

# CONFLICT OF INTEREST 2.0: BEYOND DATA COLLECTION

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## Presented by

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## Agenda

- Review the intricacies of COI policy evolution
- Discuss updates and advancements in CMS' Open Payments Database
- Provide useful skills and tools to help you conduct investigations and implement conflict management plans

# COI: ORIGIN STORY

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Key Points

## Before I Was Born

1962

- Preventing COI for gov. consultants

1964

- AAUP/ACE statement on COI for gov. sponsored research

1971

- NAS letter "On Potential Sources of Bias"

1978

- Ethics in Government Act

## Baby Andrew

December 2, 1978



## The 1980's

- 1981: Economic Recovery Tax Act (private investments in univ. research)
- 1982: Hearings on university-industry cooperation in biotech
- 1983: UC's lack of disclosure of faculty interests in research-funding companies
- 1984: *New England Journal of Medicine* announces COI policy
- 1985: AAU and ACE – publications on lack of COI policy enforcement at universities
- 1987: PHS Grants Policy Statement requires grant recipients to have written COI rules
- 1988: House hearing on scientific misconduct and conflicts of interest
- 1989: Omnibus Reconciliation Act (Stark Law)

Source: Conflicts of Interest in Medical Research, Education, and Practice, 2009, NIH

## The 1990's

- *Are Scientific Misconduct and Conflicts of Interest Hazardous to Our Health?*
- AAMC – Guidelines for Dealing with Faculty Conflicts of Commitment and Conflicts of Interest in Research
- AMA and ACP – Publications on inappropriate gifts to physicians from industry
- NAS report *Responsible Science* "The issues associated with conflict of interest in the academic research environment are sufficiently problematic that they deserve thorough study and analysis by major academic and scientific organizations."
- 1994: NSF creates Investigator Financial Disclosure Policy
- 1995: PHS 42 CFR 50 on promoting objectivity in research
- 1998: FDA 63 FR 5233 clinical investigators must disclose financial relationships

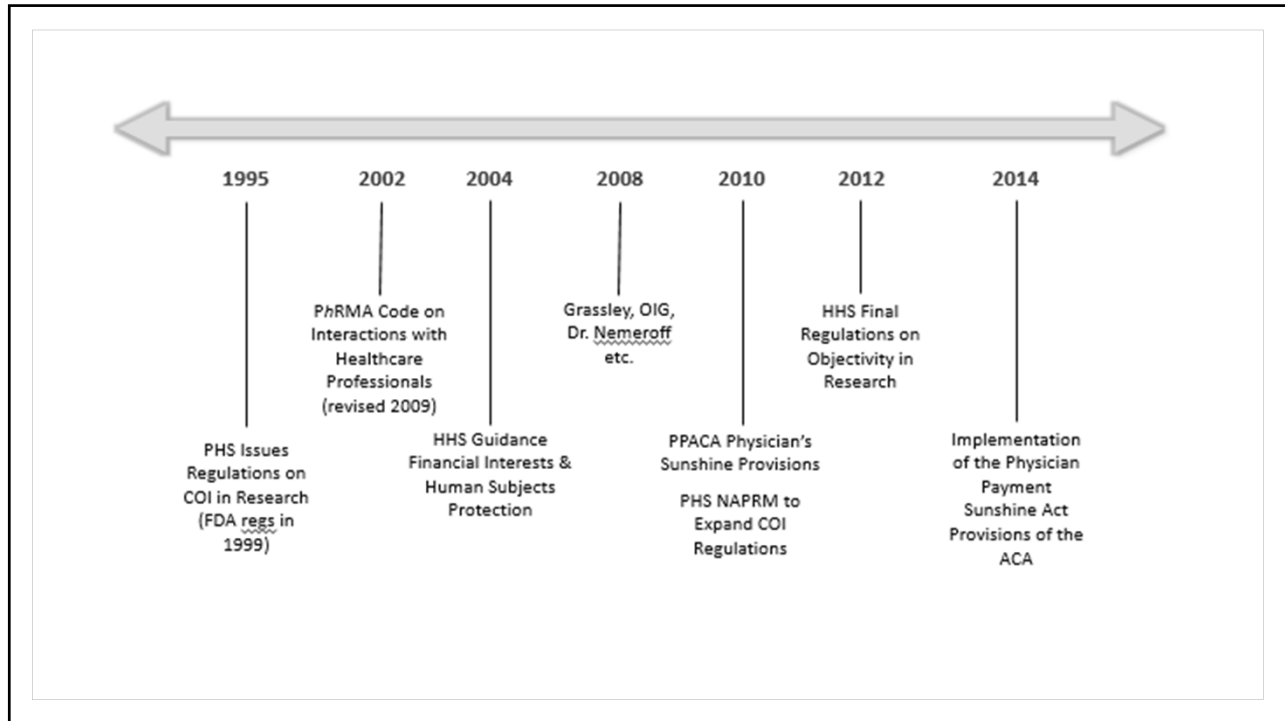
Source: Conflicts of Interest in Medical Research, Education, and Practice, 2009, NIH

