, charges J&J subsidiary DePuy Inc. with conspiracy and violations of the FCPA in connection with the payments to public physicians in Greece.

Athens Economic Crime Squad in Greece

The agreement recognizes J&J's timely [illegible] duct; the extraordinary cooperation provided by the company to the department, the SEC and multiple foreign enforcement authorities, including significant assistance in the industry-wide investigation; and the extensive remedial efforts and compliance improvements undertaken by the company. In addition, J&J received a reduction in its criminal fine as a result of its cooperation in the ongoing investiga[illegible]as also reduced in light of its anticipated resolution in the United [illegible] provement of its compliance systems and internal controls, as we[illegible] a corporate monitor, but it must report to the department on implementation of its remediation and enhanced compliance efforts every six months for the duration of the agreement.

Regional Prosecutor's Office in Radom, Poland

In a related matter, J&J reached a[illegible] profits, including pre-judgment interest.

the Fraud Squad of the West Yorkshire Police

This case is being prosecuted by Trial Attorn[illegible]m the FBI's Washington Field Office's dedicated FCPA squad. The Criminal Divisi[illegible]

United Kingdom's Serious Fraud Office

The Justice Department acknowledges and expresses its appreciation for the significant assistance provided by the authorities of the 8 thOrdinary Interrogation Department of the Athens Court of First Instance and the Athens Economic Crime Squad in Greece; the 5 thInvestigation Department of the Regional Prosecutor's Office in Radom, Poland; the Fraud Squad of the West Yorkshire Police Department in the United Kingdom; and the SEC's Division of Enforcement, as well as the coordination and cooperation with the authorities of the United Kingdom's Serious Fraud Office.

11-446

Criminal Division

Enforcement Landscape: The Sales Agents and the Distributors (cont'd)

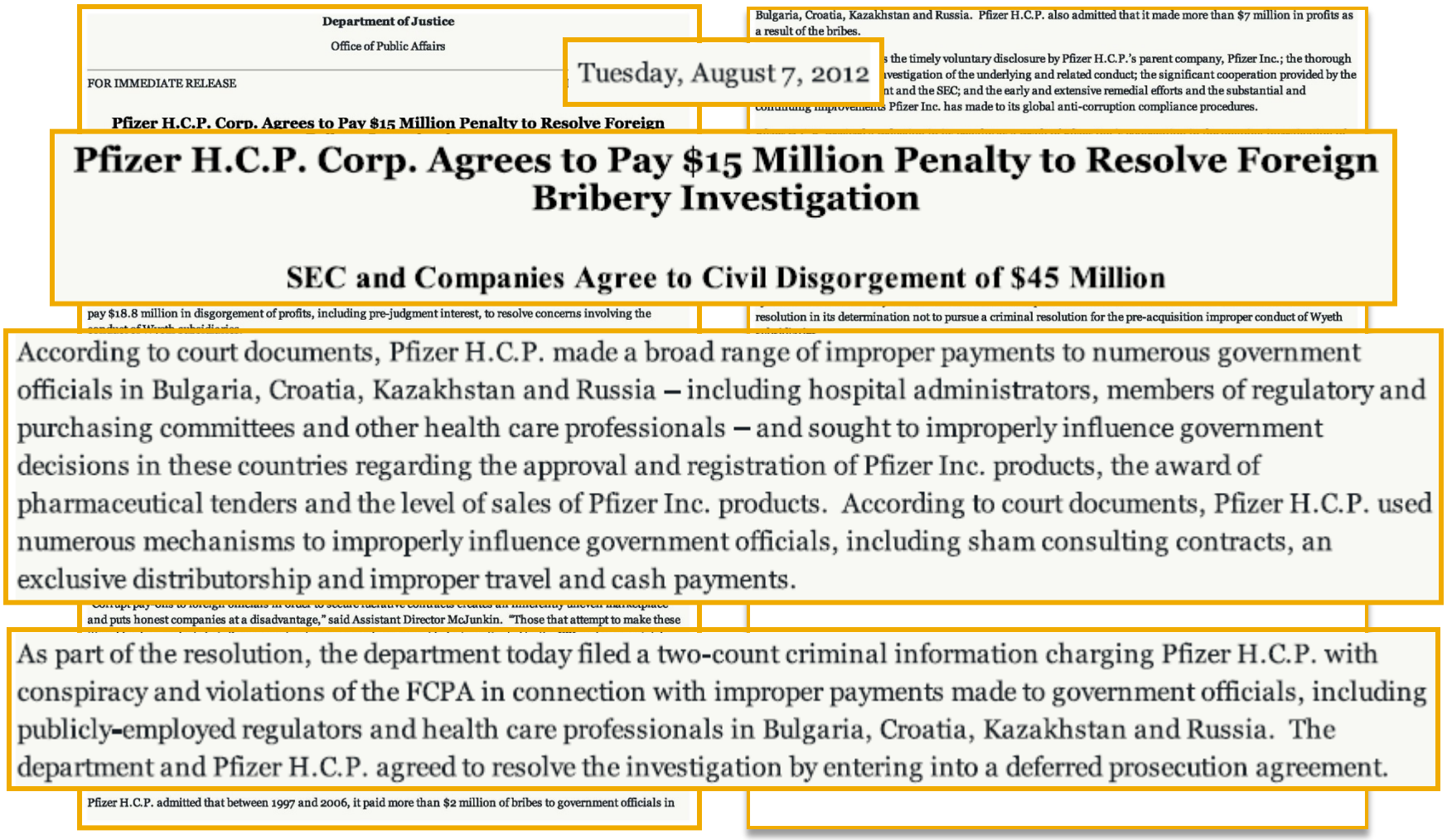
- Johnson & Johnson (2011)
  - Large Discounts and High Commissions
    - Commonly owned exclusive distributor and consultant in Greece received large discounts and commissions, respectively
    - A portion of the monies was paid to Greek surgeons to induce them to buy DePuy products
  - Speaker Programs and Clinical Trials
    - Contracts for lecturing, leading workshops and conducting clinical trials were awarded to Polish publicly-employed HCPs sitting on tender committees
    - Sales reps were not required to provide company with proof of performance
    - 4,400 such contracts over six years
    - Some of the contracts were provided as an inducement or reward for purchasing J&J products

