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?

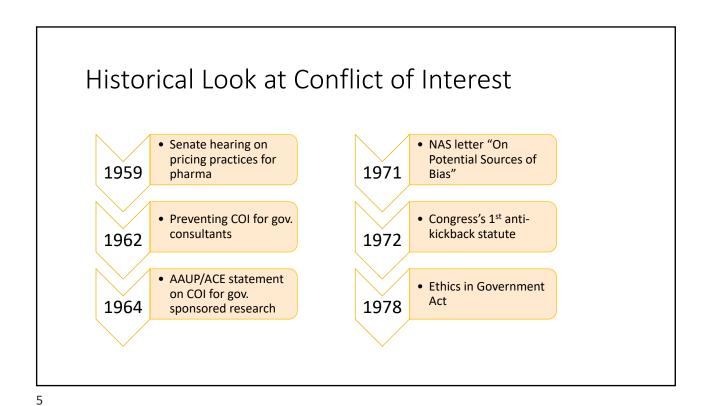
- I'm brand new here
- I've been doing this for one to three years
- I've been a COI manager for four to eight years
- I've been doing this since dinosaurs roamed the earth

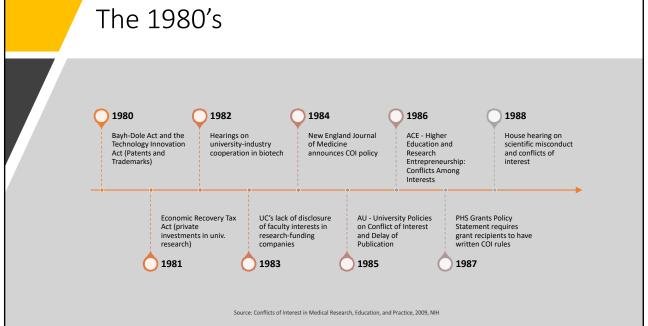
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COI: Origin story

Presented by Rebecca Scott, Compliance/Privacy Manager, UK HealthCare

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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

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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, 2009, NIH

The Rest of the 1990's

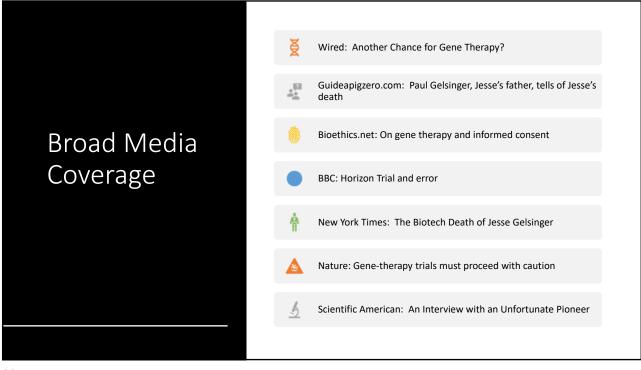
- NAS report Responsible Science "The issues associated with conflict of interest in the academic research environment are sufficiently problematic that they deserve thorough study and analysis by major academic and scientific organizations."
- 1993: Minnesota law limiting drug company gifts and requiring 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, NIH

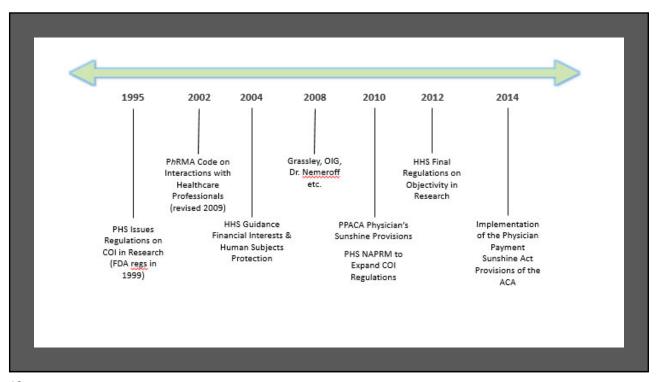
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Jesse Gelsinger

