Pharmaceutical Marketing Expenditures in the District of Columbia, 2015



Government of the District of Columbia Department of Health Health Regulation and Licensing Administration

Prepared by Milken Institute School of Public Health The George Washington University

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This report was submitted to the District of Columbia Department of Health on February 28, 2017.

Executive Summary

Overview

This report discusses pharmaceutical marketing expenditures in the District of Columbia in 2015. Pharmaceutical manufacturers are required to report expenditures to the District of Columbia Department of Health (DOH), as required by the AccessRx Act of 2004. The report is supplemented with data reported to the federal government through the Centers for Medicare and Medicaid's (CMS) Open Payments system. Open Payments collects information about gifts from pharmaceutical and medical device manufacturers to physicians and teaching hospitals. Reporting requirements can be found in Appendices A and B.

Pharmaceutical marketing totaled \$96.1 million for all gift, advertising, and aggregate employee expenses reported in the District of Columbia in 2015. One hundred and forty pharmaceutical manufacturers reported to AccessRx, and 438 pharmaceutical and medical device manufacturers reported to Open Payments; altogether, 463 individual companies reported to one or both programs. It bears noting that \$80.1 million was reported to AccessRx and \$16 million was reported to Open Payments.

This report discusses pharmaceutical marketing as a whole and analyzes marketing by subgroups, including physicians, nurses, teaching hospitals, and organizations. This report also provides information on the quality of company submissions and makes recommendations for the reporting and utility of data in future years.

Key Findings

In 2015, pharmaceutical and device manufacturers reported a total of \$96.1 million in gift, advertising, and aggregate (detailing) expenses in the District of Columbia. *Aggregate (Detailing) Expenses* accounted for \$66.2 million (68.9% of the total expenses), *Gift Expenses* for \$24.4 million (25.3%), and *Advertising Expenses* for \$5.6 million (5.9%).

Between 2014 and 2015:

- Total expenditures increased by \$5 million (5.4%), from \$91.1 million in 2014 to \$96.1 million in 2015.
- Aggregate (Detailing) Expenses increased by \$5.5 million (9.1%), from \$60.7 million in 2014 to \$66.2 million in 2015.
- Gift Expenses increased by \$1.8 million (8.0%), from \$22.6 million in 2014 to \$24.4 million in 2015. This includes \$8.4 million reported to AccessRx as gifts to organizations, other healthcare facilities (including non-teaching hospitals), and non-physician health care providers, and \$16 million reported to Open Payments as gifts to physicians and teaching hospitals.
- *Advertising Expenses* decreased by \$2.3 million (29%), from \$7.9 million in 2014 to \$5.6 million in 2015.

- Gifts to Individual Recipients totaled \$13.8 million.
 - *Physicians*, reported to Open Payments, received \$13.1 million in gifts (95% of the total value of gift expenses).
 - The 25 physicians who received the highest total gift values, received a total of \$5.1 million. This accounted for 39.3% of all gifts to physicians and 37% of total individual gifts.
 - Advanced Practice Nurses (nurse-practitioners, nurse-midwives, and nurse-anesthetists, all of whom can prescribe drugs) received a total of \$317,118, or 2.3% of individual gifts.
 - Registered Nurses received \$122,312, Physician Assistants received \$68, 696, Pharmacists received \$33,348, Other Healthcare Providers received \$108,187, and Other Recipients received \$40,533 in gift payments. This accounted for <1% of the total value of individual gifts.
 - Companies paid more than \$5.8 million in *Speaking* fees to individual healthcare providers in 2015. Speaking payments made up the largest proportion of total value of gifts given to both *Physicians* and *Advanced Practice Nurses*, with *Physicians* receiving a median speaking fee of \$2,000 and *Advanced Practice Nurses* receiving a median speaking fee of \$1,400.
- *Gifts to Non-individual* recipients totaled \$10.6 million.
 - Teaching Hospitals accounted for the largest portion with \$4.1 million in gifts (38.2%). This included \$3.8 million reported to Open Payments and an additional \$247,663 reported to AccessRx.
 - Washington Hospital Center received the highest total value of gifts (\$2.8 million) accounting for 73.2% of all gifts to Teaching Hospitals.
 - Academic medical centers received the next largest gift totals among teaching hospitals: Georgetown University Hospital (\$601,264), George Washington University Hospital (\$184,592), and Howard University Hospital (\$142,059).
 - The remaining teaching hospitals received less than \$50,000 in total gifts, which included Children's Hospital (\$45,577), Providence Hospital (\$23,164), National Rehabilitation Hospital (\$16,500), and Sibley Memorial Hospital (\$6,146).
 - Professional Organizations accounted for \$2.3 million in gifts (22.0%). This was a notable decrease from the \$4.4 million they received in 2014, when they accounted for 40% of total non-individual gifts.
 - Advocacy Organizations and Clinical Organizations accounted for \$1.7 million (15.8%) and \$1.1 million (10.5%) respectively. This was an increase in gift value to Clinical Organization with \$263,550 in 2014.
 - The remaining *Non-Individual Recipients* accounted for less than 6% each of total value. These included *Universities* (\$567,151), *Continuing Medical Education Organizations* (\$97,368), *Other Organizations* (\$351,763), and *Other, Unnamed Recipients* (\$418,700).