Enforcement Landscape: The Sales Agents and the Distributors (cont'd)

- Johnson & Johnson (2011)
  - Sponsorship of HCPs in Poland
    - Tender Committee members sponsored to attend medical conferences
    - $7.6 M spent on sponsorships over six years
    - Sponsorship to influence decision-making
  - Use of distributors in Romania as pass-throughs for cash payments to HCPs
  - Sales reps overcharging travel to generate cash for HCPs in Romania

Enforcement Landscape: The Consultants and the Distributors

- Pfizer H.C.P. Corp. (2012)



Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Tuesday, August 7, 2012

Pfizer H.C.P. Corp. Agrees to Pay $15 Million Penalty to Resolve Foreign Bribery Investigation

SEC and Companies Agree to Civil Disgorgement of $45 Million

pay $18.8 million in disgorgement of profits, including pre-judgment interest, to resolve concerns involving the

According to court documents, Pfizer H.C.P. made a broad range of improper payments to numerous government officials in Bulgaria, Croatia, Kazakhstan and Russia – including hospital administrators, members of regulatory and purchasing committees and other health care professionals – and sought to improperly influence government decisions in these countries regarding the approval and registration of Pfizer Inc. products, the award of pharmaceutical tenders and the level of sales of Pfizer Inc. products. According to court documents, Pfizer H.C.P. used numerous mechanisms to improperly influence government officials, including sham consulting contracts, an exclusive distributorship and improper travel and cash payments.

and puts honest companies at a disadvantage," said Assistant Director McJunkin. "Those that attempt to make these

As part of the resolution, the department today filed a two-count criminal information charging Pfizer H.C.P. with conspiracy and violations of the FCPA in connection with improper payments made to government officials, including publicly-employed regulators and health care professionals in Bulgaria, Croatia, Kazakhstan and Russia. The department and Pfizer H.C.P. agreed to resolve the investigation by entering into a deferred prosecution agreement.

Pfizer H.C.P. admitted that between 1997 and 2006, it paid more than $2 million of bribes to government officials in

Bulgaria, Croatia, Kazakhstan and Russia. Pfizer H.C.P. also admitted that it made more than $7 million in profits as a result of the bribes.

the timely voluntary disclosure by Pfizer H.C.P.'s parent company, Pfizer Inc.; the thorough investigation of the underlying and related conduct; the significant cooperation provided by the nt and the SEC; and the early and extensive remedial efforts and the substantial and Pfizer Inc. has made to its global anti-corruption compliance procedures.

resolution in its determination not to pursue a criminal resolution for the pre-acquisition improper conduct of Wyeth

Enforcement Landscape: The Law Firms

- Stryker (2013)
  - Payments on behalf of foreign subsidiaries included payments made by third parties
    - Mexican law firm payment to government employee reimbursed by subsidiary and booked as legitimate legal expenses, though no legal services were provided
  - Payments from 2003 to 2008 in five countries, totaling $2.2 million, incorrectly described in books and records
    - $7.5 million profits
    - $13.2 million payment to settle SEC charges of books and records and internal controls violations

Enforcement Landscape: The Travel Agents

- IBM (2013)
  - From 2004-2009, IBM China employees used travel agencies as conduits to pay for foreign officials' travel that was prohibited by IBM policy
  - From 1998-2009, employees of Korean subsidiary, using JVs and business partners as conduits, alleged to have provided government officials in charge of purchasing for 16 different government agencies with cash, gifts and travel expense reimbursement totaling $207,000
  - Inflated invoices by business partner/installer used to generate monies to officials
  - Although **IBM had forms and policies** designed to prevent paying for officials' side trips when traveling for product training, 114 such trips were entered in IBM's records as travel for training

Enforcement Landscape: The Travel Agents (cont'd)

- IBM (2013)
  - IBM charged in SEC Complaint with violating the books and records and internal control provisions of the FCPA
  - Result: Agreement to entry of Final Judgment enjoining IBM from violating the books and records/internal controls provisions, disgorgement of $5,300,000, payment of $2,700,000 in prejudgment interest, and $2,000,000 in civil penalties

Enforcement Landscape: The Regulatory Consultant

- SciClone Pharmaceuticals (2016)

5. Although SciClone has local distributor relationships in China, its sales and marketing activities there are conducted through SPIL. Sales representatives in China regularly reported to senior management of SPIL on their efforts to increase sales. In these reports, sales representatives openly referred to instances in which they provided weekend trips, vacations, gifts, expensive meals, foreign language classes, and entertainment to HCPs in order to obtain an increase in prescriptions from those HCPs. As described by one sales manager, this was "luring them with the promise of profit."

