Sunshine Data: Will it Help Qui Tam Whistleblowers and their Attorneys?

PHARMACEUTICAL COMPLIANCE FORUM

SIXTH ANNUAL SUMMIT ON DISCLOSURE, TRANSPARENCY AND AGGREGATE SPEND FOR DRUG, DEVICE AND BIOTECH COMPANIES

NEIL V. GETNICK
LESLEY ANN SKILLEN

GETNICK & GETNICK LLP
NEW YORK, NY

Introduction

- Under the Sunshine laws, the public will have access to information about payments made by health care manufacturers and group purchasing organizations to physicians, as well as physicians' interests in drug and device companies
- Both the government and the public will have visibility in an area that was previously opaque
- Sunshine data likely will both help and hurt False Claims Act *qui tam* whistleblowers

False Claims Act Basics

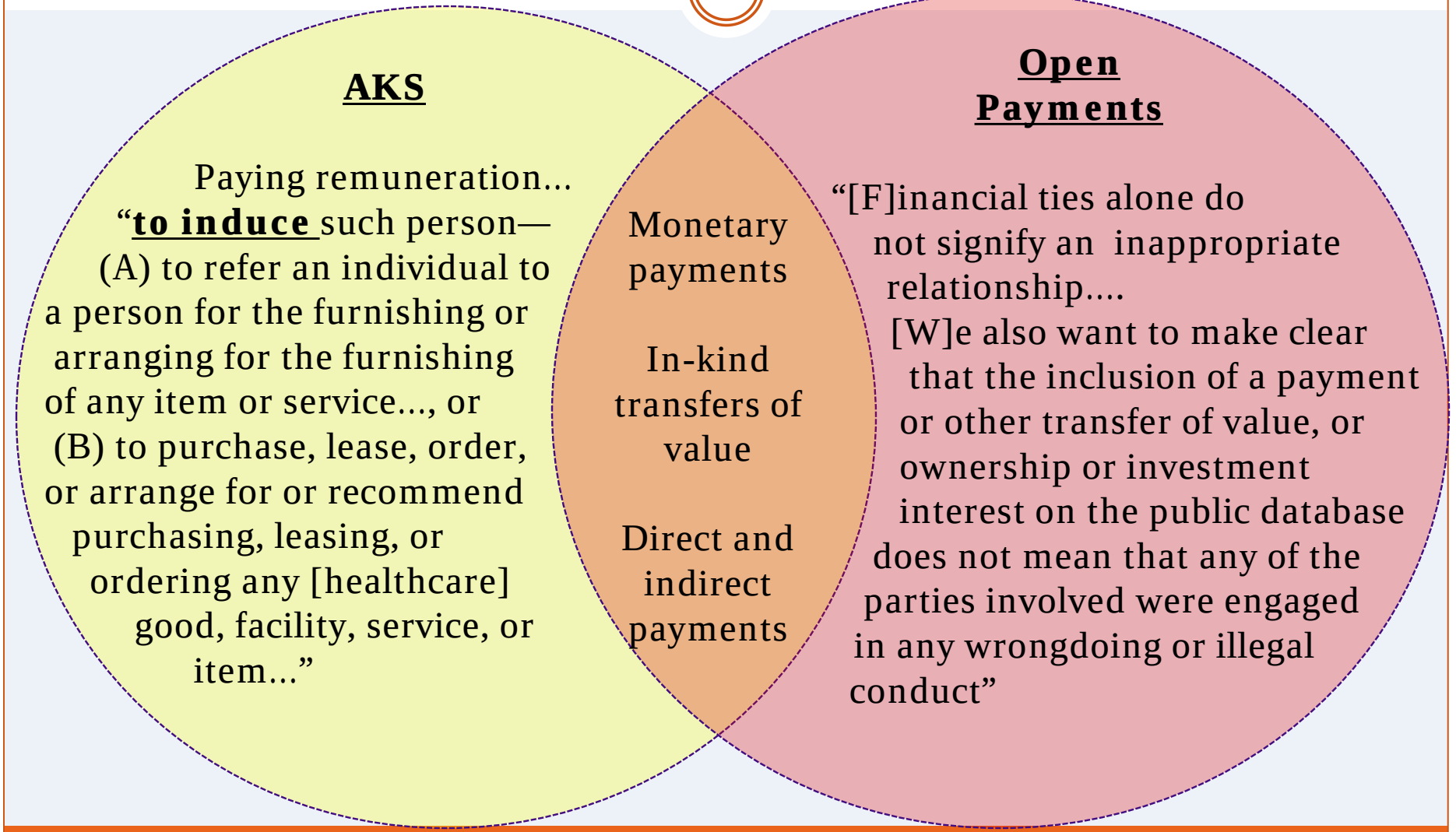
- Creates a civil cause of action for fraud on the government
- Treble damages and penalties of $5,500-$11,000 per violation
- Allows an action to be brought either by the government or by a private citizen in the name of the government (the *qui tam* "relator")
- Relator is entitled to receive an award of 15-30% of the proceeds, plus attorneys fees and costs
- Over $12 billion recovered in healthcare FCA cases in the last five years, nearly $11 billion in *qui tam* cases