Recommendations for AccessRx

After analyzing 2015 pharmaceutical marketing data, we make the following recommendations. These proposed changes would strengthen the implementation of the original goals of AccessRx and would make the statute more consistent with the federal Open Payments reporting system. Some suggestions would require amending the AccessRx Act.

1. Improve instructions on data requirements in order to improve the quality of data received by AccessRx.

Manufacturers appear to be confused about some aspects of reporting to AcccessRx; gaps and inconsistencies in reporting are common and lead to limitations in data analyses. Many companies continue to report physician gifts that should only be reported to Open Payments to both AccessRx and Open Payments, resulting in double counting of some gifts. Other errors include reporting gifts to physician's offices and staff as gifts to individual physicians and gifts to individual physicians being included in non-individual gift totals to their offices.

New strategies to improve reporting accuracy should be put in place to ensure that the District receives reports that accurately reflect spending patterns. A clarification of reporting instructions is necessary to further specify when to exclude reporting gifts to physicians to AccessRx. Specifically, further guidance in needed on how to properly report gifts to physicians' offices and staff without including individual gifts to physicians in these totals.

Transitioning AccessRx to an online reporting system would make reporting to AccessRx much easier. An online system would limit responses in select columns to options detailed in the instructions, would only accept correctly reported responses, and would require companies to fill out all fields. This could also increase efficiency in reporting and make it more convenient for companies, as well for researchers collecting and organizing data.

2. Continue to collect all required AccessRx information, while utilizing Open Payments data to complement and conduct unique analyses of pharmaceutical marketing in the District of Columbia.

DC DOH maintains the most comprehensive databases on pharmaceutical marketing activity of any jurisdiction in the United States. AccessRx provides unique information to the District to explore pharmaceutical marketing practices, including millions in spending on aggregate salaries of detailing staff, advertising, and gift expenses not exposed by the federal Open Payments system. By analyzing gifts to physicians and teaching hospitals reported to Open Payments in concert with gifts to nurses, physician assistants, and other expenses reported only to AccessRx, the District's analysis of gift trends provides information that cannot currently be analyzed by any other state or federal entity. With a growing national focus on healthcare transparency, maintaining reporting requirements allows the DC DOH to continue to analyze changing trends and assess the impact on healthcare.

3. Make all reports submitted pursuant to the AccessRx Act publicly available, consistent with the Federal Open Payments system.

With data on gifts to physicians and teaching hospitals now publicly available by the Open Payments system, it would be appropriate to also make the information collected in the AccessRx system publicly available. Currently, the database containing AccessRx data is developed each year for use solely by the Department of Health, but the AccessRx Act requires that it remain confidential. In the interest of informed healthcare decision making, patients should have access to information about marketing efforts that affect their health care providers, clinical settings, and health-related organizations. This would also streamline comparative analyses of the two databases.

4. Require "product marketed" information for gift expenses, consistent with Federal Open Payments requirements.

Unlike Open Payments, the District does not require reports to specify which product is being marketed. Requesting "product marketed" information for gift expenses reported to the AccessRx system would help researchers calculate how much companies spend on marketing specific drugs, and reports of this information could also help patients make more informed decisions about their healthcare, such as selecting a generic version of a drug or asking questions of a provider who suggests a new medication. This would also allow researchers to compare how products are marked in the District and nationally.

