



## Industry Financial Relationships in Neurosurgery in 2015: Analysis of the Sunshine Act Open Payments Database

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**OBJECTIVE:** The 2013 Physician Payments Sunshine Act mandates that all U.S. drug and device manufacturers disclose payments to physicians. All payments are made available annually in the Open Payments Database (OPD). Our aim was to determine prevalence, magnitude, and nature of these payments to physicians performing neurologic surgery in 2015 and to discuss the role that financial conflicts of interest play in neurosurgery.

**METHODS:** All records of industry financial relationships with physicians identified by the neurological surgery taxonomy code in 2015 were accessed via the OPD. Data were analyzed in terms of type and amounts of payments, companies making payments, and comparison with previous studies.

**RESULTS:** In 2015, 83,690 payments (totaling \$99,048,607) were made to 7613 physicians by 330 companies. Of these, 0.01% were >\$1 million, and 73.2% were <\$100. The mean payment (\$13,010) was substantially greater than the median (\$114). Royalties and licensing accounted for the largest monetary value of payments (74.2%) but only 1.7% of the total number. Food and beverage payments were the most commonly reported transaction (75%) but accounted for only 2.5% of total reported monetary value. Neurologic surgery had the second highest average total payment per physician of any specialty.

**CONCLUSIONS:** The neurological surgery specialty receives substantial annual payments from industry in the United States. The overall value is driven by a small

number of payments of high monetary value. The OPD provides a unique opportunity for increased transparency in industry-physician relationships facilitating disclosure of financial conflicts of interest.

### INTRODUCTION

The increase in industry and concurrent decline in publicly funded research has resulted in device manufacturers and pharmaceutical companies becoming responsible for the majority of spending in biomedical research.<sup>1</sup> For example, in 2015, industry made \$3.89 billion in research-related payments to physicians in the United States.<sup>2</sup> The extensive financial connections between scientific investigators, clinicians, academic institutions, and industry raise concerns regarding bias owing to conflicts of interest (COIs) in biomedical research.<sup>3</sup> In addition, industry financial relationships with physicians through royalties, consulting and speaker's fees, and continuing medical education introduce financial COIs into the realm of patient care.<sup>4</sup> Therefore, transparent and complete COI declarations have become essential for ensuring public trust in the scientific process, ensuring public faith in quality clinical care, and maintaining clinical and research credibility and integrity.<sup>5</sup>

The International Committee of Medical Journal Editors defines a COI as "exist[ing] when professional judgment concerning a primary interest (such as patient care) may be influenced by a secondary interest (such as financial gain)."<sup>6</sup> In neurosurgery, COIs are encountered in research, clinical practice, and

#### Key words

- Conflicts of interest
- Ethics
- Industry
- Neurosurgery
- Open Payments Database
- Sunshine Act

#### Abbreviations and Acronyms

**AAMC:** Association of American Medical Colleges

**ABNS:** American Board of Neurological Surgery

**COI:** Conflict of interest

**NPI:** National Provider Identifier

**OPD:** Open Payments Database

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academia.<sup>7</sup> These COIs are inevitable and ubiquitous and do not in and of themselves imply unethical behavior if managed properly.<sup>8</sup> However, poorly managed COIs have the potential to not only negatively impact patient care but also to erode public trust in the integrity of scientific research.<sup>8</sup> Recently, growing concern regarding physician financial COIs has provided the impetus for health care reform legislation in the United States that requires public disclosure of physician financial relationships with industry.<sup>9</sup>

The Physician Payments Sunshine Act (2013)<sup>10</sup> made it mandatory for all drug and device manufacturers in the United States to disclose individual payments to physicians >\$10. A record of these payments is available in the Open Payments Database (OPD), a publicly accessible, searchable database.<sup>2</sup> The data collected include industry payments for travel, research, gifts, speaking fees, and meals as well as ownership interests and royalties to physicians and their immediate families.<sup>2</sup> The publicly available data are updated annually on the OPD website (<https://www.cms.gov/openpayments>).