## Jesse Gelsinger

- **FDA investigated Gelsinger's death**
  - PI ignored exclusion criterion in clinical trial
  - University didn't report serious adverse events from gene therapy
  - Didn't disclose death of monkeys in pre-human trials
- **Widely covered in the media**
  - Wired: Another Chance for Gene Therapy?
  - Guideapigzero.com: Paul Gelsinger, Jesse's father, tells of Jesse's death
  - Bioethics.net: On gene therapy and informed consent
  - BBC: Horizon Trial and error
  - New York Times: The Biotech Death of Jesse Gelsinger
  - Nature: Gene-therapy trials must proceed with caution
  - Scientific American: An Interview with an Unfortunate Pioneer

## Dr. Charles B. Nemeroff

- \$2.8M in consulting for pharma from 2000 to 2007
- Example: Disclosed less than \$10,000 in one year, but earned \$170,000 from GSK
- At one point consulted for 21 drug and device companies simultaneously
- Consulted for companies while engaging as PI in their clinical trials
- Still practicing today
  
- Led to Senator Grassley's investigation into other physicians and pharma's influence on their prescribing practices
- Example: Dr. Joseph Beiderman



# SUNSHINE ACT

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## 2014

## Purpose

- Promote transparency in financial interactions between pharmaceutical and medical device companies and certain healthcare providers
- Created by the Affordable Care Act

## Mandate

- Manufacturers of a drug, device, biological or medical supply covered under Medicare, Medicaid or the Children's Health Insurance Program must report most payments or other transfers of value made to a covered recipient (*i.e.*, physicians and teaching hospitals)
- Applies only to manufacturers
- Transactions reported involve teaching hospitals and physicians

## Reporting

- Manufacturers of a drug, device, biological or medical supply covered under Medicare, Medicaid or the Children's Health Insurance Program must report most payments or other transfers of value made to a covered recipient (*i.e.*, physicians and teaching hospitals)
- Applies only to manufacturers
- Transactions reported involve teaching hospitals and physicians
- Manufacturers must annually register and submit reports to the Centers for Medicare & Medicaid Services (CMS) by 90 days after calendar year end
- Separate reports for general transfers of value and research transfers of value
- Annual reports cover transfers of value made in the preceding calendar year

## Open Payments Overview



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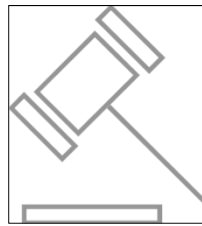




# What We're Going to Cover



Overview of Open Payments



Enforcement Scenarios



Exploring the Data



# Overview of Open Payments

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**CMS.gov**  
Centers for Medicare & Medicaid Services

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Home > Open Payments

**Open Payments** | About | Explore the Data | Program Participants | FAQs | Contact Us

**Happening Now: Data Submission**

The Open Payments System is now available for Program Year 2017 data submissions and attestations. Learn more about Open Payments registration, data submission and attestation on the Resource Page.