5. Require reporting by device manufacturers, consistent with Federal Open Payments requirements.

AccessRx requires reporting by any "manufacturer or labeler of prescription drugs dispensed in the District that employs, directs, or utilizes marketing representatives in the District," resulting in the reporting of 153 companies in 2014. Comparatively, Open Payments requires manufacturers of "drugs, devices, biologicals, or medical supplies" to report expenses, which included 486 companies in 2014. As in previous years, we recommend that AccessRx requirements should be expanded to provide a more complete picture of marketing practices in the District and to remain consistent with the Open Payments system.

I. Summary of Pharmaceutical Marketing Expenditures

In 2015, pharmaceutical and medical device companies reported spending \$96.1 million* on marketing, including gifts, advertising, and aggregate (detailing) expenses in the District of Columbia.

One hundred forty pharmaceutical manufacturers and labelers reported \$80.1 million in marketing expenditures to the DC AccessRx program.

Four hundred thirty-eight pharmaceutical and device manufacturers reported spending \$16 million on gifts to physicians and teaching hospitals in the District to the CMS Open Payments system.

Some companies reported only to AccessRx; others reported only to Open Payments. After removing overlapping data, a total of 463 unique pharmaceutical and device companies reported marketing expenses in the District of Columbia. Two companies reported physician gifts to AccessRx that were not reported to Open Payments as are required.

Total Expenses

Table 1 displays expenses in each category from 2006 to 2015. Reporting beginning in 2013 and 2014 includes data collected from Open Payments. There was a modest increase in the total reported expenditures in 2015 from 2014.

Pharmaceutical Marketing Expenditures by Type of Expenditure					
Reporting Year	Gift Expenses	Advertising Expenses	Aggregate (Detailing) Expenses	Grand Total	
2015	\$ 24,362,166	\$5,631,108	\$66,225,062	\$96,103,450	
2014	\$22,562,396	\$7,903,100	\$60,671,713	\$91,137,209	
2013	\$30,686,134	\$5,673,841	\$65,158,392	\$101,518,367	
2012	\$30,487,486	\$5,445,732	\$61,537,192	\$97,470,410	
2011	\$18,859,946	\$6,879,230	\$57,815,759	\$83,554,935	
2010	\$21,010,822	\$6,791,214	\$57,551,911	\$85,353,946	
2009	\$22,034,979	\$7,569,036	\$66,483,622	\$96,087,637	
2008	\$27,090,335	\$8,108,052	\$101,425,020	\$136,623,408	
2007	\$31,337,226	\$10,253,274	\$116,573,964	\$158,164,463**	
2006	\$34,440,072	\$10,890,983	\$99,889,040	\$145,220,094	

 Table 1:

 Pharmaceutical Marketing Expenditures by Type of Expenditure

^{*} This total does not include \$30.3 million in gifts reported to AccessRx from a pharmaceutical company to a single Federal government agency; because these payments are outside the scope of AccessRx's directive, they have been excluded from all analyses.

^{**}The apparent increase in total expenditures between 2006 and 2007 is likely due to improvements in the reporting system rather than an actual increase in spending.

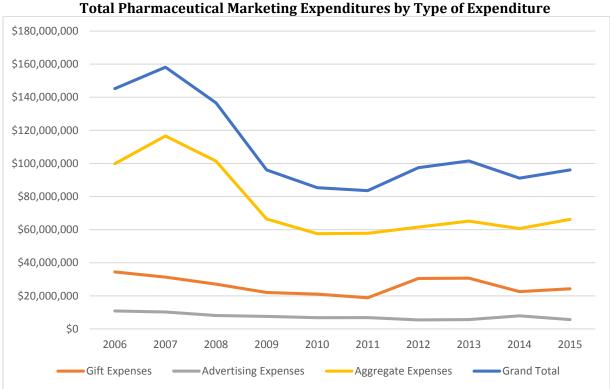
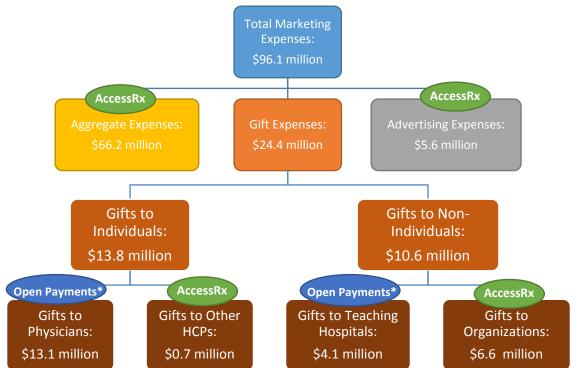


