Conflict of Interest 101
Identifying, Managing, and Preventing Research Risk

HCCA Virtual Research Compliance Conference
June 3, 2020

What We’ll Cover Today

• Understanding the Sunshine Act, including recent changes and how they impact your research organization

• Gain useful insight and tools for managing COI research risk at your institution

• Learn to identify risks using the Open Payment database

Disclaimer: None of the speakers are attorneys and are not providing legal advice.
Polling Question 1-

How many years of experience do you have in conflict of interest management?

- I’m brand new here
- I’ve been doing this for one to three years
- I’ve been a COI manager for four to eight years
- I’ve been doing this since dinosaurs roamed the earth

COI: Origin story

Presented by Rebecca Scott, Compliance/Privacy Manager, UK HealthCare
Historical Look at Conflict of Interest

1959
- Senate hearing on pricing practices for pharma

1962
- Preventing COI for gov. consultants

1964
- AAUP/ACE statement on COI for gov. sponsored research

1971
- NAS letter “On Potential Sources of Bias”

1972
- Congress’s 1st anti-kickback statute

1978
- Ethics in Government Act

The 1980’s

1980
- Bayh-Dole Act and the Technology Innovation Act (Patents and Trademarks)

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
- AU - University Policies on Conflict of Interest and Delay of Publication

1986
- ACE - Higher Education and Research Entrepreneurship: Conflicts Among Interests

1987
- PHS Grants Policy Statement requires grant recipients to have written COI rules

1988
- House hearing on scientific misconduct and conflicts of interest

Source: Conflicts of Interest in Medical Research, Education, and Practice, 2009, AAM
Omnibus Budget Reconciliation Act (‘89)

STARK LAW!!
Bans self-referral arrangements for clinical laboratory services under Medicare
Later updated in 1993 and 2004, expanding and defining restrictions

1990

- 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 – statement on inappropriate gifts to physicians from industry
- ACP – paper on physicians and pharma

Source: Conflicts of Interest in Medical Research, Education, and Practice, 2003, p144
The Rest of the 1990’s

• 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.”
• 1993: Minnesota law limiting drug company gifts and requiring disclosure
• 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, NH

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
Broad Media Coverage

- 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

2010
Purpose

- Promote transparency in financial interactions between pharmaceutical and medical device companies and certain healthcare providers
- Created by the Affordable Care Act
- Implemented in 2014

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 and group purchasing organizations
- 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.

Types of Reporting Requirements

<table>
<thead>
<tr>
<th>Research Payments</th>
<th>Payments or other transfers of value if (1) made in connection with “research” and (2) protocol or written agreement</th>
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</thead>
<tbody>
<tr>
<td>General Payments</td>
<td>All other transfers of value</td>
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</table>
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

Covered Recipients

Physicians

• Licensed physician, osteopath, dentist, dental surgeon, podiatrist, optometrist, or chiropractor
• Legally authorized to practice medicine
• U.S. or U.S. territory (Puerto Rico, Virgin Islands, Guam and American Samoa) even if living abroad
• Excludes:
  • Employee of manufacturer
  • Residents

Teaching Hospitals

• Any institution receiving Medicare direct or indirect graduate medical education payments
• CMS posts list annually on Open Payments website and manufacturers may rely on that list
Research Transfers of Value

• Manufacturers must track and report the following information for research transfers of value related to clinical research:
  • Name of individual/entity directly receiving the transfer of value
    • Physician: Name, business and email addresses, National Provider Identifier (NPI), state license number and state, specialty (as per the taxonomy and code in National Plan and Provider Enumeration System (NPPES)) and type of medicine practiced (M.D., D.O., D.P.M., O.D., or D.C.P.)
    • Teaching Hospital: Name, business and email addresses, TIN and NPI (if applicable)
    • Other Third Party: Name and business and email addresses

Data Elements

• Total amount, date and form of research payment
• Name of research study
• Whether the product is a Covered Product, a non-Covered Product, a combination, or neither
  • Covered Product: Prescription drug or medical device if premarket approval by or premarket notification to the FDA is required and payment is available under Medicare, Medicaid or the Children’s Health Insurance Program
• Name of related covered product(s)
• Information on physician principal investigators (same as for physicians above)
More Data Elements

