

# CONFLICT OF INTEREST 2.0: BEYOND DATA COLLECTION

2018 HCCA Compliance Institute, Las Vegas, NV

## Presented by

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# Agenda

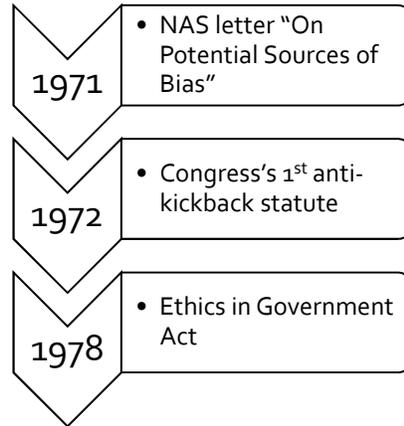
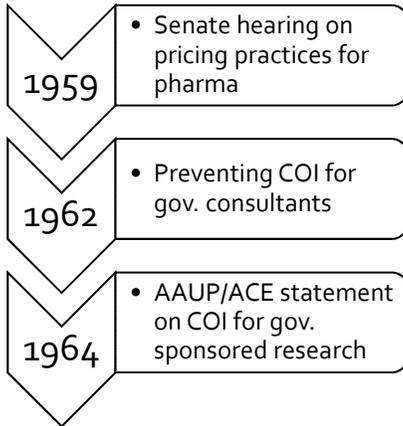
- Review the intricacies of COI policy evolution
- Discuss updates and advancements in CMS' Open Payments Database
- Provide useful skills and tools to help you conduct investigations and implement conflict management plans

# COI: ORIGIN STORY

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Key Points

## Before I Was Born



## Baby Andrew

December ??, 1978

## 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, NIH

## 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, 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

## Jesse Gelsinger

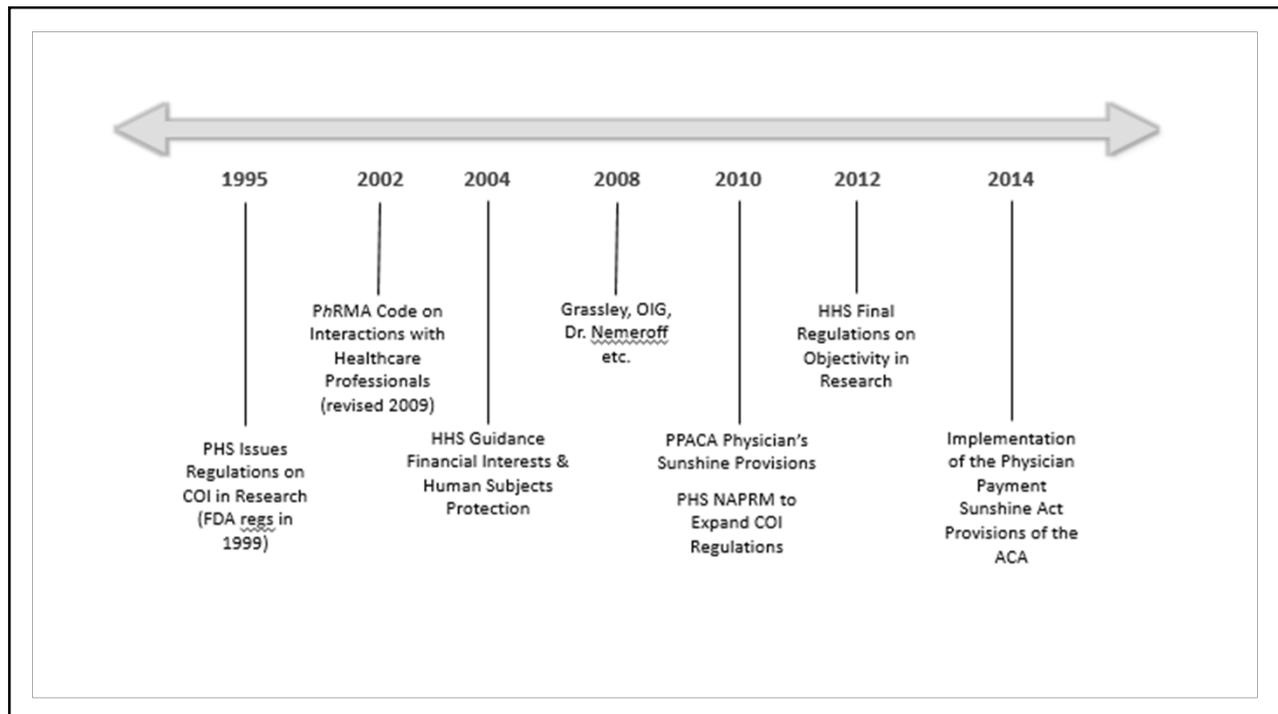
- FDA investigated Gelsinger's death
  - PI ignored exclusion criterion in clinical trial
  - University didn't report serious adverse events from gene therapy
  - Didn't disclose death of monkeys in pre-human trials

