

Recent Trends in Criminal Enforcement

Overview of recent criminal cases and criminal prosecution priorities

Food and Drug Law Institute
Enforcement, Litigation, and Compliance Conference

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Agenda

- Overview
- Key Areas of Enforcement
 - Good Manufacturing Processes
 - Foreign Inspection
 - Synthetic Opioids
- Individual Accountability





Panel

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Enforcement Overview

- FDA Advisory Actions
 - Untitled letter
 - Warning letter
 - Regulatory meeting
- Administrative Actions
 - Administrative detention
 - Civil money penalties hearing
 - “FDA initiated” recall
 - Exclusion, Suspension, Debarment
- Civil Enforcement Actions
 - Civil Litigation (False Claims Act, etc.)
 - Seizure
 - Injunction
- **Criminal Enforcement Actions**
 - **Corporate**
 - **Individual**

Criminal Prosecution under the FDCA

- Sources of Authority:
 - Misdemeanor conviction punishable by up to one year imprisonment
 - Felony conviction punishable by up to three years imprisonment
 - violations with “intent to defraud or mislead.”
 - if previously convicted of FDCA misdemeanor, no need to show knowledge or intent
- DOJ is a key decision maker
 - FDA lacks independent litigation authority, so must rely on DOJ to bring cases
 - Seizures and injunctions typically brought at FDA’s request
 - DOJ and FDA litigators work together closely in enforcement actions

Good Manufacturing Practices



Foreign Inspections



Synthetic Opioids – New Enforcement Trends



Individual Accountability

