Yale University Department of Economics Undergraduate Program

## The Effect of the Sunshine Act on Industry Payments to Physicians in Orthopedic Surgery and Other Surgical Specialties

Senior Thesis

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April 2018

New Haven, Connecticut

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## Acknowledgements

I would like to express my gratitude to my thesis advisor, Dr. Joseph S. Ross, MD, MHS, for his patience, immense knowledge, invaluable support and continued advising throughout the creation of this paper. I am also very thankful to Greg Rhee, PhD, MSW, whose guidance and expertise on statistical data analyses were of tremendous help. My sincere thanks also go to Dr. Howard Forman, MD, MBA, for sparking my interest in the area of health economics and encouraging me to explore this field in my thesis research.

## **1.Introduction and Background**

#### 1.1. Historical Overview of Physician-Industry Financial Relationships

Financial relationships between physicians and the pharmaceutical industry have received considerable public attention due to their rising prevalence in the United States during the last three decades. These relationships range from research funding to physicians or healthcare institutions, personal investment and ownership interests, to individual payments to physicians, which include speaker fees, education coverage, travel expenses and consulting services (1).

One of the first systematic reviews of the nature of financial relationships of physicians with the industry in the United States for the period between 1982 and 1997 showed that physicians met with industry representatives on average four times a month, while residents accepted an average of six gifts per year from the industry (2). Interactions of physicians with pharmaceutical companies often begin during medical school education and continues at a rising frequency during resident training and among practicing physicians (2). In fact, a national survey of physicians conduced in 2001 and in 2007 showed that 92% to 94% of all surveyed physicians received drug samples, 61% received compensations for travels, meals and events, while 13% received payments in form of financial benefits (3, 4, Figure 1).

Until 2013, there was no federal law in place that would enforce payment disclosure and increase the transparency of financial relationships that physicians have with the biopharmaceutical and medical device industry. Although an increasing number of companies made public disclosures with physicians' names and compensation values on their websites and in their financial reports, many issues persisted in terms of the consistency and transparency of reporting. In fact, the majority of the companies continued refraining from disclosure of payments that they made to healthcare professionals and institutions (5).



#### Figure 1. Types of Industry Payments Received by Physicians

Have you ever accepted any of the following from a drug industry

representative?

Source: Kaiser Family Foundation, National Survey of Physicians, March 2002 (conducted March-October 2001)

### 1.2. Conflicts of Interest and Distortions in Prescribing Behaviors

The increasingly common practice of monetary payments to physicians by pharmaceutical companies in the United States has raised concerns about the distortive effect that these transactions might have on prescribing behaviors, potentially resulting in non-optimal treatment decisions, or biased outcomes of research studies. In fat, financial conflicts of interests in clinical research were associated with a number of inaccuracies and biases observed in industry-sponsored clinical studies. These range from a higher probability of positive study outcomes that align with the sponsor's interests (6-8), biased study designs (9), to failures to report negative results (10), and influence on behavior of clinical investigators (9).

In addition to the concern that these financial relationships might generate conflicts of interest in clinical research, recent studies have also found that industry payments may have influence on prescribing behaviors of physicians. A ProPublica analysis matched prescribing patterns under Medicare Part D with physicians in five medical specialties. The study found that doctors who receive industry payments from the biopharmaceutical and medical device industry are more likely to prescribe brand-name drugs than physicians who do not have any financial relationships with the industry (11). In fact, the data show a linear relationship between the amount of money that physicians receive from the industry and the frequency at which they prescribe brand-name drugs of their industry sponsors (Figure 2). Doctors who received industry payments above \$5,000 in 2014 were found to prescribe most brand-name medications. By contrast, their colleagues who did not receive any such payments had prescribing behaviors that involved an average of 10% lower frequency of brand-name prescriptions (11). Another study found that interactions with industry representatives were associated with requests made by physicians to add their sponsors' drugs to hospital's prescribing lists. In addition, continuing medical education programs that were sponsored by drug companies showed higher likelihood of promoting the sponsor's drugs when compared to other non-industry sponsored programs (2).

While these results do not prove a causal relationship between industry payments received by physicians and their prescribing behaviors, they show a clear association of such financial relationships with the tendency to prescribe brand-name drugs in a way that benefits drug companies. However, the widespread associations between industry payments and prescribing behaviors open a number of healthcare concerns, given the unsustainable costs of medical care and the fact that a number of generic drugs show comparable levels of patient satisfaction and efficiency in healthcare outcomes by Food and Drug Administration (FDA) standards (12).

While financial relationships between pharmaceutical manufacturers and healthcare providers are often criticized for being against the interests of patients, the proponents assess them as a way to educate physicians about new treatment technologies for the benefit of patients. Compensations for conferences and financial support for professional training that physicians receive from the industry may enhance the quality of continued medical education. Another potential benefit of these relationships is the possibility to spread information about new scientific developments and communicate their value to physicians, especially when it comes to medications or treatment strategies that are underused in the United States in spite of their cost-effectiveness (13).



Figure 2. Physicians Compensated by Industry Prescribe More Brand-name Drugs

Source: Centers for Medicare and Medicaid Services; ProPublica analysis, https://projects.propublica.org/docdollars/

#### 1.3. Early Efforts and Impact of Payment Disclosure Requirements

As a response to reports that identified substantial amount of industry payments made to physicians and the lack of transparency associated with these financial relationships, there was an increasing need for public disclosure of industry payments. Some of the first disclosure efforts were made by the Institute of Medicine in 2009, which recommended that potential conflicts of interest be identified and limited "without affecting constructive collaborations with industry" (14). A number of pharmaceutical companies and drug manufacturers proceeded with voluntary disclosure of financial ties with physicians and healthcare providers following these recommendations (14).

Several states made public disclosures of industry payment data prior to the enactment of this requirement at the federal level. The first law of that kind was passed in Minnesota in 1993, followed by similar laws in California, Maine, Vermont, West Virginia, Massachusetts and the District of Columbia (15, 16).

Some of these state disclosure legislations are defined in an even more rigorous way than the later enacted federal policy. For instance, the disclosure law in Massachusetts obliges companies to report payments to anyone "who prescribes, dispenses or purchases prescription drugs or medical devices in the Commonwealth". This includes several groups of individuals and institutions that are not required to disclose payments as part of the federal law, such as pharmacists, nurse practitioners, clinical laboratories and home nursing facilities (17).

#### *1.4. Payment Disclosure Requirements for Orthopedic Surgery*

A unique feature of orthopaedic surgery compared to other surgical subspecialties is the fact that five device manufacturers accounting for almost 95% of the market for total hip and knee prostheses – Zimmer, DePuy, Smith and Nephew, Biomet and Stryker - were required to disclose all payments that they made to physicians. This requirement was mandated as a settlement with the U.S. Department of Justice beginning in 2007 (18). This law exposed orthopaedic surgeons to payment disclosure requirements almost 6 years earlier than was the case with their colleagues in other surgical subspecialties. For this reason, newly published CMS OPP payment data in orthopaedic surgery may provide a source of comparison with the same data published for surgeons in other specialties.

Similar to other medical specialties, self-disclosure of financial relationships prior to legal disclosure requirements showed a number of reporting inaccuracies in orthopaedic surgery (19). However, numerous studies found that orthopaedic surgery is one of the specialties receiving the highest industry payments (20). Most of these payments come in form of royalties and license fees, which fall under the category of share ownership (20, Figure 3).

Figure 3. Specialties with the Highest Value of Shares Based on 2013 CMS Payments Database

- Orthopedic surgery-\$48 702 415.57
- Obstetrics and gynecology—\$42 701 713.89
- Internal medicine/gastroenterology-\$41 910 224.26
- Internal medicine/cardiovascular disease—\$35 744 397.64
- Ophthalmology-\$31160068.76

Source: Table 5, BMJ 2014;349:g6003

#### 1.5. Physician Payments Sunshine Act and Open Payments Program

Self-disclosure of industry-physician financial relationships have often resulted in reporting inconsistencies among a number of medical specialties (1, 19). To address these inaccuracies and conflicts of interest in the United States, a federal law was enacted in 2013 that mandates all drug and device manufacturing companies to report to the Centers for Medicare and Medicaid Services (CMS) all industry payments made to physicians. As part of the Patient Protection and Affordable Care Act of 2010, the CMS are required to comply with the Physician Financial Transparency Reports Act, also known as the "Sunshine Act", with the initial release date being September 30, 2014, which encompasses payments made between August 1, 2013 and December 31, 2013 (21). The Sunshine Act mandates companies that manufacture drugs, devices and biological agents to publicly disclose individual payments on items of value greater than \$10 made to physicians and teaching hospitals. This information is reported through the Open Payments Program (OPP) on a website that contains a searchable database of all direct and indirect payments made to physicians since August 2013. This includes compensations for consulting and advisory services, food and beverages, travel, gifts, and payments for research (22). The OPP database also releases information about individual physicians receiving payments, including their address, the drug or device of the sponsoring company with which they have financial connections and the data on payment date, type and amount. The payment data collected is divided into three main categories: i. general payments, ii. research payments, iii. investment and ownership payments.

