

6th Annual Forum on Sunshine Act, Open Payments, and Aggregate Spend Compliance

October 20-22, 2014

Planning for 2015 – Bracing for the Impact of the Public Reports

Colin J. Zick
Partner & Co-Chair, Health
Care Practice Group
Foley Hoag LLP (Boston, MA)

Robyn S. Shapiro
Partner and Chair, Life
Sciences Group
Drinker Biddle & Reath LLP
(Milwaukee, WI)

Jodie Gillon
Head, External Interface
Office
AstraZeneca
(Gaithersburg, MD)

Tweeting about this conference?

#ACISunshineAct



Disclaimer

The views expressed in this session are all our own and do not represent that of our respective companies.

For this session there will be no photos, tweeting or reposting views expressed.

*Please note that these slides have been modified from their original version to remove certain proprietary materials.

[#ACISunshineAct](#)



Physician Payment Sunshine Act Database Launches

Financial Ties Between Doctors and Health Care Firms Are Detailed

By KATIE THOMAS and RACHEL ABRAMS OCT. 2, 2014

“For some doctors, treating patients isn’t the only way to make money.”

Doctors Net Billions From Drug Firms Companies Paid at Least \$3.5 Billion in Last Five Months of 2013

“Drug and medical-device companies paid at least \$3.5 billion to U.S. physicians and teaching hospitals during the final five months of last year, according to the most comprehensive accounting so far of the financial ties that some critics say have compromised medical care.”

Physician Payment Sunshine Act Database Launches

Payments Reveal Range of Doctors' Ties With Industry

Many of Biggest Sums Paid to Physicians Didn't Involve Patient Care

“The database calls attention to the wide reach industry has into all corners of medicine, from marketing drugs and funding clinical trials to tapping physicians' knowledge to develop new products.”

How Much Money Does Your Doctor Get From Medical Companies?

“some research suggests that even cursory relationships with industry do affect a doctor's behavior.”

#ACISunshineAct



How many disputes did you receive?

- 1) 0-20
- 2) 20-50
- 3) 50-100
- 4) 100-200
- 5) Over 200



Summary of reviews and disputes of the September 30 publication

Categories	Totals
Number of Physicians that registered to Review and Dispute	26,000*
Number of Teaching Hospitals that registered to Review and Dispute	405*
Number of Records that were Disputed	12,579
Number of Unresolved disputes at the end of review period	9,000*
Number of Records that were Affirmed	17,994

*rounded

In which category did most disputes fall?

- 1) Meals
- 2) Dates
- 3) TOV such as publications or drug supply
- 4) Other research
- 5) Speaking fees



Disputes

- Can be a burden if large number and not resourced
- However can also be a good source of info:
 - QC
 - Process Improvement
 - Communication
- The challenge is when they come from all angles and there's no patience for the "process"
- Guide HCPs to help center and colleagues towards media relations



Business Objects

- 1) Spend by quarter
 - a) HCP
 - b) Institution
- 2) Spend by category
 - a) Meals
 - b) Travel
 - c) Research
 - d) Grants
- 3) # of HCPs by spend level
- 4) Top 10 HCPs by quarter
- 5) Total, high, average by category
- 6) # of institutional payees by spend
- 7) Top 10 institutions by quarter



Open Payments Disputes: Changes to Process

Discuss categories/assumptions with King & Spaulding coalition

Goal: Alleviate the frequency of re-disputes and improve HCP external perception of dispute handling

- Modified response letters to covered recipients
 - Disputes-Standard Responses document updated
 - Clearer language on decision to update or remove line from CMS website
 - Added benefit to internal processing for resubmission
 - Include additional sources of information in response to HCP/HCI, where applicable
 - For meals, include the sign-in sheet and receipts to support calculation
 - Work with meeting companies to better track and account for AZ people
 - Communicate process so admins don't over order and HCPs may opt out



Communication is key

- Analyze disputes
- Create 800 # and fully train staff
- Train all field staff (sales and medical)
- Need to partner with communications and media relations groups
- Discuss and tailor internal communications
- Send from senior management of each business unit
- Prepare media relations teams and have quotes, replies prepared
- Discuss external/proactive communications
- What to communication to HCPs and HCIs and how
- Partner with groups such as PhRMA/King & Spaulding etc. – even Propublica!
- Remind entire organization of proper channels and disputes and resolutions process



Getting the Message Out

Did your company proactively post background information about Sunshine on its website?