Kickbacks As Basis of an FCA Case

- Anti-Kickback Statute (42 U.S.C. 1320a-7b): "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act]"

- In final rule, CMS "emphasize[d] that [Sunshine] compliance does not exempt [any] persons from any potential liability associated with payments or other transfers of value, or ownership or investment interests (for example, potential liability under the Federal Anti-Kickback statute or the False Claims Act)" (78 Fed. Reg. 9460 (Feb, 8, 2013))

Kickbacks vs. "Covered Payments"



Stark Violations As Basis of an FCA Case

- Stark regulations (42 C.F.R. 411.353): "a physician who has a direct or indirect financial relationship with an entity....may not make a referral to that entity for the furnishing of [designated health services] for which payment otherwise may be made under Medicare"
- Submitting claims for such items or services constitutes an FCA violation (See, e.g., United States ex rel. Kosenske v. Carlisle HMA, Inc., 554 F.3d 88, 94, (3d Cir. 2009))
- Companies will now have to disclose ownership or investment interests held by physicians, including the amount of the investment

Data Will Be Accessible and Specific

- Statute requires Sunshine data to be searchable and "easily aggregated and downloaded"

- Database will include:
  - Manufacturer's name
  - Physician's name, specialty, and address
  - Payment information: amount, date, as well as the nature and form
  - Which drug, device or biologic the payment relates to (if any)
  - Name of any intermediary entities
  - Optional explanation of context
  - Amount and value of any ownership or investment interests

Data Will Be Accessible and Specific

- If payment is associated with research, database will also include:
  - Name of recipient research entity
  - Name of study and subject product
  - Principal investigator
  - Context of research
  - ClinicalTrials.gov identifier (optional)
- Data covering August – December 2013, will be released to public in September 2014; data will be released annually in June every year thereafter, covering the prior year

How Sunshine Data Could Help Qui Tam

- Initial investigation of potential relator's allegations
  - Corroborate allegations or confirm suspicions of widespread conduct
- Additional information for complaint or disclosure statement
  - May add specificity for Rule 9(b) compliance (e.g. exact dates and amounts of payments)
  - May expand alleged scope of conduct if similar payments made elsewhere
- Data mining as basis for FCA?

How Sunshine Data Could Hurt Qui Tam

- False Claims Act public disclosure bar: 31 U.S.C. Sec 3730(e)(4)

- Government knowledge “defense”

The Public Disclosure Bar

- False Claims Act bars *qui tam* actions if "**substantially the same allegations** or transactions as alleged in the action or claim **were publicly disclosed** ...**in a** congressional, Government Accountability Office, or other **Federal report**, hearing, audit, or investigation...unless ...the person bringing the action is an original source of the information."