A free electronic application is available to all physicians active in the CMS network to help them track industry payments that they receive. Rigorous penalties are mandated both for inadvertent failures to report payments (\$150,000), and for intentional disclosure failures (up to \$1 million dollars) (23).

## 2. Hypothesis

The main objective of this study is to determine the impact of the payment disclosure requirement (Sunshine Act) extension on research and general industry payments received by physicians in the United States. The CMS Open Payments database for years 2014, 2015 and 2016 was used to evaluate the trends in industry payments to physicians since enactment of the Sunshine Act. Regression analyses were performed to evaluate the interaction effect of time and payment disclosure requirement on per capita payment value for different payment types. Given the early exposure to payment disclosure that was present in orthopaedic surgery, unlike in other surgical specialties, orthopaedic surgeons constitute the control group in the regression analyses, while non-orthopaedic surgical specialties constituted the treatment group, where treatment effect is the exposure to the Sunshine Act. The interaction analyses were stratified into two periods, 2014-15 and 2014-16, to compare the time effect of earlier and later treatment exposure on payment trends.

Considering that the data in the OPP database are reported as a large number of individual transactions, the payments data were presented in a more consistent and comprehensive way, with the aim of understanding the impact of the Sunshine Act on industry payment trends by analyzing potential differences between surgical specialties.

Our hypothesis is that industry payment trends for general payments made to physicians between 2014 and 2016 would show a statistically significant difference between orthopaedic surgery and other surgical subspecialties, holding all other variables constant and assuming that the treatment and the control groups are sufficiently similar in parameters other than the exposure to the federal disclosure policy.

#### **<u>3. Methods and Data</u>**

#### 3.1. Center for Medicare and Medicaid Open Payments Database (OPD)

As a provision of the Physician Payments Sunshine Act, the first dataset was publicly disclosed on 30 September 2014, covering the last 5 months of the year 2013. The open payments database was accessed and downloaded on 11 October 2017, at which point it contained from August 2013 to December 2016. The time period from January 2014 to December 2016 was used for the analyses. The data extracted from the dataset include the value and number of financial transactions for each physician, the nature of each payment, the unique physician profile identification number, the country of the primary payment recipient, the year of received payment and the specialty of each recipient physician. OPD is divided into separate datasets by payment type (general payments, research payments and ownership), and by year in which the transaction was made (2014, 2015 and 2016).

## 3.2 Definition of Active US-based Physicians

In order to estimate percentage changes in the number of physicians receiving industry payments, the total number of active US-based physicians was used as a common denominator. These numbers were derived from the most recent annual census conducted by the Association of American Medical Colleges (AAMC), for the year 2015 (Table 1).

<b>Total Active Physicians</b>	Other Surgical Specialties <sup>2</sup>	<b>Orthopaedic Surgery</b>
860, 917	45,433	19,145

Table 1. Number of Active Physicians in the US by Specialty, Based on the 2015 Census Re	port <sup>1</sup>
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As determined by the OECD Health (Organization for Economic Cooperation and Development), AAMC uses the following inclusion criteria to define active physicians in the United States for its annual census<sup>3</sup>:

- All physicians, including members and non-members of the AMA and graduates of foreign medical schools who are practicing in the United States and meet educational standards for physician recognition;
- International medical graduates residing in the United States, provided that their medical training programs are accredited by the Accreditation Council on Graduate Medical Education (ACGME)
- Physicians licensed to practice in the United States, but temporarily residing abroad.

## 3.2. Data Inclusion and Exclusion Criteria

For the purpose of this study, only general and research payments were included, all ownership and interest payments were excluded. The exclusion criteria encompassed three ownership payment sources: i.All ownership payments datasets; ii.*Royalty or License* from general

<sup>&</sup>lt;sup>1</sup> Statistics for the number of physicians in the US is published only biennially by the Association of American Medical Colleges. Most recent published reports are for 2013 and 2015; *Source: AMA Physician Masterfile (December 2015)* - <u>https://www.aamc.org/data/workforce/reports/458480/1-1-chart.html</u>, accessed on 10 March, 2018.

<sup>&</sup>lt;sup>2</sup> This number includes only the 5 most prevalent surgical specialties: General surgery (25,251) + Neurological surgery (5,346) + Plastic surgery (7,020) + Thoracic surgery (4,458) + Vascular Surgery (3,358) = 45,433

<sup>&</sup>lt;sup>3</sup> © OECD Health Statistics 2017: http://www.oecd.org/health/health-data.htm

payments datasets; iii. *Current or Prospective Ownership or Investment Interest* from general payments datasets (Figures 4-6).

Royalties, ownership and interest payments were excluded from the analysis because they are non-discretionary payments reported as a cumulative quantity. These payments represent value of all stocks held by an individual, independent of the time period in which the financial transaction was made. For this reason, it is not possible to reliably identify which of the reported payments were made during a given reporting period, and which were only a transferred value of stock from previous periods. OPD differentiates between teaching hospitals and physicians as primary recipients of payments. This analysis was narrowed to covered recipient physicians in the United States, excluding payments made to teaching hospitals, non-covered entities and individuals, and physicians outside of the United States (Figures 4-6). In order to test the main hypothesis of whether there is a difference in industry payment trends between orthopedic surgeons and all other surgical specialties in the U.S, three separate datasets were created based on the variable *Physician Specialty:* 

- i. Orthopedic Surgery;
- ii. All Other Surgical Specialties;
- iii. All Non-Surgical Specialties.

Seven subspecialties were identified within the specialty of orthopedic surgery, and seventeen subspecialties were identified within all other surgical specialties (Table 2). The flowcharts in Figures 1-3 provide a sample representation of inclusion and exclusion criteria, using the number of payments in each year as the primary endpoint.





#### Figure 5. Flow of Study Samples, 2015 CMS Open Payments Database.





#### Figure 6. Flow of Study Samples, 2016 CMS Open Payments Database.

Table 2. S	ubspecialties i	n Orthopaedi	c Surgery	Included in	the Statistical	Analyses
			<i>U J</i>			

Subspecialties in Orthopaedic Surgery
Adult Reconstructive Orthopaedic Surgery
Foot and Ankle Surgery
Hand Surgery
Orthopaedic Surgery of the Spine
Orthopaedic Trauma
Pediatric Orthopaedic Surgery
Orthopaedic Surgery   Sports Medicine

 Table 3. Non-Orthopaedic Surgical Subspecialties Included in the Statistical Analyses

Non-Orthopaedic Surgical Subspecialties
Colon and Rectal Surgery
Dermatology MOHS-Micrographic Surgery
Neurological Surgery
Oral & Maxillofacial Surgery
Facial Plastic Surgery
Female Pelvic Medicine and Reconstructive Surgery
Plastic Surgery within the Head & Neck
Plastic Surgery Surgery of the Hand
Surgery Hospice and Palliative Medicine
Pediatric Surgery
Plastic and Reconstructive Surgery
Surgical Critical Care
Surgical Oncology
Trauma Surgery
Vascular Surgery
Thoracic Surgery (Cardiothoracic Vascular Surgery)
Transplant Surgery

#### **4.Statistical Models**

#### 4.1. Variables

The data obtained from the OPD datasets were further processed to extract key endpoint variables for regression analyses of the interaction effect between surgical subspecialty and time period on industry payment patterns. These variables include the total number and value of industry payments to physicians (per capita payment), separated by general and research payments; time period (year 2014, 2015 or 2016), and treatment or control specification, where orthopaedic surgery is the control group, and all other surgical subspecialties are the treatment group. Each transaction was connected to a unique physician identification number, and cumulative payments per capita were calculated for each identification number.

#### Logarithmic Transformation of Dependent Variables

The payment value in terms of US dollars, which is the dependent variable and the key endpoint in the regressions, was found to be skewed to the right and is not normally distributed. In a rightskewed distribution, the peak is off center and a tail stretches away from it to the right (24). For instance, the histogram of plotted research payment values per capita received by physicians in surgical specialties in years 2014 and 2015 shows that the data are heavily skewed to the right, which means that the majority of payments per capita are concentrated around lower values (Figures 7A - 12A). For this reason, running a simple regression model with the ordinary least squares (OLS) assumption would result in biased findings.

