
Centinel Spine[®]
THE AFFORDABLE CARE ACT'S MEDICAL DEVICE AND SUPPLY CHAIN


THE SUNSHINE ACT

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Castellvi Spine - May 21, 2016

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Background

- The Sunshine Act was initiated in 2007 by Senator Grassley, passed as part of the Affordable Care Act in 2010
- The Sunshine Act 's Premise is Patients & Tax Payers have a right to know because they pay billions each year
- "The goal is to let the **SUN SHINE IN** and make information available to foster accountability" Senator Grassley
- Case Law Support: 1990 Moore v. Regents of the University of California: "A physician who is seeking a patients' consent for a medical procedure must, in order to satisfy his fiduciary duty and to obtain the patient's informed consent, disclose personal interests unrelated to the patients health, whether research or economic, that may affect his medical judgment"

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Open Payments: The Basics

- Manufacturers of drugs, devices, biologics, and medical supplies report "payments and other transfers of value" to Physicians and Teaching Hospitals to CMS
- All payments and transfers of value are to be reported whether or not they relate to a device, drug, or biologic
- Manufacturers and GPOs report ownership and investments of Physicians and their immediate family members; ownership in publicly traded securities are excluded
- Data will be collected and displayed on a website searchable by **ANYONE IN THE WORLD**
- Data from August 1, 2013 to December 31, 2013 and full year 2014 is now available
- The website will be updated annually

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2014 Summary

The Facts About Open Payments Data

2013 Total **2014 Total** Total All Program Years

Total US Dollar Value

\$6.45
Billion

Total Records Published

11.37
Million

→ SOURCE: OPEN PAYMENTS

Total Completed
Initial Payments

1,442

Total Physicians
with Open Records

607,000

Total Teaching
Hospitals
with Open Records

1,122

Research Payments (All Dollar Value) \$2.52 Billion	Research Payments (All Associated Research Funding) (All Dollar Value) \$68.47 Million	Research Payments (All Dollar Value) \$542 Million
Research Payments (All Dollar Value) \$3.22 Billion	Research Payments (All Associated Research Funding) (All Dollar Value) \$477 Million	Research Payments (All Dollar Value) \$704 Million
Research Payments (All Dollar Value) \$477 Million	Research Payments (All Associated Research Funding) (All Dollar Value) \$477 Million	Research Payments (All Dollar Value) N/A
Research Payments (All Dollar Value) \$703 Million	Research Payments (All Associated Research Funding) (All Dollar Value) \$703 Million	Research Payments (All Dollar Value) N/A

<https://openpaymentsdata.cms.gov/>

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Surgeon's CMS Report

Summary Information for Program Year 2014

\$678,737.57 <small>Total General Payments</small>	8 <small>Total General Transactions</small>	\$35,317.60 <small>Total Amount Invoiced</small>	2 <small>Total Invoiced Transactions</small>
N/A <small>Total Research Payments</small>	0 <small>Total Research Transactions</small>	\$30,316.15 <small>Total Value of Interest</small>	
\$15,005.37 <small>Total Associated Research Funding</small>	10 <small>Total Associated Research Transactions</small>	0 <small>Total Disputed Payments</small>	18 <small>Total Undisputed Payments</small>

General |
 Research |
 Associated Research |
 Ownership

<https://openpaymentsdata.cms.gov/physician/XXXXX>

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Payment Detail

Payments that are not associated with a research study

General Payments Received

Company Making Payment	Reason of Payment	Date	Amount	Third Party Payment	Disputed?	Comment
DefJoy Termites Sales Inc.	Food and Beverage	05/07/2014	\$125.88	No Third Party Payment	No	
Medtronic Sofamor Danek USA, Inc.	Royalty or License	02/01/2014	\$168,711.00	No Third Party Payment	No	
Medtronic Sofamor Danek USA, Inc.	Royalty or License	05/06/2014	\$103,675.00	No Third Party Payment	No	
Medtronic Sofamor Danek USA, Inc.	Royalty or License	09/14/2014	\$187,548.00	No Third Party Payment	No	
Medtronic Sofamor Danek USA, Inc.	Royalty or License	11/14/2014	\$172,348.00	No Third Party Payment	No	
Greiner Corporation	Food and Beverage	12/02/2014	\$140.87	No Third Party Payment	No	