## 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

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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 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

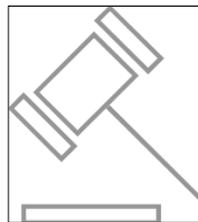


19

# What We're Going to Cover



Overview of  
Open Payments



Enforcement  
Scenarios



Exploring the Data

20



# Overview of Open Payments

21

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Centers for Medicare & Medicaid Services

Learn about your health care options

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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**

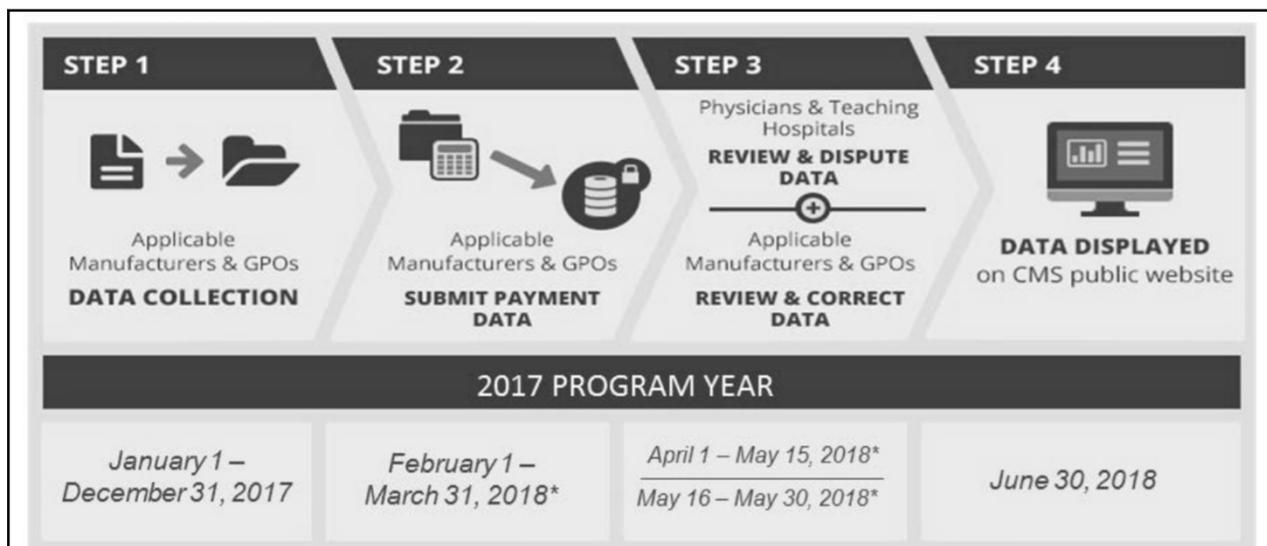
- Use the search tool to look up doctors, hospitals, or

