Understanding orthopaedic surgery industry alignment and financial relationships through the Sunshine Act

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Abstract With increasing healthcare cost and changing demographics of the country, organisations such as the Centers for Medicare and Medicaid Services are implementing innovative programmes to improve the value of healthcare. These programmes require physician hospital alignment. To understand the amount of physican-industry alignment represented by industry provider payments, Medicare initialised the public release of Sunshine Act data in September 2013. The goal of this study was to 1) ascertain the industry-physician alignment by understanding the dollar amount and most common reasons for industry payments to orthopaedic subspecialists, and 2) ascertain which medical companies pay the largest sums of money to each orthopaedic subspecialty. The authors downloaded and analysed the publicly available sunshine data for the twelvemonth period from January-December 2015. Only orthopaedic surgeons were analysed, all other physicians were excluded. Adult reconstructive specialists had the highest amount of industry alignment as they received the highest mean total amount of payment $($2,769 \pm 231)$ while paediatric specialists received the lowest $($479 \pm 42)$. Across all subspecialties, food and beverage related costs contributed to the largest proportion of number of industry payments while travel and lodging related costs were unanimously the second most prevalent type of payment. Furthermore, the mean payment was highest for royalty or licensure. When involvement of each medical company to industry payments was assessed, the company Stryker was noted to be one of the top five payment contributors for all orthopaedic subspecialties. This paper illustrates that while adult reconstructive orthopaedic surgeons receive the highest mean total payments from industry, the most prevalent and highest paying types of financial relationships were relatively homogenous across the seven orthopaedic subspecialties analysed. Thus, all orthopaedic subspecialties had financial relationships with industry which promoted alignment. Furthermore, the top five industry players contributed to a significant portion of total number of financial relationships among all subspecialties, with Stryker being the most predominant company.

KEYWORDS: orthopaedic surgery, Sunshine Act, industry payments, Medicare and Medicaid Services

INTRODUCTION

In an effort to control the unsustainable rise in healthcare costs, the Federal Government has mandated that by 2018, 50 per cent of Medicare reimbursement be for alternative payment models based on value rather than volume. These programmes include bundled payments for services and accountable care organisations (ACOs). Both of these payment models rely on physician-hospital alignment to achieve their goals of improved outcomes and decreased costs. Traditionally, physicians, especially device-using orthopaedic surgeons have been more closely aligned with industry rather than hospitals. As a part of the Affordable Care Act of 2010, the Physicians Payment Sunshine Act (PSSA) requires full public disclosure of financial transfers from all drug, medical device, and biologics companies to physicians and teaching hospitals. The impetus for this was to increase the transparency of financial support between industry and doctors, and simultaneously reduce physician industry alignment.^{1,2} The initial release of the Sunshine Act Data by the CMS was made on 30 September, 2014, with a second release on 19 December, 2014, and includes 4.4 million individual payments, worth US\$3.5bn to 546,000 physicians and 1,360 teaching hospitals.³

Orthopaedic surgery is a device and implant driven specialty. There is a long tradition of surgeon-industry collaboration on implant and instrument development, which has greatly benefitted our patients. This has fostered physician-industry alignment.⁴ Prior reports have suggested that orthopaedics is one of the leading medical specialties in terms of industry payments, and recent data examining the Sunshine Act database noted that orthopaedic surgeons accounted for 3.5 per cent of physicians represented while receiving almost 20 per cent of total payments.^{3,5,6} These payments are a surrogate for physician-industry alignment. Additionally, these studies also suggested that large proportional discrepancies existed among the amount of funding received by top earners, and the median payment to orthopaedic surgeons were comparable to other medical and surgical specialties. While the Sunshine Act database has given a new glimpse into the financial ties and alignment present in orthopaedics with respect to other specialties, there is a paucity of information regarding the effect of subspecialty interest on industry support.7

The goal of this study is to 1) measure physician industry alignment by determining the dollar amount and most common reasons for industry payments to orthopaedic subspecialists, and 2) determine which medical companies provide the largest sums of money to each orthopaedic subspecialty.