- Manufacturers must track and report the following abbreviated information for research transfers of value related to pre-clinical research:
  - Name of individual/entity receiving the transfer of value
    - Physician: Name, business and email addresses, NPI, state license number and state, specialty and type of medicine practiced
    - Teaching Hospital: Name, business and email addresses, TIN and NPI (if applicable)
    - Other Third Party: Name, business and email addresses
  - Total amount, date and form of the transfer of value
  - Information on physician principal investigators

Review Process

- Manufacturers and covered recipients have 45 days to review information through secure website prior to public disclosure
  - Covered recipients register to review manufacturer submissions
- Reviewers may indicate agreement/disagreement with information posted
- CMS will not arbitrate disputes between manufacturers and covered entities
- If dispute not resolved, CMS will post information as reported by manufacturer but note that information is in dispute
Penalties for Non-Compliance

- **Failure to Report**: Civil money penalty from $1,000 to $10,000 for each unreported transfer of value up to $150,000

- **Knowing Failure to Report**: Civil money penalty from $10,000 to $100,000 for each unreported transfer of value up to $1,000,000

Corrections

- Manufacturers must report discovered errors or omissions in information submitted immediately

- CMS notifies affected covered recipients and updates website posting annually

- CMS may undertake interim “refreshes” of data posted
Documentation Retention

• Manufacturers must maintain all records sufficient to enable audit of compliance with reporting requirement

• Records mentioned for at least 5 years from date that transfer of value is publicly posted not date that transfer of value is reported

Meanwhile, at NIH

• Significant Financial Interest (SFI)
  • Consist of one or more of the following interests of the investigator (and those of the investigator’s spouse and dependent children) that reasonably appears to be related to the investigator’s institutional responsibilities
  • A SFI exists if the value of remuneration received from the entity in the 12 months preceding disclosure and the aggregated value exceeds $5,000
  • SFI does not include...salary, royalties, certain IP rights, investment vehicles
  • SFI does not include...income from seminars, lectures, teaching if sponsored by a federal, state, or local government agency, higher education institution, academic teaching hospital, medical center, it’s affiliated research institute, income from advisory committees or review panels, from groups named above
Open Payments Defined

- Section 6002 of the Affordable Care Act (Public Law No. 111-148)
- Health Care and Education Reconciliation Act of 2010 (Public Law No. 111-152)
- Substance-Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act for Patients and Communities Act (Public Law No. 115-271)

“The opioid epidemic has taught us a terrible lesson: without full transparency, pharmaceutical companies can operate under the cover of darkness, possibly using gifts and payments to influence the prescribing practices of medical professionals like nurse practitioners and physicians assistants. That's why it is absolutely essential that pharmaceutical companies disclose gifts and payments made to additional health care providers who prescribe opioids and other drugs – not just doctors.”

Senator Richard Blumenthal (D-CT)
Fighting the Opioid Epidemic with Sunshine Act of 2018

- Introduced May 2018
- Proposed effective date of January 1, 2020
- Related legislation: HEAL Act, CRIB Act, SUPPORT Act, TeleCAST Act, Opioid Addiction Treatment Programs Enhancement Act, Securing Flexibility to Treat Substance Use Disorders Act, Help for Moms and Babies Act, Assessing Barriers to Opioid Use Disorder Treatment Act, Building Capacity for Family-Focused Residential Treatment Act, Comprehensive Screenings for Seniors Act of 2018, etc...

SUPPORT ACT

- Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act
- Massive set of opioid crisis Acts
- More than 170 titles
- Signed into law October 25, 2018
- Section 6111: Fighting the Opioid Epidemic with Sunshine (FOES?) Grassley, Brown, and Blumenthal repackaged
Impact on Open Payments

Expands the definition of a covered recipient
- Physician Assistants
- Nurse Practitioners
- Clinical Nurse Specialists
- Certified Nurse Midwives
- Certified Registered Nurse Anesthetists

Allows National Provider Identifiers (NPIs) to be publicly available
- Weren’t they already?