To address this bias, the dependent variable was transformed into the logarithmic form and a log-transformed regression was performed (Table 3). In addition to transforming skewed variables into normally distributed ones, logarithmic transformations of variables in a regression model also result in a non-linear relationship between the independent and the dependent variable, while

keeping the linearity of the regression model. Plotting the histogram of log-transformed dependent

variable of research payment values per capita for surgical specialties in 2014 and 2015 how results

in a normal distribution (Figures 7B – 12B).

Variable Name	<b>Regression Notation</b>	Description
Physician Profile ID	ID	Unique identification number assigned to physicians who are the primary recipients of an industry payment.
Total Amount of Payment in USD		This variable denotes the value of each individual financial transaction in US Dollars.
Payment Value per capita in USD	payment	This variable was calculated as the sum of all <i>Total</i> Amount of Payment in USD variables for a given Physician Profile ID
Log-transformed Payment Value	log_payment	This variable was generated as a log-transformed value of the dependent variable: generate log_payment = log(payment)
Number of industry payments	Ν	N = Count [Total Amount of Payment in USD]
Year	t	Creation of dummy variables for the time period: generate t=0 if Year=2014 replace t=0 if Year>2014
Physician Specialty	tr	<ul> <li>Control: Orthopaedic Surgery</li> <li>Treatment:All Other Surgical Specialties</li> <li>Creation of dummy variables (tr) for treatment/control:</li> <li>-for control observations, tr = 0</li> <li>-for treatment observations, tr = 1</li> </ul>
Interaction Effect	txtr	Dummy variable that denotes the interaction effect between treatment/control (tr) and time period (t): generate t x tr = t·tr

<sup>1</sup>Variables written in *italic* were derived from the OPD datasets in their original form, while all other variables were generated by combining the existing variables from the dataset. The process of generating new variables is explained in the "Description" column of the table.

**Figure 7.** Distribution of Per Capita Payment Values for General Payments Received by All Surgeons in 2014 and 2015.



A Right-skewed distribution



**Figure 8.** Distribution of Per Capita Payment Values for Research Payments Received by All Surgeons between 2014 and 2015.

A Right-skewed distribution

#### **B** Normal distribution



**Figure 9.** Distribution of Per Capita Payment Values for General Payments Received by Orthopaedic Surgeons between 2014 and 2015.



A Right-skewed distribution



**Figure 10.** Distribution of Per Capita Payment Values for Research Payments Received by Orthopaedic Surgeons between 2014 and 2015.

**A** Right-skewed distribution

**B** Normal distribution



**Figure 11.** Distribution of Per Capita Payment Values for General Payments Received by Non-Orthopaedic Surgeons between 2014 and 2015.



- A Right-skewed distribution
- **B** Normal distribution

**Figure 12.** Distribution of Per Capita Payment Values for Research Payments Received by Non-Orthopaedic Surgeons between 2014 and 2015.

A Right-skewed distribution

**B** Normal distribution



## 4.2. Specification of Interaction Analyses

#### Objective:

Determine the impact of the payment disclosure requirement (Sunshine Act) extension on per capita payment values for physicians who received payments that were disclosed in the CMS Open Payments database between 2014 and 2016.

- Treatment: Sunshine Act extension
- Control group: orthopaedic surgeons
- Treatment group: all non-orthopaedic surgeons
- Key endpoint: per capita payment value in US dollars
  - Stratification by payment type:
  - 1. General payments, excluding: royalties and license fees, current and prospective ownership interest;
  - 2. General payments, excluding: royalties and license fees, current and prospective ownership interest, food and beverages;
  - 3. Research payments
- Time period:
  - Early exposure:  $t_1 = 2014$
  - Later exposure:  $t_2 = 2015$  or  $t_2 = 2016$

All interaction analyses were performed using Stata SE statistical software (Version 11.2;

StataCorp, College Station, Texas).

To test the hypothesis that industry payments have experienced a more significant change in surgical specialties outside of orthopaedic surgery since the Sunshine Act extension, the following linear regression model was defined:

 $payment = \beta_0 + \beta_1 (tr) + \beta_2 (t) + \beta_3 (t \cdot tr) + \varepsilon, \qquad (1)$ 

- tr = treatment (Sunshine Act extension)
- t= time period (year of financial transaction)
- t•tr = interaction effect of treatment and time

Due to the right-skewness of the dependent variable, the linear regression model was transformed into the logarithmic form by generating the log-transformed dependent variable for the per capita payment value:

$$\log(\text{payment}) = \beta_0 + \beta_1 (\text{tr}) + \beta_2 (\text{t}) + \beta_3 (\text{t} \cdot \text{tr}) + \varepsilon, \qquad (2)$$

The primary endpoint of the analysis is the log-transformed per capita payment for which a physician is the primary recipient, as specified by inclusion criteria in Figures 1-3. All analyses were performed separately for both general and research payments, using the previously defined linear regression model with logarithmic transformation.

4.2.1.

4.2.1.1. Interaction Analysis I: General payment value per capita as the endpoint, comparing years 2014 and 2015

4.2.1.2. Interaction Analysis II: General payment value per capita as the endpoint, comparing years 2014 and 2016

Regression Specification

 $\log(\text{general payment}) = \beta_0 + \beta_1 (1) + \beta_2 (1) + \beta_3 (1 \cdot 1)$ (3)

tr = 0, if physician specialty = orthopaedic surgery (control group)
tr = 1, if physician specialty = other surgical specialties (treatment group)
t = 0, if year = 2014;
t = 1, if year = 2015 (for analysis 4.2.1.1) or if year = 2016 (for analysis 4.2.1.2.)

The independent variable that stratifies control and treatment groups was defined as a dummy variable, taking the value tr=0 for the control group and tr=1 for the treatment group. The independent variable that accounts for the time effect was defined as a dummy variable, such that it equals t=0 in the year 2014 and t=1 in the year 2015. The dependent variable is the log-transformed general payment value per capita made to each physician in orthopaedic surgery (control  $\rightarrow$  tr=0) and other surgical specialties (treatment  $\rightarrow$  tr=1) between years 2014 (t=0) and 2015/2016 (t=1). The interaction of treatment and time was defined as txtr, such that interaction effect = t\*tr.

4.2.2.

4.2.2.1. Interaction Analysis III: Research payment value per capita as the endpoint, comparing years 2014 and 2015

4.2.2.2. Interaction Analysis IV: Research payment value per capita as the endpoint, comparing years 2014 and 2016

Regression Specification

 $\log(\text{research payment}) = \beta_0 + \beta_1 (1) + \beta_2 (1) + \beta_3 (1 \cdot 1)$ (4)

tr = 0, if physician specialty = orthopaedic surgery (control group)
tr = 1, if physician specialty = other surgical specialties (treatment group)
t = 0, if year = 2014;
t = 1, if year = 2015 (for analysis 4.2.2.1) or if year = 2016 (for analysis 4.2.2.2.)

The independent variable that stratifies control and treatment groups was defined as a dummy variable, taking the value tr=0 for the control group and tr=1 for the treatment group. The independent variable that accounts for the time effect was defined as a dummy variable, such that it equals t=0 in the year 2014 and t=1 in the year 2015/2016. The dependent variable is the log-transformed research payment value per capita made to each physician in orthopaedic surgery (control  $\rightarrow$  tr=0) and other surgical specialties (treatment  $\rightarrow$  tr=1) between years 2014 (t=0) and 2015/2016 (t=1). The interaction of treatment and time was defined as txtr, such that interaction effect = t\*tr.

#### **5.Results**

#### 5.1. Summary Statistics

According to the data on industry payments extracted from OPD and processed according to the previously defined inclusion and exclusion criteria, the summary statistics for general and industry payments in 2014, 2015 and 2016 is shown in Tables 4-6. Physician specialties are separated into three groups: i. All medical specialties excluding surgery; ii. All surgical specialties excluding orthopaedic surgery; iii. Orthopaedic surgery. The data on the number of physicians who were reported as the primary recipient of industry payments show that approximately 66% of all active physicians other than surgeons received general and research payments. This number did not show any significant changes across the 2014-2016 time period. In orthopaedic surgery, 116% of active physicians received general and research payments during each of the three years, with no relative change over time. Unlike these two groups, surgical specialties excluding orthopaedic surgery, which constitute the treatment group of our analysis, showed a relative increase between 2014 and 2016. From 95.7% in 2014, this number rose to 97.7% in 2015 and 98.2% in 2016, as a fraction of all active surgeons in this group that were reported as primary recipients of general and research payments.