SciClone Pharmaceuticals, Inc. | OF 1934, MAKING FINDINGS, AND IMPOSING A CEASE-AND-DESIST ORDER

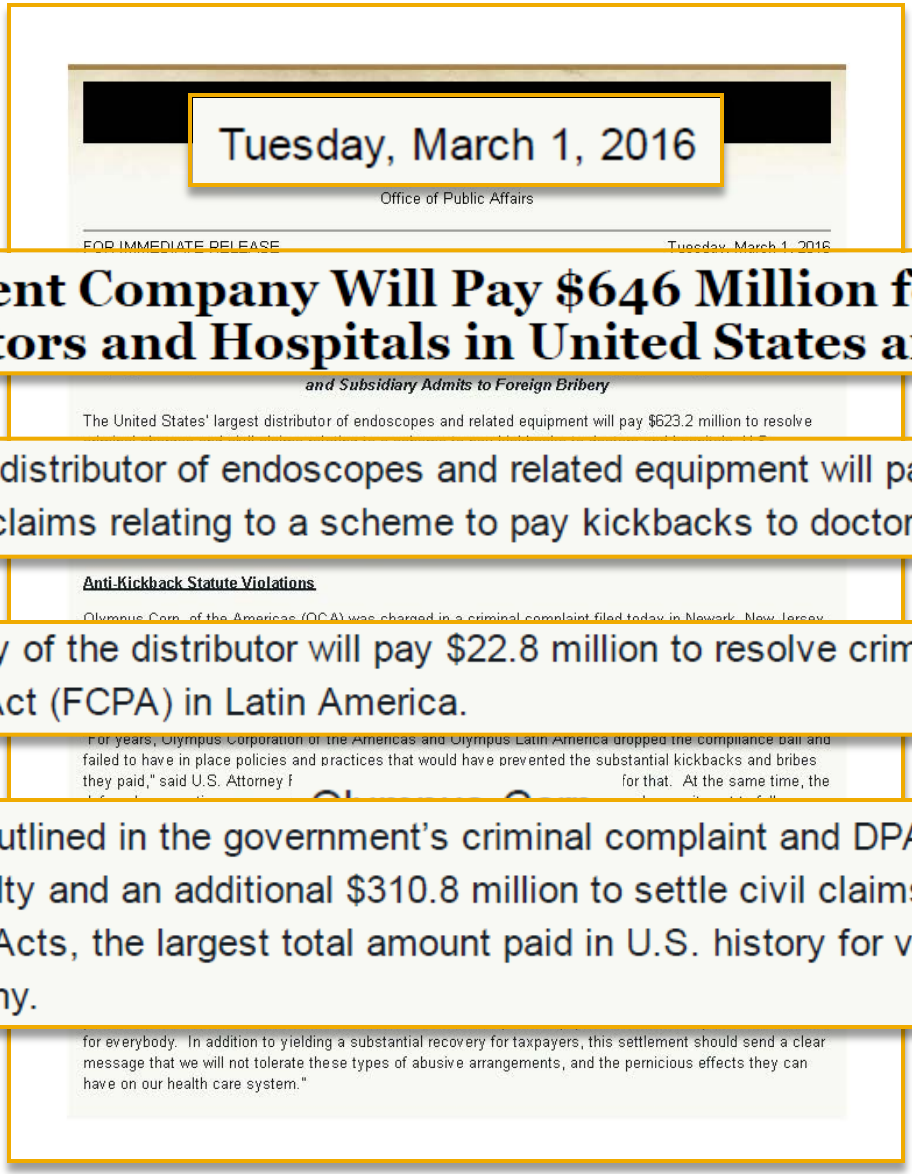
such things as:

7. In 2007, SciClone submitted a license application to the State Food and Drug Administration for a new medical device product and had a renewal pending for its largest product. SciClone hired a well-connected regulatory affairs specialist ("Specialist") to facilitate that licensing.

8. The Specialist arranged trips for two foreign officials to attend an academic conference in Greece at SciClone's expense. The conference was solely related to the new medical device. One of the foreign officials had oversight over new product approvals, and the other foreign official had oversight over renewals for existing licensed products. At the time the trip was arranged, both SciClone's renewal application and its application for a new license were pending.

9. As the foreign officials were unable to obtain travel visas in time to attend the conference in Greece, the Specialist instead provided them at least $8,600 in lavish gifts.

Enforcement Landscape: FCPA and the FCA



Tuesday, March 1, 2016

Office of Public Affairs

FOR IMMEDIATE RELEASE Tuesday, March 1, 2016

Medical Equipment Company Will Pay $646 Million for Making Illegal Payments to Doctors and Hospitals in United States and Latin America

and Subsidiary Admits to Foreign Bribery

The United States' largest distributor of endoscopes and related equipment will pay $623.2 million to resolve

The United States' largest distributor of endoscopes and related equipment will pay $623.2 million to resolve criminal charges and civil claims relating to a scheme to pay kickbacks to doctors and hospitals

Anti-Kickback Statute Violations

a subsidiary of the distributor will pay $22.8 million to resolve criminal charges relating to the Foreign Corrupt Practices Act (FCPA) in Latin America.

For years, Olympus Corporation of the Americas and Olympus Latin America dropped the compliance ball and failed to have in place policies and practices that would have prevented the substantial kickbacks and bribes they paid," said U.S. Attorney f for that. At the same time, the

As a result of the conduct outlined in the government's criminal complaint and DPA, OCA has agreed to pay a $312.4 million criminal penalty and an additional $310.8 million to settle civil claims under the federal and various state False Claims Acts, the largest total amount paid in U.S. history for violations involving the AKS by a medical device company.

for everybody. In addition to yielding a substantial recovery for taxpayers, this settlement should send a clear message that we will not tolerate these types of abusive arrangements, and the pernicious effects they can have on our health care system."

Enforcement Landscape: FCPA and the FCA

In a separate DPA, Olympus Latin America Inc. (OLA), a subsidiary of OCA, will pay a $22.8 million criminal penalty for violations of the FCPA.

receive $44,102, 573 million from the federal share and $7 million from the state share of the civil settlement amount.

