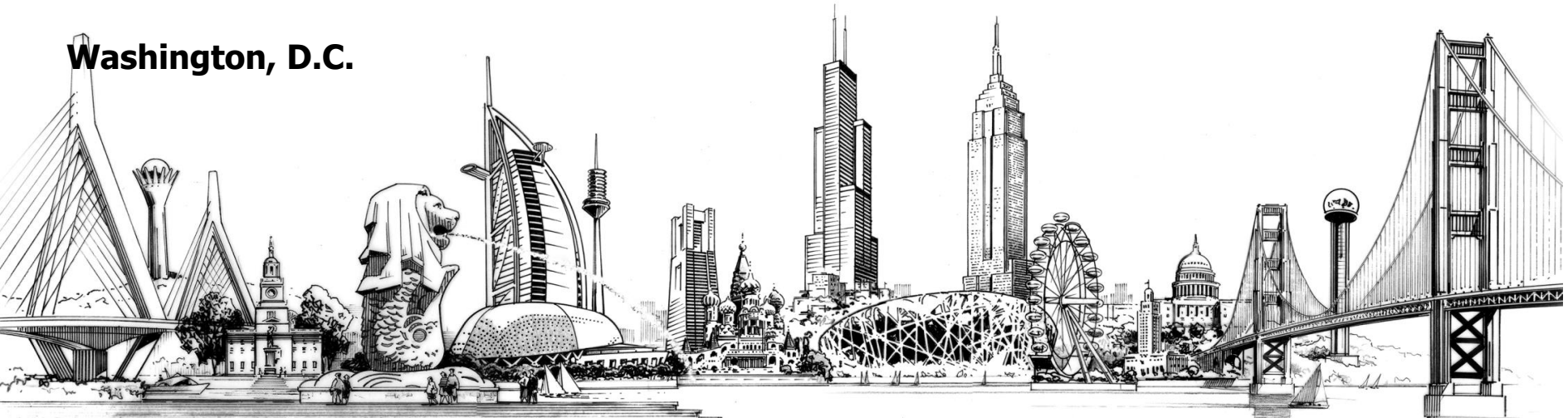
# 20TH ANNIVERSARY PHARMACEUTICAL AND MEDICAL DEVICE COMPLIANCE CONGRESS

# THE CHANGING FACE OF QUI TAM

**November 7, 2019**

**Washington, D.C.**



# The Changing Face of Qui Tam

- Meredith S. Auten
  - Morgan Lewis, Philadelphia
  - www.morganlewis.com
- Marc S. Raspanti
  - Pietragallo Gordon Alfano Bosick & Raspanti, Philadelphia
  - www.pietragallo.com
- Virginia A. Gibson
  - Hogan Lovells, Philadelphia
  - www.hoganlovells.com

# Agenda

- Who is pursuing Qui Tams?
  - Competitors and Vendors as relators
  - States and their Qui Tam authorities
  - Rise of international whistleblowers
- What are the trending theories?
  - Are off-label marketing cases dead?
  - New frontier of private equity exposure
- When to fight and when to resolve?
  - Granston dismissals
  - Does intervention matter?
- How much?
  - Recent DOJ Enforcement Statistics – Driven by Qui Tams

# WHO?

# New Voices

- Competitors
- Vendors
- Compliance Officers
- Litigation Funders:  Solidly in qui tam world
- Impact of Globalization of the pharmaceutical industry:
  - Whistleblowers no longer have borders
  - More international whistleblowers coming forward under the U.S. FCA
  - Other countries have whistleblower laws but typically lack financial reward or anti-retaliation protections for whistleblowers

# New Enforcement Interest in States

- Over 30 states with their own FCAs
- Aggressive and active enforcement by many State AGs
- Decisions by USDOJ not to intervene and join as plaintiff are not impacting them
- Willing to pursue qui tams without USDOJ and on their own
- Achieving substantial recoveries on their own
- Willing to negotiate settlements *ahead of* and *instead of* the Feds

# New Defendants: Private Equity Investors

- Private equity has poured into the life sciences industry
- Impact of the scienter standard
- First major settlement of qui tam against private equity investor in September 2019
  - *United States ex rel. Medrano and Lopez v. Diabetic Care Rx LLC, d/b/a Patient Care America, et al.*, No. 15-CV-62617 (S.D. Fla.).
- Watch for more