PATIENTS AND METHODS Data Source and Examined Variables

We measured alignment by analysing the Sunshine Act Open Payment general payments database, which we accessed on 1st August, 2016 through the CMS website (https:// www.cms.gov/openpayments/).This database is publicly available and contains records of all payments made from medical manufacturers to hospitals and physicians within a twelvemonth interval (1st January, 2015 and 31st December, 2015). Medical companies report payment specific data directly to the CMS, and 45 days are allotted for any potential disputes or inaccuracies that physicians may report.

Examined Variables and Statistical Analysis

Physicians were chosen if and only if an orthopaedic physician specialty was indicated. Variables obtained and recorded from the data set included orthopaedic subspecialty, the total dollar amount paid to the physician including the value of each individual relationship, the number of and type of financial relationship, and the name of each company giving out payments. During the twelve-month time period, the total mean amount of payment to each subspecialty was recorded and compared using an Analysis of Variance (ANOVA) testing with Bonferonni correction.

We recorded the total number and total amount of US dollars allotted for of each type of industry payment for each subspecialty. Additionally, we determined the top five most prevalent medical and device companies in terms of number of financial relationships and transactions for each orthopaedic subspecialty.

RESULTS

A total of 22,121 orthopaedic subspecialists were identified, encompassing a total of 293,747 financial payments. Orthopaedic surgery subspecialties included Adult Reconstructive (n = 765, 3.5 per cent), Foot and Ankle (n = 641, 2.9 per cent), Hand Surgery (n = 1,367, 6.2 per cent), Orthopaedic Surgery of the Spine (n = 1,495, 6.8 per cent), Orthopaedic Trauma (n = 506, 2.3 per cent), Paediatric Orthopaedic Surgery (n = 331, 1.5 per cent), Sports Medicine (n = 1,985, 9.0 per cent), and 'unspecified' specialty of orthopaedic surgery (n = 15,031, 67.9 per cent).

In the twelve-month period between 1st January, 2015 and 31st December, 2015, adult reconstructive specialists received the highest mean total amount of payment (US\$2,769 \pm 231) while paediatric specialists received the lowest (US\$479 \pm 42, p < 0.05 for all post hoc comparisons) (Table 1).

Across all subspecialties, food and beverage contributed to the largest proportion of number of industry payments (60 to 76 per cent), while travel and lodging was unanimously the second most prevalent type of payment (13 to 23 per cent) (Table 2). Furthermore, the mean payment was highest for royalty or licensure (US\$4,438 to US\$50,993, p < 0.05 for all post hoc comparisons) across all subspecialties, while payment for serving as a speaker contributed to the second highest mean dollar amount for five out of seven subspecialties (Table 3).

When involvement of each medical company to industry payments was assessed, the company Stryker was noted to be one of the top five payment contributors for all orthopaedic subspecialties, and the top five most prevalent companies encompassed a significant proportion of the total number of financial contributions for each subspecialty (40 to 80 per cent) (Table 4).

DISCUSSION

Our data demonstrates several essential points that illustrate the amount of physician-industry alignment and detail the effect of subspecialty interest on industry alignment. First, adult reconstructive orthopaedic surgeons appeared to receive the highest mean dollar amount (US\$2,769) while spine surgeons received the second highest amount (US\$2,697) from medical companies compared to all other orthopaedic subspecialties. In contrast, paediatric orthopaedic surgeons make the least amount of money from industry ties (US\$479). This may be explained through the significant use of implantable devices within these fields (eg, arthroplasty implants, plates, screws, cages, etc) and assistive technology (eg, C-arm, computer-assisted surgery, etc) in spine surgery and arthroplasty, while paediatric orthopaedic surgeons perform significantly

more soft-tissue procedures.⁸⁻¹⁰ Consequently, the alignment and opportunity for royalties, licensure and consulting fees is likely greater for the former.