**Data Refresh and Program Year 18 Resources**

The Open Payments data has been refreshed to reflect any changes made between June 30, 2017 and December 31, 2017. To view the data visit: <https://openpaymentsdata.cms.gov/>. The Program Year 2018 Teaching Hospital List and Key (de minimus) Thresholds are now available.

### Open Payments

Open Payments is a federal program, required by the Affordable Care Act, that collects information about the payments drug and device companies make to physicians and teaching hospitals for things like travel, research, gifts, speaking fees, and meals. It also includes ownership interests that physicians or their immediate family members have in these companies. This data is then made available to the public each year on this website. Learn more about Open Payments.



**Search & Explore Open Payments Data**

- Use the search tool to look up doctors, hospitals, or



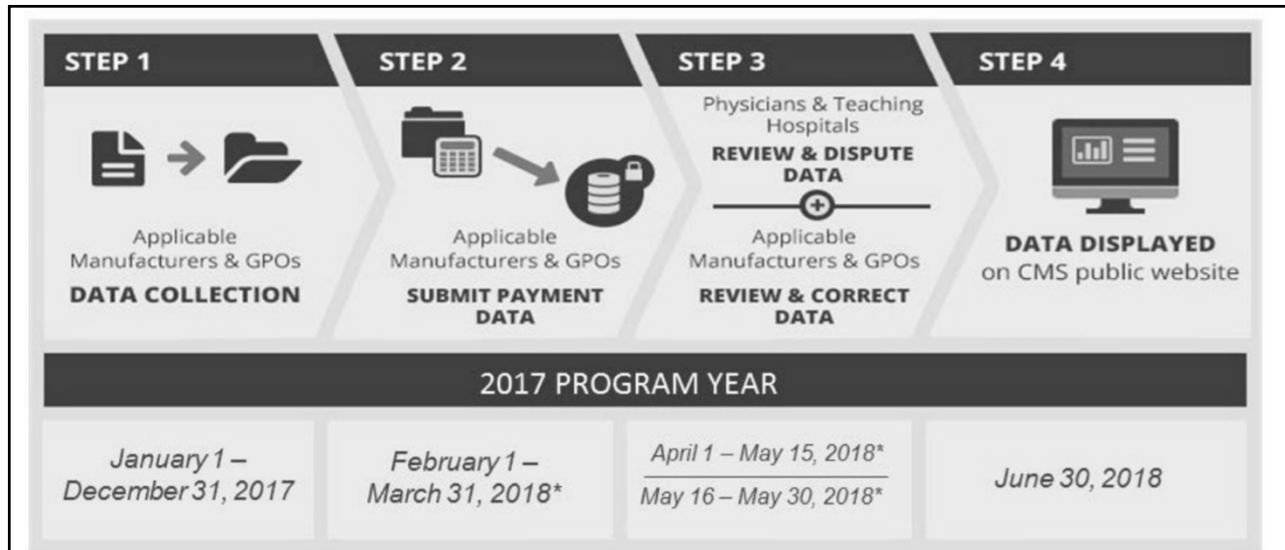
**Physicians and Teaching Hospitals**

- Learn how to register to review (and dispute) your financial data.



**Applicable Manufacturers and Group Purchasing Organizations**

- Learn How to register.



Note: Review and Dispute activities start on April 1st and can continue until end of the calendar year. The end dates provided on this slide are the cutoff for disputes and corrections to appear in the June 30th data publication.