2020 Medicare Physician Fee Schedule

- Effective on or after January 1, 2020
- Reflects the same five provider types new to Open Payments
- Includes three new payment/transfer of value types
  - Debt forgiveness
  - Long term medical supply or device loan
  - Acquisitions
- Merges the two types of education programming into one
- Adds requirements for reporting unique device identifier numbers
- Effective on or after January 1, 2022
Effective Dates in Conflict

• 2020 Medicare Physician Fee Schedule effective on or after January 1, 2020

• SUPPORT Act
  • Change applies to information required to be submitted on or after January 1, 2022
  • Effective for data collection beginning in calendar year 2021 for reporting to CMS 2022

MITIGATING RISK

Program Development, Investigations, and Management Plans

Presented by Andrew Hill, Compliance Analyst/Auditor, UK HealthCare
Polling Question 2

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

01
Determine the frequency of reporting
• Annual? Biannual? Continuous?
• Update existing disclosure? Provide new disclosure for each new conflict?

02
Construct an effective questionnaire
• Broad questions vs specific inquiries
• Revise!!

03
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”?  

Conflict of Interest

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

- Faculty members cousin's son works part-time in the ER as dietician
- Royalties from work prior to joining institution
- TIAA/CREF managed retirement plan investments
- Service on church board
- Stock in Disney
- Money earned as part of a wind ensemble that plays on the weekends

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
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?

COI Management Plan Steps

- Disclosure
- Review
- Escalation
- Investigation
- Management Plan
- Management Plan Monitoring
- Management Plan Auditing
- Assessment
- Recommendations
- Planning
Deming’s Model of Continuous Improvement (PDCA)

Plan
what is needed

Do it

Act to
improve performance

Check that it works
Identifying Risks Through the Open Payments Database

CJ Wolf, Director, Conflict of Interest Program
Intermountain Healthcare, Salt Lake City, UT
cj.wolf@imail.org

Polling Question 3 -

What is the primary method you use when searching the OpenPayments data?

- I don’t know, I haven’t used the data search features yet
- I primarily use the OpenPayments, online single physician/single teaching hospital search tools
- I download the data sets from OpenPayments and search offline
- Other
Drug Maker Mallinckrodt Agrees to Pay Over $15 Million to Resolve Alleged False Claims Act Liability for “Wining and Dining” Doctors

Pharmaceutical company Mallinckrodt ARD LLC (formerly known as Mallinckrodt ARD Inc. and previously Questcor Pharmaceuticals Inc. "Questcor"), has agreed to pay $15.4 million to resolve claims that Questcor paid illegal kickbacks to doctors, in the form of lavish dinners and entertainment, to induce prescriptions of the company’s drug, H.P. Acthar Gel (Acthar) from 2009 through 2013.

The Federal Anti-Kickback Statute prohibits a pharmaceutical company from offering or paying, directly or indirectly, any remuneration — which includes money or any other thing of value — with the intent to induce a health care provider to prescribe a drug reimbursed by a federal health care program, including Medicare. This prohibition extends to such practices as “wining and dining” doctors to induce them to write Medicare prescriptions of a company’s products.

The government alleged that, from 2009 to 2013, twelve Questcor sales representatives marketing Acthar provided illegal remuneration to health care providers in the form of lavish meals and entertainment expenses. The company paid this remuneration, the government alleges, with the intent to induce Acthar Medicare referrals from those health care providers.

DOJ Files Suit against Spine Device Manufacturer and Executives Alleging Kickbacks to Surgeons through Sham Consulting Payments

The Justice Department announced today that the United States intervened and filed a complaint in two whistleblower cases filed under the False Claims Act against SpineFrontier, Inc. (SpineFrontier) and related entities and executives, alleging that the defendants paid kickbacks to spine surgeons to induce use of SpineFrontier surgical devices, in violation of the Anti-Kickback Statute (AKS). According to the United States’ complaint, the defendants paid spine surgeons over $8 million in sham “consulting” payments ostensibly for product evaluations, when in fact the payments were for use of SpineFrontier devices.