# New Reactions

- USDOJ:  Number and rate of decisions to intervene remains constant at 20-25%
- COURTS: Sea change of positive reception for whistleblowers who proceed on their own
- RELATORS: More willing to proceed to take the case even if USDOJ decides not to intervene
  - Some relators prefer to proceed without the government
- DEFENDANTS:  Taking more discovery under new case law requiring that the falsity or fraudulent acts or statements are MATERIAL TO THE GOVERNMENT"S DECISION TO PAY THE CLAIM
  - USDOJ not interested in discovery proceeding against its programs and employees
- RECOVERIES:  Relators on their own are achieving larger recoveries – over 500 million in FY 2017

# WHAT VIOLATIONS AND THEORIES TO WATCH FOR?

# Trending Theories

- It's all about kickbacks
  - Medical Device focus
  - Patient Assistance Programs still in focus
- Medical necessity
  - *Aseracare* decision
  - Opioids and whether treatment was medically necessary
- Technology in Medicine
  - Telemedicine Quality of Care:  Misrepresenting capability and delivery of services
  - Electronic Health Record relationships with Pharma:  Potential for kickback risk and misleading messaging
  - It's all in the Data!

# Are Off-label Marketing Cases Dead?

- Where is the false claim in off-label marketing now?
  - FDA Guidance in 2018 on "Misbranding":
    - "Scientifically appropriate and statistically sound" data can now support promotional claims for approved product following string of First Amendment Court Decisions
    - Past standard was "Two adequate and Well-Controlled Trials"
  - Move to REMS violation
  - Back to "Off-Label Plus"
  - Move to Medical Necessity fraud
  - Move to AntiKickback violation

# Granston Dismissals

- The "Granston" Memo (now incorporated into the *Justice Manual*) encouraged government dismissal of non-meritorious qui tam actions.
  - Instructs prosecutors to "consider whether the government's interests are served . . . by seeking dismissal [of qui tam actions] pursuant to 31 U.S.C. § 3730(c)(2)(A)."
  - Observes that Section 3730(c)(2)(A) is "an important tool to advance the government's interests, preserve limited resources, and avoid adverse precedent."
- DOJ is using the authority to dismiss more than in the past – some pushback from courts on "unfettered discretion" to dismiss
- Defense making regular "Granston pitches" on declined qui tams

# HOW TO CATCH A BREAK?

# Cooperation Credit from DOJ in Civil FCA Cases

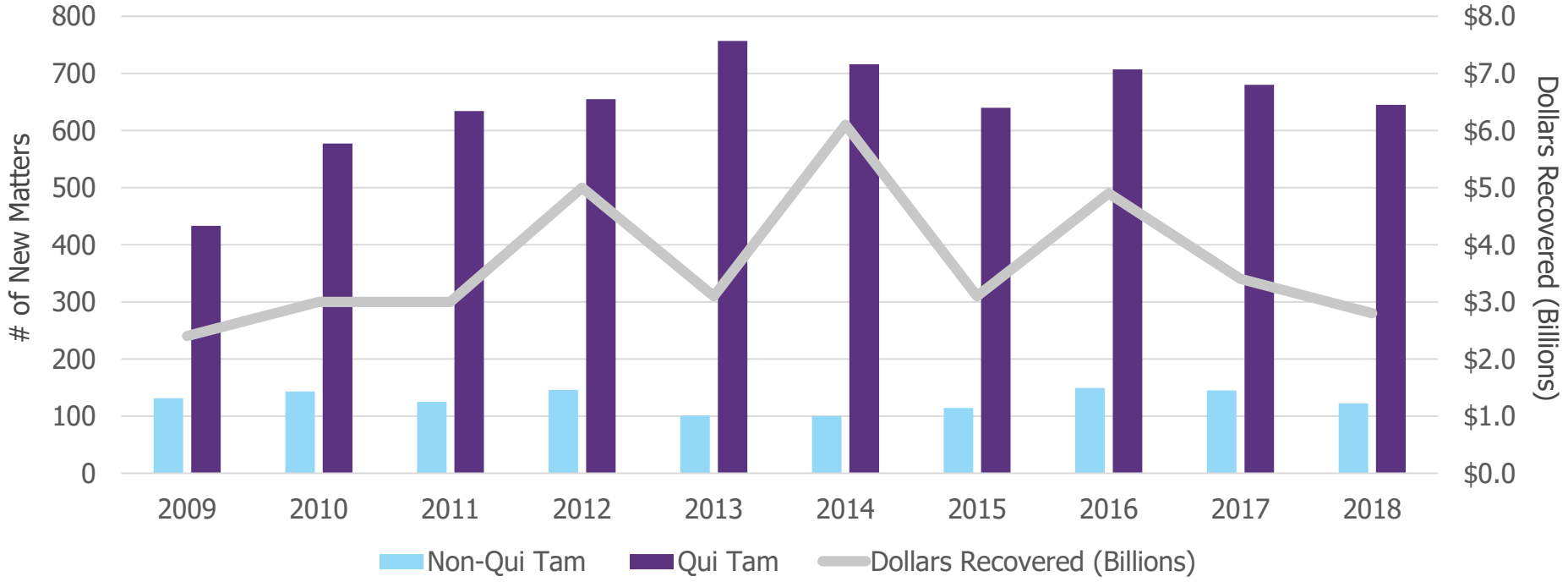
- **May 7, 2019 Announcement:** DOJ scales back the "all or nothing" approach to cooperation credit set forth in the 2015 Yates Memorandum.
- **New Justice Manual Section 4-4.112:**
  - Voluntary self-disclosure of conduct unknown to the Government
  - Give "Meaningful Assistance" by disclosing relevant facts and opportunities for the government to obtain relevant evidence
    - Preserve and disclose relevant documents beyond existing business practices or legal requirements
    - Identify individuals with relevant information about operations, policies, and procedures
    - Make employees with relevant information available for meetings, interviews, or depositions
    - Disclose facts gleaned during an internal investigation
  - Undertake Remedial Steps through New and Improved Compliance Programs

