



EMERGING TRENDS IN LATIN AMERICA

17th Annual Pharmaceutical & Medical Device
Compliance Congress

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AGENDA

- **U.S. Enforcement in the Region**
- **Foreign Enforcement in the Region**
- **Risk Areas for Pharma and Medical Device Companies**
- **Other Factors Affecting Enforcement**
- **Key Themes**



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U.S. Enforcement in the Region

- **Historical attention to activities in the region**
 - More than 15 U.S. enforcement actions involving conduct in Brazil, Mexico, and Argentina in the past three years
 - Per FCPABlog, conduct in Latin American countries covers at least 30% of all active FCPA investigations by DOJ/SEC
 - High-profile nature of certain ongoing investigations only intensifies attention to the issue

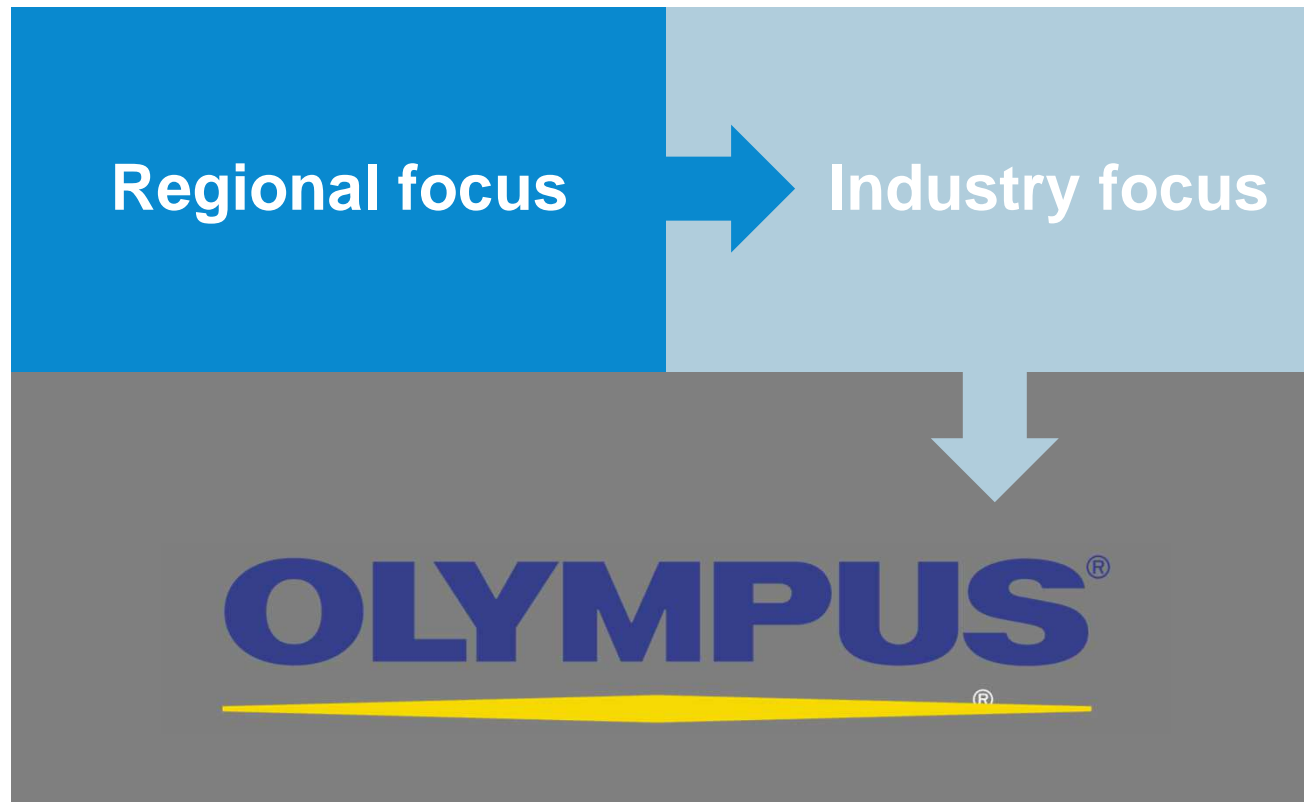


U.S. Enforcement in the Region

- Regulator statements about pharma industry
 - February 19, 2016: Chief of the SEC’s FCPA Unit states that the Commission’s future enforcement efforts will “[go] back to the *pharma industry after a break for a period of years.*”
 - March 13, 2015: Director of SEC’s Enforcement Division: “Our FCPA focus obviously covers many industries...but *the pharma industry is one on which we have been particularly focused in recent years.*”



U.S. Enforcement in the Region



U.S. Enforcement in the Region

- **Olympus investigations**
 - Conduct in question
 - Healthcare professionals at state-owned healthcare institutions designated by the company as “Key Opinion Leaders” received about \$3 million in benefits, such as cash, gifts, entertainment
 - Healthcare professionals were selected for benefits based on their ability to influence purchasing decisions at state-owned medical facilities, and the payments resulted in profits for Olympus totaling approximately \$7.5 million
 - Relevant countries
 - Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Mexico
 - Parallel enforcement with other U.S. statutes
 - FCPA settlement as bookend to anti-kickback & FCA resolutions