It is important to note that the total number of active orthopaedic surgeons that AAMC identified in its 2015 census report is smaller than the number of orthopaedic surgeons reported to have received industry payments in the CMS Open Payments Database that we analyzed. This discrepancy implies that there might be approximately 3,000 orthopaedic surgeons in the U.S. who are not clinically active when it comes to treating patients, but are active in the industry or research. This observation explains why our reported number of roughly 116% for orthopaedic surgeons that accepted payments in 2014, 2015 and 2016 exceeds 100%.

**Table 4.** Summary Data for Non-Surgical Specialties, Non-Orthopaedic Surgical Specialties and Orthopaedic Surgery for 2014 from the Open Payments Database.<sup>4</sup>

	Physician Specialty					
	All Non-Surgical Specialties	All Other Surgical Specialties <sup>4</sup>	Orthopaedic Surgery			
Number of p	hysicians receiving pay	ments [N, (%) <sup>5</sup> ]				
General	559,216 (64,9%)	43,473 (95.7%)	22,179 (115.9%)			
Research	6,126 (0.7%)	678 (1.5%)	318 (1.7%)			
Total	565,342 (65.7%)	43,492 (95.7%)	22,188 (115.9%)			
Number of payments made to physicians [N]						
General	10,939,681	654,770	298,096			
Research	31, 888	2,506	798			
Total	10,971,569	657,276	298,894			
Companies r	reporting payments <sup>2</sup> [N]					
General	1,614	773	559			
Research	599	111	62			
Total value of payments made to physicians <sup>3</sup>						
General	\$1,296,811,978	\$155,484,908	\$118,042,875			
Research	\$84,839,616	\$14,630,462	\$3,055,353			
Total	\$1,381,651,594	\$170,115,370	\$121,098,228			

<sup>1</sup>Reporting period: January 2014 – December 2014.

<sup>2</sup> The metrics for the number of companies reporting payments is derived from the variable

Applicable\_Submitting\_Manufacturer.

<sup>3</sup> All payments are in US Dollar values.

<sup>4</sup> Selection for the variable *Physician\_Specialty* – Inclusion criteria: *Surgery*; Exclusion criteria: *Orthopaedic Surgery*.

<sup>5</sup> Percentage out of the total number of active physicians in a given group of specialties, as determined by the 2015 census report of AAMC.

**Table 5.** Summary Data for Non-Surgical Specialties, Non-Orthopaedic Surgical Specialties and Orthopaedic Surgery for 2015 from the Open Payments Database.<sup>5</sup>

	Physician Specialty					
	All Non-Surgical Specialties	All Other Surgical Specialties <sup>4</sup>	Orthopaedic Surgery			
Number of physicians receiving payments [N, (%) <sup>5</sup> ]						
General	559,216 (65.0%)	44,217 (97.3%)	22,240 (116.2%)			
Research	6,855 (0.8%)	797 (1.8%)	315 (1.7%)			
Total	566,071 (65.8%)	44,383 (97.7%)	22,249 (116.2%)			
Number of payments made to physicians [N]						
General	10,442,995	689,439	286,078			
Research	52,321	3,983	1,583			
Total	10,495,316	693,422	287,661			
Companies reporting payments <sup>2</sup> [N]						
General	1,614	773	559			
Research	599	111	62			
Total value of payments made to physicians <sup>3</sup>						
General	\$1,125,607,244	\$152,487,636	\$113,176,911			
Research	\$97,622,642	\$11,614,155	\$4,839,404			
Total	\$1,223,229,886	\$164,101,791	\$118,016,315			

<sup>1</sup>Reporting period: January 2015 – December 2015

<sup>2</sup> The metrics for the number of companies reporting payments is derived from the variable

Applicable\_Submitting\_Manufacturer

<sup>3</sup> All payments are in US Dollar values

<sup>4</sup> Selection for the variable *Physician\_Specialty* – Inclusion criteria: *Surgery*; Exclusion criteria: *Orthopaedic Surgery* 

<sup>5</sup> Percentage out of the total number of active physicians in a given group of specialties, as determined by the 2015 census report of AAMC.

**Table 6.** Summary Data for Non-Surgical Specialties, Non-Orthopaedic Surgical Specialties and Orthopaedic Surgery for 2016 from the Open Payments Database.<sup>6</sup>

	Physician Specialty						
	All Non-Surgical Specialties	All Other Surgical Specialties <sup>4</sup>	Orthopaedic Surgery				
Number of ph	Number of physicians receiving payments [N, (%) <sup>5</sup> ]						
General	559,216 (65.0%)	44,568 (98.1%)	22,134 (115.6%)				
Research	5,937 (0.6%)	565 (1.2%)	239 (1.3%)				
Total	565,342 (65.7%)	44,618 (98.2%)	22,147 (115.7%)				
Number of pa	yments made to physic	cians [N]					
General	10,272,089	674,205	298,919				
Research	44,849	1,635	731				
Total	10,316,938	675,840	299,650				
Companies reporting payments <sup>2</sup> [N]							
General	1,614	773	559				
Research	599	111	62				
Total value of payments made to physicians <sup>3</sup>							
General	\$1,230,098,301	\$155,258,004	\$129,857,158				
Research	\$88,121,163	\$4,515,633	\$2,577,829				
Total	\$1,318,219,464	\$159,773,637	\$132,434,987				

<sup>1</sup>Reporting period: January 2016 – December 2016

<sup>2</sup> The metrics for the number of companies reporting payments is derived from the variable

 $Applicable\_Submitting\_Manufacturer$ 

<sup>3</sup> All payments are in US Dollar values

<sup>4</sup> Selection for the variable *Physician\_Specialty* – Inclusion criteria: *Surgery*; Exclusion criteria: *Orthopaedic Surgery* 

<sup>5</sup> Percentage out of the total number of active physicians in a given group of specialties, as determined by the 2015 census report of AAMC.

# 5.2 Payment Types Received by Physicians in Orthopaedic Surgery and Non-Orthopaedic Surgical Specialties

Within the general payment data in the CMS Open Payments Database, the most prevalent payment types (i.e. consulting fees, education etc.) were identified (Table 7). The analysis of payment types showed that the fees that orthopaedic surgeons received from the industry for consulting services ranged from 48% to 55% of the total value, followed by payments for non-consulting services and travel and lodging, which account for the average of 17% and 15.5%, respectively, with minimal fluctuations over the 3-year period. While consulting fees received by non-orthopaedic surgeons accounted for a smaller fraction of total payment value, they showed more volatility, with an increase from 8.7% in 2014 to 23% in 2015. For this group of surgeons, non-consulting service payments showed less fluctuations than in orthopaedic surgery, with a constant 20% share of total payment value (Table 8).

In terms of the frequency of payments, by far the highest number of transactions are made for food and beverages, with an average of 71% and 60% of the total number of payments, respectively for orthopaedic surgery and non-orthopaedic surgical specialties. However, these payments were among the lowest in terms of the per capita median value for both groups. Food and beverage payments are followed by travel and lodging compensations, whose frequency accounts for the average of 18% for orthopaedic surgeons, and 10.5% for other surgeons.

While considerably lower in frequency than food and beverage payments, consulting service fees have the highest per capita median value for orthopaedic surgery, ranging from \$6,000 to \$9,400 across the 3-year period. The second highest per capita median value is attributed to non-consulting services, ranging from \$4,000 to \$6,000. Although grant payments had a very high per capita median of \$10,000 in 2014, these payments experienced a significant decline in value during

the subsequent two years, falling by almost 70% by year 2016. For non-orthopaedic surgical specialties, the highest per capita median value of \$4,567 was observed for non-consulting services, followed by \$4,186 for grants, and 3,618 for consulting fees, all values being averaged across 2014-16.

The most remarkable fluctuations in payments during the 2014-2016 period were observed for speaker fees between accredited/certified and nonaccredited/noncertified continuing education programs (CEPs). While the total payments made to orthopedic surgeons speaking at noncertified CEPs fell by 89% from 2014 to 2016, the value of payments made to speakers at certified CEPs rose by 146% during the same time period. Although the same direction of payment trends for these two payment types were also observed in case of non-orthopaedic surgeons, those changes were much smaller in magnitude than for orthopaedic surgeons (Table 8). Further studies are needed to validate the extent to which these two opposite shifts in payments for certified and noncertified CEPs are linked with each other and to explain why they appear in significantly higher magnitude for orthopaedic surgery.