# RECENT DOJ ENFORCEMENT STATISTICS AND PRIORITIES

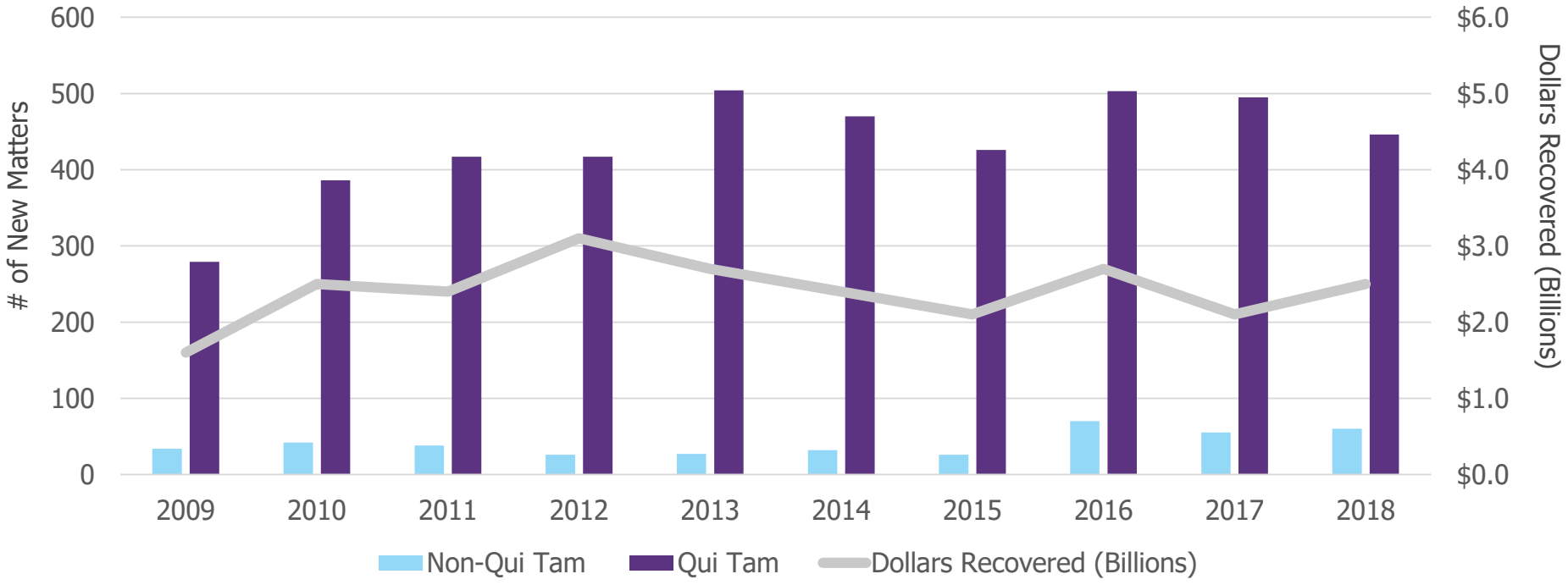
# DOJ by the Numbers
# Current Administration Enforcement Statistics