In a separate criminal complaint filed today in Newark federal court, OCA's Miami-based subsidiary OLA was charged with FCPA violations in connection with improper payments to health officials in Central and South America, and OLA entered into a separate three-year DPA. According to court documents, from 2006 until August 2011, OLA implemented a plan to increase medical equipment sales in Central and South America by providing payments to health care practitioners at government-owned health care facilities. These payments included cash, money transfers, personal grants, personal travel and free or heavily discounted equipment.

compliance programs. Unlike other medical and surgical products companies, Olympus did not create the

department's commitment to ensuring the integrity of the health-care equipment market, regardless whether the illegal bribes occur in the U.S. or abroad."

The criminal complaint alleges that the improper payments happened while Olympus lacked training and

The department reached this resolution based on a number of factors, including that OLA did not voluntarily disclose the misconduct in a timely manner, but OLA did receive credit of a 20 percent reduction on its penalty for its cooperation, including its extensive internal investigation, translation of numerous foreign language documents and collecting, analyzing and organizing voluminous evidence.

Larry Mackey, a former federal prosecutor best known for trying the Oklahoma City bombing cases, has been

- compliance responsibilities for OCA management and the board of directors;

- OCA must adopt an executive financial recoupment program requiring executives who engage in

In addition to the criminal and civil resolutions, Olympus executed a corporate integrity agreement (CIA)

various state False Claims Acts. The federal share of the civil settlement is $267,288,323, and Olympus will pay $43,512,053 million to participating states that contributed to the falsely claimed Medicaid payments at issue.

The civil settlement resolves a lawsuit filed by John Slowik, the former chief compliance officer of OCA, in the District of New Jersey, under the federal and various state False Claims Acts. The acts permit whistleblowers to file suit for false claims against the government entities and to share in any recovery. Mr. Slowik will

- review procedures for testing the compliance program.

"Olympus Corp. of the Americas' and its subsidiaries' greed-fueled kickback scheme threatened the impartiality of medical decision-making and the financial integrity of Medicare and Medicaid," said Special Agent in Charge Scott J. Lampert of the U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG). "Working with our law enforcement partners, we remain vigilant and committed to

Enforcement Landscape: The DOJ's New FCPA Voluntary Disclosure Pilot Program

- On April 5, 2016, DOJ announced an FCPA Voluntary Disclosure Pilot Program
  - Requires elements of cooperation including source of information for facts presented (i.e., which employee said what when interviewed)
  - Requires existing compliance program
  - Capped reduction in penalties may be available if DOJ satisfied with cooperation and compliance program
  - Declination not available if management involved in violation

Enforcement Landscape: The DOJ's New FCPA Voluntary Disclosure Pilot Program (cont'd)

- What is the baseline for your compliance program in order to be eligible for credit?
  - The establishment of a culture of compliance
  - The dedication by the corporation of sufficient resources to the compliance function
  - The hiring of experienced and qualified compliance personnel
  - The compliance function retaining its independence
  - An effective risk assessment has been performed and the compliance program has been tailored based on that assessment
  - A procedure for establishing how compliance personnel are compensated and promoted *vis-à-vis* effectiveness
  - An audit function to assure the compliance program's effectiveness
  - The establishment of a reporting structure for compliance personnel within the company
  - A procedure to appropriately discipline employees identified by the corporation as responsible for misconduct
  - Compliance personnel compensation is akin to or better than other employees' compensation

Compliance Expectations: DOJ/SEC Guidance

- One size does not fit all: effective compliance program tailored to entity's specific business and risks
- Organizational culture that encourages ethical conduct and a commitment to compliance
- Three basic questions:
  - Is the entity's compliance program well designed?
  - Is it being applied in good faith?
  - Does it work?

Compliance Expectations: DOJ/SEC Guidance (cont'd)

- Tone at the top
- Clearly articulated policy, including:
  - compliance responsibilities, authority and autonomy
  - internal controls—staffing and resources
  - risk assessment
  - risk-based third-party due diligence and monitoring
  - auditing and testing
  - documentation policies
  - disciplinary procedures and incentives
  - confidential reporting and internal investigation
  - M&A Due Diligence

Compliance Expectations: Breaking It Down

- All Life Sciences Anticorruption Policies Should Address
  - Definitions:
    - Who Is a "Foreign Official," Defining "Physician"
    - What is "Anything of Value"?
  - Basic Interactions with Foreign Officials:
    - Entertainment and Gifts: Caps, Aggregation and Auditing
    - Charitable Donations Requested by Foreign Officials
    - Political Contributions to Overseas Candidates
    - Facilitation Payments
    - Drug Approvals
    - Clinical Trials
  - Required Internal Approvals and Documentation:
    - Due Diligence and Approvals for All Dealings with Third Parties Operating Abroad
    - Anticorruption Contract Language
    - Due Diligence and Approvals for Engaging a Foreign Official
    - Approvals for Vendors Recommended by a Foreign Official
    - Due Diligence and Approvals for Hiring Employees—Connection to Foreign Official
  - Training Regarding Interactions with Foreign Officials
  - Monitoring and Audits

Compliance Expectations: Approvals and Documentation

- Overseas Consultants, Overseas Employees and Vendors
  - Choosing an Overseas Consultant, Employee or Vendor—Due Diligence
    - Key questions:
      - Recommended by or related to a Foreign Official?
      - Working with a government agency?
      - Any red flags indicating will not comply with FCPA?
    - Decision Tree
    - Questionnaire & Checklist
  - Ensuring the Consultant, Employee and Vendor Do Not Violate the FCPA
    - FCPA & Anticorruption Summary
    - Contracts with Anticorruption Language
    - Certification of Training
  - Payments to Consultants, Overseas Employees and Vendors—Further Ensuring Compliance
    - Invoices with backup for proof of services rendered should be submitted before any payments are made
    - Invoices with service provider receipts should be submitted before any payments for expenses are made
    - Aggregating mechanism for monitoring and auditing