Another payment type that experienced relatively large shifts in payment value, but not in frequency are grants made to orthopaedic surgeons. The median per capita grant value declined from \$10,000 in 2014 to roughly \$3,000 in the subsequent two years. At the same time, the total value of grants experienced a 59% decline between 2014 and 2015, reverting back to an upward trend in 2016, with a 56% increase in total grant value (Table 7). Compared to payment trends in orthopaedic surgery, other surgical specialties did not show such a volatile pattern for grant payments, as the total grant value in this group changed by +12.7% and -0.8% in 2015 and 2016, respectively (Table 8).

<u>Payment</u> <u>Type</u> Year	Value of Payments [US Dollars]	Share of Total Value [%]	Number of Payments [N]	Share of Total Number of Payments [%]	Median of Per Capita Payment Value [US Dollars]	Q1-Q3 <sup>1</sup> [US Dollars]
<b>Overall pay</b>	ments					
2014	118,042,875	100.00%	298,096	100.00%	367.67	23.46-16,340.04
2015	113,176,911	100.00%	286,078	100.00%	380.44	23.25-16,233.70
2016	129,857,158	100.00%	298,919	100.00%	436.56	24.62-17,334.52
Consulting f	ees					
2014	57,066,748	48.34%	13,775	4.62%	6,000.00	20.85-65,071.57
2015	62,075,520	54.85%	14,924	5.22%	8,505.83	700.00-76,086.20
2016	62,350,551	48.01%	14,376	4.81%	9,400.00	700.00-77,625.00
Non-consult	ing services	·				
2014	19,061,105	16.15%	5,696	1.91%	4,000.00	225.00-54,082.50
2015	17,271,954	15.26%	5,784	2.02%	4,500.00	150.00-48,495.90
2016	26,356,889	20.30%	6,714	2.25%	6,000.00	310.00-63,118.50
Travel and l	Lodging	·				
2014	18,237,134	15.45%	50,317	16.88%	1,065.58	86.42-6,878.32
2015	18,293,911	16.16%	50,449	17.63%	1,059.75	110.20-7,163.25
2016	19,794,647	15.24%	57,037	19.08%	1,106.34	135.53-7,215.30
Food and Be	everages	·			·	
2014	8,995,011	7.62%	212,918	71.42%	214.85	21.62-1,230.54
2015	9,138,365	8.07%	210,135	73.45%	216.79	21.26-1,271.36
2016	9,276,203	7.14%	209,902	70.22%	225.06	21.62-1,270.58
Education	1				1	
2014	5,036,581	4.27%	12,970	4.35%	253.80	13.14-2,808.17
2015	4,928,502	4.35%	11,980	4.19%	320.00	13.54-3,297.00
2016	6,149,943	4.74%	8,670	2.90%	485.00	25.70-4,158.66
Speaker, no	naccredited and	noncertified C	EP		1	
2014	4,243,263	3.59%	894	0.30%	4,837.50	100.00-56,934.38
2015	862,745	0.76%	362	0.13%	3,000.00	360.74-24,225.00
2016	492,327	0.38%	213	0.07%	1,225.00	46.30-13,173.44
Grant	1				1	
2014	3,676,931	3.11%	434	0.14%	10,000.00	729.42-40,000.00
2015	1,549,085	1.37%	335	0.12%	3,062.50	562.50-17,500.00
2016	2,563,221	1.97%	453	0.15%	3,278.15	205.00-27,708.34
Speaker, acc	credited and cert	ified CEP				
2014	9,767	0.008%	3	0.001%	2,000.00	767.20-7,000.00
2015	51,692	0.046%	50	0.016%	502.65	402.12-2,756.50
2016	1,293,611	0.996%	527	0.176%	2,500.00	767.50-9,505.00

Table 7. General Payments to Orthopaedic Surgeons Who Received Payments; Stratified by Payment Type

<sup>&</sup>lt;sup>1</sup> The interquartile range (IQR) is defined as the difference between the third quartile (Q3) and the first quartile (Q1).

**Table 8.** General Payments to Non-Orthopaedic Surgeons Who Received Payments between 2014 and 2016;Stratified by Payment Type

<u>Payment</u> <u>Type</u> Year	Value of Payments [US Dollars]	Share of Total Value [%]	Number of Payments [N]	Share of Total Number of Payments [%]	Median of Per Capita Payment Value [US Dollars]	Q1-Q3 [US Dollars]		
<b>Overall payments</b>								
2014	155,484,908	100.00%	654,770	100.00%	229.51	17.71-7,492.80		
2015	152,487,636	100.00%	689,439	100.00%	230.89	17.03-6,983.74		
2016	155,258,004	100.00%	674,205	100.00%	227.82	17.30-7,286.68		
<b>Consulting</b>	iees							
2014	13,663,004	8.79%	9,028	1.38%	3,720.00	250.00-36,103.75		
2015	35,788,160	23.47%	10,289	1.49%	3,134.88	225.00-34,700.00		
2016	34,263,730	22.07%	9,961	1.48%	4,000.00	271.88-37,639.52		
Non-consult	ing services							
2014	32,537,548	20.93%	9,058	1.38%	3,520.00	182.74-42,475		
2015	30,446,871	19.97%	10,100	1.46%	4,581.25	85.49-41,005.00		
2016	29,618,456	19.08%	9,677	1.44%	5,600.00	227.00-44,822.50		
Travel and	Lodging							
2014	23,706,774	15.25%	68,097	10.40%	1,005.66	109.52-5,420.48		
2015	23,687,116	15.53%	69,910	10.14%	1,012.10	150.90-5,372.80		
2016	24,735,870	15.93%	72,745	10.79%	1,035.87	168.01-5,326.48		
Food and B	everages	1			1			
2014	17,131,400	11.02%	403,535	61.63%	179.42	17.80-1,251.68		
2015	18,079,550	11.86%	413,946	60.04%	176.40	16.72-1,303.69		
2016	18,319,718	11.80%	412,045	61.12%	170.30	16.95-1,331.64		
Education								
2014	14,326,317	9.21%	17,030	2.60%	90.33	7.56-7,750.00		
2015	10,780,312	7.07%	11,900	1.73%	105.05	9.57-6,750.00		
2016	12,965,655	8.35%	10,484	1.56%	290.00	9.18-9,000.00		
Speaker, no	naccredited and	noncertified C	EP					
2014	1,884,302	1.21%	597	0.091%	3,300.00	310.72-31,250.00		
2015	1,467,237	0.96%	566	0.082%	2,500.00	40.39-19,827.50		
2016	1,508,583	0.97%	631	0.094%	3,000.00	252.64-24,868.75		
Grant		1			1			
2014	1,552,580	1.00%	179	0.027%	4,166.67	141.66-32,329.72		
2015	1,749,872	1.15%	234	0.034%	4,987.50	134.12-30,833.50		
2016	1,735,856	1.12%	237	0.035%	3,404.84	96.56-26,135.42		
Speaker, ac	credited and cert	tified CEP						
2014	59,274	0.038%	31	0.005%	1,750.00	950.00-5,662.2		
2015	103,597	0.068%	57	0.008%	1,002.12	125.00-7,500.00		
2016	335,338	0.216%	156	0.023%	2,702.00	812.50-7,378.75		

<u>Surgical Specialty</u> Year	Value of Payments [US Dollars]	Number of Payments [N]	Median of Per Capita Payment Value [US Dollars]	Q1-Q3 [US Dollars]		
<b>Orthopaedic Surgery</b>						
2014	3,055,353	798	3,652.50	41.34-31,731.84		
2015	4,839,404	1,583	1,980.00	138.46-13,528.52		
2016	2,577,829	731	2,410.00	193.75-24,177.20		
Non-Orthopaedic Surgical Specialties						
2014	14,630,462	2,506	3,587.50	200.00-71,557.10		
2015	11,614,155	3,983	1,139.11	162.28-20,699.50		
2016	4,515,633	1,635	1,365.00	257.50-26,382.75		

**Table 9.** Research Payments to Orthopaedic and Non-Orthopaedic Surgeons Who AcceptedPayments between 2014 and 2016

#### 5.3. Distribution of General Payments by Surgical Subspecialty

In Table 10, general payments are presented for non-orthopaedic surgical specialties with the most prevalent physician-industry financial ties. The specialty that received the highest amount of general payments was neurological surgery during the entire analyzed time period, accounting for 60%, 65% and 58% of total payment value respectively for years 2014 to 2016. Thoracic surgery comes second, with the average of 16% share of total general payment value across the 3-year period, followed by plastic surgery with the average of 14% share of total payment value.

