



# Enforcement Update: Department of Justice and Office of the Inspector General

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**Moderated by Jennifer Bragg**, Partner, Skadden, Arps, Slate, Meagher & Flom LLP, and  
Chair, FDLI Board of Directors

# 2019 FDLI Advertising and Promotion for Medical Products Conference

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**Gus Eyer, Director**  
**Consumer Protection Branch**  
**U.S. Department of Justice**

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**Mary Riordan, Senior Counsel**  
**Office of Counsel to the Inspector General**  
**Department of Health and Human Services**

*The presenters' views are their own and do not express official policy.*

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# Discussion Topics

- **Office Overviews – Enforcement Roles**
- **Coordination between CPB and OCIG**
- **Enforcement Priorities**

# Consumer Protection Branch



- Main Justice component of approximately 75 prosecutors.
- Leads DOJ efforts to enforce criminal and civil laws that protect Americans' health, safety, economic security, and identity integrity.
  - Titles 18 and 21 Offenses
  - Primary DOJ authority over FDCA and FTCA (JM 4-1.313.8-9)
- Represents the FDA and other consumer protection agencies in defensive litigation.
- <https://www.justice.gov/civil/consumer-protection-branch>

# HHS - OIG



- **The Office of Inspector General (OIG) is one operating division of the U.S. Dept. of Health and Human Services (HHS).**
- **HHS-OIG's mission is to:**
  - **Prevent and detect fraud and abuse in HHS programs (including Medicare and Medicaid); and**
  - **Improve efficiency in HHS programs (including through program audits and reviews.)**
- **OIG website: [www.oig.hhs.gov](http://www.oig.hhs.gov)**

# Coordination

- **Investigations – HHS-OIG agents investigate sophisticated health care frauds in collaboration with DOJ components.**
- **Resolution Negotiations – While DOJ is engaging with a party, OCIG offers DOJ and the party:**
  - **Input on monetary terms and other settlement aspects**
  - **Guidance on likely application of OIG’s exclusion authorities**
- **Resolution:**
  - **OCIG determines application of OIG’s exclusion authorities**
  - **OCIG may craft and enforce a corporate integrity agreement (CIA)**

# Exclusion / CIAs

- **Waiver of permissive exclusion authorities:**
  - As part of civil FCA settlements, **OIG** may agree to release permissive exclusion in exchange for defendant's agreement to enter a **Corporate Integrity Agreement (CIA)**.
- **CIAs:**
  - 5-year contracts between **OIG** and defendant under which defendant agrees to establish/maintain a corporate compliance program to govern future conduct.
  - **Negotiated/monitored by **OIG**.**
  - **Posted on **OIG** website.**

# Enforcement Priorities

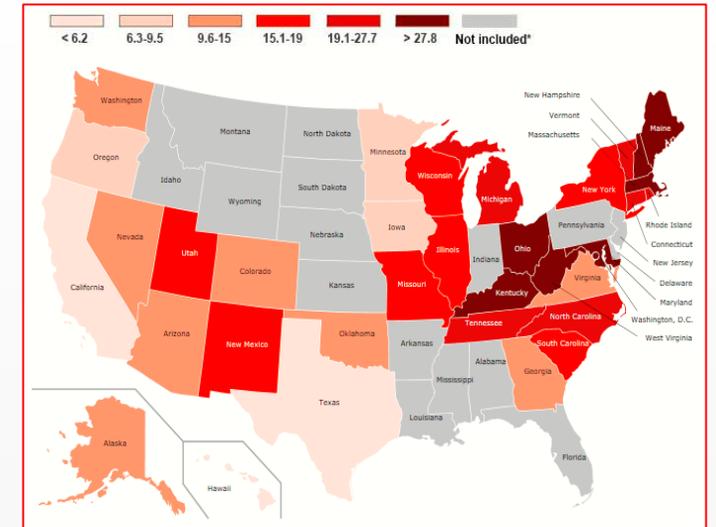
- **False and Misleading Data and Marketing**
- **Opioids and Other REMS Drugs**
- **Anti-Kickback Statute (AKS) Issues**
- **Dietary Supplements**

# False and Misleading Marketing and Data

- **Refined enforcement of “off-label promotion”**
- **False or misleading claims / data**
  - Untrue statements
  - Manipulated or selectively chosen data
- **Consumer harm or substantial risk**

# Opioids and Other REMS Drugs

- 130 deaths from overdose every day
- CDC: total economic burden of prescription opioid misuse in U.S. is \$78.5 billion.
- Substantial Actions:
  - Insys (D. Mass.)
  - Indivior / RB Group (W.D. Va.)
  - Rochester Drug Co-op (S.D.N.Y.)
  - National Prescription Opiate MDL (N.D. Oh.)



*Opioid deaths per capita by state*

- Risk Evaluation and Mitigation Strategies - FDA can require for certain medications with serious safety concerns; designed to support the safe use of associated medication – Aegerion (D. Mass.) / Chelius (D. Haw.)
- REMS compliance is tethered to marketing

# Anti-Kickback Statute Issues

- **Matters involving copay assistance programs**
- **False Claims Act settlements**  
(Some of these matters also involved other issues.)

- Astellas Pharma US, Inc.
- Amgen, Inc.
- US WorldMeds LLC
- Jazz Pharmaceuticals plc

- Lundbeck LLC
- Alexion Pharmaceuticals, Inc.
- Actelion Pharmaceuticals US, Inc.
- Insys Therapeutics

# Anti-Kickback Statute Issues

- **False Claims Act matters involving other types of AKS issues**
  - **Speaker Program Issues**
  - **Patient Registry Issues**
  - **Practice and Market Development Support**
  - **Other Issues (e.g., meals and entertainment)**

# Dietary Supplements

- **\$130b industry in 2018;  
\$210b by 2026**
- **Ingredient integrity**
  - Intended use?
  - Declaration/labeling?
  - Foreign sources?
- **Unauthorized claims lead to consumer risk**





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