In 2011, selected neurosurgeons were involved in a controversy that served as a major driving force behind the passage of the Sunshine Act.<sup>11</sup> The role that financial payments, and the failure to disclose these payments, made to the authors of several publications that focused on the use of recombinant bone morphogenetic protein (INFUSE; Medtronic, Minneapolis, Minnesota, USA) as an adjunct to spinal fusion led to headlines in prominent print media in the United States.<sup>11</sup> This was ultimately a catalyst to the legislation that led to the

OPD. The U.S. Senate Finance Committee issued a report that was highly critical of Medtronic's influence on the INFUSE clinical studies.<sup>12</sup>

In 2015, the U.S. Centers for Medicare and Medicaid Services Open Payments program reported \$7.52 billion in health care industry manufacturer payments and ownership investment interests to physicians and teaching hospitals.<sup>2</sup> There was \$2.60 billion paid in general (i.e., non—research related) payments.<sup>2</sup> General payments include payments for royalties and licensing, food and beverages, consulting fees, honoraria, ownership and investment interests, travel, lodging, and entertainment (Table 1).<sup>2</sup> The mission of the Open Payments program is to “achiev[e] a high-quality health care system that ensures better care, access to coverage and improved health at lower cost” through transparency regarding the financial relationships between physicians and industry.<sup>2</sup> According to the 2015 data set, physicians identified by taxonomy code as providing neurologic surgery services (not necessarily neurosurgeons) received an average total payment of \$13,010 per physician in 2015, the second highest of all medical and surgical activities after orthopedic surgery.<sup>2</sup>

In August 2016, Chao and Gangopadhyay<sup>4</sup> compared surgical subspecialties in terms of industry financial relationships found in the OPD in 2014 and found the highest prevalence of these relationships among physicians were identified by the neurologic surgery taxonomy code (87.8%). The 2015 dataset represents the second full year of data available and therefore the first opportunity to compare data with previous years. To

**Table 1.** Distribution of Types of Industry Payments to Neurosurgeons by Number and Monetary Value

Type of Payment	Number of Payments	Percentage of Payments	Total Value of Payments	Percentage of Total Dollars	Dollars per Payment
Food and beverages	62,779	75.01%	\$2,436,280.52	2.46%	\$38.81
Travel and lodging	13,148	15.70%	\$4,513,881.33	4.56%	\$343.31
Consulting fee	2834	3.39%	\$11,014,753.50	11.12%	\$3886.65
Compensation for services other than consulting, including serving as faculty or as speaker at a venue other than a continuing education program	2075	2.48%	\$5,930,896.03	5.99%	\$2858.26
Royalty and license	1389	1.66%	\$73,443,003.70	74.15%	\$52,874.73
Education	767	0.92%	\$149,799.66	0.15%	\$195.31
Gift	284	0.34%	\$309,931.63	0.31%	\$1091.31
Honoraria	168	0.20%	\$108,879.15	0.11%	\$648.09
Compensation for serving as faculty or as speaker for a nonaccredited and noncertified continuing education program	92	0.11%	\$259,480.59	0.26%	\$2820.44
Entertainment	87	0.10%	\$6204.19	0.01%	\$71.31
Grant	46	0.05%	\$396,837.47	0.40%	\$8626.90
Compensation for serving as faculty or as speaker for an accredited or certified continuing education program	14	0.02%	\$19,859.83	0.02%	\$1418.56
Current or prospective ownership or investment interest	4	0.00%	\$414,423.09	0.42%	\$103,605.77
Charitable contribution	3	0.00%	\$44,378.56	0.04%	\$14,792.85
Total	83,690		\$99,048,607		

better understand the incidence, magnitude, and nature of these relationships, we sought to create a snapshot of industry payments to neurosurgeons in 2015 made available through the OPD.

## MATERIALS AND METHODS

The Physician Payment Sunshine Act requires that all monetary exchanges from pharmaceutical, device, biologic, and medical supply manufacturers to physicians and teaching hospitals be published annually in a publicly accessible, searchable database.<sup>2</sup> The database is limited to manufacturers and group purchasing organizations that operate in the United States. Industry payment data for the period from January 1, 2015, to December 31, 2015, were accessed online through the OPD (<https://www.cms.gov/openpayments>) on August 11, 2016. This period represents the second full year of data available through the online database and the first opportunity to compare data with previous years. Given that this study used publicly accessible data, local institutional review board approval was not required.

In contrast to the data returned by the OPD search tool available on the OPD website (<https://www.cms.gov/OpenPayments/Explore-the-Data/Data-Explorer.html>), the Data Explorer is not limited to physician specialty as verified through the National Plan and Provider Enumeration System National Provider Identifier (NPI) Registry (<https://npiregistry.cms.hhs.gov/registry/>).<sup>13</sup> A health care provider's NPI is a lasting identifier intended to endure changes to health care provider identifiers such as name, address, and taxonomy.<sup>14</sup> Taxonomy codes are self-selected, and a health care provider may employ >1 taxonomy code simultaneously to appropriately describe the scope of their practice and specialization.<sup>14</sup> Therefore, physicians in the Data Explorer may have ≥1 taxonomy codes depending on their self-specified specialty involvement.<sup>13</sup>

The data accessed through the OPD Data Explorer were limited to payments involving medical doctor and doctor of osteopathy physicians with a neurologic surgery taxonomy code, and the records were extracted for further analysis. To compare the OPD with other existing databases, we accessed the Association of American Medical Colleges (AAMC) 2016 Physician Specialty Data Report (<https://www.aamc.org/data/workforce/reports/457712/2016-specialty-databook.html>).