- 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



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





Purpose

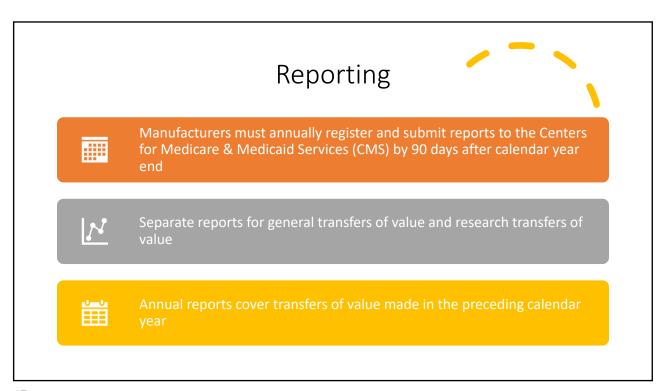
- Promote transparency in financial interactions between pharmaceutical and medical device companies and certain healthcare providers
- Created by the Affordable Care Act
- Implemented in 2014

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昴 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



Types of Reporting Requirements

Research Payments

Payments or other transfers of value if
(1) made in connection with "research"
and (2) protocol or written agreement

General Payments All other transfers of value

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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 nonaccredited 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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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 <u>related to clinical research</u>:
 - Name of individual/entity <u>directly</u> receiving the transfer of value
 - <u>Physician</u>: 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.)
 - <u>Teaching Hospital</u>: Name, business and email addresses, TIN and NPI (if applicable)
 - Other Third Party: Name and business and email addresses

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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
 - <u>Covered Product</u>: 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 <u>pre-clinical</u> research:
 - · Name of individual/entity receiving the transfer of value
 - <u>Physician</u>: Name, business and email addresses, NPI, state license number and state, specialty and type of medicine practiced
 - <u>Teaching Hospital</u>: 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

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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

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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

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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)

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Grassley, Brown, and Blumenthal

"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."

Richard Blumenthal (D-CT)

Senator

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...

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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?

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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

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MITIGATING RISK

Program Development, Investigations, and Management Plans

Presented by Andrew Hill, Compliance Analyst/Auditor, UK HealthCare

Polling Question 2

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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
- Revisel

03

Decide on a management tool

- Flectronic vs pape
- Databases vs spreadsheet
- What can be simplified using the proper tool?

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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?

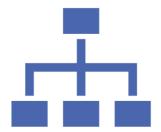
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Conducting Investigations

- 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"?



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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?

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

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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

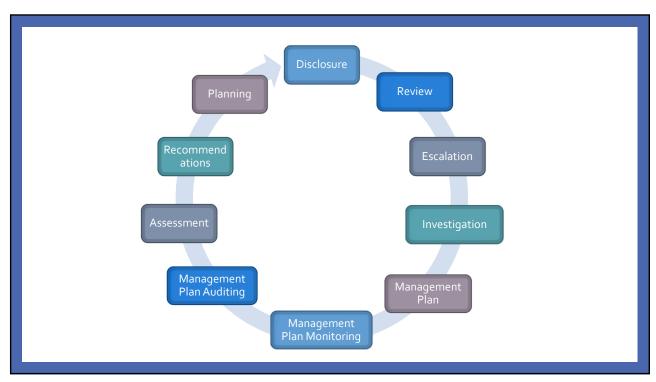
Management Plan Monitoring

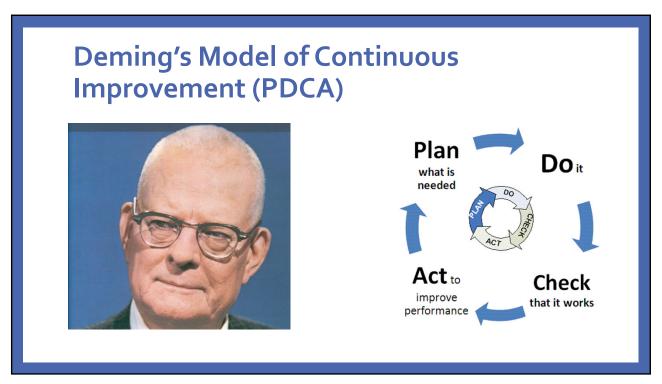
- Depending on the size and scope of your organization, monitoring your management plans could become unruly.
- Where do the plans "live"?
- Central, division, department, college, enterprise?
- How often are they reviewed?
- Who is responsible for the review?
- What is the process in the event of non-compliance?