U.S. Enforcement in the Region

- **Issues in non-pharma matters in the region**
 - Travel & entertainment provided, directly or indirectly, for officials at state-owned companies in exchange for service contracts
 - Key Energy Services
 - Payments to government officials delivered through sham consulting agreements
 - LATAM Airlines (formerly LAN Airlines)



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Foreign Enforcement in the Region

- Legislative infrastructure most closely resembling US/UK
 - Clean Companies Act (2013)
- Active investigative environment
 - *Fantástico* Report: Pharma and Medical Device Industries
 - Operation Zealot: Tax Officials
 - Operation Greenfield: Asset Management Industry
 - Operation Mr. Hyde: Medical Device Industry
- Pharma industry & the “Judicialization of Healthcare”
 - Policy debate viewed as recipe for fraudulent acquisition of therapeutic treatments



Foreign Enforcement in the Region

- **Petrobras investigation**

- In March 2014, Brazilian authorities began money laundering investigation that eventually expanded into massive corruption scandal
- Alleged that Brazil's state oil company Petrobras received improper payments for contracts using company profits
- Cooperation resulted in massive expansion of investigation and prosecutions, including numerous high-profile individuals, shaking the entire country

THE WALL STREET JOURNAL.

BUSINESS | EARNINGS

Brazil's Petrobras Reports Nearly \$17 Billion in Asset and Corruption Charges

State-run oil company writes off \$2.1 billion of alleged bribe payments

Foreign Enforcement in the Region

- Wave of prosecutions has had far-reaching impact – numerous Brazilian and multinational public companies implicated in corruption scandals
 - Major companies that have been linked to the Petrobras scandal include SBM Offshore, Saipem SpA Rolls-Royce, and Braskem SA
- Cooperation resulted in massive expansion of investigation and prosecutions, including numerous high-profile political officials and other individuals, shaking the entire country



Foreign Enforcement in the Region

- **Legislative efforts targeting bribery and corruption**
 - Creates independent anti-corruption prosecutor
 - Enhances whistleblower protections
 - Streamlines cooperation across all levels of enforcement
 - Increases transparency obligations of public sector officials



Foreign Enforcement in the Region

- Potential legislative changes in Argentina
 - Bill under consideration would enable prosecutors to criminally charge corporations for bribery and corrupt acts
- Law 1778 in Colombia
 - Imposes administrative and criminal penalties on companies and individuals who bribe public officials
 - Extends liability for bribery and corruption to corporate subsidiaries and other parent company assets





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Risk Areas for Pharma and Medical Device Companies

- Use of distributors and sub-distributors
- Customs clearance process
- Acquisition of product registrations
- Promotional concerns regarding access to unapproved drugs and devices
- Joint ventures
- Tax obligations



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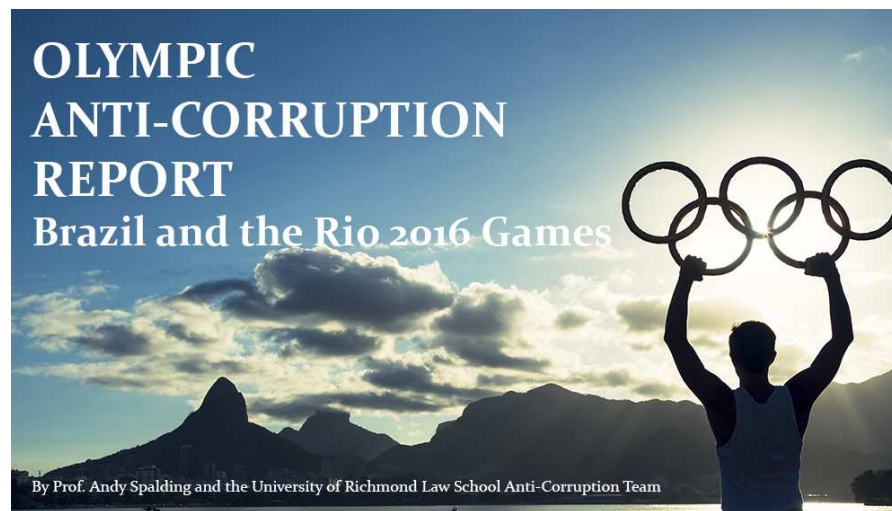
Other Factors Affecting Enforcement

- Increasing cross-border collaboration
 - *Embraer* : US/Brazilian collaboration
 - *PetroTiger*. US/Colombian collaboration
 - *Petrobras*: Increased use of plea agreements
- Political unrest



Other Factors Affecting Enforcement

“The corruption itself, by most any account, is not new.... What is new – or rather, news – is that we know about the corruption in specific and comprehensive detail... Those once subject to little more than resentment are now held accountable under the law. And at least as important, other would-be perpetrators are plainly on notice that Brazil is not what it once was.”





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Key Themes

- Continued headlines relating to scandal and corruption have **renewed calls for “clean government” across many Latin American countries**
- As a result, Latin American regulators—like their counterparts in the US—are **devoting significant resources to investigating allegations of corruption and fraud**
- What is more, US and foreign investigative trends indicate that **the pharmaceutical industry will remain a prominent target for enforcement efforts** and that **cross-border collaboration is expected to increase**

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