The Open Payments data accessed did not include data that were marked as delayed in publication. These data are not made publicly available on the OPD publication site until the delay is removed by the reporting entity or the delay has expired.<sup>13</sup> Payments made to physicians identified by the neurologic surgery taxonomy code were analyzed with regard to 1) types and monetary value of payments, 2) companies making payments, and 3) payments compared with previous years. The types of payments and companies were examined with respect to the incidence and value of these payments. Industry payments to the neurologic surgery specialty in 2015 were descriptively compared with payments in 2014 using data previously published by Chao and Gangopadhyay.<sup>4</sup>

Descriptive statistics were used for the evaluation of study data. We presented the payments to physicians identified by the neurologic surgery taxonomy code descriptively using frequencies and proportions. Statistical testing was not employed for comparison between payments. Microsoft Excel 2016 (Microsoft Corp., Redmond, Washington, USA) and IBM SPSS Version 20.0 (IBM Corp., Armonk, New York, USA) were used for data analyses.

## RESULTS

We identified 83,690 individual payments in the 2015 OPD made to 7613 physicians identified by the neurologic surgery taxonomy code in the United States. Of these payments, 14 (0.02%) were listed as having been disputed by a physician. The total monetary value of the payments was \$99,048,607.32, with 73.18% of these payments being <\$100 in value; 8 (0.01%) payments were listed as being >\$1 million (Table 2). The average payment per individual neurologic surgery specialty code in 2015 was \$13,010.46. The median payment per physician was \$114.22.

### Comparison with Other Databases

Within the AAMC database, we identified 5346 active neurosurgeons in 2015; 4920 were listed as being involved in patient care, 52 were listed as being involved in research, 33 were listed as being involved in teaching, and 341 were listed as "other." The 7613 neurologic surgery specialty codes identified in the OPD exceeded the AAMC data because physicians in the OPD may have ≥1

**Table 2.** Distribution of Individual Industry Financial Relationships with Neurosurgeons in the Open Payments Database by Monetary Value

Dollar Value of Payment	Number of Payments	Percentage of Payments	Percent of Total Dollars
\$0–\$100	61,243	73.18%	1.70%
\$100–\$1000	16,771	20.04%	4.58%
\$1000–\$10,000	4847	5.79%	16.45%
\$10,000–\$100,000	732	0.87%	19.66%
\$100,000–\$1,000,000	89	0.11%	22.22%
>\$1,000,000	8	0.01%	35.39%
Total	83,690		

taxonomy codes depending on their self-designated specialty involvement.<sup>13</sup> We accessed the NPI Registry and American Board of Neurological Surgery (ABNS) websites; however, neither of these groups provided a publically available report of the total number of neurosurgeons in 2015 or a means with which to calculate this number. The ABNS website employs a search function instead of allowing for a dataset download. The NPI Registry website provides a dataset download for the current time period but does not allow for the investigation of a previous time period.

### Types of Payments

The specific payment types and their distributions by number and dollar value are shown in **Table 1**. Food and beverage payments were the most common, with 62,779 total payments, accounting for 75.01% of the total reported transactions. However, food and beverages accounted for only 2.46% of total reported monetary value. Food and beverages were followed in frequency by travel and lodging (15.70%); consulting fees (3.39%); and compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program (2.48%).

Based on monetary value, royalties and licensing accounted for the largest percentage of payments, 74.15%, for a total of \$73,443,003.70. However, royalties and licensing accounted for only 1.66% of the total number of payments, with the average payment being \$52,874.73, as opposed to \$38.81 for food and beverages. Consulting represented the second largest portion of total reported value (11.12%), followed by compensation for services other than consulting (5.99%) and travel and lodging (4.56%). The smallest payment reported was \$0.01 for food and beverages, and the largest payment was \$12,962,363.00 for royalties and licensing.

