CONFLICT OF INTEREST 2.0: BEYOND DATA COLLECTION

2018 HCCA Research Compliance Conference, Austin, TX

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

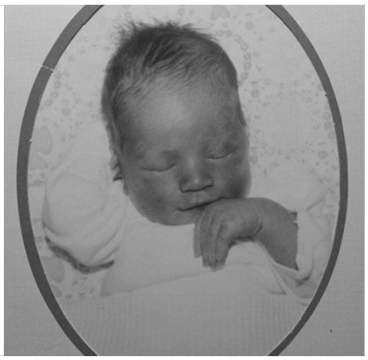
Key Points

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

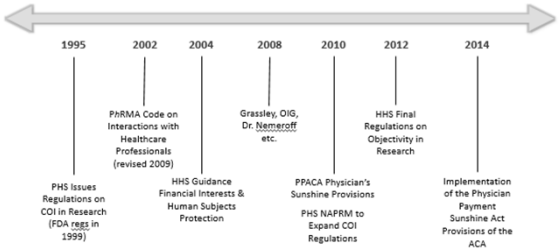
Jesse Gelsinger

- **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

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

CJ Wolf MD, COC, CPC, CHC, CCEP, CIA
Healthicity | Senior Compliance Executive

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What We're Going to Cover

Overview of Open Payments

Enforcement Scenarios

Exploring the Data

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Overview of Open Payments

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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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PhRMA
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http://phrma-docs.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008.pdf

AdvaMed
Advanced Medical Technology Association

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

MDMA
MEDICAL DEVICE MANUFACTURERS ASSOCIATION
Innovation Today for Better Health Care Tomorrow™

http://c.ymcdn.com/sites/www.medicaldevices.org/resource/resmgr/Docs/MDMA_Code_July09.pdf?hhSearchTerms=%22code%22

COMPLIANCE CONTACTS FOR CODE CERTIFYING COMPANIES

ADVAMED 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

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How Might the Data be Used?

- WHERE BUSINESS MEETS POLICY -

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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
Office of Public Affairs

SHARE

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

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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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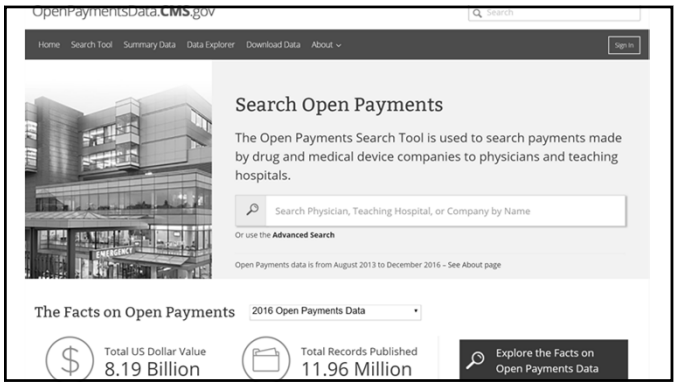


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Form_of_Payment_or_Transfer_of_Value
Nature_of_Payment_or_Transfer_of_Value
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$4,980.00 12/08/2016 1 Cash or cash equivalent Entertainment
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Food and Beverage
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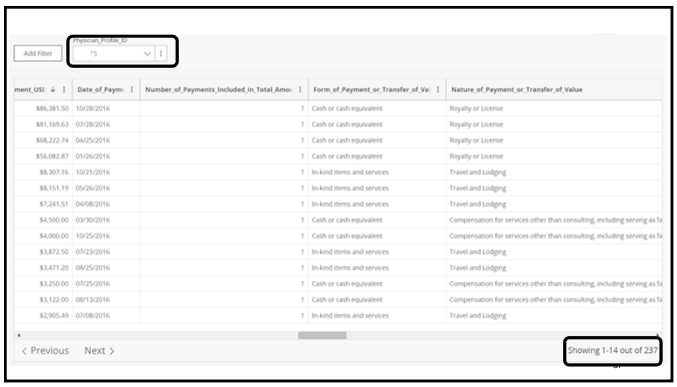

Exporting Data

- Physician Example
- Spreadsheet Demonstration

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MITIGATING RISK

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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