While the Sunshine Act database details the industry-surgeon relationships and alignment within orthopaedic surgery, its inherent limitations must be taken into account. First, the five-month data collection period is relatively short and only provides a small view into the financial ties between orthopaedic surgeons and the medical and device industry. Surgeons who received payments outside this time interval may have been completely missed by this dataset, and it is also possible that physicians prematurely discontinued their financial ties with these companies due to the onset of public financial disclosure. Another limitation is the fact that orthopaedic surgeons with 'unspecified' subspecialty training are included in the Sunshine Act database, which encompassed a significant portion of total orthopaedic surgeons within the dataset. It is possible that had these physicians been included if more specific subspecialty details were recorded, our results may have been different. Finally, some financial relationship details, such as research on new products, payments to nurse practitioners and physician assistants in orthopaedic practices, the exact nature of consulting and royalty payments, and financial R&D contract relationships were excluded from the database and hence could not be analysed in our study.

Physician-industry alignment is engendered through a variety of industry payments. While the most common types of industry payments were for food and beverage, and travel and lodging across all seven examined orthopaedic subspecialties, the largest mean payments to surgeons were for royalties and licensing followed by serving as a speaker for all and six of the seven subspecialties respectively. While some previous studies did not show as significant contribution from royalties, potentially due to reporting inaccuracies and incomplete datasets, our results are in

Orthopaedic Subspecialty	Mean Total Amount of Payment (USD)
Sports Medicine	\$1053 ± 139
Pediatrics	\$479 ± 42
Trauma	\$839 ± 65
Spine	\$2697 ± 960
Hand	\$503 ± 37
Foot and Ankle	\$767 ± 67
Adult Reconstructive	\$2769 ± 231
Overall	\$1392 ± 111

Table 1: Mean amount of payment per orthopaedic subspecialty

agreement with previous analyses of the CMS Sunshine Act database. ^{3,5,6,11,12} Although with these substantial royalty payments, there are obvious concerns for clinical conflicts of interest, the contributing roles that physicians have served with respect to intellectual property continue to contribute significantly to the continued innovation in orthopaedics. Thus, patients do benefit from this form of physician-industry alignment. Furthermore, while compensation for the time spent on intellectual property development by physicians is typically viewed favourably, expenses for food, travel and other gifts are often viewed negatively by patients, as this form of alignment does little to benefit patients.^{13,14} Interestingly, the most common and largest types of industry ties are relatively homogenous across the seven orthopaedic subspecialties examined.

Furthermore, an important result to note from our data is that the top five medical and device companies for each subspecialty contribute a significant proportion of total number of financial transactions throughout all orthopaedic subspecialties. This was especially the case within adult reconstructive (70 per cent of all financial transactions) and orthopaedic trauma (80 per cent). While a few substantial players dominated industry ties, Stryker was shown to be one of the largest payment contributors and was within the top five most prevalent companies across all seven subspecialties. While the sales data for these top manufacturers is limited, Stryker reported US\$9.9bn in sales in 2015, which have been steadily increasing year by year in their most recent annual report (http://www.stryker .com/files/SYK_AR15_Narrative_v10b .pdf). Depuy Synthes and Smith & Nephew were the second and third most dominant players (top five contributors for six and four out of the seven subspecialties respectively). Hence, although joint arthroplasty, spine and orthopaedic trauma subspecialties are typically noted for their predominant use of implants and ties with a few big industry players, our results show that only a few companies dominate the majority of financial transactions across all orthopaedic subspecialties. The implications of this data are unclear as there is no evidence to suggest that these results may deter physicians from receiving industry payments, and whether that may subsequently lead to a deleterious effect on medical innovation and development.¹⁵ However, it cannot be debated that traditionally these payments have resulted in a long tradition of physician-industry alignment.

