The Impact of the Opioid Crisis on the Pharmaceutical Industry

Breakfast Roundtable
November 8, 2018

John C. Richter
Partner, King & Spalding LLP

Rachael Honig
First Assistant United States Attorney,
United States District of New Jersey
Agenda

I. Opioid Crisis Overview

II. Public Response to Crisis

III. Investigation and Litigation Trends

IV. Investigative Focuses and Enforcement Theories

V. Compliance Lessons for Pharmaceutical Companies
Opioid Crisis Overview

• During 1990s, the introduction of new opioid products and increased advocacy for pain treatment led to a change in prescription trends

• From 2000s to present, there has been a significant proliferation of the use, misuse, and abuse of opioids in United States

• More than 350,000 people died from an opioid-related overdose between 1999 and 2016

• According to CDC, increase in opioid fatalities driven by three phenomena:
  • Increase in opioid prescriptions;
  • Increase in heroin overdose deaths; and
  • Increase in overdose deaths involving synthetic opioids, particularly illicitly-manufactured fentanyl
Public Response to Crisis

• Heightened media focus on opioid overdoses and drug safety

• Rapid changes in industry attitudes and practices
  • Rapid shift in norms and attitudes towards pain treatment
  • Significant decrease in opioid prescriptions
  • Heightened payer and provider scrutiny

• Increased executive and legislative focus on crisis and reform efforts
  • Congressional investigations
  • President’s Commission on Combating Drug Addiction and the Opioid Crisis
  • SUPPORT for Patients and Communities Act of 2018
Investigative Focuses and Enforcement Theories

- U.S. Department of Justice
  - Multiple wide-ranging investigations of stakeholders’ practices
  - Commitment of increased resources
  - Appointment of Director of Opioid Enforcement and Prevention Efforts
  - Prescription Interdiction and Litigation Task Force

- State Attorneys General (AGs)
  - Nearly every state AG is investigating the industry
  - Bipartisan coalition of state AGs investigating pharmaceutical companies

- Multidistrict Litigation
Investigation and Enforcement Theories

- Multipronged focus on health-care providers, manufacturers, and distributors
  - Focus on pharmaceutical companies’ marketing/promotional practices; and
  - High volume opioid prescribers

- Variety of legal theories
  - Anti-Kickback Statute
  - Racketeering Influenced and Corrupt Organizations (RICO) Act
  - Controlled Substances Act
  - Health Care Fraud Statute
  - Food, Drug, & Cosmetic Act - criminal misbranding

- Increasing focus on individuals
  - Yates Memo on “Individual Accountability for Corporate Wrongdoing”
  - Park Responsible Corporate Officer Doctrine
Compliance Lessons for Pharmaceutical Companies

• Widely accepted norms and industry-wide practices can shift rapidly and drastically in response to public scrutiny

• Continued government scrutiny will likely spread beyond opioid space and lead to changes in pharmaceutical companies’ broader marketing and promotional practices

• All pharmaceutical companies should respond to heightened scrutiny by demonstrating a robust internal commitment to compliance and proactively engaging with regulators and enforcement agencies