### Companies

In the OPD, 330 companies were identified as having made payments to physicians assigned a neurologic surgery specialty code in 2015. The average amount paid by each company was \$300,147.30, with a median of \$2177.07. The company with the largest amount of spending was Medtronic, with payments totaling \$32,011,089.59, and the company with the smallest amount of spending was Halozyne Inc. (San Diego, California, USA), with payments totaling \$5.51.

### Comparison with Previous Years

We found that 7613 physicians identified by a neurologic surgery taxonomy code received some payment from industry in 2015 compared with 7278 in 2014.<sup>4</sup> Neurologic surgery reported the second highest average total payment per physician in both 2014 and 2015, increasing from \$11,867.00 in 2014<sup>4</sup> to \$13,010.46 in 2015. According to the OPD annual report, orthopedic surgery had the highest average total payment per physician in 2014, followed by neurologic surgery.<sup>2</sup> In 2015, nuclear medicine moved to the top of the list, again with neurologic surgery as the second highest.<sup>2</sup> The numbers provided by the OPD for the average payment per physician differed from the numbers reported by both our study and that of Chao and Gangopadhyay<sup>4</sup> because the OPD included data that was marked

as delayed in publication and therefore was not publicly available for our investigations.

### DISCUSSION

Financial relationships with industry have been steadily increasing in neurosurgery.<sup>8</sup> The impact of these financial relationships on research and patient care remains unclear. In industry-sponsored research, subtle biases in study design and interpretation may arise when a sponsor stands to benefit from a positive report.<sup>1</sup> This is because any company investigating or funding an investigation of their own product inherently has a vested financial interest in the trial outcome, and this may impact the capacity for complete objectivity when conducting research.<sup>15</sup> Bekelman et al.<sup>3</sup> have demonstrated that industry-funded trials have a significantly greater chance of resulting in positive results compared with nonsponsored research. The influence of monetary relationships from industry and clinical behavior of physicians remains controversial. Payments from pharmaceutical companies to physicians have been shown to influence prescribing patterns.<sup>16</sup> Although no studies have been undertaken demonstrating a similar influence between payments from device manufacturers to surgeons and subsequent device utilization, the possibility that such payments do influence clinical behavior requires further investigation.

Disclosing financial COIs is essential for clinicians, institutions, and the public to accurately appraise claims made within a study and judge the relevance of these COIs themselves.<sup>1</sup> The OPD has provided increased transparency and incentive for neurosurgeons to more readily disclose a potential COI when publishing clinical research, as the data are now made publicly available. McDonald et al.<sup>17</sup> compared the incidence of disclosures made in the *Journal of Neurosurgery* group of publications before and after the implementation of the Sunshine Act in 2013 and found a significant increase in disclosure rates only in the *Journal of Neurosurgery: Spine*. This lack of change of COI disclosure may reflect the novelty of the OPD or difficulties in navigating the large database.<sup>18</sup>

Whereas medical specialties tend to have financial relationships with the pharmaceutical industry, surgical specialties are more likely to have involvement with industries providing instrumentation, implanted devices, and biologic materials.<sup>4</sup> We found that Medtronic contributed to almost one third of the total value of payments to neurologic surgery in 2015. Our investigations revealed that the 10 largest individual payments to physicians identified as neurosurgeons by the neurologic surgery code in 2015 were for royalties and licensing, all made by divisions of Medtronic. These findings suggest that the comparatively high average financial payment in neurosurgery is driven up by a small number of large payments for aspects of technology development. We found that the median total payment received per physician was substantially lower than the mean. These large payments, which attract attention because of their size, may represent appropriate compensation for time and intellectual property spent in these endeavors; further examination of these payments and their specific impact on patient care and research is warranted.

Our study revealed that 8 payments valued at >\$1 million were made to individual physicians identified by the neurologic surgery taxonomy code and that 11 physicians identified by this code received >\$1 million in total from industry in 2015. Although these payments were made to a very small number of physicians, they account for a disproportionate amount of the total monetary value paid out. Journal reviewers and readers and the general public might find payments of this magnitude relevant, regardless of whether or not the authors believe they are or, indeed, whether they are related to the published study or not.<sup>19,20</sup> This has implications for further research that could examine the prevalence and accuracy of payment disclosures by neurosurgeons in publications, employing the Open Payments data as a comparison. Similarly, it is equally important to note, and for journal reviewers, readers, and the public to know, that although most neurosurgeons receive some form of industry payment, for the vast majority, the amount of that payment is small and not likely to influence clinical practice and research results.

