

WAITING ON SUNSHINE

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DISCLOSURES

- Not an official presentation of City of New York
- Vacation time
- No City Funds or time used in connection with presentation
- Statement of Interests
 - Shares in Johnson & Johnson

BLOOMBERG ADMINISTRATION

- Measure it to manage it
- Sources and reliability of Data
- Data Analytics Commitment and Tools in Enforcement

THE SUNSHINE ACT

- The Physician Payments Sunshine Act by its terms required companies to begin recording any physician payments that are worth more than \$10 in 2012 and to report each payment by March 31, 2013. That includes stock options, research grants, gifts, consulting fees and travel. The details were to be posted in a searchable database starting Sept. 30, 2013.
- Did not happen

THE SUNSHINE ACT

- Also includes reporting of physician investment interests

ENFORCEMENT ACTIONS- PAYMENTS TO PHYSICIANS

- 02-16-2010 Palm Beach County physician agreed to pay \$650,000. The OIG alleged that the physician solicited and received kickbacks in the form of consulting payments from two medical device manufactures in exchange for using their orthopedic hip and knee products.
- DePuy Orthopedics in February 2003
- Smith & Nephew in April 2006

ENFORCEMENT ACTIONS- PAYMENTS TO PHYSICIANS

- 2010 Palm Beach Gardens orthopedic surgeon paid \$65,000 and was excluded from Medicare for three years
- Allegedly solicited payments from device manufacturers

ENFORCEMENT ACTIONS- PAYMENTS TO PHYSICIANS

- Victory Pharma- 12/27/12
- \$11.4 million settlement, DPA
- Employee Whistleblower
- Alleged tickets to sports events, concerts and plays; spa, golf and ski outings; dinners at expensive restaurants; paying for a doctor's staff to go to a strip club; and helping a doctor make a house payment.
(WSJ)

PAYMENTS TO PHYSICIANS

- After the New Jersey enforcement actions against orthopedic medical device makers in 2007, their consulting payments to surgeons dropped from \$272 million in 2007 to \$105 million in 2008, a 61% reduction. The number of physicians receiving money declined by 63%.

WAITING ON SUNSHINE

- Required CMS regulations-
- December 14, 2011 proposed reg- 76 FR78724
 - Was to be issued in final 2012, data collection start in 2013
 - May 3, 2012- CMS Information on Implementation of Sunshine Act (i.e., delay)
 - Sometime in 2013 for final regulation?
 - Sometime in 2013 for data collection?
 - Someday in 2014 for publishing data?
 - 320 comments!

WAITING ON SUNSHINE

- CMS submits final Sunshine Regulations to Office of Management and Budget- 11/29/12
- Transparency Reports and Reporting of Physician Ownership of Investment Interests (CMS-5060-F)
- The final rule has to be issued 90 days after receipt of the final rule by OMB which is Monday, February 25, 2013.

PRE-EMPTION OF STATE LAWS

- Section 6002 of the health care reform law preempts any State or local laws requiring reporting of payments or other transfers of value made by applicable manufacturers to covered recipients after Jan. 1, 2012
- CMS urges manufacturers to continue to report information to states with reporting requirements until CMS finalizes the regulations and begins collecting this information.

STATE LAWS

- Massachusetts, Vermont, Minnesota, California-not Florida

PROPOSED RULE-PHYSICIAN OWNED DISTRIBUTORS (PODs)

- CMS proposes to include traditional GPOs that do not purchase products directly, as well as organizations that purchase products for resale or distribution. This proposed definition would include reporting of ownership and investment interests in physician-owned distributors (PODs).

INFORMATION NOW-FROM PRO PUBLICA WEBSITE

- Public Database of Payments to Physicians:
“Dollars for Docs”
- “How Industry Dollars Reach Your Doctors”
- <http://projects.propublica.org/docdollars/> **Has Your Health Professional Received Drug Company Money?**
- Searchable database by physician, city, institution, state
- Updated in October 2012 to include more years, more companies

PRO PUBLICA DATABASE

<http://projects.propublica.org/docdollars/>

- Over 400 Florida physicians and institutions
- Examples: asthma/allergy physicians- over \$100,000/year each
- One pulmonologist over \$260,000
- Cardiologist- \$92,000
- \$2.9 Million to one non- university based Miami physician for “clinical research” or “physician research”

MEDIA FOCUS ON PHARMA SPEAKERS TO INTENSIFY UNDER PPACA SUNSHINE ACT RULES

- Pro Publica mobile website will allow patients to check out their physician while in waiting room
- Pro Publica looks for Speakers with:
 - State disciplinary actions
 - FDA warning letters
 - Criminal convictions
 - Multiple malpractice suits (on some state licensing websites)
 - False Claims suits/IRS 990 disclosures/govt. disclosure forms

HOW WILL MEDIA/BLOGS ADDRESS DISCLOSURES

- Some Florida examples from PRO PUBLICA
 - Oncology/chemotherapy physician- \$225,000 for research, \$27,000 speaking fees for her husband
 - Family practice physician- \$70,000 speaker fees
 - Urologist- \$85,000 speaker fees
 - Pain management physician- \$80,000 in speaker fees

PRO PUBLICA ADVICE TO REPORTERS ON PAYMENTS

- “In several cases we could find almost nothing [published] on some of the top-paid speakers, but also that their colleagues around the country had no idea who they were, even sometimes in their own towns had no real sense of their qualifications.”