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COI Management Plan Steps

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





Identifying Risks Through the Open Payments Database

CJ Wolf, Director, Conflict of Interest Program
Intermountain Healthcare, Salt Lake City, UT
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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

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Wednesday, September 4, 2019

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,

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FOR IMMEDIATE RELEASE

Thursday, March 5, 2020

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

Thursday, March 5, 2020

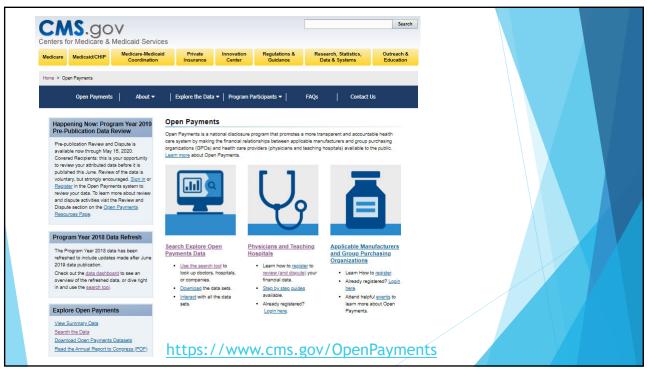
U.S. Attorney Sues Spinal Device Company and Its Executives for Allegations that they Paid Kickbacks to Surgeons

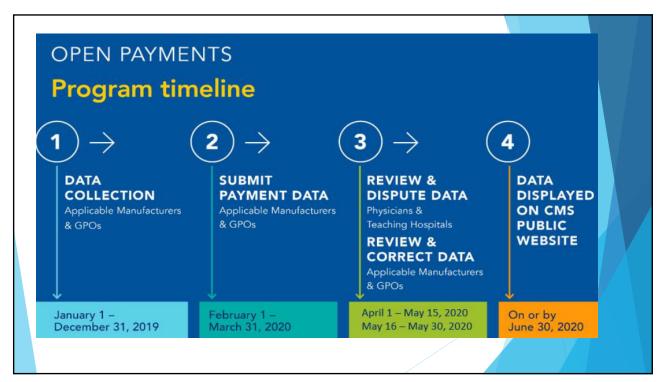
Five doctors admit to taking kickbacks and will pay \$1.56 million

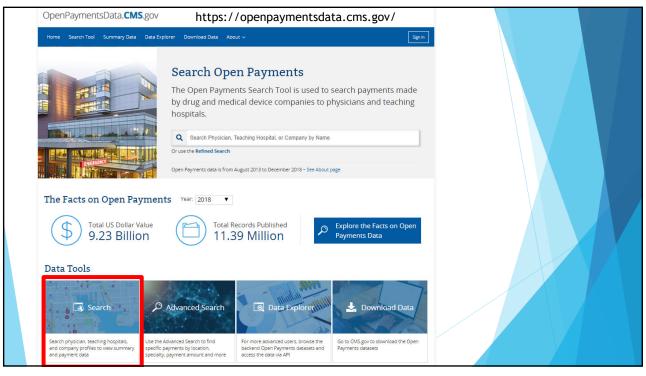
BOSTON – The U.S. Attorney's Office has filed a civil health care fraud complaint against SpineFrontier, Inc. (SpineFrontier); Impartial Medical Experts, LLC (IME); Kingsley Chin, the founder and CEO of SpineFrontier; Aditya Humad, the CFO of SpineFrontier; Vanessa Dudley, Chin's wife and the Business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