The incorporation of alternative payment models as mandated by the Federal Government will require increased physicianhospital alignment. Frequently, physicianindustry alignment is at odds with physicianhospital alignment. The release of the Sunshine Act dataset by the CMS allows for more transparency in the financial industry ties between medical manufacturers and orthopaedic surgeons. This data helps us to

Nature of Barmont			Orthol	oaedic Subspecialty			
	Adult Reconstructive	Foot and Ankle	Hand	Spine	Trauma	Pediatric	Sports
Charitable Contribution	1 (0%)	0 (%0) 0	3 (0%)	10 (0%)	0 (0%)	3 (0%)	2 (0%)
Payment for serving as a speaker	12 (0%)	6 (0%)	3 (0%)	25 (0%)	1 (0%)	(%0) 0	23 (0%)
Consulting Fee	1204 (8%)	548 (7%)	298 (3%)	2044 (7%)	358 (6%)	109 (5%)	772 (4%)
Current or prospective ownership or investment interest	12 (0%)	(%0) 0	(%0) 0	33 (0%)	(%0) 0	4 (0%)	8 (0%)
Education	309 (2%)	174 (2%)	320 (3%)	288 (1%)	86 (1%)	43 (2%)	1196 (6%)
Entertainment	1 (0%)	4 (0%)	6 (0%)	29 (0%)	0 (0%)	0 (0%)	0 (0%)
Food and Beverage	8819 (60%)	5348 (68%)	7029 (76%)	21757 (69%)	4360 (67%)	1511 (74%)	15065 (70%)
Gift	2 (0%)	0 (0%)	57 (1%)	94 (0%)	6 (0%)	0 (0%)	19 (0%)
Grant	1 (0%)	3 (0%)	2 (0%)	11 (0%)	4 (0%)	2 (0%)	40 (0%)
Honoraria	7 (0%)	11 (0%)	25 (0%)	69 (0%)	8 (0%)	0 (0%)	17 (0%)
Royalty or License	631 (4%)	212 (3%)	231 (2%)	1437 (5%)	81 (1%)	69 (3%)	299 (1%)
Travel and Lodging	3458 (23%)	1322 (17%)	1180 (13%)	5295 (17%)	1468 (23%)	296 (14%)	3506 (16%)
Total	14791	7810	9307	31435	6485	2055	21572

 Table 2:
 Total number of industry payments

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Table 3: Mean amount of paymen	nt by type of payment						
			Ortho	paedic Subspecialty			
Nature of Fayment	Adult Reconstructive	Foot and Ankle	Hand	Spine	Trauma	Pediatric	Sports
Charitable Contribution	\$1250 ± N/A	N/A	\$108 ± 4	\$26,100 ± 5429	N/A	\$49 ± 0	\$100 ± 0
Payment for serving as a speaker	\$1268 ± 743	\$3732 ± 381	\$2131 ± 264	\$4443 ± 230	\$4679 ± 433	\$1306 ± 527	\$3136 ± 208
Consulting Fee	\$5031 ± 191	\$ 2406 ± 160	\$3672 ± 235	\$4131 ± 109	\$6113 ± 333	\$3668 ± 386	\$3413 ± 154
Current or prospective ownership or investment interest	\$33,804 ± 11,314	N/A	N/A	\$53,825 ± 13,027	N/A	\$1097 ± 1063	\$2079 ± 455
Education	\$226 ± 146	\$1154 ± 108	\$493 ± 42	\$ 274 ± 73	\$ 328 ± 106	\$511 ± 120	\$657 ± 42
Entertainment	\$34 ± N/A	\$104 ± 29	\$663 ± 374	\$96 ± 15	N/A	N/A	N/A
Food and Beverage	\$49 ± 1	\$46 ± 1	\$45 ± 1	\$44 ± 0	\$53 ± 1	\$52 ± 1	\$42 ± 0
Gift	\$4628 ± 4492	N/A	\$106 ± 10	\$370 ± 254	\$6388 ± 6234	N/A	\$2153 ± 986
Grant	\$8060 ± N/A	\$400 ± 50	\$1021 ± 0	\$5530 ± 3399	\$1381 ± 105	\$8063 ± 1938	\$2938 ± 515
Honoraria	\$4636 ± 764	\$804 ± 53	\$1104 ± 88	\$137 ± 57	\$1134 ± 330	N/A	\$2720 ± 845
Royalty or License	$50,124 \pm 5034$	\$14,614 ± 2167	\$9820 ± 1261	\$48,381 ± 20,970	\$22,829 ± 4056	\$4438 ± 741	\$50,993 ± 9572
Travel and Lodging	\$381 ± 15	\$322 ± 15	\$399 ± 23	\$359 ± 11	\$408 ± 22	\$448 ± 51	\$334 ± 11
Note prices in USD							