- U.S. spends more than $3 trillion every year on federal health care programs
- In FY 2018 there was an overall decrease in FCA enforcement actions by DOJ
- DOJ recovered more than $2.8 billion in settlements and judgments in the fiscal year ending September 30, 2018.
  - Of the $2.8 billion recovered, $2.1 billion came from **qui tam actions**.
  - Recoveries in FCA cases since 1986 now total more than $60 billion.
- As in past years, the largest percentage of recovery dollars in FY 2018 came from the health care industry, from which DOJ obtained $2.5 billion in settlements and judgments.
  - DOJ has now recovered more than $2 billion from the healthcare industry in nine consecutive years.
- $118 million of recovery dollars in FY 2018 were driven by relators after the government declined to intervene, as compared to $599 million in FY 2017 (second highest amount, behind $514 million in FY 2015).

# Overall Fraud Statistics: 2009-2018



# Healthcare Fraud Statistics: 2009-2018



# DOJ POLICIES THAT IMPACT QUI TAMS

# The "Granston" Memorandum (1/10/2018)

- The "Granston" Memo (now incorporated into the *Justice Manual*) encouraged government dismissal of non-meritorious qui tam actions.
- Instructs prosecutors to "consider whether the government's interests are served . . . by seeking dismissal [of qui tam actions] pursuant to 31 U.S.C. § 3730(c)(2)(A)."
- Observes that Section 3730(c)(2)(A) is "an important tool to advance the government's interests, preserve limited resources, and avoid adverse precedent."
- Provides a non-exhaustive list of seven-factors that can serve as a basis for dismissal standing alone, or in combination with other factors:
    1. Curbing meritless quit tams that facially lack merit (either because relator's legal theory is inherently defective, or the relator's factual allegations are frivolous);
    2. Preventing parasitic or opportunistic qui tam actions that either duplicate pre-existing government investigation or add no useful information to the investigation;
    3. Preventing interference with the administration of agency policy or programs;
    4. Controlling litigation brought on behalf of the United States, in order to protect DOJ's "litigation prerogatives"
    5. Safeguarding classified information and protecting national security interests
    6. Preserving government resources, particularly where expected costs are likely to exceed any expected gain
    7. Addressing egregious procedural errors that could frustrate the government's efforts to conduct a proper investigation

# The "Brand" Memorandum (1/25/2018)

- The "Brand" Memo prohibited DOJ reliance on agency guidance in FCA cases.
- Now incorporated into the *Justice Manual,* the guidance states that "[c]riminal and civil enforcement actions brought by the Department of Justice must be based on violations of applicable legal requirements, not mere noncompliance with guidance documents issued by federal agencies, because guidance documents cannot by themselves create binding requirements that do not already exist by statute or regulation."
- The policy does not prohibit DOJ from doing the following:
  - Where agency guidance describes a relevant statute or regulation, DOJ may use a party's awareness of the guidance (or its contents) as evidence of intent, notice, or knowledge.
  - DOJ may use the guidance as probative evidence of whether the party has satisfied, or failed to satisfy, professional or industry standards or practices.
  - DOJ may use a party's compliance or noncompliance with guidance as evidence directly relevant to particular claims at issue in the case.

# DOJ's "No Piling-On" Policy (5/9/2018)

- The "Policy on Coordination of Corporate Resolution Penalties" (now incorporated into the *Justice Manual*) does the following:
  - Reminds DOJ attorneys they may not use threat of criminal prosecution to extract larger settlements from companies in civil/administrative cases.
  - Instructs DOJ attorneys to "coordinate with one another to avoid the unnecessary imposition of duplicative fines, penalties, and/or forfeiture against the company."
  - Encourages DOJ attorneys "to coordinate with other federal, state, local, or foreign authorities seeking to resolve a case with a company for the same misconduct."
  - Gives specific factors for DOJ to consider in assessing "whether multiple penalties serve the interests of justice," including "the egregiousness of the misconduct; statutory mandates regarding penalties; the risk of delay in finalizing a resolution; and the adequacy and timeliness of a company's disclosures and cooperation with the Department."