Yes

No

If yes:

- 1) Information was general
- 2) Information was specific to company's reported payments/TOVs
- 3) Information dealt with Sunshine as well as related issues (e.g., conflicts of interest, etc.)



Did your company proactively communicate with covered recipients about Sunshine reports?

Yes

No

If yes:

- 1) Communication was via targeted emails prior to release of payment information
- 2) Communication was via targeted email following release of payment information
- 3) Communication was via targeted email following lodging of dispute



Did your company receive questions, communication from the public about Sunshine reports?

Yes

No

If yes:

- Approximately how many?
 - 1) 0-20
 - 2) 20-50
 - 3) 50-100
 - 4) 100-200
 - 5) Over 200
- Each question, communication was responded to
 - Yes
 - No
- Responses were:
 - 1) Individualized
 - 2) Generic



Did your company receive questions, communication from covered recipients about Sunshine reports?

Yes

No

If yes:

- Approximately how many?
 - 1) 0-20
 - 2) 20-50
 - 3) 50-100
 - 4) 100-200
 - 5) Over 200
- Each question, communication was responded to
 - Yes
 - No
- Responses were:
 - 1) Individualized
 - 2) Generic



Challenges to “Getting the [Right] Message Out”

- **Incomplete data**
 - 1/3 data withheld due to potential inaccuracies
 - Reporting year only includes data from Aug. – Dec. 2013
- **Inaccuracies, due to, e.g.**
 - Physicians may have several NPI #s
 - Physicians may have listed state license # incorrectly
 - Data could become outdated quickly
 - Errors in categories used
- **Inability of covered recipient to review certain data**
 - e.g., Physicians cannot view teaching hospital data; teaching hospital research payments may be attached to physician PI name



Concerns About the Data

- Inadequate contextual information e.g., large research payments associated with one physician PI
- Variable value methodologies
- Limited background knowledge on part of public about collaboration between industry and physicians



Open Payment Data Published on 9/30/2014

Categories

Total

- | | |
|--|---------------|
| • Total Value | \$3.5 billion |
| • Total Number of Records | 4.4 million |
| • Total Number of Physicians | 546,000 |
| • Total Number of Teaching Hospitals | 1,360 |
| • Total Number of Reporting Applicable Manufacturers and
Group Purchasing Organizations | 1,419 |



The State of Industry Spending

- Royalties and licensing are not going away, even if speakers bureaus and dinners do.