Compliance Expectations: Setting Contractual Obligations

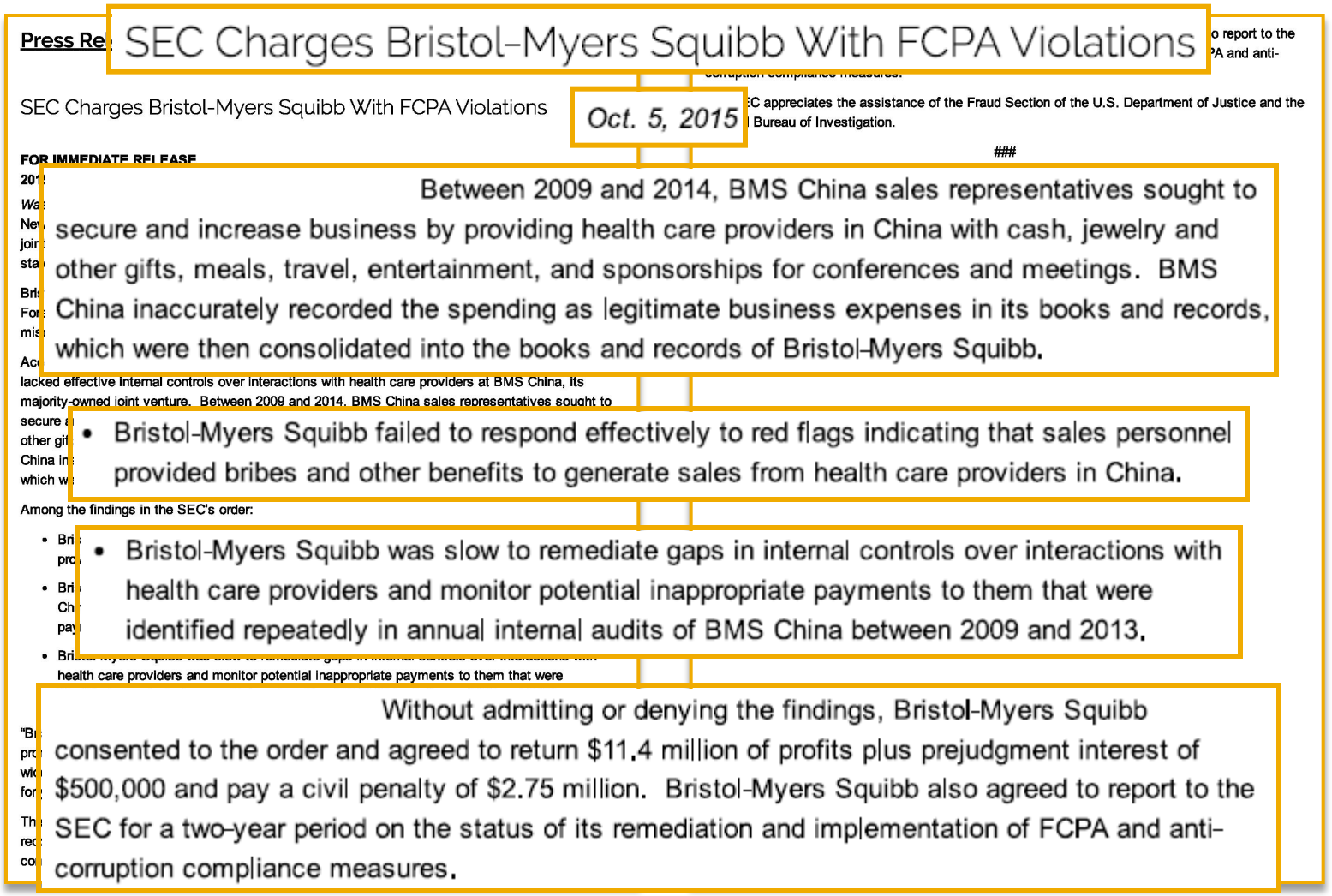
- Provisions to Include in Agreements with Third Parties:
  - Representation that Third Party has no business or family ties to any Foreign Official that could have any influence with respect to Client's business
  - Representation and warranty that the Third Party will not bribe Foreign Officials
  - Termination of the agreement and withholding of any amounts due in the event representations are violated (where allowed under local law)
  - Clawback where permissible under local law
  - Consider milestone payment provisions with proof of service provided
  - Require submission of receipts if reimbursement of expenses is contemplated
  - Indemnification of attorney's fees if they were incurred due to improper conduct by Third Party
  - Audit Rights
  - Training

Compliance Expectations: Approvals and Documentation

- Engaging a Foreign Official
  - Due diligence: Key question is whether official responsibilities dovetail with consulting. If so, cannot engage that official
  - Written contract detailing responsibilities, tasks, and FMV payment
  - Certification
    - Contractual duties unrelated to official duties
    - Government entity aware of arrangement—no ethical violations allowed under local law
    - Promise to recuse if matter relating to Company is before them
    - Won't bribe another Official

Compliance Expectations: And Don't Be Slow to Address Red Flags

- Bristol-Meyers Squibb (2015)



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THE FALSE CLAIMS ACT

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Litigation
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False Claims Act – Implied False Certification

- Implied Certification under the False Claims Act: *United Health Services v. U.S. ex rel. Escobar*
- Implications for Pharmaceutical and Medical Device Companies
- Potential Outcomes

- The False Claims Act
  - Liability for any person who
    - "knowingly"
    - "presents, or causes to be presented"
    - to the United States
    - a **"false or fraudulent"** claim for payment
      - Or a false statement that is **material** to a false or fraudulent claim.