The most common type of payment to neurosurgeons by specialty code was for food and beverages. This finding is in keeping with similar studies that employed the OPD to examine industry financial relationships within other surgical subspecialties.<sup>4</sup> Greater variation exists among specialties with regard to types of payments that result in the largest dollar value.<sup>21</sup> Chao and Gangopadhyay<sup>4</sup> found that royalties and licensing accounted for the largest percentage of payment value among plastic surgeons, orthopedic surgeons, and neurosurgeons, whereas consulting fees represented the largest proportion among otolaryngologists, and speaker fees represented the largest proportion among urologists. As stated, food and beverages account for a significant majority of the individual payments to neurosurgeons and for a monetary value sufficiently low as to make it unlikely that they influence clinical or research behavior. Both the public and the profession should be reassured by this finding.

### Limitations

The Centers for Medicare and Medicaid Services OPD is currently the most comprehensive database that delineates financial relationships between industry and physicians in the United States.<sup>4</sup> However, the OPD is still relatively new, and there are a number of limitations with regard to the data and interpretation presented in this article. First, the AAMC reported 5346 active neurologic surgeons in 2015, which is considerably smaller than the 7613 neurologic surgery taxonomy codes identified within the OPD. The OPD is attempting to describe industry payments in the practice of neurologic surgery as defined by taxonomy codes as opposed to individual neurosurgeons as defined by the NPI Registry. In 2016, Babu et al.<sup>22</sup> employed the “Verify a Neurosurgeon” function on the ABNS website (<http://www.abns.org/Verify-a-Neurosurgeon>) to examine the OPD data. They found that the proportion of correctly identified ABNS neurosurgeons in OPD was 62% in 2013 and 63% in 2014. However, the OPD documents physicians who have defined their practice with the neurologic surgery taxonomy code, which includes approximately one third nonneurosurgeons.<sup>13</sup> Similarly, approximately one third of ABNS certified neurosurgeons employ a taxonomy code other than neurologic surgery to define part of their practice. This is likely because a number of

neurosurgical procedures are performed by nonneurosurgeons, such as interventional radiologists, otolaryngologists, and orthopedic spine surgeons. Similarly, not all neurosurgeons practicing in the United States are ABNS certified and thus may not be noted on the ABNS website. This method of identifying neurosurgeons within the OPD may be seen as a database limitation, as it makes it difficult to compare the OPD with other databases, such as the AAMC, ABNS, and NPI Registry. However, by representing speciality practice, as opposed to individuals, taxonomy codes may provide a more appropriate representation of industry involvement within a given speciality. Second, a method for independent verification of the accuracy of company reporting does not currently exist.<sup>9</sup> At this time, data verification is left to physicians who have the opportunity to review and dispute payments before the annual publication of the database. However, in 2015, the OPD reported that only 14 of 83,690 (0.02%) payments were disputed by physicians. Although this may reflect the accuracy of reporting in the OPD, alternative explanations for the low rate of disputes include physician unfamiliarity with the database and its dispute mechanism, frustration with the dispute process, or a perception that there is limited utility to disputing a low monetary value payment, among others. Third, the database does not include nonmonetary items, such as free samples or devices, both of which have monetary value.<sup>20</sup> Fourth, the database spreadsheets are difficult to navigate, and the full file size precludes downloading the dataset to Excel. As a program that is advertised as allowing for further transparency among the general population, it falls short of being a readily accessible database for the public.<sup>18</sup> Finally, although the database is comprehensive, it is limited to payments made by U.S. manufacturers and group purchasing organizations, and an analogous database does not exist at the present time outside the United States. The database is also limited to physician-industry relationships and does not address institution-industry relationships.<sup>22</sup> Therefore, in the interest of transparency and to more fully understand potential COIs in the rest of the world, we advocate for a more comprehensive database of industry payments to physicians and institutions worldwide.

### CONCLUSIONS

Many U.S. physicians identified by the neurologic surgery taxonomy code have industry financial relationships documented in the OPD. This method of identifying physicians may represent a paradigm shift as the procedures performed by various specialties, such as neurosurgery and interventional radiology, begin to merge, and industry influence in a particular field becomes better identified by specialty practice, rather than by the individual specialty. The vast majority of individual payments are of a relatively small monetary value and consist largely of payment for food and beverages. A substantial proportion of the overall monetary value of these relationships is driven by royalty and licensing payments to a small number of physicians, skewing the average payment upward. These payments may represent appropriate compensation for intellectual property and time spent on device development. The OPD provides a novel vehicle for increased transparency in industry-physician relationships and will facilitate the interpretation of research in light of financial

conflicts of interest. Further research is warranted into the nature of these relationships and their impact on clinical research, clinical practice, and patient care.

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