PRO PUBLICA ADVICE TO REPORTERS ON PAYMENTS

- Find out where these payrolled doctors work, and ask the doctors' employers and patients for reactions. Some reporters have already found that the institutions where the doctors are employed aren't aware of all of the fees they are collecting on the side.
- "Sometimes the *wives* don't even know that they're making the speaker money,"

PSYCHIATRIST-\$144,000

- "Much of any discussion is centered around clinical trials and evidence-based information as it pertains to medication within a disease state. There has been an on going push to ensure that medical practice is based on clear and pertinent evidence.... Providing educational programs in a variety of contexts has helped me to become a better clinician and researcher."

PAIN MANAGEMENT PHYSICIAN- \$77,000

- “When Lyrica was approved, suddenly we saw large-scale marketing surrounding fibromyalgia for the first time . . .”
- “I view this as an opportunity to provide a service that allows me to have an income commensurate with my non-primary care peers.”
- Chicago Tribune 10/18/2010

PRIMARY CARE PHYSICIAN

- "Being an independent physician these days isn't easy and it isn't fun. I have two offices and I'm the medical director for two nursing homes. Do I tell my patients about everything I do? No. I don't see why that would change anything I do for them."
- Chicago Tribune- doctor who received \$75,000 from 5 companies

RETIRED PSYCHIATRIST SPEAKING ON ZYPREXA-\$73,000

- "I'm not a natural speaker. The challenge for me was synthesizing the material and getting it across in a way that was useful.... But in the last five years, it's become distinctly less interesting to me. To be given a slide set and be told this is what you can and cannot say was not exactly drawing on my expertise."
- Chicago Tribune

“(STANDFORD) FLUNKS AT KEEPING FACULTY OFF PHARMA SPEAKING CIRCUIT”

- “Last year, in a blow to its physicians’ wallets, Stanford banned them from giving paid promotional talks for pharmaceutical companies. One thing it didn’t do was make sure its faculty followed that rule.”
- “More than a dozen of the school’s doctors were paid speakers in apparent violation of its policy— two of them earning six figures since last year.”

Stanford Flunks-2011

- “Dr. Philip Pizzo, the dean of Stanford’s medical school, sent an e-mail to all medical school staff after news report calling the conduct “unacceptable.” Some doctors’ excuses, he wrote, were “difficult if not impossible to reconcile with our policy.” See (well-written) policy
- <http://med.stanford.edu/coi/overview.html>

OTHER INTERESTED PARTIES IN DISCLOSURES

- Colleagues/Competitors
- Opposing Counsel/Due Diligence
- University Administrators/Dept. Chairs
- Bloggers
- Whistleblowers
- Academic Journals/CME Programs
- Clinical Practice Guidelines

STATE INTEREST IN PHARMA AND DEVICE CASES

- 121 settlements and \$14.8 billion in restitution and penalties over the last five years. (2006-2010)
- Growing interest in qui tam cases since passage of state false claims acts
- Traditional law enforcement problem solved - mapping payees and amounts from pharma against ordering physicians in public programs

AMSA SCORING SYSTEM

- (AMSA) American Medical Student Association www.amsascorecard.org
 - Gifts and meals policy
 - Consulting relationships
 - Industry speaking relationships
 - Criteria for disclosure-industry relationships
 - Oversight mechanism
 - Penalties for non-compliance

HOW ARE COI POLICIES WORKING?

- **Conflict of Interest Reporting by Authors Involved in Promotion of Off-Label Drug Use: An Analysis of Journal Disclosures – Kesselheim et al 8/2012**
- <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001280>

HOW ARE COI POLICIES WORKING?

- Aaron Kesselheim and colleagues investigate conflict of interest disclosures in articles authored by physicians and scientists identified in whistleblower complaints alleging illegal off-label marketing by pharmaceutical companies.

DISCLOSURES IN OFF-LABEL JOURNAL ARTICLES

- 39 conflicted individuals in whistleblower complaints. They published 404 articles related to the drugs at issue in the whistleblower complaints, only 62 (15%) of which contained an adequate disclosure statement

DISCLOSURE-USE AS DATA

- What does data tell us about-
- High-ordering prescribers
- High-using patients
- Seeding
- Off-label uses/populations
- Adverse outcomes/negative results
- Product substitution and patient conversion
- Pharmacy impact on use patterns
- Intervention impact on use patterns

MINING THE IRS-990 DATA

- Economic Research Institute provides on line access to filed 990s and allows search by entity name: <http://www.eri-nonprofit-salaries.com/index>
- Guidestar does similar searches-requires sign-in and offers premium services for a price: <http://www2.guidestar.org/>

IRS Form 990 Questions for Non-Profits on Governance Policies

Part VI Governance, Management, and Disclosure (Sections A, B, and C request information about policies not required by the Internal Revenue Code.)

Section A Governing Body and Management

Section B. Policies

	Yes	No
12a Does the organization have a written conflict of interest policy? If "No", go to line 13 . . .	Yes	
b Are officers, directors or trustees, and key employees required to disclose annually interests that could give rise to conflicts?	Yes	
c Does the organization regularly and consistently monitor and enforce compliance with the policy? If "Yes," describe in Schedule O how this is done	Yes	
13 Does the organization have a written whistleblower policy?	Yes	
14 Does the organization have a written document retention and destruction policy?	Yes	
15 Did the process for determining compensation of the following persons include a review and approval by independent persons, comparability data, and contemporaneous substantiation of the deliberation and decision		
a The organization's CEO, Executive Director, or top management official?	Yes	
b Other officers or key employees of the organization?	Yes	
Describe the process in Schedule O		

WHERE CAN WE FIND DATA?

(Sunshine data is just one source)

- Media/Website databases
- Claims warehouses
- Other payors
- Data consolidators (e.g., Lexis/Nexis)
- Centralized claims processors and their business partners
- Vital Statistics-States
- Social Security/Medicare files
- Geo mapping
- Internal company data systems
- State and federal websites (South Carolina)
- Crawling, scraping, bots

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