31 U.S.C. § 3729(a)(1), (2).

- Financial Consequences
  - Damages
    - at least double
    - usually treble
  - Costs and attorneys' fees
  - Mandatory civil penalty $5,500 to $11,000
    - per claim

31 U.S.C. §§ 3729(a), 3730(d).

The False Claims Act

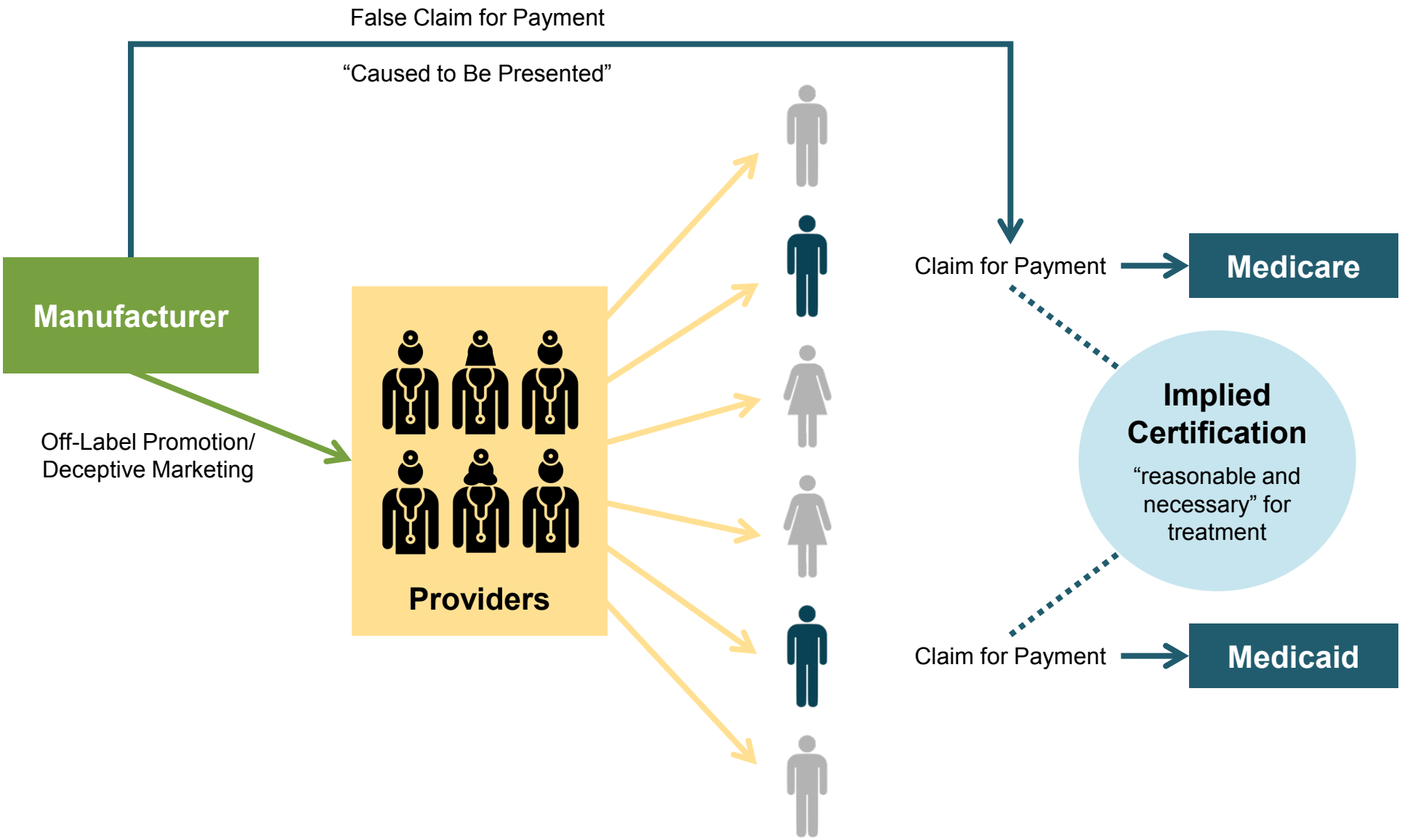
- The False Claims Act
  - Whistleblower lawsuits
    - Qui tam provisions
    - Government can decline to intervene
    - Relator's counsel controls case

- Implied False Certification
  - Submission of claim for payment implicitly (and falsely) certifies compliance with a law or regulation
  - Circuit split
    - Regulation must be express condition of payment – 2nd, 3rd, 6th, 8th Circuits
      - condition of participation versus condition of payment
    - "Fact-intensive" analysis – 1st, 4th and D.C. Circuits
    - Implied certification not adopted – 5th and 7th Circuits
      - Potential exception "worthless services"

- Implied False Certification as to Drug and Device Companies
  - Government as purchaser (e.g., Veterans Affairs)
    - Withholding information from FDA
      - *U.S. ex rel. Krahling v. Merck & Co.*, 44 F. Supp. 3d 581 (E.D. Pa. 2014)
    - Undisclosed breaches of commercial procurement contracts
      - E.g., implied certification of merchantability
        - *U.S. ex rel. Steury v. Cardinal Health*, 625 F.3d 262 (5th Cir. 2010)

- Implied False Certification as to Drug and Device Companies
  - Government as payor (e.g., Medicare, Medicaid)
    - Deceptive marketing, off-label promotion, misbranding
    - Other regulatory requirements
      - E.g., FDA's Current Good Manufacturing Practices
        - *U.S. ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694 (4th Cir. 2014)

Off-Label Promotion as Implied False Certification



Escobar

- United Health Services v. U.S. ex rel. Escobar
  - MassHealth provider, Arbour Counseling Services
  - Counseling services to relators' child – died during care
  - Qui tam action
  - Implied false certification
    - MassHealth regs regarding qualifications and supervision of caregivers
  - District court – dismissed
    - Conditions of participation versus conditions of payment
  - 1st Circuit – reversed
    - rejects the participation versus payment distinction
    - fact-intensive inquiry as to whether the regulatory non-compliance rendered a claim for payment false or fraudulent