## Payments Categories



- Consulting Fee
- Honoraria
- Gift
- Entertainment
- Food and Beverage
- Travel and Lodging
- Education
- Charitable Contribution
- Royalty or License
- Grant
- Research
- Compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program;
- Current or prospective ownership or investment interest;
- Compensation for serving as faculty or as a speaker for a non-accredited and noncertified continuing education program;
- Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program;
- Space rental or facility fees

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[http://phrma-docs.phrma.org/sites/default/files/pdf/phrma\\_marketing\\_code\\_2008.pdf](http://phrma-docs.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008.pdf)



<http://www.advamed.org/issues/code-ethics/code-ethics>



[http://c.ymcdn.com/sites/www.medicaldevices.org/resource/resmgr/Docs/MDMA\\_Code\\_July09.pdf?hhSearchTerms=%22code%22](http://c.ymcdn.com/sites/www.medicaldevices.org/resource/resmgr/Docs/MDMA_Code_July09.pdf?hhSearchTerms=%22code%22)

COMPLIANCE CONTACTS FOR CODE CERTIFYING COMPANIES

**ADVANCED MEMBER COMPANIES**

**3M Health Care**  
 (Infection Prevention Division  
 and Skin & Wound Care  
 Division)      Maureen Harms  
 651.733.4879 (phone)  
 maharms@mmm.com

**Abbott Laboratories**  
 United States Medical  
 Products Divisions      Hotline: 1-855-294-4584  
 Website: speakup.abbott.com

**ABIOMED, Inc.**      Hotline: 888.475.8376  
 Stephen McEvoy  
 978.646.1819 (phone)  
 smcevoy@abiomed.com

**Acclarent, Inc.**      Susan Clarke

**NON-MEMBER COMPANIES**

**AccelSPINE**      Sheetal Patel  
 214.545.5852 (phone)  
 compliance@accelspine.com

**AccuVein, Inc.**      Sue Vallejo  
 631.367.0393 (phone)  
 sue@accuvein.com

**Acumed LLC**      Ed Boehmer  
 503.627.9957 x1293 (phone)  
 eboehmer@acumed.net



# Enforcement Scenarios

## How Might the Data be Used?



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### Sunshine Data Helps Feds Uncover Fraud

Aug 30, 2016 By Jill Wechsler

The \$7.5 billion in "transfers of value" made in 2015 by pharma companies to physicians and hospitals through the federal Open Payments program has caught the attention of the Department of Justice (DoJ) and federal and state prosecutors investigating fraud throughout the health care system. Enforcement agencies see this wealth of industry data as a ready resource for uncovering unusual arrangements or heavy spending to certain providers that

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## 2017 OIG Work Plan: Data Brief on Open Payments Program



### New: Data Brief on Financial Interests Reported Under the Open Payments Program

- ACA § 6002 requires that manufacturers disclose to CMS payments made to physicians and teaching hospitals.
- Manufacturers and group purchasing organizations must also report ownership and investment interests held by physicians.



# 2017 OIG Work Plan: Data Brief on Open Payments Program



OIG will also determine how much Medicare paid for drugs and DMEPOS ordered by physicians who had financial relationships with manufacturers and group purchasing organizations.

OIG will determine the volume and total dollar amount associated with drugs and DMEPOS ordered by these physicians in Medicare Parts B and D for 2015.



# Settlements



**JUSTICE NEWS**

Department of Justice SHARE ↗  
Office of Public Affairs

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FOR IMMEDIATE RELEASE Tuesday, March 11, 2014

**Pharmaceutical Company to Pay \$27.6 Million to Settle Allegations Involving False Billings to Federal Health Care Programs**

Pharmaceutical manufacturer Teva Pharmaceuticals USA Inc. and a subsidiary, IVAX LLC, have agreed to pay the government and the state of Illinois \$27.6 million for allegedly violating the False Claims Act by making payments to induce prescriptions of an anti-psychotic drug for Medicare and Medicaid beneficiaries . Teva Pharmaceuticals USA is located in North Wales, Pa., and IVAX LLC is a Florida company.