**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.

Program Activities	Program Timeline
Industry collects data	January 1-December 31 of program year
Industry submits and attests to data in the Open Payments system	February-March of the calendar year after the program year
Physicians and teaching hospitals review the reported data and dispute any data they believe is inaccurate; industry makes corrections to the data (reflected in the initial publication)	Review and dispute period: April-May AM/GPO Correction period: May-June
Initial program year initial data publication Prior program year data refresh publication	June 30
Physicians and teaching hospitals continue to review and dispute data; industry continues to make corrections to the data (reflected in the data refresh publication)	June – December 31
Open Payments data refresh	Early in the following year

# 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

25

# Reporting Thresholds



Program Year	Data Collection Period	Small Payment or Other Transfer of Value Amount	Total Annual Amount of Payments or Transfers of Value
2013	October 1, 2013 - December 31, 2013	\$10.00	\$100.00
2014	January 1, 2014 - December 31, 2014	\$10.18	\$101.75
2015	January 1, 2015 - December 31, 2015	\$10.21	\$102.07
2016	January 1, 2016 - December 31, 2016	\$10.22	\$102.19
2017	January 1, 2017 - December 31, 2017	\$10.32	\$103.22
2018	January 1, 2018 - December 31, 2018	\$10.49	\$104.90

26

## “Immediate Family Member”



Applicable manufacturers and GPOs must report certain information regarding the ownership or investment interests held by physicians or the immediate family members of these physicians. Immediate family member means any of the following:

- Spouse
- Natural or adoptive parent, child, or sibling
- Stepparent, stepchild, stepbrother, or stepsister
- Father-, mother-, daughter-, son-, brother-, or sister-in-law
- Grandparent or grandchild
- Spouse of a grandparent or grandchild

27

## Open Payments System Enhancements



28

Open Payments system now allows reporting entities to enter a telephone number for the two “Points of Contact” during registration in the U.S. format (999-999-9999) or non-U.S. format (up to 20 digits)

- Phone numbers that are 10 digits with no dashes will be accepted; however, phone numbers that are 10 digits and include dashes must be in the U.S. format (999-999-9999)

**Points of Contact**

The two identified points of contact will receive important notification emails regarding Open Payments.

Being entered as a point of contact does not register that individual in the Open Payments system or give that individual access to the system. Individuals must be registered in the system if they want to access the Open Payments system.

**Primary Point of Contact**

**\*Name:**  **\*Business Telephone Number:**   
999-999-9999 or Maximum 20 digits

**\*Title at the Entity:**  **\*Business Email Address:**

**Backup Point of Contact**

**\*Name:**  **\*Business Telephone Number:**   
999-999-9999 or Maximum 20 digits

**\*Title at the Entity:**  **\*Business Email Address:**

## Covered Recipient: Review and Dispute Enhancements



To improve covered recipients’ (physicians and teaching hospital users) user experience with the review and dispute process, the Open Payments system now:

- Displays all records in one view, regardless of the payment year (i.e., covered recipients can now perform review and dispute activities across program years)
- Provides a dashboard view of summarized information
- Allows covered recipients to see payments that are being edited by the entities
- Allows covered recipients to see payments that have been deleted by the entity making the payment as a result of a dispute

## Review and Dispute Overview –

**Summary Data:**  
Displays the count of payments and the payment amount for a selected physician or Teaching Hospital by Program Year and Payment Category

Home
Review and Dispute  
Review, Affirm, Dispute
My Profile  
Account, Roles, Nominations
Resources

### Review and Dispute Overview

A field with an asterisk (\*) is required.