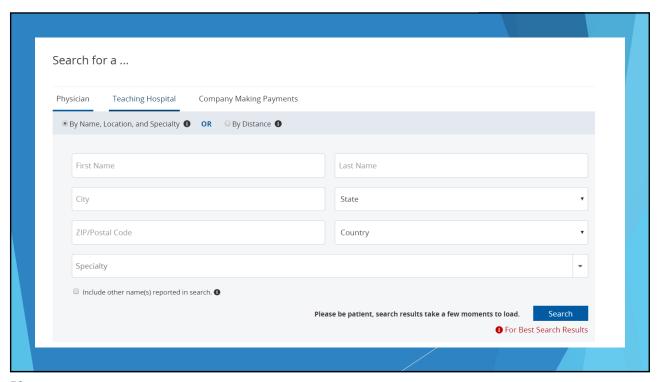
The government alleges that SpineFrontier, based in Malden, Mass., and the other defendants paid, and conspired to pay, kickbacks in the form of sham consulting fees via a sham third-party, IME. The lawsuit alleges that the defendants made these payments to surgeons to induce them to use SpineFrontier's 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.

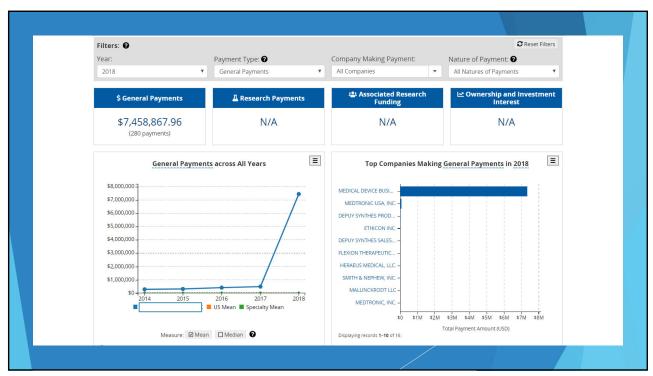
In addition, the U.S. Attorney's Office has settled civil health care fraud claims against five physicians, each of whom admits to seeking and obtaining kickbacks from SpineFrontier, via the sham third-party