Figure 1: Total Pharmaceutical Marketing Expenditures by Type of Expenditure

Figure 2: Breakdown of Pharmaceutical Marketing Expenditures in DC in 2015



*Companies are required by federal law to report gifts to physicians and teaching hospitals to Open Payments. Some payments to these categories are still reported to AccessRx and are included in these totals.

Aggregate (Detailing) Expenses

The District of Columbia is the only jurisdiction in the United States that gathers information on money spent on salaries of drug representatives and other personnel involved in marketing. In the District, pharmaceutical companies spent \$66,225,062 in salaries and other expenses for personnel involved in marketing drugs in Washington DC. This category consistently represents the largest proportion of marketing expenses.

One hundred twenty-six companies reported \$66.2 million in *Aggregate Expenses* in 2015. Aggregate or detailing expenses are the salaries and other expenses for employees and contractors engaged in marketing activities in DC. *Aggregate (Detailing) Expenses* represent more than two-thirds of total marketing expenses. Only 14 of the 140 companies that reported to AccessRx reported no aggregate (detailing) expenses.

Total Reported Value	Number of Companies	% of Total Number	Total Value	% of Total Value
More than \$1,000,000	14	10%	\$47,113,526	71.1%
\$500,001 - \$1,000,000	12	8.6%	\$9,418,962	14.2%
\$250,001 - \$500,000	13	9.3%	\$4,135,364	6.2%
\$100,001 - \$250,000	20	14.3%	\$3,327,349	5.0%
\$25,001 - \$100,000	38	27.1%	\$1,945,575	2.9%
\$1 - \$25,000	29	20.7%	\$284,287	0.4%
No Reported Costs	14	10.0%	_	
Total	140	100.0%	\$66,225,062	100.0%

Table 2: Distribution of Aggregate (Detailing) Expenses in DC

Information on detailing costs is highly relevant because drug representative visits ensure that physicians choose the newest, most expensive drugs, whether or not those drugs are superior to older, less expensive drugs. Pharmaceutical companies spend 70% or more of their sales and marketing budgets on sales force expenditures because drug representatives are so effective. The return on investment for promotion of top-selling drugs is \$11.60 for each dollar spent on detailing.¹

Drug representatives earn substantial salaries. In 2016, the average pharmaceutical sales rep earned a total of \$122,107 (median: \$115,000); specialty drug representatives earned \$138,150 (median: \$125,000). In 2016, the average base salary for drug representatives was \$90,862 (median: \$85,000); for specialty representatives, average base salary was \$97,784 (median: \$95,000).² The difference between baseline and total salaries - about a quarter of total salaries - is primarily due to bonuses that drug representatives receive based on how much of targeted drugs are sold in their territory.

¹ Symonds, Gerhard. A Real Return on Investment: Which marketing channel yields the best ROI? Pharmaceutical Executive Europe. Feb 01, 2008. http://www.pharmexec.com/real-return-investment#a

² MedReps 2016 Pharmaceutical Sales Salary Report https://www.medreps.com/medical-salescareers/pharmaceutical-sales-salary-report/

Aggregate expenses also included other members of sales and marketing teams. Drug representatives were variously called Pharmaceutical Sales Representative, Pharmaceutical Detailer, Clinical Sales Specialist or Specialty Sales Representative. Supervisors of drug representatives were variously called Regional Sales Director, Territory Manager, or Senior Territory Manager. Medical Science Liaison (MSLs) salaries were also reported; these are physician or pharmacist employees of pharmaceutical companies that answer questions from prescribers that drug representatives are not allowed to answer. Other employee titles reported included Area Business Manager, Regional Account Manager, Institutional Accounts Manager, and Key Account Manager.