“Kickbacks undermine the integrity of federal health care programs and can result in unnecessary or harmful medical care,” said Assistant Attorney General Jody Hunt of the Department of Justice’s Civil Division. “The Department of Justice will pursue unlawful kickback arrangements in whatever form they occur to ensure the integrity of the medical care received by federal program beneficiaries.”

According to the United States’ complaint, Dr. Kingsley Chin is the founder and Chief Executive Officer of SpineFrontier, a spine device manufacturer headquartered in Malden, Massachusetts, which sells spinal implant devices across the United States. Dr. Chin is also the founder and principal owner of KIC Management Group Inc. and KICVentures LLC, which own
FOR IMMEDIATE RELEASE

U.S. Attorney Sues Spinal Device Company and Its Executives for Allegations that they Paid Kickbacks to Surgeons

Five doctors admit to taking kickbacks and will pay $1.56 million

BOSTON – The U.S. Attorney’s Office has filed a civil health care fraud complaint against SpineFrontier, Inc. (SpineFrontier); Impartial Medical Experts, LLC (IME); Kingsley Chin, the founder and CEO of SpineFrontier; Aditya Humad, the CFO of SpineFrontier; Vanessa Dudley, Chin’s wife and the Business Administrator of IME; and other entities Chin owns and controls.

The government alleges that SpineFrontier, based in Malden, Mass., and the other defendants paid, and conspired to pay, kickbacks in the form of sham consulting fees via a sham third-party, IME. The lawsuit alleges that the defendants made these payments to surgeons to induce them to use SpineFrontier’s devices in spinal surgeries. The government contends that the defendants violated the Anti-Kickback Statute, and as a result caused federal health care programs to pay millions of dollars in false claims.

In addition, the U.S. Attorney’s Office has settled civil health care fraud claims against five physicians, each of whom admits to seeking and obtaining kickbacks from SpineFrontier, via the sham third-party IME. The government and the defendants have agreed to settle the claims in exchange for $1.56 million.

https://www.cms.gov/OpenPayments
Open Payments Advanced Search

The Open Payments Advanced Search lets you search Open Payments data based on the filters you apply below. The results include a summary table of the total number of payments and total amount of those payments and a link to download the data as a CSV file. The payments data is grouped by year and you can sort by each column. You can also click on the Recipient or Company Making Payment link to view more profile page. Please note the results do not include Associated Research Payments. You can also continue to use the Data Explorer to view and download the data or connect via API to all of the backed Open Payments datasets and/or download the datasets for offline use.

Please be patient, search results may take a few moments to load.

Search  Reset

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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 by Name:

- Search by Physician, Teaching Hospital, or Company by Name
- Or use the wildcard search

Open Payments data is from August 2013 to December 2018. See about page.

The Facts on Open Payments

- Total US Dollar Value: $9.23 Billion
- Total Records Published: 11.39 Million

Data Tools

- Search
- Advanced Search
- Data Explorer
- Download Data

For more advanced users, browse the bundled Open Payments dataset and access the data via API.
<table>
<thead>
<tr>
<th>Date of Payment</th>
<th>Amount of Payment</th>
<th>Number of Payments Included in Total Amos</th>
<th>Form of Payment or Transfer of Value</th>
<th>Nature of Payment or Transfer of Value</th>
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### Food and Beverage

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<th>Item</th>
<th>Total Amount of Payments</th>
<th>Date of Payment</th>
<th>Number of Payments Included in Total Amount</th>
<th>Form of Payment or Transfer of Value</th>
<th>Nature of Payment or Transfer of Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>$3,500.00</td>
<td>07/30/2016</td>
<td>1 Cash or cash equivalent</td>
<td>Food and Beverage</td>
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<tr>
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Showing 1-14 out of 757,430

### Physician Profile ID

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<tr>
<th>Item</th>
<th>Item</th>
<th>Number of Payments Included in Total Amount</th>
<th>Form of Payment or Transfer of Value</th>
<th>Nature of Payment or Transfer of Value</th>
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<tbody>
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<td>Travel and Lodging</td>
<td></td>
</tr>
</tbody>
</table>

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Questions?

- Rebecca Scott: rebecca.scott@uky.edu
- Andrew Hill: Andrew.hill@uky.edu
- CJ Wolf: cj.wolf@imail.org