**Physician Records**  
To see a summary of a physician's records, select the physician name from the drop-down list below, then select the "Show Summary" button. This will display the summary of the number of payment records and their total amounts across program years available for review and dispute during the calendar year.  
[Read More](#)

**Summary of Payment Records**

\*Choose a Covered Recipient:  
Thomas Camaggio

General			
Program Year	Number of Records		Total Amount
2016	25		\$264.36
2015	0		\$0.00
2014	0		\$0.00
2013	0		\$0.00

Research				
Program Year	Physician		Principal Investigator	
	Number of Records	Total Amount	Number of Records	Total Amount
2016	0	\$0.00	1	\$53.56
2015	0	\$0.00	0	\$0.00
2014	0	\$0.00	0	\$0.00
2013	0	\$0.00	0	\$0.00

Ownership/Investment			
Program Year	Number of Records	Amount Invested	Value of Interest
2016	0	\$0.00	\$0.00
2015	0	\$0.00	\$0.00
2014	0	\$0.00	\$0.00
2013	0	\$0.00	\$0.00

## Review and Dispute Payment Records Page:

Displays the payment records that are "Available for Review and Dispute" and "Unavailable for Review and Dispute" under two different tabs:

- Available for Review and Dispute tab displays all payment records that are currently available to the covered recipient for Review and Dispute and are in "Attested" status
- Unavailable for Review and Dispute tab displays all payment records that were available for review and dispute but are deleted or in the process of being edited and have not been re-attested by the reporting entity

Showing Results for:  
Payment Category: Research Payments

Available for Review and Dispute
Unavailable for Review and Dispute

Showing 10 of 1 Entries Page 1 of 1 Page 1

Record ID 535325		
Entity Making Payment La Pinata	Program Year 2016	Record Status In Progress
Record ID 535325	Affirmed No	Payment Category Research Payments
Total Payment Amount \$53.56	Value of Interest N/A	Delay in Publication of Research Payment Indicator Yes
Date of Payment 2016-03-20	Principal Investigators Associated Yes	Physician Listed as PI Only Yes

Dispute ID 272 (Resolved)

**Dispute Details**  
dispute again

- Initiated on 2017-06-05 by Thomas Camaggio
- Resolved on 2017-09-12 by Amanda Brehart Gore

**Resolution Comments**  
Marking dispute resolved as the payment got edited

Dispute ID 271 (Resolved)

Showing 10 of 1 Entries Page 1 of 1 Page 1



[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

<b>3M Health Care</b> (Infection Prevention Division and Skin & Wound Care Division)	Maureen Harms 651.733.4879 (phone) maharms@mmm.com
<b>Abbott Laboratories</b> United States Medical Products Divisions	Hotline: 1-855-294-4584 Website: <a href="http://speakup.abbott.com">speakup.abbott.com</a>
<b>ABIOMED, Inc.</b>	Hotline: 888.475.8376 Stephen McEvoy 978.646.1819 (phone) smcevoy@abiomed.com
<b>Acclarent, Inc.</b>	Susan Clarke

NON-MEMBER COMPANIES

<b>AccelSPINE</b>	Sheetal Patel 214.545.5852 (phone) compliance@accelspine.com
<b>AccuVein, Inc.</b>	Sue Vallejo 631.367.0393 (phone) sue@accuvein.com
<b>Acumed LLC</b>	Ed Boehmer 503.627.9957 x1293 (phone) eboehmer@acumed.net



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Fax: 202 783 8750  
www.AdvaMed.org

September 1, 2016

**Via Overnight Mail**

Erin Skinner, Esq.  
Centers for Medicare & Medicaid Services  
U.S. Department of Health & Human Services  
Attention: CMS-1654-P - Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**Re: CMS-1654-P: Medicare Program: Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Reports of Payments or Other Transfers of Value to Covered Recipients**

Dear Ms. Skinner:

On behalf of the members of the Advanced Medical Technology Association ("AdvaMed"), we write in response to the Department of Health and Human Services, Centers



# Enforcement Scenarios

# 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

37

# 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

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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

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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

# Settlements



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## JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Thursday, December 15, 2016

### **Forest Laboratories and Forest Pharmaceuticals to Pay \$38 million to Resolve Kickback Allegations Under the False Claims Act**

Forest Laboratories LLC, located in New York, New York, and its subsidiary, Forest Pharmaceuticals Inc., have agreed to pay \$38 million to resolve allegations that they violated the False Claims Act by paying kickbacks to induce physicians to prescribe the drugs Bystolic®, Savella®, and Namenda®, the Department of Justice announced today.