Pharma Company:  
March 2014

## Settlements



### JUSTICE NEWS

Department of Justice

Office of Public Affairs

SHARE 

FOR IMMEDIATE RELEASE

Friday, February 13, 2015

#### **Illinois Physician Pleads Guilty to Taking Kickbacks from Pharmaceutical Company and Agrees to Pay \$3.79 Million to Settle Civil False Claims Act Case**

The Department of Justice announced today that an Illinois physician, Dr. Michael J. Reinstein, pleaded guilty to a federal crime for receiving illegal kickbacks and benefits totaling nearly \$600,000 from two pharmaceutical companies in exchange for regularly prescribing an anti-psychotic drug – clozapine – to his patients. Reinstein also agreed to pay the United States and the state of Illinois \$3.79 million to settle a parallel civil lawsuit alleging that, by prescribing clozapine in exchange for kickbacks, Reinstein caused the submission of false claims to Medicare and Medicaid for the clozapine he prescribed for thousands of elderly and indigent patients in at least 30 Chicago-area nursing homes and other facilities.

Physician: February 2015

## Other Potential Ramifications



- Zero Tolerance Policies
- Reconciling Internal Attestations with Public Data
- Grant Applications and Attestations
- Reputational Damage

## Professional Discussions



JAMA issue May 2, 2017, Vol 317, No. 17, Pages 1707-1812

- “Conflict of Interest: Why Does It Matter?” Harvey V. Fineberg, MD, PhD
- “Payments to Physicians-Does the Amount of Money Make a Difference?” Bernard Lo, MD; Deborah Grady, MD, MPH
- “Physicians, Industry Payments for Food and Beverages, and Drug Prescribing” Robert Steinbrook, MD
- “Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing”  
Ian Larkin, PhD; Desmond Ang, MS; Jonathan Steinhart, MA; et al

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## Exploring the Data




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OpenPaymentsData.CMS.gov Search

Home Search Tool Summary Data Data Explorer Download Data About Sign In



## Search Open Payments

The Open Payments Search Tool is used to search payments made by drug and medical device companies to physicians and teaching hospitals.

🔍 Search Physician, Teaching Hospital, or Company by Name

Or use the **Advanced Search**

Open Payments data is from August 2013 to December 2016 - See About page

**The Facts on Open Payments** 2016 Open Payments Data

\$  
**Total US Dollar Value**  
8.19 Billion

📁  
**Total Records Published**  
11.96 Million

🔍 Explore the Facts on Open Payments Data

Add Filter Entertainment

Amount of Payment	USD	Date of Payment	Number of Payments Included in Total Amount	Form of Payment or Transfer of Value	Nature of Payment or Transfer of Value	City of Transaction
\$7,800.00		09/28/2016		1 Cash or cash equivalent	Entertainment	
\$4,980.00		12/08/2016		1 Cash or cash equivalent	Entertainment	
\$3,609.96		03/18/2016		1 Cash or cash equivalent	Entertainment	
\$3,492.70		02/02/2016	14	Cash or cash equivalent	Entertainment	
\$3,462.75		10/15/2016	17	Cash or cash equivalent	Entertainment	
\$2,500.00		04/06/2016	1	In-kind items and services	Entertainment	
\$2,500.00		08/15/2016	1	Stock	Entertainment	
\$2,135.33		06/07/2016	3	Cash or cash equivalent	Entertainment	
\$2,022.75		09/23/2016	22	Cash or cash equivalent	Entertainment	
\$2,000.00		12/16/2016	1	Cash or cash equivalent	Entertainment	
\$1,655.00		08/05/2016	1	Cash or cash equivalent	Entertainment	
\$1,500.00		07/21/2016	1	In-kind items and services	Entertainment	
\$1,442.07		10/10/2016	4	Cash or cash equivalent	Entertainment	
\$1,442.07		10/10/2016	4	Cash or cash equivalent	Entertainment	

< Previous Next >
Showing 1-14 out of 8,448

Add Filter

Gift TX Covered Recipient P...

