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CLIENT ALERT

# Changes to FCPA Enforcement – What Do the Tea Leaves Tell Us?

The new US Administration has recently signaled a significant shift in the approach to anti-bribery and anti-corruption efforts concerning global multinational corporations. The President's January 20, 2025 directive "to revise existing national security and counter-narcotics strategies to pursue total elimination of Cartels and Transnational Criminal Organizations" appears to have set the tone.

On February 10, 2025, the President issued an executive order freezing the initiation of all new Foreign Corrupt Practices Act (FCPA) investigations and enforcement actions for 180 days. This directive follows a February 5, 2025 memorandum from the Attorney General, which prioritizes investigations related to foreign bribery that facilitates criminal operations of cartels and transnational criminal organizations (TCOs).

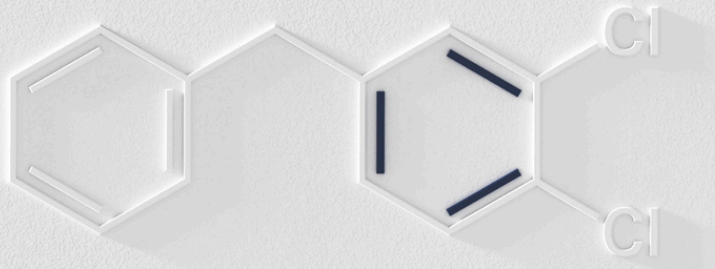
## Key Changes and Implications

### 1. Pause on FCPA Enforcement
The executive order mandates a 180-day freeze on new FCPA investigations and enforcement actions with a potential for extension.

### 2. Shift in Focus
The DOJ is instructed to prioritize cases related to cartels and TCOs, moving away from investigations lacking such connections.

### 3. Review of Existing Cases
The Attorney General is directed to review all existing FCPA investigations and take appropriate action to "restore proper bounds on FCPA enforcement."

### 4. New Guidelines
The order calls for updated guidelines to promote the President's authority in foreign affairs and prioritize American interests and competitiveness.




## Impact on Pharmaceutical and Medical Device Companies

While these changes may seem significant, their practical impact on pharmaceutical and medical device companies may be limited:

### 1. Maintained Compliance
Companies should continue to maintain robust compliance and Anti-Bribery and Anti-Corruption (ABAC) programs, including strong monitoring programs, to identify potential shifts in employee behavior.

### 2. Third-Party Risks
The industry's reliance on third-party vendors and distributors in international markets remains a key risk area. Companies should conduct appropriate due diligence prior to engaging third-parties and should have a process in place for reevaluating existing third-parties.

### 3. Whistleblower Protections
Companies should maintain and even strengthen whistleblower protections and encourage ethical reporting of incidents of non-compliance.

### 4. Government Interactions
Frequent interactions with government officials for regulatory approvals and sales to state-run healthcare systems continue to present bribery risks.

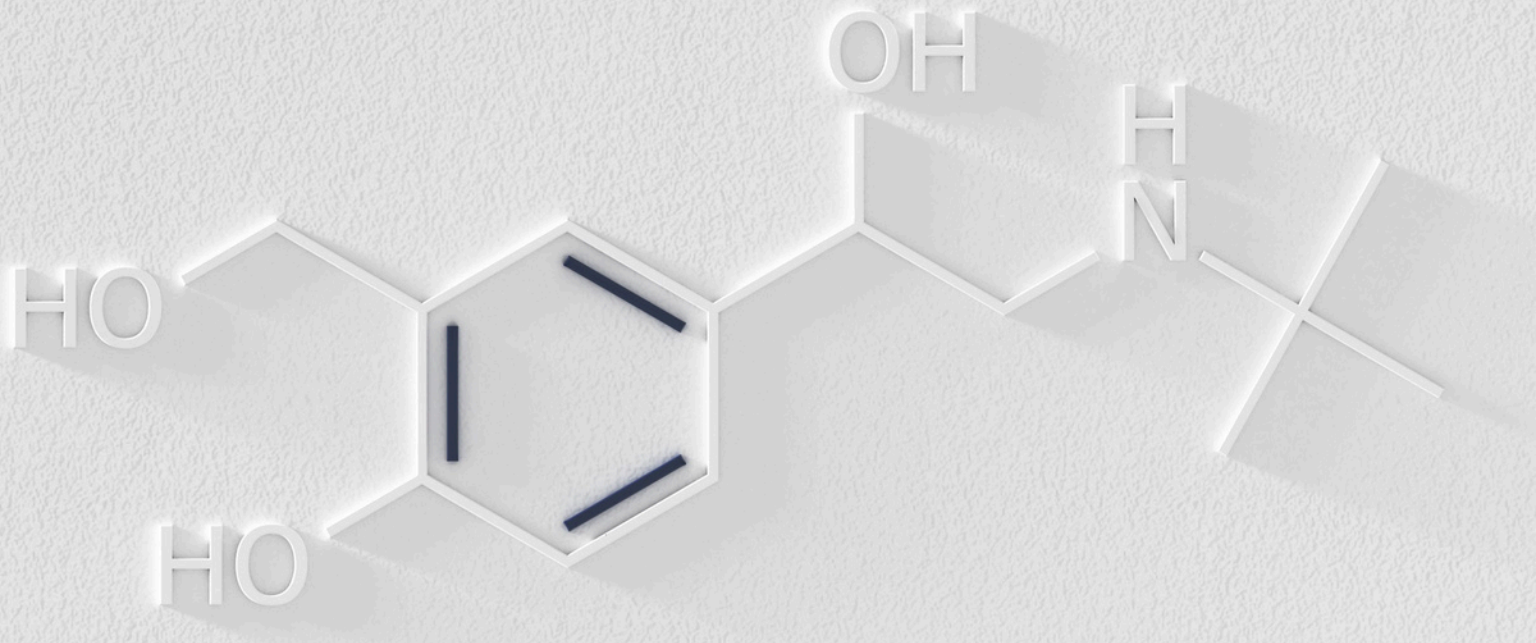
**5. High-Risk Jurisdictions**
Operations in countries with high corruption risks still require vigilance.

**6. International Regulations**
Companies must navigate evolving international anti-corruption laws, which may become more stringent in response to the US shift.

**7. Individual Liability**
The focus may shift toward prosecuting individuals rather than companies, potentially reducing corporate liability for employee misconduct.

While the recent changes signal a potential relaxation of FCPA enforcement, medical device and pharmaceutical companies should maintain robust compliance programs. The shift in focus toward cartels and TCOs may reduce scrutiny on certain corporate activities, however, other international anti-corruption laws may fill the vacuum. Maintaining strong ABAC compliance programs remains the best defense against potential risks.

Epsilon Life Sciences continues to work with clients on developing, implementing and testing ABAC compliance programs and third-party vendor risk management programs, built on decades of FCPA enforcement experience.



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