"Kickback schemes undermine the integrity of medical decisions and increase the costs of health care for everyone," said Principal Deputy Assistant Attorney General Benjamin C. Mizer, head of the Justice Department's Civil Division. "Such schemes are particularly of concern when they are designed to influence drug prescriptions and the Department of Justice will



### **Medical Device Manufacturer NuVasive Inc. to Pay \$13.5 Million to Settle False Claims Act Allegations**

California-based medical device manufacturer NuVasive Inc. has agreed to pay the United States \$13.5 million to resolve allegations that the company caused health care providers to submit false claims to Medicare and other federal health care programs for spine surgeries by marketing the company's CoRoent System for surgical uses that were not approved by the U.S. Food and Drug Administration (FDA), the Justice Department announced today. The settlement further resolves allegations that NuVasive caused false claims by paying kickbacks to induce physicians to use the company's CoRoent System.

"The Justice Department is committed to holding medical device manufacturers accountable, which includes requiring that they follow all laws designed to ensure that medical devices are safe and effective," said Principal Deputy Assistant Attorney General Benjamin C. Mizer, head of the Justice Department's Civil Division. "It is also imperative that manufacturers not improperly influence the selection of medical devices in order to ensure that these decisions are based on the needs and interests of patients, not on a physician's own financial interests."

The United States alleged that between 2008 and 2013, NuVasive promoted the use of the CoRoent System for surgical uses that were not approved or cleared by the FDA, including for use in treating two complex spine deformities, severe scoliosis and severe spondylolisthesis. As a result of this conduct, the United States alleged that NuVasive caused physicians and hospitals to submit false claims to federal health care programs for certain spine surgeries that were not eligible for reimbursement.

The settlement agreement also resolves allegations that NuVasive knowingly offered and paid illegal remuneration to certain physicians to induce them to use the CoRoent System in spine fusion surgeries, in violation of the federal Anti-Kickback Statute. The illegal remuneration consisted of promotional speaker fees, honoraria and expenses relating to physicians' attendance at events sponsored by a group known as the Society of Lateral Access Surgery (SOLAS). SOLAS was allegedly created, funded and operated solely by NuVasive, despite its outward appearance of independence.

## 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

45

# Exploring the Data



46



## 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

< Previous Next >

Showing 1-49 out of 3,488

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 60t of 757,436

Physician\_Profile\_ID

Add Filter 15

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

< Previous    Next >

Showing 1-14 out of 237

## Exporting Data



- Physician Example
- Spreadsheet Demonstration

# Dollars for Docs

By Charles Ornstein, Lena Groeger, Mike Tigas, and Ryann Grochowski Jones, ProPublica. Updated December 13, 2016

Pharmaceutical and medical device companies are now required by law to release details of their payments to a variety of doctors and U.S. teaching hospitals for promotional talks, research and consulting, among other categories. Use this tool to search for general payments (excluding research and ownership interests) made from August 2013 to December 2015. | Related Story: We've Updated Dollars for Docs. Here's What's New. »

## Has Your Doctor Received Drug or Device Company Money?

All States

For example: Andrew Jones, Boston, 10013

**\$6.25B** in disclosed payments **810,716** doctors **1,171** teaching hospitals **1,866** companies

Totals listed below account for all payments from August 2013 to December 2015.

### About the Dollars for Docs Data

Details behind our drug company money database.

### Download the Data

The entire data set is available for purchase in the ProPublica Data Store.