Manufacturer General Payments Breakdown

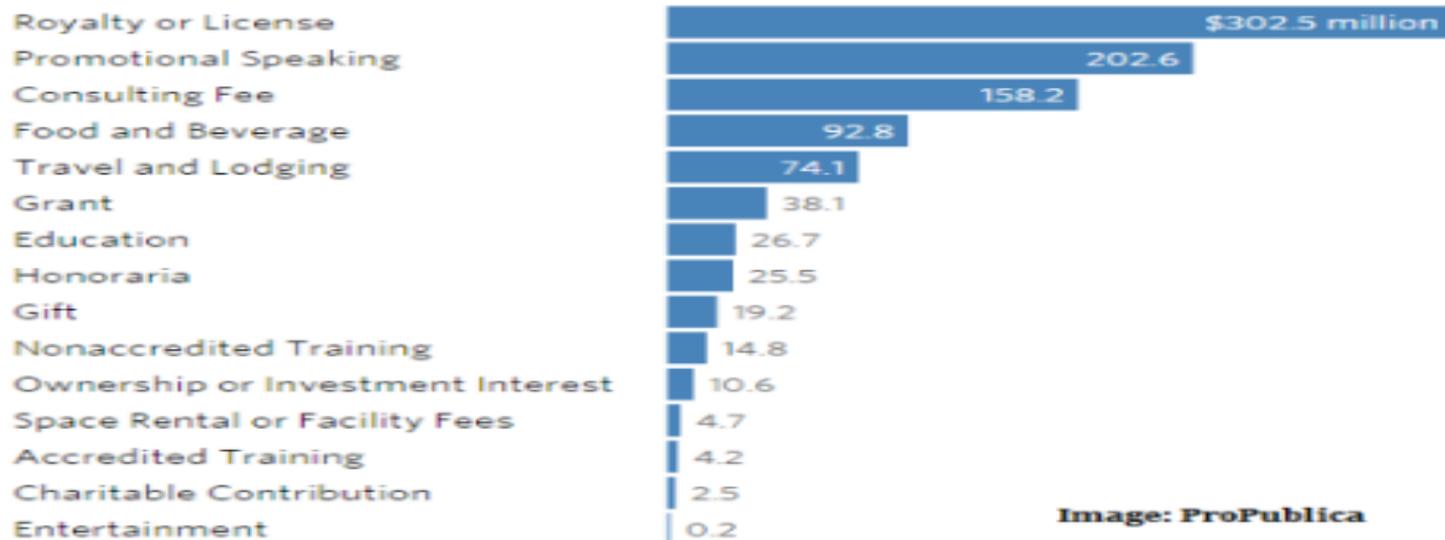
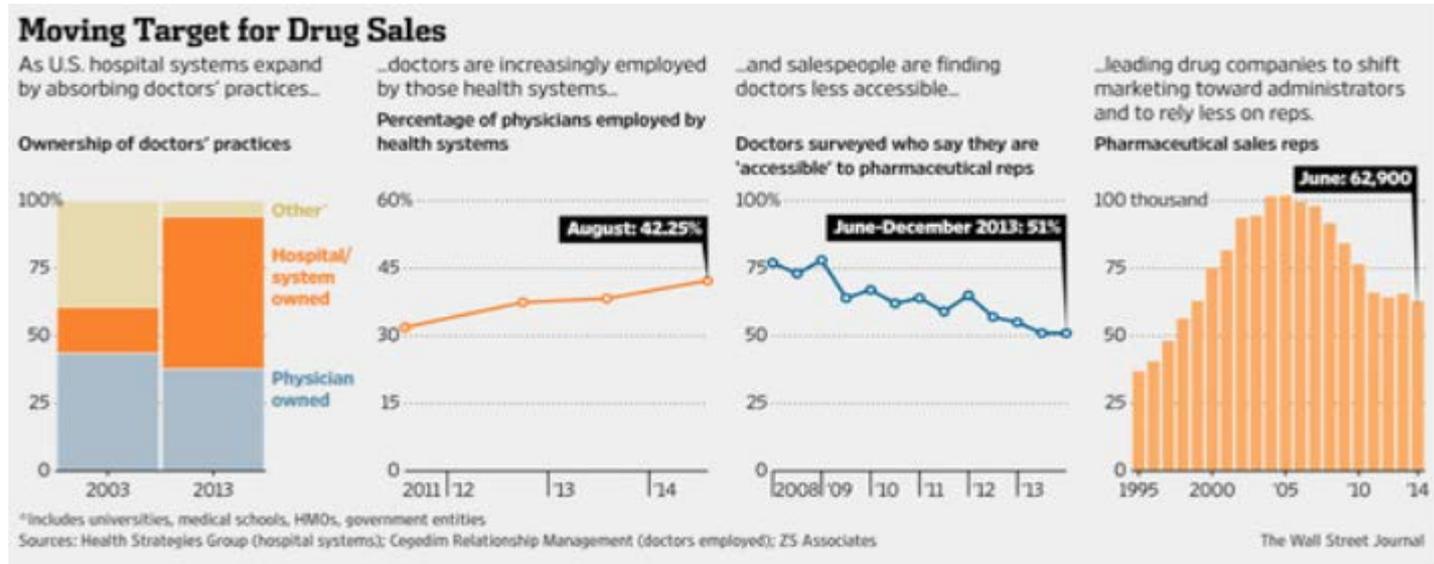


Image: ProPublica



Is the Debate About Dealing with HCPs Already Over? Pharma Reacts....

- The Wall Street Journal, “As Doctors Lose Clout, Drug Firms Redirect the Sales Call: At Big Hospital Systems, Salespeople Woo Administrators to Get on 'Formulary’” September 24, 2014
- ProPublica: “As Full Disclosure Nears, Doctors’ Pay for Drug Talks Plummet: As transparency increases and blockbuster drugs lose patent protection, drug companies have dramatically scaled back payments to doctors for promotional talks.”



Will Qui Tam Relators React?

- If the data is not accurate, it does not help anyone.
- Disclosures could help qui tam plaintiffs:
 - Publicly available data such could provide missing pieces of information sufficient to build a viable qui tam case; or
 - Allows relators to support allegations of wrongdoing where those allegations might otherwise fail for lack of specificity.
- Disclosures could hurt qui tam plaintiffs:
 - Public disclosure might bar some *qui tam* filings;
 - The False Claims Act's public disclosure bar mandates the dismissal of any qui tam action, unless dismissal is opposed by the Government, if substantially the same allegations or transactions alleged in the action were publicly disclosed in a federal criminal, civil, or administrative hearing in which the government is a party, a congressional or other federal report, hearing, audit, or investigation, or by the news media.