Total_Amount_of_Payment_USD	Date_of_Payment	Number_of_Payments_Included_in_Total_Amount	Form_of_Payment_or_Transfer_of_Value	Nature_of_Payment_or_Transfer_of_Value
\$43,588.54	12/31/2016		1 In-kind items and services	Gift
\$19,044.31	12/31/2016		1 In-kind items and services	Gift
\$11,390.00	06/30/2016		1 In-kind items and services	Gift
\$9,786.43	02/23/2016		1 In-kind items and services	Gift
\$9,000.00	04/29/2016		1 In-kind items and services	Gift
\$7,989.00	05/23/2016		1 In-kind items and services	Gift
\$7,549.96	04/29/2016		1 In-kind items and services	Gift
\$7,476.00	02/08/2016		1 In-kind items and services	Gift
\$7,000.00	07/22/2016		3 Cash or cash equivalent	Gift
\$6,971.00	06/03/2016		1 In-kind items and services	Gift
\$5,399.46	04/29/2016		1 In-kind items and services	Gift
\$5,093.49	08/30/2016		1 In-kind items and services	Gift
\$4,490.00	05/12/2016		1 In-kind items and services	Gift
\$3,852.20	04/29/2016		1 In-kind items and services	Gift

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Add Filter

Food and Beverage FL Covered Recipient P...

Total_Amount_of_Payment_USD	Date_of_Payment	Number_of_Payments_Included_in_Total_Amount	Form_of_Payment_or_Transfer_of_Value	Nature_of_Payment_or_Transfer_of_Value
\$3,500.00	07/28/2016		1 Cash or cash equivalent	Food and Beverage
\$2,600.00	04/22/2016		37 Cash or cash equivalent	Food and Beverage
\$2,585.86	10/22/2016		1 In-kind items and services	Food and Beverage
\$2,500.00	07/01/2016		1 Cash or cash equivalent	Food and Beverage
\$2,450.00	09/15/2016		1 Cash or cash equivalent	Food and Beverage
\$2,430.00	05/10/2016		1 Cash or cash equivalent	Food and Beverage
\$2,275.00	08/04/2016		1 Cash or cash equivalent	Food and Beverage
\$2,000.00	05/13/2016		1 In-kind items and services	Food and Beverage
\$1,600.00	12/01/2016		1 Cash or cash equivalent	Food and Beverage
\$1,500.00	05/03/2016		1 In-kind items and services	Food and Beverage
\$1,500.00	11/16/2016		1 Cash or cash equivalent	Food and Beverage
\$1,401.60	08/02/2016		5 In-kind items and services	Food and Beverage
\$1,400.00	06/09/2016		1 Cash or cash equivalent	Food and Beverage
\$1,333.44	03/09/2016		1 In-kind items and services	Food and Beverage

< Previous Next >

Showing 1-14 86t of 757,436

Add Filter

Physician\_Profile\_ID  
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Amount_USD ↓	Date_of_Payment	Number_of_Payments_Included_in_Total_Amount	Form_of_Payment_or_Transfer_of_Value	Nature_of_Payment_or_Transfer_of_Value
\$86,381.50	10/28/2016		1 Cash or cash equivalent	Royalty or License
\$81,169.63	07/28/2016		1 Cash or cash equivalent	Royalty or License
\$68,222.74	04/25/2016		1 Cash or cash equivalent	Royalty or License
\$56,082.87	01/26/2016		1 Cash or cash equivalent	Royalty or License
\$8,307.16	10/21/2016		1 In-kind items and services	Travel and Lodging
\$8,151.19	05/26/2016		1 In-kind items and services	Travel and Lodging
\$7,241.51	04/08/2016		1 In-kind items and services	Travel and Lodging
\$4,500.00	03/30/2016		1 Cash or cash equivalent	Compensation for services other than consulting, including serving as fa
\$4,000.00	10/25/2016		1 Cash or cash equivalent	Compensation for services other than consulting, including serving as fa
\$3,872.50	07/23/2016		1 In-kind items and services	Travel and Lodging
\$3,471.20	08/25/2016		1 In-kind items and services	Travel and Lodging
\$3,250.00	07/25/2016		1 Cash or cash equivalent	Compensation for services other than consulting, including serving as fa
\$3,122.00	08/13/2016		1 Cash or cash equivalent	Compensation for services other than consulting, including serving as fa
\$2,905.49	07/08/2016		1 In-kind items and services	Travel and Lodging

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# Exporting Data

- Physician Example
- Spreadsheet Demonstration

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## MITIGATING RISK

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Program Development, Investigations, Management Plans, and  
Auditing

### Conflict of Interest Reporting – Develop Your Program

- Appoint a Conflict Manager to oversee day-to-day monitoring plan
  - Reviewing disclosed potential conflicts
  - Conducting investigations
  - Creating management plans
- Create well-defined policies
  - Determine reporting limits
    - How much outside activity is too much?
  - Provide faculty with clear expectations and definitions
    - “What is honoraria?”