Escobar

- Decision / Predictions
  - Predictors
    - *Husky International Electronics v. Ritz*, 136 S.Ct. 1581 (May 16, 2016)
      - "The term 'actual fraud' in [the Bankruptcy Code] encompasses forms of fraud, like fraudulent conveyance schemes, that can be effected without a false representation."
      - 7-to-1 decision
  - Oral Argument
    - Kagan, Sotomayor, Kennedy
      - "Knowingly" and "materially" is enough for fraud
    - Breyer, Roberts
      - line-drawing

- Decision / Predictions
  - Oral Argument (cont'd)
    - Guns, boots and staplers
    - "basic to the transaction" versus "material"
      - Justice Breyer: "But what's the difference between what you just said and what he said?"
    - No mention of "condition of participation"

ANTITRUST ISSUES IN PHARMACEUTICAL LIFECYCLE MANAGEMENT

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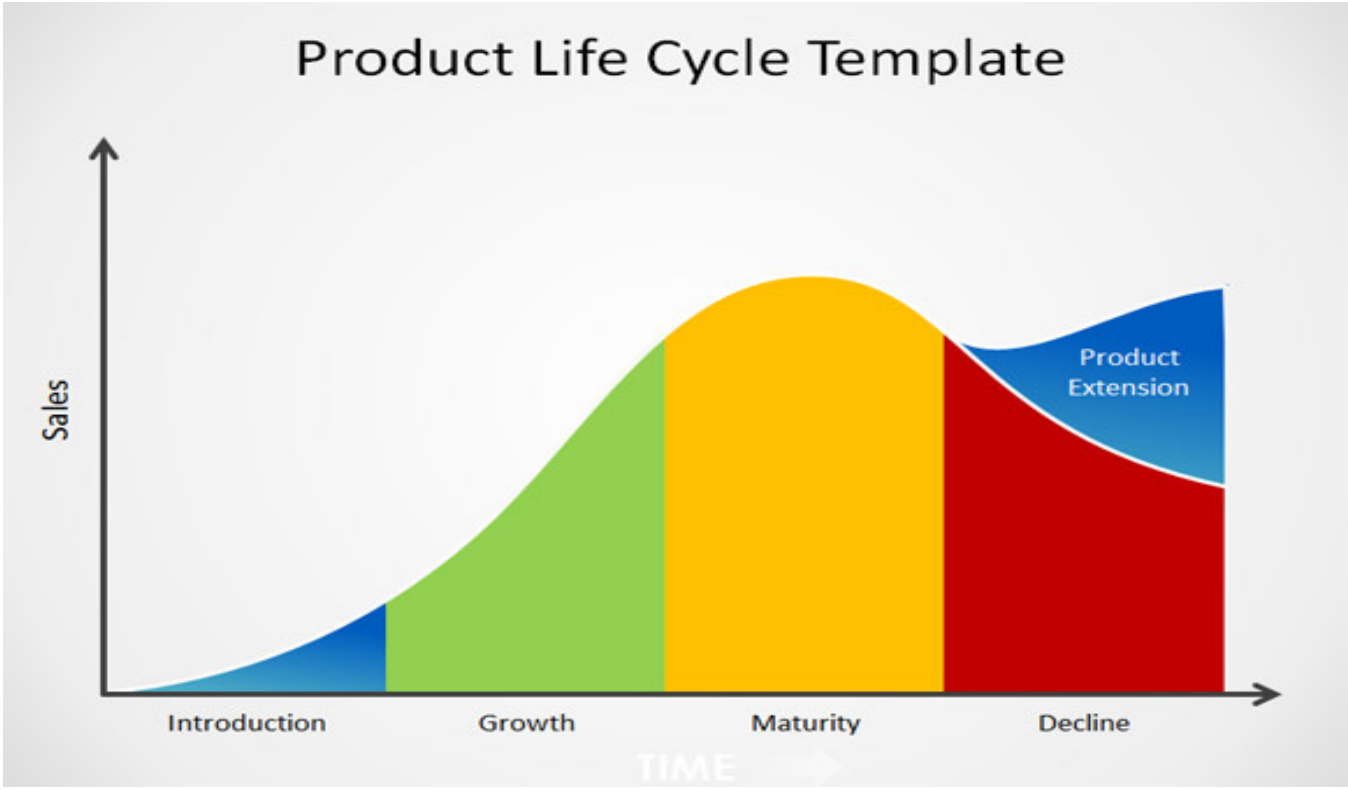
Pharmaceutical Lifecycle Management

- As pharmaceutical products mature, sales growth diminishes:
  - Competitors develop similar or improved products
  - As patent protections expire, generic versions enter – mandatory substitution laws create a "patent cliff"



Pharmaceutical Lifecycle Management

- Product Lifecycle Management – techniques used to defend market share and maximize profits from key products even as they mature
- Techniques:
  - Innovations and enhanced product features to differentiate from competitors – product design, new indications, formulations, administration and dosing
  - Pricing and distribution strategies – price changes, product bundles, discounting and other incentives, Rx-to-OTC switches, authorized generics
  - Patent litigation
  - Agreements with competitors

Antitrust Framework

- Antitrust laws seek to protect competition by prohibiting conduct that may restrain trade
  - Adverse impact on competition usually identified by increased prices, reduced output or reduced incentives to innovate

Type of conduct	Legal provision	Prohibition	Example
Joint	Sherman Act Section 1	Prohibits combinations, combinations or conspiracies between competitors that restrain trade	"Reverse payment" patent settlements
Unilateral	Sherman Act Section 2	Prohibits monopolization and attempted monopolization	"Product hopping" and refusals to provide drug samples to generic competitors
Other	Section 5 FTC Act	Prohibits unfair methods of competition	?

