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## **QUI TAM CONFERENCE**

February 28 – March 1

FHI 360 Conference Center • Washington, D.C.

# **The FCA and Opioids**

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## PRELIMINARY STATEMENT

- The panel will discuss only publicly available information.
- The statements of the panel members are their own and do not reflect the views or positions of their firms, clients, or the Department of Justice.



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## FEDERAL INITIATIVES

- **President's Commission on Combating Drug Addiction and the Opioid Crisis**

[https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final\\_Report\\_Draft\\_11-1-2017.pdf](https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf)

- **DOJ Initiatives**

- **Opioid Fraud & Abuse Detection Unit**

<https://www.justice.gov/opa/pr/attorney-general-sessions-announces-opioid-fraud-and-abuse-detection-unit>

- **Prescription Interdiction & Litigation (PIL) Task Force**

<https://www.justice.gov/opa/pr/attorney-general-sessions-announces-new-prescription-interdiction-litigation-task-force>

- **SUPPORT for Patient and Communities Act**

<https://www.congress.gov/bill/115th-congress/house-bill/6>



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## President's Commission on Combating Drug Addiction and the Opioid Crisis

- Report issued in April 2017
  - 56 recommendations including:
    - Better addressing illegal, non-prescription opioids
    - Education for patients and prescribers of prescription opioids
    - Address addiction and substance use disorders (research and treatment

**SUPPORT Act – treatment and education**



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## DOJ Initiatives

- **Opioid Fraud & Abuse Detection Unit**

<https://www.justice.gov/opa/pr/attorney-general-sessions-announces-opioid-fraud-and-abuse-detection-unit>

- **Announced in August 2017**
- **“focus specifically on opioid-related health care fraud using data to identify and prosecute individuals that are contributing to this prescription opioid epidemic.”**



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## DOJ Initiatives

- **Prescription Interdiction & Litigation (PIL) Task Force** <https://www.justice.gov/opa/pr/attorney-general-sessions-announces-new-prescription-interdiction-litigation-task-force>
- **Announced in February 2018**
- **DOJ review of “every level of the distribution chain” for illegal activity related to prescription opioids**



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## Prescription opioids are FDA approved

### DOJ policies, *Escobar* and *Gilead*

- Yates Memo (2015)

<https://www.justice.gov/archives/dag/file/769036/download>

- *Escobar* – scienter and materiality

- *Universal Health Services Inc. v. U.S. ex rel Escobar*, 136 S.Ct. 1989 (2016)

- Granston Memo (2018)

- Amendments to the Justice Manual / Brand Memo

- *Gilead*

- *U.S. ex rel Campie v. Gilead Sciences Inc.*, 862 F.3d 890 (9<sup>th</sup> Cir 2017) cert. denied 2019 WL 113075 (January 7, 2019)



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## *Qui tam* cases with government intervention

- 5 cases against Insys regarding opioid product Subsys <https://www.justice.gov/usao-cdca/pr/us-intervenes-whistleblower-lawsuits-alleging-insys-therapeutics-paid-illegal-kickbacks>
  - Criminal cases against Insys employees and Subsys prescribers
- 4 cases against Indivior and Reckitt
- Case against Arriva Medical and Alere  
<https://www.justice.gov/usao-mdtn/pr/united-states-joins-false-claims-act-lawsuit-against-arriva-medical-llc-and-alere-inc>
  - Government intent to add individual defendant (reimbursement consultant)



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## ***Qui tam* cases where government is seeking dismissal**

- **December 17, 2018 DOJ filed motions to dismiss in 11 *qui tam* cases:**
  - *U.S. ex rel. Health Choice Group LLC v. Bayer Corp et al.*, No. 5:17-00126 (E.D. Tex.)
  - *U.S. ex rel. SAPF, LLC, v. Amgen, Inc.*, No. 16-cv-5203 (E.D. Pa.)
  - *U.S. ex rel. SMSPF, LLC v. EMD Serono, Inc.*, No. 16-cv-5594 (E.D. Pa.)
  - *U.S. ex rel. SMSF, LLC v. Biogen, Inc.*, No. 1:16-cv-11379-IT (D. Mass.)
  - *U.S. ex rel. NHCA-TEV, LLC v. Teva Pharms.*, No. 17-cv-2040 (E.D. Pa.)
  - *U.S. ex rel. SCEF, LLC v. Astra Zeneca PLC*, No. 17-cv-1328 (W.D. Wash.)
  - *U.S. ex rel. Miller, v. AbbVie, Inc.*, No. 3:16-cv-2111 (N.D. Tex.)
  - *U.S. ex rel. Carle, v. Otsuka Holdings Co.*, No. 17-cv-966 (N.D. Ill.)
  - *U.S. ex rel. CIMZNHCA v. UCB, Inc.*, No. 3:17-cv-00765 (S.D. Ill.)
  - *U.S. ex rel. Health Choice Alliance, LLC v. Eli Lilly & Co.*, No. 5:17-cv-123 (E.D. Tex.)
  - *U.S. ex rel. Health Choice Advocates, LLC v. Gilead, et al.*, No. 5:17-cv-121 (E.D. Tex.)



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## Recent FCA statistics

- 2018 published data on FCA settlements and judgments reported by DOJ Civil Division
  - \$2.8 Billion total settlements and judgments for all FCA cases (HHS, DOD, non-HHS and non-DOD)
  - \$4.6 Million of that from opioid prescribers according to Bloomberg Law News.

<https://news.bloomberglaw.com/health-law-and-business/fraudulent-opioid-prescribers-can-expect-more-federal-charges>



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