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		Adult Reco	nstructive		
Company	n	%	Total Contribution of Top 5 Payers		
Stryker	4133	28%			
Zimmer Biomet Holdings	2905	20%			
DePuy Synthes	1760	12%	70%		
Smith & Nephew	1157	8%			
Horizon Pharma	434	3%			
		Foot and	l ankle		
Company	n	%	Total Contribution of Top 5 Payers		
Wright Medical Technology	1764	23%			
Stryker	1332	17%			
Arthrex	831	11%	61%		
Zimmer Biomet Holdings	501	6%			
Smith & Nephew	329	4%			
		Han	d		
Company	n	%	Total Contribution of Top 5 Payers		
Stryker	1469	16%			
Zimmer Biomet Holdings	688	7%			
Horizon Pharma	588	6%	40%		
DePuy Synthes	515	6%			
AxoGen	496	5%			
		Spir	ne		
Company	n	%	Total Contribution of Top 5 Payers		
Medtronic	4236	13%			
DePuy Synthes	3974	13%			
Stryker	3726	12%	55%		
NuVasiv, Inc	3658	12%			
LDR Spine USA, Inc	1794	6%			
Trauma					
Company	n	%	Total Contribution of Top 5 Payers		
Stryker	1970	30%			
Smith & Nephew	1216	19%			
DePuy Synthes	1183	18%	80%		
Zimmer Biomet Holdings	687	11%			
Mallinckrodt LLC	124	2%			
		Pedia	trics		
Company	n	%	Total Contribution of Top 5 Payers		
DePuy Synthes	401	20%			
Stryker	231	11%			
Smith & Nephew	223	11%	59%		
Medtronic	214	10%			
OrthoPediatrics Corp.	148	7%			

Table 4: Top five payers by orthopaedic subspecialty

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Table 3. Top five payers by orthopaedic subspecialty (Continued)					
Sports					
Company	n	%	Total Contribution of Top 5 Payers		
Smith & Nephew	2788	13%			
DePuy Synthes	2489	12%			
Stryker	2494	12%	55%		
Arthrex	2145	10%			
Zimmer Biomet Holdings	1998	9%			

 Table 5:
 Top five payers by orthopaedic subspecialty (Continued)

understand the magnitude of and reasons for physician-industry alignment. Our results show that while adult reconstructive orthopaedic surgeons receive the highest mean total payments from industry, the most prevalent and highest paying types of financial relationships were relatively homogenous among the seven orthopaedic subspecialties analysed. Furthermore, the top five industry players contributed to a significant portion of total number of financial relationships among all subspecialties, with Stryker being the most predominant company.

AUTHOR'S NOTE Statement of Authorship

All of the following authors contributed significantly to the development of this manuscript through data analysis, manuscript preparation, or analysis and editing of the final manuscript.

Conflicts of Interest and Source of Funding

No conflict of interest or sources of funding exist for any of the authors listed for the purpose of this study.

Ethical Approval

No human or animal subjects were examined in this study. The Centers of Medicare and Medicaid Services (CMS) Sunshine Act Open Payment general payments database does not require institutional review board (IRB) approval. De-identified patient information is freely available to the general public. This implements the protections afforded by the Health Insurance Portability and Accountability Act (HIPAA) of 1996.

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