Joint Conduct: Patent Settlements

- The Hatch Waxman Act
  - An expedited FDA approval process for generic drug applications (Abbreviated New Drug Application or ANDA)
  - Market exclusivity period for first ANDA filer of 180 days – blocks FDA approval of generic competitors but not branded drug manufacturer
  - A unique patent litigation process triggered by a generic drug company's submission of an application for FDA approval

Joint Conduct: Patent Settlements

- Patent challenges under Hatch Waxman
  - Generic manufacturer submitting ANDA must certify that either there is no relevant patent, the patent has expired or will expire before approval or that the relevant patent is invalid or will not be infringed by the generic drug
  - Certifying invalidity or non-infringement potentially triggers patent litigation – the generic manufacturer must give notice of the certification to the branded drug manufacturer
  - Patentee can sue generic manufacturer upon receipt of notice letter – this stays FDA approval for 30 months
  - After 45 days from notice letter, generic manufacturer can sue patentee for declaratory judgment that patent is invalid

Joint Conduct: Patent Settlements

- Hatch Waxman patent settlements implicate historic tension between patent and antitrust laws
  - In order to encourage innovation, patent laws grant a monopoly to patent holder
  - Antitrust laws seek to prevent monopolies and encourage competition
  - Settlements within the “scope of the patent” traditionally immune from antitrust scrutiny
- Competing incentives in Hatch Waxman settlements
  - Both sides – litigation risk that patent will be found valid/not valid, plus costs of patent litigation
  - Patent holder wants to enjoy monopoly profits from branded drug for as long as possible, at least the duration of the patent
  - Generic manufacturer has not yet commercialized so not liable for royalties; wants to enter market first and gain share and profits from first-filer exclusivity
- “Reverse payment” settlements
  - Provide for payment from patent holder to generic manufacturer in return for generic’s agreement to abandon challenge and stay out of the market

Joint Conduct: Patent Settlements

- *Actavis* decision (2013)
  - Solvay patented Androgel in 2003 (used for treating low testosterone levels in men).
  - Actavis filed patent for generic drug modeled after Androgel later that year, and submitted ANDA asserting there was no valid patent. Solvay sued Actavis for patent infringement.
  - FDA approved Actavis' generic for the market after the dispute over the validity of Solvay's patent continued for three years.
  - Actavis entered into a settlement agreement with Solvay in 2006 – Actavis would keep its generic drug off the market for a "specified number of years" and also agree "to promote Androgel to doctors." In exchange, Actavis would receive monetary compensation.
  - FTC sued, alleging that Actavis had unlawfully abandoned its patent challenge by agreeing to share in the "monopoly profits" of Solvay, and withdrawing its generic drug from the market. Solvay was simultaneously accused of attempting to extend its monopoly rights further than what its patent would have conferred if otherwise left as valid.
  - Supreme Court held:
    - Reverse payment settlements have potential for genuine adverse effects on competition
    - Settlements could violate the antitrust laws where payments are "large" and "unjustified"
    - FTC needs to prove illegality under rule of reason – not presumptively illegal

Joint Conduct: Patent Settlements

- Active enforcement environment
  - Many class actions against pharma manufacturers
  - FTC prosecutions, including for disgorgement of profits
  - New requirement to report Hatch Waxman patent settlements to FTC – has led to reduction in number of settlements with reverse payments
- Developments post-*Actavis*
  - Doctrine extended to non-cash payments – side deals benefiting generic manufacturer
  - "No authorized generic" agreements under attack – agreement by branded manufacturer not to market its own generic in the first filer's 180-day exclusivity period

Unilateral Conduct: Product Hopping

- Product hopping – a strategy of moving patients from an older drug product losing exclusivity to a similar but modified product for which exclusivity is still available
- *New York v. Actavis* (Namenda)
  - Forest Labs launched new extended release version of Namenda with patent protection until 2029 and removed older, immediate-release version
    - Older version withdrawn before generic entry – patients forced to switch to new ER version
    - Generics of old Namenda could not be substituted for prescriptions for Namenda ER
  - State of NY sued Forest – District Court granted injunction and 2nd Circuit upheld
  - Key holdings:
    - A product design change can be anticompetitive when it "coerces customers and impedes competition"
    - "Soft switch" tactics, such as discounts, rebates or promotional efforts, may be permissible

Unilateral Conduct: Product Hopping

- FTC: will investigate product changes that are only minor and conduct intended to destroy competition for old drug
- Class action cases continue against different product-hopping scenarios
  - Suboxone – older drug left on market before generic entry (“soft switch”)
  - Mylan v. Warner – incremental changes over several years

Unilateral Conduct: Refusal to Supply

- Antitrust laws (Section 2) permit firms to supply whomever they want, subject to some limitations:
  - Where seller has market power; and
  - Where refusal to supply would foreclose competition
- Risk, Evaluation and Mitigation Strategies (REMS) programs can form basis for Section 2 claim:
  - Generic drug manufacturers must conduct bioequivalence testing before receiving FDA approval – need access to samples
  - Branded drug manufacturers argue that selling samples of REMS-protected drugs violates terms of REMS and may subject them to legal liability if generic manufacturers do not take adequate safety precautions
  - FDA has not enforced provisions of FDA Act prohibiting branded drug manufacturers from using REMS to block or delay approval of a generic manufacturer's ANDA

Unilateral Conduct: Refusal to Supply

- Recent private cases:
  - Generic manufacturers have alleged that refusal to supply REMS-restricted drug samples violates antitrust laws
  - Branded drug manufacturers have sought declarations that they have no obligation to supply drug samples to generic competitors
  - Key holdings:
    - Prior course of dealing not required to impose obligation to supply
    - Reliance on "government mandated safety concerns" will not justify refusal to deal if there is evidence that branded drug manufacturer is seeking to maintain monopoly

Questions?

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