### Source

The Centers for Medicare and Medicaid Services Open Payments data.

### Archive

## Dollars for Doctors

How Industry Money Reaches Physicians



### Top 50 Companies

Click on a company to see how its payments break down by drug, device or doctor. Or, see all companies »

COMPANY	PAYMENTS
GENENTECH, INC.	\$72M
DEPUY SYNTHES PRODUCTS LLC	\$167M
STRYKER CORPORATION	\$153M
MEDTRONIC SOFAMOR DANEK USA, INC.	\$147M
ASTRAZENECA PHARMACEUTICALS LP	\$145M
PFIZER INC.	\$128M
ARTHREX, INC.	\$108M
MEDTRONIC VASCULAR, INC.	\$106M
JANSSEN PHARMACEUTICALS, INC	\$106M
ALLERGAN INC.	\$105M
ZIMMER BIOMET HOLDINGS, INC.	\$103M
SMITH & NEPHEW, INC.	\$97.2M
ABBVIE, INC.	\$94.1M

### Highest-Earning Doctors

NAME	PAYMENTS
ROGER JACKSON Orthopaedic Surgery of the Spine	\$54.1M
SUJATA NARAYAN Family Medicine	\$43.9M
STEPHEN BURKHART Orthopaedic Surgery	\$43.4M
KEVIN FOLEY Neurological Surgery	\$39.8M
KAREN UNDERWOOD Pediatric Critical Care Medicine	\$28.5M

### Doctors Paid the Most Often

NAME	PAYMENTS
ANA STANKOVIC Nephrology	2,839
FARHAD ZANGENEH Endocrinology, Diabetes & Metabolism	2,433
ROBERT BUSCH Endocrinology, Diabetes & Metabolism	2,334

**Yearly Payment Breakdown:** 2015 ▾

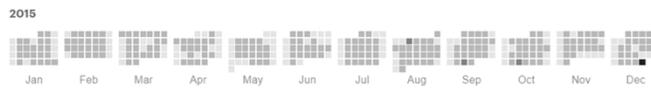
**All Payments: At a Glance**

2015	<b>828</b> PAYMENTS	<b>\$16,344,350</b> PAYMENT TOTAL	<b>148</b> COMPANIES PAID THIS TEACHING HOSPITAL
2014	<b>1,008</b> PAYMENTS	<b>\$13,173,822</b> PAYMENT TOTAL	<b>152</b> COMPANIES PAID THIS TEACHING HOSPITAL
2013	<b>527</b> PAYMENTS	<b>\$9,173,420</b> PAYMENT TOTAL	<b>106</b> COMPANIES PAID THIS TEACHING HOSPITAL

**Payment Calendar in 2015**

This hospital received a payment on **246** days in 2015.

Each box below represents a single day during the disclosure period. A gray box indicates no payments. The darker the color, the more payments a hospital received that day.



**Types of Payments in 2015**

CATEGORY	PAYMENTS	PAYMENT VALUE
ROYALTY OR LICENSE	97	\$9.6M
CONSULTING	90	\$2.66M

# 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

## Monitoring Conflicts – Am I getting the whole story?

An effective COI management program will examine information that is reported AND look for what wasn't reported

- Conduct audits of faculty reporting no conflicts
- Check information against CMS databases
- What should raise a red flag?
  - High dollar amounts vs frequency of outside activity – what is your institution's limit?

## Monitoring Conflicts – Am I getting the whole story?

Example: Dr. A reports \$10,000 in consulting fees with ABC Pharmaceuticals

- Matches what is publicly reported
- Potential conflict of interest?
- Create a management plan?
- High dollar amounts might trigger further investigation
  - Nature of the relationship between the doctor and the company?