Relative to the number of surgeons reported as primary payment recipient in each specialty, thoracic surgery has the highest per capita median payment value of \$708, followed by colorectal surgery with \$372, averaged across 2014-2016.

While most payment parameters show a steady pattern over time, payment values in neurological, plastic and critical care surgery experienced more pronounced fluctuations. The amount of general payments made to plastic surgeons rose by 25.3% between 2014 and 2016, while the number of plastic surgeons receiving payments decreased, which explains the proportional rise in median payment per capita value observed for this subspecialty. By contrast, neurological surgeons received 17.5% less money in 2016 compared to 2014, and this trend was followed by proportional declines in median per capita payments. Although critical care surgery experienced a 50.7% increase in total payment value, the number of physicians in this specialty also increased total value. In addition, although the overall payments made to physicians in obstetric and gynecological surgery account for a modest share relative to other surgical subspecialties, it is notable that the total payment value reported for this specialty increased by 92% between 2014 and 2016, followed by an increase in the number of reported surgeons.

**Table 10.** Distribution of General Payments among Surgeons in Non-Orthopaedic Surgical Subspecialties WhoReceived Payments between 2014 and 2016

<u>Surgical</u> <u>Subspecialty</u> Year	Number of Physicians Receiving Payments [N]	Share of All Reported Non- Orthopaedic Surgeons <sup>1</sup> (%)	Total Value of Payments [US Dollars]	Share of Total General Payment Value for Non- Orthopaedic Surgeons <sup>1</sup> (%)	Number of General Payments [N]	Median Per Capita Payment Value [US Dollars]	Q1-Q3 <sup>2</sup> [US Dollars]
Neurological S	Surgery						
2014	7,311	16.86%	32,696,836	60.17%	94,752	166.19	17.34-12,573.64
2015	7,627	17.31%	25,582,342	65.27%	84,070	113.44	13.86-10,647.22
2016	7,868	17.71%	26,972,252	58.39%	80,525	102.58	14.18-9,445.92
Plastic Surger	'y						
2014	7,290	13.10%	14,771,400	16.00%	66,007	200.46	18.11-3,363.51
2015	7,268	12.43%	15,706,870	11.82%	78,033	250.25	20.92-4,007.44
2016	6,967	11.78%	18,510,267	13.22%	78,103	255.12	21.50-5,053.26
Thoracic Surg	gery						
2014	3,671	8.46%	18,325,741	14.71%	62,356	621.37	27.18-13,027.97
2015	3,647	8.26%	21,817,276	16.74%	66,257	688.51	29.63-12,695.24
2016	3,711	8.34%	20,269,450	18.21%	70,990	813.66	34.06-14,600.10
<b>Colorectal Su</b>	rgery						
2014	1,261	2.90%	5,790,480	4.07%	19,171	415.34	21.8-13,856.74
2015	1,270	2.87%	4,504,436	3.18%	16,963	339.70	21.27-8,618.49
2016	1,279	2.87%	4,877,534	3.34%	17,037	359.96	21.72-11,770.94
Surgical Onco	ology						
2014	715	1.64%	2,334,109	2.08%	6,011	163.83	16.62-9,639.57
2015	745	1.68%	3,152,423	2.68%	7,001	173.08	19.20-10,272.37
2016	802	1.80%	3,158,279	2.66%	7,539	187.00	18.58-10,998.81
Critical Care	Surgery						
2014	522	1.20%	601,404	6.61%	2,958	111.55	14.18-3,997.70
2015	568	1.28%	661,909	3.72%	3,287	115.02	13.86-2,513.96
2016	594	1.33%	906,618	2.01%	3,446	97.32	13.20-3,997.86
Transplant Su	irgery						
2014	418	0.96%	1,523,483	0.98%	3,506	174.14	17.14-9,741.46
2015	434	0.98%	1,753,422	1.15%	3,347	165.98	14.94-10,792.17
2016	477	1.07%	1,327,289	0.85%	3,449	124.74	12.20-8,285.02
Obstetric and	Gynecologic	al Surgery	1		1		
2014	283	0.65%	599,974	1.15%	3,048	219.68	19.74-7,166.55
2015	336	0.82%	684,803	0.66%	4,016	210.70	21.72-7,288.83
2016	369	0.83%	1,154,886	1.07%	4,939	270.48	21.39-7,615.12

<sup>1</sup>Orthopaedic surgeons are excluded from all computations in this table.

<sup>2</sup>The interquartile range (IQR) is defined as the difference between the third quartile (Q3) and the first quartile (Q1).

#### 5.4. Interaction Analyses

#### 5.4.1. Interpretation of Regression Results

For general payments, the treatment effect alone resulted in a decline of general payment value per capita for non-orthopaedic surgeons by 37.3% (p<0.001), both during the 2014-15 and 2015-16 periods. The interaction effect of time and treatment in the regression analyses of per capita payment value received by non-orthopaedic surgeons showed a statistically significant 39.4% decrease (p<0.001) in per capita payments due to the interaction effect of time and physician specialty (Table 11). Comparing time trends between exposure in 2014 and later exposure in 2016 (Table 12) showed a statistically significant effect of treatment and time interaction, which was a decline in per capita payment value by 45.5% (p<0.001).

For research payments, the interaction effect of time and physician specialty resulted in declines by 7.7% (p=0.299) and 19.0% (p=0.060) in per capita payment value, respectively for 2014-15 and 2014-16 periods, for non-orthopaedic surgical specialties, neither of which were statistically significant, based on the p-values (Tables 13 and 14).

All calculations of percentage changes in the log-transformed payment dependent variable are shown in Table 15.

**Table 11.** Results for the Log-Transformed Regression Analysis of Per CapitaPayment Value for General Payments Received by Surgeons between 2014 and2015, Excluding Royalties and Ownership Payments

Variable	В	Robust SE	p-value	95% CI		
t	0.012	0.020	0.560	(-0.028) - (0.051)		
tr	-0.467	0.017	< 0.001	(-0.501) - (-0.434)		
txtr	-0.034	0.024	< 0.001	(-0.081) - (0.014)		
tr + txtr	-0.501	0.017	< 0.001	(-0.534) – (-0.467)		
Intercept	6.123	0.014	< 0.001	(6.096) - (6.151)		
Observations		132,062				
<b>R</b> <sup>2</sup>		0.0125				
F-statistics		535.77				

**Table 12.** Results for the Log-Transformed Regression Analysis of Per Capita Payment Value for General Payments Received by Surgeons between 2014 and 2016, Excluding Royalties and Ownership Payments

Variable	В	Robust SE	p-value	95% CI	
t	0.127	0.020	< 0.001	(0.088) – (0.167)	
tr	-0.467	0.017	<0.001	(-0.501) - (-0.434)	
txtr	-0.140	0.024	<0.001	(-0.188) - (-0.092)	
tr + txtr	-0.607	0.017	< 0.001	(-0.641) – (-0.573)	
Intercept	6.123	0.014	< 0.001	(6.096) - (6.151)	
Observations	vations		132,354		
<b>R</b> <sup>2</sup>			0.0154		
F-statistics	660.81				

**Table 13.** Results for the Log-Transformed Regression Analysis of Per CapitaPayment Value for Research Payments Received by Surgeons between 2014 and2015

Variable	В	Robust SE	p-value	95% CI	
t	-0.301	0.130	0.021	(-0.557) - (-0.045)	
tr	0.488	0.144	0.001	(0.206) - (0.770)	
txtr	-0.568	0.158	0.299	(-0.878) - (-0.257)	
tr + txtr	-0.080	0.066	0.299	(-0.209) – (0.050)	
Intercept	7.670	0.121	< 0.001	(7.433) - (7.908)	
Observations	3,571				
<b>R</b> <sup>2</sup>	0.0328				
F-statistics			34.04		

**Table 14.** Results for the Log-Transformed Regression Analysis of Per CapitaPayment Value for Research Payments Received by Surgeons between 2014 and2016

Variable	В	Robust SE	p-value	95% CI	
t	0.026	0.149	0.863	(-0.267) - (0.319)	
tr	0.488	0.144	0.001	(0.206) - (0.771)	
txtr	-0.698	0.182	0.060	(-1.054) - (-0.341)	
tr + txtr	-0.210	0.111	0.060	(-0.428) - (0.008)	
Intercept	7.670	0.121	< 0.001	(7.433) - (7.908)	
Observations	1,917				
<b>R</b> <sup>2</sup>	0.0219				
F-statistics			11.57		