- The government can override the public disclosure bar

FOIA As Basis for Qui Tam

- Supreme Court held that information obtained through FOIA request is "disclosed 'in' a report for the purposes of the public disclosure bar."
  - *Schindler Elevator Corp. v. United States ex rel. Kirk*, 131 S. Ct. 1885, 1893 (2011)

- A 2010 S.D.N.Y. case held that a searchable government database was "an administrative report under section 3730(e)(4)(A)" – *US ex rel. Rosner v. WB/Stellar IP Owner, L.L.C.*, 739 F. Supp. 2d 396, 407 (S.D.N.Y. 2010)

- But under the New York State FCA information obtained through FOI laws is not "publicly disclosed"

"Original Source" Exception

- To overcome the public disclosure bar, a relator must be an "original source," meaning that he either:
  - Disclosed the information to the government *before* the information became public

    -OR-
  - Has information that is **independent of** and **materially adds** to the publicly disclosed allegations or transactions and provided such information to the government prior to filing his complaint

What This Means for Whistleblowers

- Whistleblowers must bring something additional to the table beyond the fact of payment -- in particular, "inducement"
- Creates an additional hurdle for whistleblowers alleging kickbacks
- Increased urgency to file (don't just have to beat other whistleblowers to the courthouse, but also the company's disclosures)

Example: GSK

- In 2012, GSK agreed to pay $3 billion related to *qui tam* allegations, including, in part, by sales representatives
- Included allegations that would have been covered by Sunshine law: e.g. sponsoring dinner programs, lunch programs, and spa programs related to Paxil
- But, allegations also included fact that those programs involved presentations on off-label use of Paxil in children and adolescents, and that GSK had published misleading studies on the efficacy of its products for such uses.
- Whistleblowers had independent information that would have "materially added" to the fact that payments had been made

What This Means for Whistleblowers

- Stark cases may prove highly problematic because the core of the allegations—the physician's financial relationship with the drug or device manufacturer—will be publicly disclosed

- Unless there are allegations of other unlawful activities, whistleblowers will have little to "materially add" to the publicly disclosed information

Government Knowledge "Defense"

- FCA defendant must ***knowingly*** submit a false claim or make or use a false record or statement material to a false claim (or cause another to do so)

- Government knowledge alone is not a defense to an FCA action, *but* courts have held that "the extent and the nature of government knowledge may show that the defendant did not 'knowingly' submit a false claim and so did not have the intent required by the…FCA" US ex rel. Butler v. Hughes Helicopters, 71 F.3d 321, 327 (9th Cir. 1995)

What This Means for Whistleblowers

- Defendants may assert government knowledge based on the fact that the government was aware of the payments they made, particularly where they've provided additional context information

- While CMS has said that reporting does not exempt reporting entities or recipients from liability under the AKS or FCA, government knowledge arising from Sunshine disclosure may pre-empt or compromise a *qui tam* claim

Exceptions and Limits of Sunshine Law

- Several areas remain prime territory for whistleblowers, e.g.:
  - Discounts and rebates (esp. where doctor purchases and resells DME)
  - Free product, either for charity or as a free sample
  - Kickbacks to pharmacies
  - Payment for services of non-physicians (e.g. payments to administrative staff)
- May see more kickbacks in these and other non-reportable areas
- Reporting is not live—data will be between 6 and 18 months old when it is published

Consequences of Non-Reporting

- Reporting payments under Sunshine laws could result in prosecution if payments are kickbacks or Stark violations; failure to report risks Sunshine penalties (up to $100,000 per violation; up to $1 million total) *and* AKS or Stark *and* FCA liability for the kickbacks

- Where a whistleblower exposes kickbacks or Stark violations that a company has failed to report, expect a hard line from the government on FCA damages (e.g., damages are full amount paid for items "tainted" by kickbacks or Stark violations)

Incentivizing Integrity

- The Sunshine law and qui tam share a common purpose: creating transparency to detect and deter fraud

- "[T]ransparency will shed light on the nature and extent of relationships, and will hopefully discourage the development of inappropriate relationships and help prevent the increased and potentially unnecessary health care costs that can arise from such conflicts." - Final Rule, 78 Fed Reg. 9458, 9459 (Feb. 8, 2013)

Questions?