## Monitoring Conflicts – Am I getting the whole story?

Example: Dr. B reports small payments for meals and travel from several outside medical device companies

- What is the potential for conflict of interest vs conflict of commitment?
  - Impact to the institution and faculty member's institutional responsibilities
- Management plans can help provide guidelines for what is acceptable outside activity

## Monitoring Conflicts – Am I getting the whole story?

Example: Dr. C reports no conflicts, but public database shows consulting and travel payments to ABC Pharmaceuticals

- Time to conduct an investigation
  - Follow up with the doctor
    - Oversight?
    - Permitted by institutional leadership?
    - Public data incorrectly reported?
  - Gather information from other sources

## 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

## 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

## Perceived or Potential Conflict

Activity	Management Plan
Faculty member receives royalties from published work, and that work is required reading.	Disclose situation to students, offer alternative reading, or allow required reading if authorized by Chair and Dean.
An employee invents a new type of stent, and the hospital would like to use it.	Disclose invention and ownership. Remove inventor from purchasing decisions. Develop IP plan/licensing.
Chief's husband owns bakery, and hospital wishes to contract with bakery.	Disclose family relationship, remove chief from contract involvement.
Faculty member does non-clinical research for company, and wishes to consult for company.	Disclose to all research personnel, including to whom they should report concerns.

## 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?

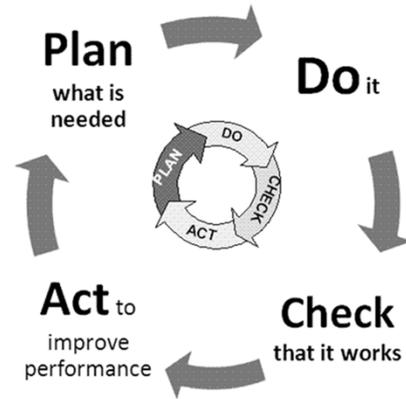
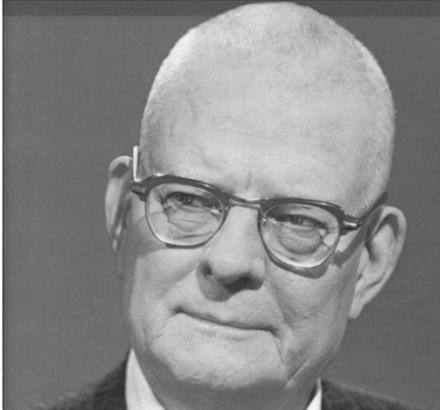
## Management Plan Monitoring

- 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?

## Three Lines of Defense

FIRST LINE OF DEFENSE	SECOND LINE OF DEFENSE	THIRD LINE OF DEFENSE
<b>Risk Owners/Managers</b>	<b>Risk Control and Compliance</b>	<b>Risk Assurance</b>
<ul style="list-style-type: none"><li>• operating management</li></ul>	<ul style="list-style-type: none"><li>• limited independence</li><li>• reports primarily to management</li></ul>	<ul style="list-style-type: none"><li>• internal audit</li><li>• greater independence</li><li>• reports to governing body</li></ul>

# Deming's Model of Continuous Improvement (PDCA)



## Three Lines of Defense

Risk Area	Unit Controls	Compliance Controls	Internal/External Audits
As Identified During Risk Assessment	What do the units do to help mitigate this risk?	What do you <u>monitor</u> to help mitigate this risk?	What type of <u>audits</u> exist to help mitigate this risk?
Management Plans	<ul style="list-style-type: none"> <li>□ Schedule regular reviews</li> <li>□ Maintain management plans</li> <li>□ Establish timeline</li> </ul>	<ul style="list-style-type: none"> <li>□ Monitor unit activity (weekly? Monthly? By quarter?)</li> <li>□ Review compliance</li> <li>□ Audit</li> <li>□ Training</li> </ul>	<ul style="list-style-type: none"> <li>□ Open Payments Comparison</li> <li>□ Dollars for Docs</li> <li>□ External Audit of internal unit controls and compliance controls (annually?)</li> </ul>

## 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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