Log-linear model specification	Model formulation	Log-transformed coefficient interpretation for interaction of time and treatment	Percentage change in per capita payment value	Log-transformed 95% CIs
Generic model	$log(payment) = \beta_0 + \beta_1 (t) + \beta_2$ $(tr) + \beta_3 (txtr)$	e^(β)	(1-e <sup>^</sup> (β))x100	(1-e <sup>^</sup> (β <sub>(95%CI)</sub> ))x100
Log-linear model for general payments, 2014-15	log(payment)=6.12+0.01(1)- 0.47(1)-0.34(1x1)	e^(-0.501) = 0.606	-39.4%	(-41.4%) – (-37.7%)
Log-linear model for general payments, 2014-16	log(payment) = 6.12 + 0.13(1) - 0.47(1) - 0.14(1x1)	e^(-0.607) = 0.545	-45.5%	(-47.3%) – (-43.6%)
Log-linear model for research payments, 2014-15	log(payment)=7.67- 0.30(1)+0.49(1)-0.57(1x1)	e^(-0.080) = 0.923	-7.7%	(-18.9%) – (+5.1%)
Log-linear model for research payments, 2014-16	log(payment) = 7.67 + 0.03(1) + 0.49(1) - 0.70(1x1)	e^(-0.210) = 0.810	-19.0%	(-34.8%) – (+0.8%)

Table 15. Calculation and Interpretation of Regression Coefficients for Log-transformed Per Capita Payment Variable

#### 5.4.2. Additional Interaction Analyses

On the aggregate level, the frequency of general payments to surgeons in the treatment group increased by 13% between 2014 and 2015 (46,687 additional transactions), and by 5% between 2014 and 2016 (18,612 additional transactions). The trend of rising payment frequency was even more pronounced for research payments, with a 40% increase in the number of payments (692 additional transactions) between 2014 and 2015. However, this trend was reversed in 2016, as shown by the 48% decline (824 fewer transactions) when comparing 2014 and 2016 in the interaction analysis of time and treatment effects.

Using the number of physicians receiving payments in each year as an aggregate level endpoint, 683 additional surgeons received payments in 2015 than in 2014, relative to the control group of orthopaedic surgeons, which makes a 1.5% increase. When comparing 2014 to the later exposure in 2016, 1140 additional physicians (2.5% increase) in the treatment group became primary recipients of general payments during that time period, as a result of the Sunshine Act extension, assuming that all other external factors were constant between orthopedic surgery and other surgical specialties. The analysis of research payments shows that this policy resulted in 122 new physicians receiving research payments in the treatment group when comparing year 2015 with 2014, which accounts for a 0.27% increase. However, the same analysis between the timepoints of 2014 and 2016 resulted in slight decline of 34 physicians (0.07%). This generally increasing trend in the number of physicians in the treatment group may be the reason behind the higher number of total payments, which were observed in some of the surgical specialties outside of orthopedic surgery following the extension of the Sunshine Act, as noted in Section *5.3*.

#### 5.4.3. Stratification of Food and Beverage Payments versus Other General Payments

Considering that we identified the majority of general payments made to surgeons as food and beverage payments, additional regression analyses were performed with stratification of food and beverage payments from all other general payment types that were included in the previous analyses. Given that food and beverage payments showed the highest frequency but the lowest per capita values, the purpose of this stratification was to confirm whether other payment types, which account for much higher values in industry-physician financial ties, would still show a declining trend across time as a result of the Sunshine Act extension when they are not confounded by food and beverage transactions.

Tables 16-19 show regression outcomes for all general payments excluding food and beverages, and for only food and beverage payments, for both 2014-15 and 2014-16 periods. Similar to previous analyses of all general payments, the regression of general payments excluding food and beverages showed a decline of 25.2% which was not statistically significant (p<0.001). However, between years 2014 and 2016, general payments did show a statistically significant decline by 30.5% (p<0.001), even when food and beverage payments were excluded. Coefficients that quantify the treatment effect on per capita payment values are summarized in Table 20 for all eight regression analyses that were performed in this study.

Variable	В	Robust SE	p-value	95% CI	
t	< 0.001	0.013	0.995	(-0.025) - (0.025)	
tr	-0.148	0.011	<0.001	(-0.170) - (-0.125)	
txtr	-0.015	0.016	<0.001	(-0.046) - (0.017)	
tr + txtr	-0.163	0.011	<0.001	(-0.185) – (-0.140)	
Intercept	5.266	0.009	<0.001	(5.249) - (5.284)	
Observations	128,435				
<b>R</b> <sup>2</sup>	0.0028				
F-statistics			123.07		

**Table 16.** Results of the Log-Transformed Regression Analysis of Per Capita Food and Beverage Payment Value for Payments Received by Orthopaedic Surgeons versus Non-Orthopaedic Surgeons between 2014 and 2015

**Table 17.** Results of the Log-Transformed Regression Analysis of Per Capita Food and Beverage Payment Value for Payments Received by Orthopaedic Surgeons versus Non-Orthopaedic Surgeons between 2014 and 2016

Variable	В	Robust SE	p-value	95% CI	
t	0.036	0.013	0.005	(0.011) - (0.061)	
tr	-0.147	0.011	< 0.001	(-0.170) - (-0.125)	
txtr	-0.058	0.016	< 0.001	(-0.090) - (-0.026)	
tr + txtr	-0.205	0.011	< 0.001	(-0.228) – (-0.183)	
Intercept	5.266	0.009	< 0.001	(5.249) - (5.284)	
Observations	128,857				
<b>R</b> <sup>2</sup>	0.0037				
<b>F-statistics</b>			163.81		

Variable	В	Robust SE	p-value	95% CI	
t	0.189	0.029	<0.001	(0.132) - (0.246)	
tr	-0.261	0.028	<0.001	(-0.315) - (-0.207)	
txtr	-0.030	0.038	<0.001	(-0.104) - (0.444)	
tr + txtr	-0.291	0.026	<0.001	(-0.342) – (-0.240)	
Intercept	6.969	0.021	< 0.001	(6.928) - (7.011)	
Observations	55.818				
<b>R</b> <sup>2</sup>	0.0053				
F-statistics			98.20		

**Table 18.** Results of the Log-Transformed Regression Analysis of Per Capita General Payment Value Excluding Food and Beverages, for Payments Received by Orthopaedic Surgeons versus Non-Orthopaedic Surgeons between 2014 and 2015

**Table 19.** Results of the Log-Transformed Regression Analysis of Per Capita General Payment Value Excluding Food and Beverages, for Payments Received by Orthopaedic Surgeons versus Non-Orthopaedic Surgeons between 2014 and 2016

Variable	В	Robust SE	p-value	95% CI			
t	0.465	0.028	< 0.001	(0.410) - (0.521)			
tr	-0.261	0.028	< 0.001	(-0.315) - (-0.207)			
txtr	-0.102	0.037	< 0.001	(-0.175) - (-0.029)			
tr + txtr	-0.363	0.025	< 0.001	(-0.412) – (-0.315)			
Intercept	6.969	0.021	< 0.001	(6.928) - (7.011)			
Observations		55,293					
<b>R</b> <sup>2</sup>	0.0138						
F-statistics			268.08				

Endpoint dependent variable	Log-transformed Coefficient for Time- Treatment Interaction Effect	Percentage Change of Per Capita Payment Value	Log-transformed 95% CIs	p-value
General <sup>1</sup> payments received by surgeons between 2014 and 2015				
Per capita general payment value	0.606	-39.4%	(-41.4%) – (-37.7%)	< 0.001
General <sup>1</sup> payments received by surgeons between 2014 and 2016				
Per capita general payment value	0.545	-45.5%	(-47.3%) – (-43.6%)	< 0.001
General <sup>1</sup> payments received by surgeons between 2014 and 2015, excluding food and beverage payments				
Per capita non-food and beverage general payment value	0.748	-25.2%	(-29.0%) - (-21.3%)	<0.001
General <sup>1</sup> payments received by surgeons between 2014 and 2016, excluding food and beverage payments				
Per capita non-food and beverage general payment value	0.695	-30.5%	(-33.8%) – (-27.0%)	<0.001
Food and beverage payments received by surgeons between 2014 and 2015				
Per capita food and beverage payment value	0.850	-15.0%	(-16.9%) – (-13.1%)	< 0.001
Food and beverage payments received by surgeons between 2014 and 2016				
Per capita food and beverage payment value	0.815	-18.5%	(-20.4%) – (-16.7%)	< 0.001
Research payments received by surgeons between 2014 and 2015				
Per capita research payment value	0.923	-7.7%	(-18.9%) – (+5.1%)	0.299
Research payments received by surgeons between 2014 and 2016				
Per capita research payment value	0.810	-19.0%	(-34.8%) – (+0.8%)	0.060

Table 20. Summary of Regression Outcomes for All Interaction Analyses

<sup>1</sup>All general payments exclude royalties, license fees, current and prospective interest ownership payments.