Doctors React....

- “Who’s My Doctor?” project
 - is a new campaign where doctors produce a voluntary, public disclosure statement, *The Total Transparency Manifesto*, <http://www.whosmydoctor.com/>
 - “Studies show that patients are more likely to follow recommendations and to have better outcomes when the advice comes from a doctor they trust. Experience with other transparency pilots such as Open Notes shows that openness leads to better communication, more trust, and better care, and we predict that Who’s My Doctor will have similar outcomes.”



Media Coverage of the Release of Public Reports

- “So Much For Transparency, Open Payments Database Toggles the Mind,” The Wall Street Journal, October 2, 2014
- “Another Government Website Rollout That Is Found Wanting,” New York Times, October 1, 2014
- “Doctor Payments Show Little Value at Launch Time,” U.S. News, October 1, 2014



Consumer Groups React....

- ProPublica's "Dollars for Docs" by category:

Manufacturer General Payments Breakdown

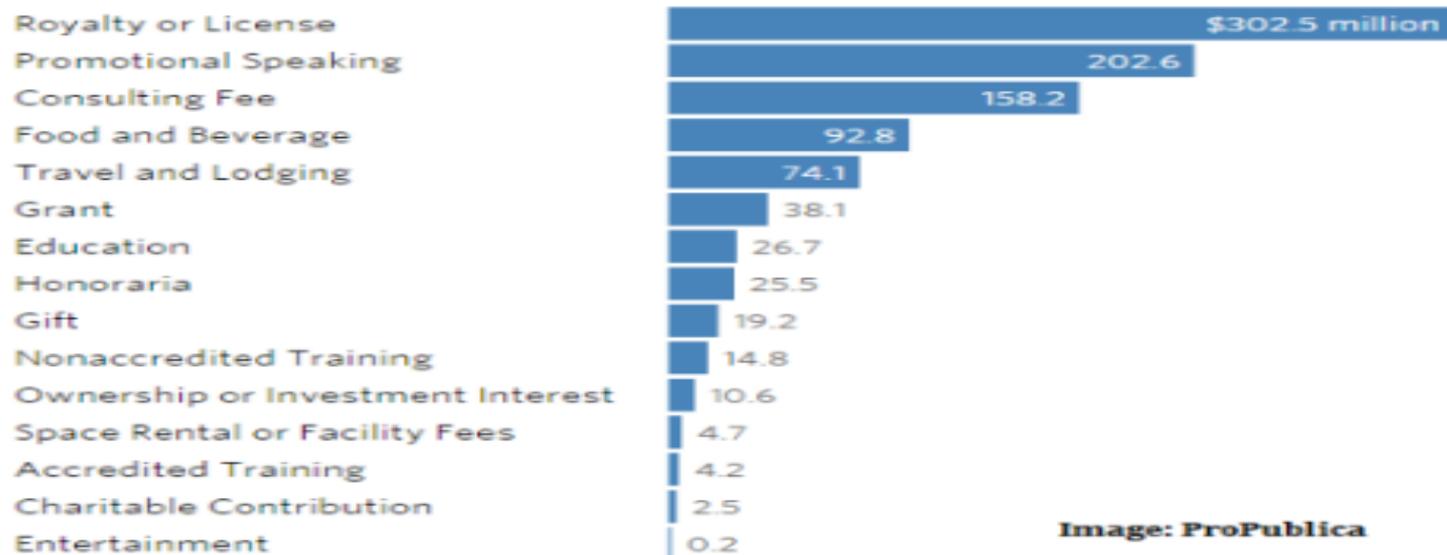


Image: ProPublica



QUESTIONS/COMMENTS?

Robyn S. Shapiro, Esq.
Drinker Biddle & Reath LLP
777 E. Wisconsin Avenue
Suite 2000
Milwaukee, WI 53202
(414) 221-6056
Robyn.Shapiro@DBR.com

Jodie Gillon
AstraZeneca
1 Medimmune Way
200 ORD 2250F
Gaithersburg, MD 20878
(301) 398-0586
Jodie.Gillon@astrazeneca.com

Colin J. Zick, Esq.
Foley Hoag LLP
155 Seaport Boulevard
Boston, MA 02210
(617) 832-1275
czick@foleyhoag.com

#ACISunshineAct