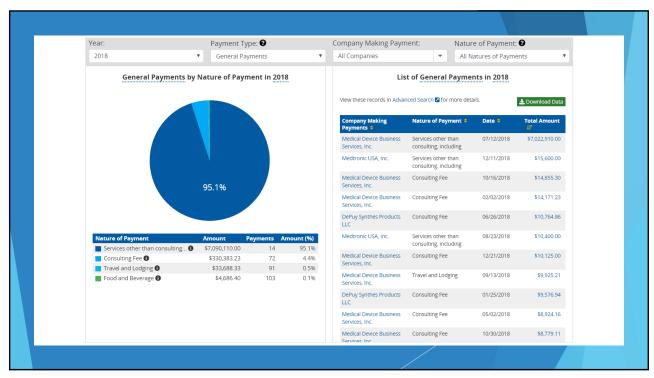


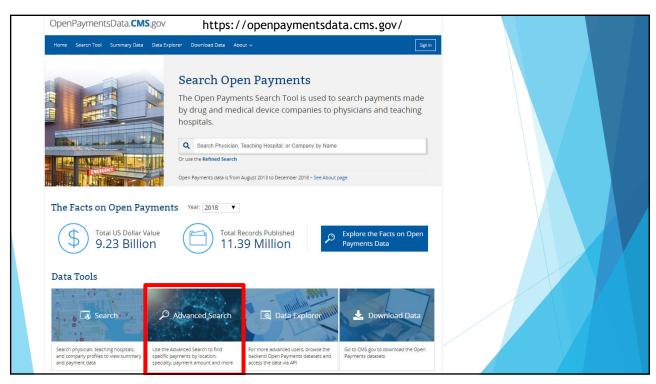


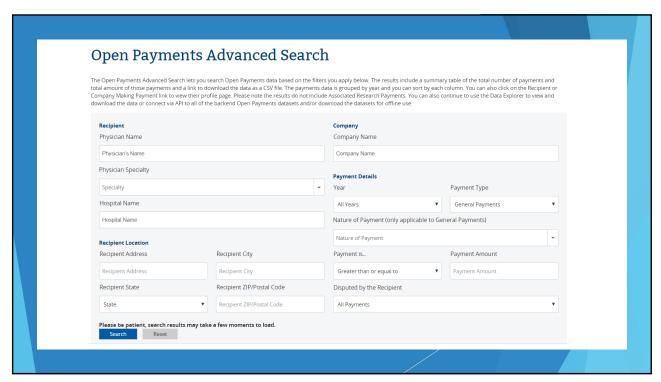


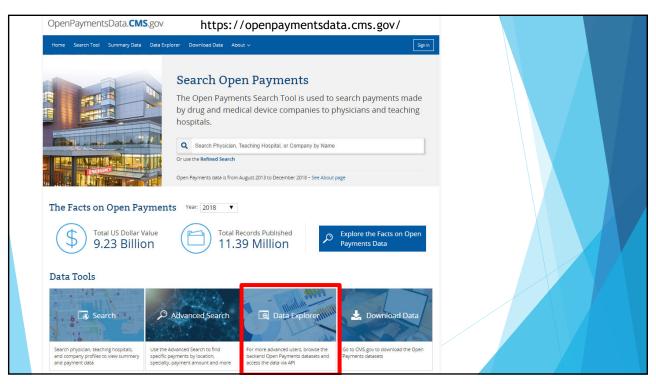


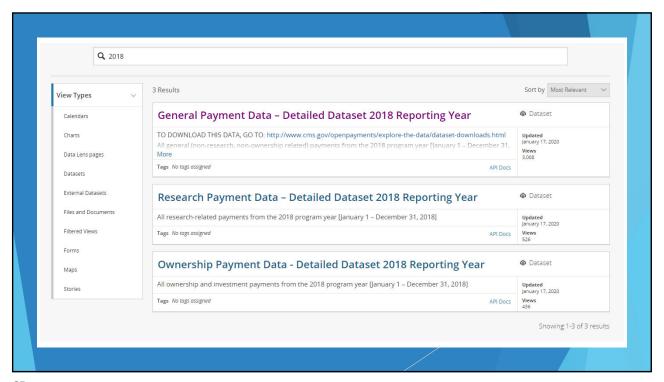


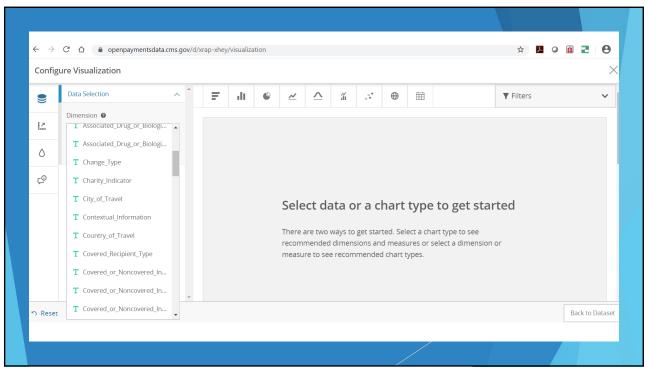


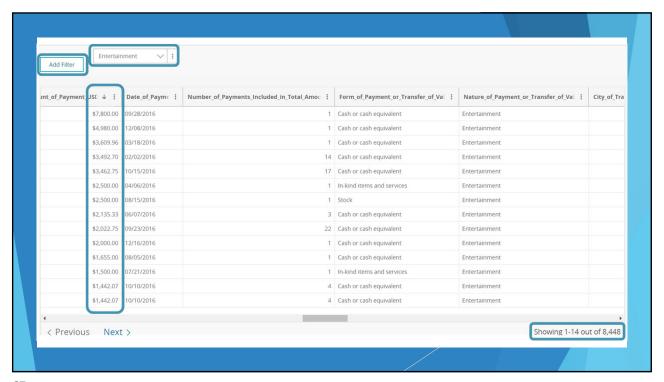


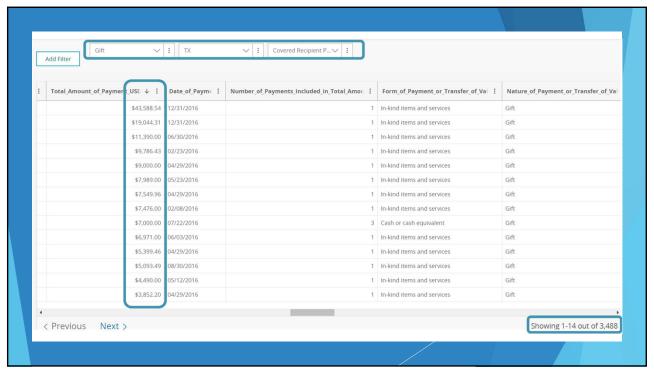


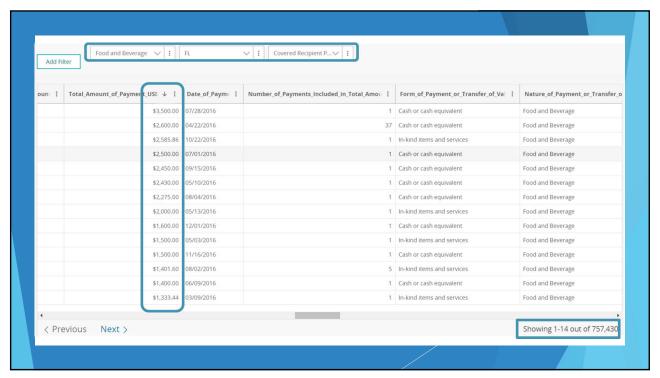


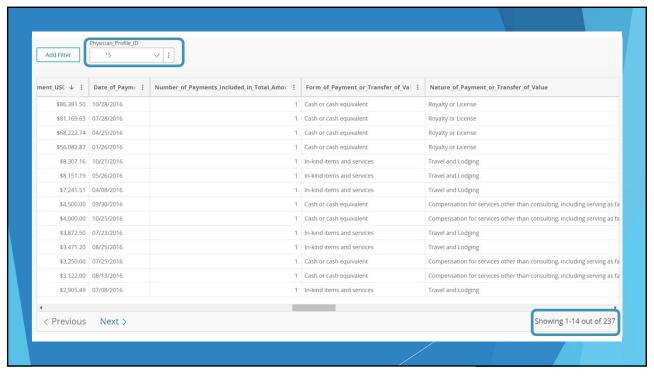


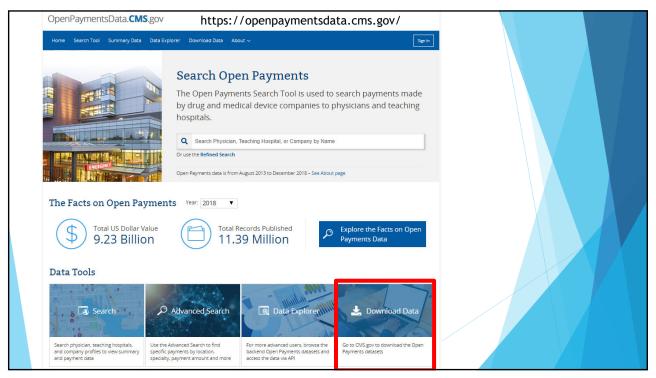












Dataset Downloads BEFORE YOU DOWNLOAD Some datasets, particularly the general payments dataset included in these zip files, are extremely large and may be burdensome to download and/or cause computer performance issues. Be advised that the file size, once downloaded, may still be prohibitive if you are not using a robust data viewing application. Microsoft Excel has limitations on the number of records it can display, which this file exceeds. CMS recommends against using Windows File Compression to decompress downloaded files. Programs recommended for file decompression are WinZip, WinRAR, and 7-Zip. Use the search tool or Data Explorer as alternatives to search and refine views of the larger Open Payments data sets. Complete 2018 Program Year Open Payments Dataset A complete set of all data from the 2018 Program Year, which includes data reported about payments made from January 1 through December 31, 2018. Download Complete 2018 Program Year Dataset Complete 2017 Program Year Open Payments Dataset A complete set of all data from the 2017 Program Year, which includes data reported about payments made

Department of Health and Human Services
OFFICE OF
INSPECTOR GENERAL

OPEN PAYMENTS DATA:
REVIEW OF ACCURACY,
PRECISION, AND
CONSISTENCY IN REPORTING

https://oig.hhs.gov/oei/reports/oei-03-15-00220.pdf



Suzanne Murrin Deputy Inspector General

August 2018 OEI-03-15-00220

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Questions?

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