## Conflict of Interest Reporting – Develop Your Program

- Determine the frequency of reporting
  - Annual? Biannual? Continuous?
  - Update existing disclosure? Provide new disclosure for each new conflict?
- Construct an effective questionnaire
  - Broad questions vs specific inquiries
  - Revise!!
- Decide on a management tool
  - Electronic vs paper
  - Databases vs spreadsheets
  - What can be simplified using the proper tool?

## COI Technology Enablement

Electronic COI management systems can be used to simplify the COI reporting process – and ultimately the investigation process – for managers and researchers.

- Electronic conflict reporting options
- Centralization of management processes
- Integration with publicly reported databases

## Conducting Investigations

Sometimes the most obvious resources are the best

- Ask the Googles!
- Industry websites
  - Dr. C and ABC Pharmaceuticals
    - What do they do?
    - How does it relate to Dr. C's research or specialty?
    - Has Dr. C spoken on their behalf? Mentioned them in lectures?

## Conducting Investigations

- Doctor's history, research and publications
  - What are the recurring themes and how do they relate to outside interests?
  - Who has the doctor worked with in the past? How might they be involved?
- Institutional records
  - Is there a record of the doctor being granted permission for the work they're doing?
  - Do we have other business agreements in place and how do they relate?

## Reporting

- Once investigations are concluded, how do you share the information?
- Who is the audience?
- What is the frequency?
- Where at your institution does the management plan “live”?

## Management Plans

1. Minimal Risk- once disclosed, activity can continue without significant management or concern
2. Perceived or Potential Conflict – once disclosed, activity can continue, but with written guardrails and agreements
3. Conflict of Interest – once disclosed, activity may or may not continue with a management plans in place

## Conflict of Interest

Activity	Management Plan?
Incoming department chair owns controlling interest in pharma drug (brand name), wishes to do clinical trial using drug	Advise chair to swap interest, divest entirely, or forego clinical trial
Surgeon, who is also department chair, wishes to hire spouse as surgeon	Nepotism. Disallow, or follow institutional process for exceptions, or have chair step down
Provider consults for pharma and accepts \$170,000/year in "honoraria" (almost exceeds salary)	Monitor prescribing practices, or treat honoraria as income, or disallow as income
Addiction researcher/provider has opened a community clinic	Disallow, or refer to non-compete, or inform research personnel, or...? Corrective Action?

## Management Plan Monitoring

- Depending on the size and scope of your organization, monitoring your management plans could become unruly.
- Where do the plans "live"?
- Central, division, department, college, enterprise?
- How often are they reviewed?
- Who is responsible for the review?
- What is the process in the event of non-compliance?



## Audit Approaches

- Baseline Audit – establish a set of benchmarks for future comparison
- Concurrent Audit – could identify problems as they arise
  - Review travel documents/absence records
  - Google employee name plus “presentations” or “speaker”
  - Random unannounced interviews using a pre-planned check-list
  - Could lead to a .....
- Retroactive Audit – review of past activity as suggestion of future behavior
  - Prior submissions on Open Payments or Dollars for Docs
  - Past management plan violations
  - Random/snowball/simple sample audits

## Audit Types

- Routine Audit
- Random Audit
- Process Audit
- Procedural Audit
- Data Audit
- Diagnostic Audit (Root Cause Analysis)

## COI Management Plan Steps

- Disclosure
- Review
- Escalation
- Investigation
- Management Plan
- Management Plan Monitoring
- Management Plan Auditing
- Assessment
- Recommendations
- Planning



## Questions?

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