## **6. Discussion and Conclusions**

This paper evaluates the impact of the 2013 Sunshine Act extension on subsequent industry payments received by physicians between 2014 and 2016. In addition to measuring the impact of this federal law, we also performed a descriptive statistical analyses of payment trends, stratified by nature of payment and most prevalent surgical subspecialties for each year.

The regression outcomes show that the Sunshine Act resulted in a 39.4% decline in per capita general payment values between 2014 and 2015, and an even more substantial decline of general payments by 45.5% during the 2-year period from 2014 to 2016, for payments that were received by non-orthopaedic surgeons, who were exposed to payment disclosure requirement for the first time during the Sunshine Act extension, compared to orthopaedic-surgeons, who were exposed to the disclosure requirement prior to this federal law. Even after excluding food and beverage payments, which were the highest in frequency but the lowest in total value shares, per capita general payments still showed a statistically significant decline of 30.5% as a result of the policy exposure, for non-orthopaedic surgeons compared to orthopaedic surgeons. By contrast, the Sunshine Act extension did not show statistically significant effects on research payment trends. These results are consistent with our hypothesis that surgeons would be less likely to receive general payments, as a result of the public disclosure policy, whereas the amount of research payments that they receive would not be affected.

Additional analyses of general payment types suggest the presence of heterogeneity in payment trends depending on the nature of payment, with most volatility in payment value across time observed between accredited and non-accredited continuing education programs, as well as for grant payments. When payment data were stratified by surgical subspecialty for the treatment group of non-orthopaedic surgeons, some subspecialty-based heterogeneity in payment trends since the Sunshine Act extension was observed. While per capita payment values were on the rise for plastic surgery between 2014 and 2016, neurosurgeons received a declining amount of payments during the same period. The absolute payment shares and per capita values were also found to vary considerably among different surgical subspecialties. In light of these variabilities within the treatment group, further studies are needed to identify the exact specialties in which industry payments were most strongly affected by the federal policy.

The main limitation of this study is the concern about inferring causal effects of policy exposure without availability of pre-exposure payment data for the treatment group. There might be confounding factors other than the treatment variable that influence changes in industry payments over time, which we may not be easily observed without a difference-in-difference analyses. This type of analysis would only be possible if we had access to data on pre-exposure trends for both the control and the treatment group. In addition, the validity of the interaction analyses depends on the assumption that the control group (orthopaedic surgery) and the treatment group (nonorthopaedic surgical specialties) are equivalent in all other factors except for the pre-treatment exposure to the payment disclosure policy that the control group was subject to. However, there might be other differences between treatment and control, or among surgical subspecialties within the treatment group, which are not explained in the datasets that we used, but which may nevertheless account for a part of payment changes observed in our regression outcomes.

This study provides the evidence that federal disclosure requirements of industry payments to surgeons resulted in statistically significant declines in per capita general payment values reported in the CMS Open Payments database. Further studies are needed to evaluate whether these changes in payment trends might have any downstream effects on both the industry and the healthcare side of the payment chain. This includes clinical research collaborations with the industry, as well as physician decision making and prescribing behaviors, all of which can have a profound influence on the welfare of patients.

## 7. References

- Norris SL, Holmer HK, Ogden LA, Burda BU, Fu R. Characteristics of physicians receiving large payments from pharmaceutical companies and the accuracy of their disclosures in publications: an observational study. BMC Med Ethics. 2012;13:24.
- Wazana A. Physicians and the pharmaceutical industry: is a gift ever just a gift? JAMA 2000;283:373-380.
- National Survey of Physicians. Part II: Doctors and prescription drugs. Washington, DC: Kaiser Family Foundation, March 2002.
- Campbell EG, Gruen RL, Mountford J, Miller LG, Cleary PD, Blumenthal D. A national survey of physician-industry relationships. N Engl J Med. 2007 Apr 26;356 (17):1742-50.
- Dollars for Docs, ProPublica. Available at: <u>https://projects.propublica.org/docdollars/</u>. Accessed on 2018 March 10.
- Okike K, Kocher MS, Mehlman CT, Bhandari M. Conflict of interest in orthopaedic research: an association between findings and funding in scientific presentations. J Bone Joint Surg Am 2007;89:608-613.
- 7. Peppercorn J, Blood E, Winer E, Partridge A. Association between pharmaceutical involvement and outcomes in breast cancer clinical trials. Cancer 2007;109:1239-1246.
- Tungaraza T, Poole R. Influence of drug company authorship and sponsorship on drug trial outcomes. Br J Psychiatry 2007;191:82-83.
- Bekelman JE, Li Y, Gross CP. Scope and impact of financial conflicts of interest in biomedical research: a systematic review. JAMA 2003;289:454-465.

- Melander H, Ahlqvist-Rastad J, Meijer G, Beermann B. Evidence b(i)ased medicine -selective reporting from studies sponsored by pharmaceutical industry: review of studies in new drug applications. BMJ 2003;326:1171-1173.
- Jones RG, Ornstein C. Matching industry payments to Medicare prescribing patterns: an analysis. March 2016. Available at: <u>https://static.propublica.org/projects/d4d/20160317-</u> <u>matching-industry-payments.pdf?22</u>. Accessed on 2018 March 20.
- Kesselheim AS, Misono AS, Lee JL, Stedman MR, Brookhart MA, Choudhry NK, Shrank WH. Clinical equivalence of generic and brand-name drugs used in cardiovascular disease: a systematic review and meta-analysis. JAMA. 2008;300(21):2514–2526. doi:10.1001/jama.2008.758.
- Holmer AF. Industry strongly supports continuing medical education. JAMA 2001;285:2012-2014.
- Lo B, Field M, eds. Conflict of interest in medical research, education, and practice.
   Washington, DC: National Academies Press, 2009.
- Ross JS, Lackner JE, Lurie P, Gross CP, Wolfe S, Krumholz HM. Pharmaceutical company payments to physicians: early experiences with disclosure laws in Vermont and Minnesota. JAMA. 2007;297(11):1216–1223. doi:10.1001/jama.297.11.1216
- National Conference of State Legislatures. 2006 Prescription drug state legislation, November 6, 2006. Available at: <u>http://www.ncsl.org/programs/health/drugbill06.htm</u>. Accessed on 2018, March 25.
- 17. Massachusetts Government, Department of Public Health. The Pharmaceutical and Medical Device Manufacturer Code of Conduct (105 CMR 970.000), 2012. Available at: http://www.mass.gov/dph/pharmamed. Accessed on 2018, March 25.

- 18. U.S. Department of Justice. Five companies in hip and knee replacement industry avoid prosecution by agreeing to compliance rules and monitoring. Available at: <u>http://www.usdoj.gov/usao/nj/press/files/pdffiles/hips0927.rel.pdf.</u> Accessed on 2018 March 12.
- Buerba RA, Fu MC, Grauer JN. Discrepancies in spine surgeon conflict of interest disclosures between a national meeting and physician payment listings on device manufacturer web sites. Spine J. 2013;13:1780–1788.
- Jarvies D, Coombes R, Stahl-Timmins W. Open Payments goes live with pharma to doctor fee data: first analysis. BMJ. 2014;349:g6003. Epub 2014 Oct 1.
- 21. Kirschner NM, Sulmasy LS, Kesselheim AS. Health policy basics: the physician payment sunshine act and the Open Payments program. *Ann Intern Med.* 2014;161:519–521.
- Centers for Medicare & Medicaid Services. CMS.gov. Open Payments. Available at: http://www.cms.gov/openpayments/. Accessed on 2017 October 20.
- S.301 111<sup>th</sup> Congress: "Physician Payments Sunshine Act of 2009". Available at: <u>https://www.govtrack.us/congress/bills/111/s301</u>. Accessed on 2018 March 25.
- 24. Tague NR. The Quality Toolbox, 2004: ASQ Quality Press, 2<sup>nd</sup> ed. 292-299.