General Payments

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Payment Detail

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General Research **Associated Research** Ownership

Funding for a research project or study where the physician is named as a principal investigator

Associated Research Funding

Company Billing Payment	Date	Amount	Request	Comment
Medtronic Sofamor Danek USA, Inc.	01/02/2014	\$1,300.00	No	
Medtronic Sofamor Danek USA, Inc.	02/05/2014	\$1,025.00	No	
Medtronic Sofamor Danek USA, Inc.	02/05/2014	\$1,245.00	No	
Medtronic Sofamor Danek USA, Inc.	04/10/2014	\$750.15	No	
Medtronic Sofamor Danek USA, Inc.	06/02/2014	\$1,758.10	No	
Medtronic Sofamor Danek USA, Inc.	07/18/2014	\$1,858.00	No	
Medtronic Sofamor Danek USA, Inc.	10/13/2014	\$1,300.00	No	
Medtronic Sofamor Danek USA, Inc.	10/13/2014	\$750.15	No	
Medtronic Sofamor Danek USA, Inc.	10/13/2014	\$750.15	No	
Medtronic Sofamor Danek USA, Inc.	10/24/2014	\$833.00	No	

Research Payments

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Ownership Detail

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Summary Information for Program Year 2014

\$359,557.65 Total General Payments	144 Total General Transactions	\$283,082.48 Total Amount Invoiced	1 Total Invoiced Transactions
N/A Total Research Payments	0 Total Research Transactions	\$512,626.73 Total Value of Invoiced	
N/A Total Associated Research Funding	0 Total Associated Research Transactions	0 Total Disputed Payments	145 Total Undisputed Payments

General Research **Associated Research** Ownership

Ownership and investment interest in companies, which describes both the actual dollar amount invested and the value of the ownership or investment interest. Results may show one or both of these values associated with them.

Ownership in Companies

Company Name	Type	Amount Invested	Value of Interest	Request
Frederick Spine, L.L.C.	SOLE PROP PARTNER/CO-OWNER OF PREFERRED UNITS	\$281,082.48	\$718,008.73	No

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Key Facts for Surgeons

- Physicians are NOT required to register with Open Payments
- Manufacturers/GPOs may give Physicians the opportunity to review the information for accuracy
 - CMS does not require this
- Between April and August Physicians may log on to: cms.gov/openpayments and review information industry has submitted for a 45 day window
- Physicians may log disputes to CMS and
 - CMS will report disputes to Manufacturers
- It is the responsibility of Manufacturers to correct; they have 15 days to make corrections
- If a dispute remains unresolved, it will appear with a notation of disputed

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Who is Really Going to be Looking?

- Patients the first time they learn about the listing
- Hospital Administration
- Plaintiff Attorneys
- State's Attorneys
- Investigational Reporters
- Department of Justice
- Your Neighbors
- Companies
- Your Peers

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Defining Transfers of Value

- Honoraria, Consulting Fees, Other fees for speaking engagements or faculty
- Royalty or Licensing payments
- Education, Research, Grants
- Gifts and Charitable Contributions
- Travel, lodging, food, beverage, and entertainment
- Ownership and Investments
- All transfers of value of \$10 or more, except related to patient education materials such as product samples

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Side Effects?

- Little Evidence to date whether the Sunshine Act is changing industry or physician behavior; limited data available
- According to an Industry Standard Research (ISR) report, one in eight investigators said that if they started to receive what looked like "too much" money from clinical trials, they would stop participating.
- Some evidence shows companies have shifted towards more marketing aimed directly at the patient instead of at health care providers.

ISR (2013), Sunshine Act and Clinical Research


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Resources

- OPEN PAYMENTS Mobile App for Physicians and for Surgeons
- Independent of data report on CMS
- Used to keep track of payments and to confirm accuracy
- Payments can be recorded by physician conveniently in real-time
- Data from App can be summarized and exported to be easily compared to data reported by Manufactures



Physician Industry

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Best Practices for Surgeons and Industry

- Physicians and Medical Device Companies should make sure relationships are based on transfers of value that relate to clinical expertise and scientific knowledge
- Services provided are well documented and are at Fair Market Value