Gift Expenses

Four hundred forty-eight companies reported *Gift Expenses* totaling \$24.4 million in 2015. *Gift Expenses* include gifts to *Individual Recipients* (usually healthcare providers) and *Non-Individual Recipients* (hospitals and healthcare organizations). Gifts to physicians are required under federal law to be reported to Open Payments, and gifts to all other *Individual Recipients* are required under DC law to be reported to AccessRx. Gifts to teaching hospitals are to be reported to Open Payments while gifts to organizations are to be reported to AccessRx.

Eighty-five pharmaceutical companies reported \$8.4 million in gifts to AccessRx under *Gift Expenses*. This includes payments ranging from less than \$1 to \$300,000, with a median gift value of \$70.

Four hundred thirty-eight pharmaceutical and device manufacturers reported \$16 million to Open Payments. In Open Payments, *Gift Expenses* ranged from less than \$1 to \$375,000, with a median gift value of \$22.

The top 10% of companies (with highest value of gifts) gave more than 85% of the value of gifts in DC. The 365 companies who reported gift expenses less than \$25,000 accounted for 75% of all companies who reported but only 5.6% of the total value of gifts. Fifteen companies reported no gift expenses to either AccessRx or Open Payments.

Distribution of Gift Expenses in DC					
	Number of	% of Total		% of Total	
Total Reported Value	Companies	Number	Total Value	Value	
More than \$1,000,000	2	0.4%	\$5,685,329	23.3%	
\$500,000 - \$999,999	8	1.7%	\$5,645,430	23.2%	
\$250,000 - \$499,999	17	3.7%	\$6,018,783	24.7%	
\$100,000 - \$249,999	20	4.3%	\$3,410,255	14.0%	
\$50,000 - \$99,999	20	4.3%	\$1,341,993	5.5%	
\$25,000 - \$49,999	25	5.4%	\$913,223	3.7%	
\$10,000 - \$24,999	47	10.2%	\$794,796	3.3%	
\$1,000 - \$9,999	123	26.6%	\$499 <i>,</i> 855	2.1%	
\$1-\$999	186	40.2%	\$52,504	0.2%	
No Reported Costs	15	3.2%	-	-	
Total	463	100.0%	\$24,362,166	100.0%	

Table 3: Distribution of Gift Expenses in DC

Advertising Expenses

Sixty-three pharmaceutical companies reported \$5.6 million in *Advertising Expenses* in 2015 to AccessRx. This is a sizable decrease of \$2.3 million from the \$7.9 million reported in 2014. *Advertising Expenses* include only local - not national - advertising expenditures. These estimates provided by companies may not be reliable because there is considerable variability among companies in the method of estimating advertising expenses in DC. It is unknown, for example, whether companies reported advertising that only occurred in DC or whether reported amounts include some portion of national advertising.

The majority of companies that reported any *Advertising Expenses* (60% or 38 companies) spent \$25,000 or less; yet these companies accounted for only 4.0% of the total value of advertising expenditures, with a combined total of \$223,912. Most expenditures on advertising (81.8% of total value) were incurred by 12 companies that spent between \$100,001 and \$1,000,000 each. These twelve companies reported a total of \$4,608,185 in *Advertising Expenditures*. Table 4 shows the distribution of total *Advertising Expenses* in 2015.

One difference in reported *Advertising Expenses* between 2015 and 2014 was in the number of companies spending more than \$1,000,000. No companies reported spending more than \$1,000,000 in *Advertising Expenses* in 2015. This is a decrease from 2014, when three companies spent more than \$1,000,000. This decrease in companies spending over a million dollars in advertising, as well as the decrease in total number of companies who reported any *Advertising Expenses* (from 68 in 2014 to 63 in 2015) could contribute to the overall decrease in total *Advertising Expenses*.

Total Reported Value	Number of Companies	% of Total Number	Total Value	% of Total Value
More than \$1,000,000	0	-	-	-
\$100,001-\$1,000,000	12	8.6%	\$4,608,185	81.8%
\$25,001-\$100,000	13	9.3%	\$799,011	14.2%
\$1-\$25,000	38	27.1%	\$223,912	4.0%
No Reported Costs	77	55.0%	-	-
Total	140	100.0%	\$5,631,108	100.0%

Table 4:Distribution of Advertising Expenses in DC

II. Gift Expenses Analysis

Pharmaceutical and device companies reported \$24.4 million in gifts to D.C. in 2015. Individuals received \$13.8 million in gifts from more than 47,000 payments. *Non-Individual Recipients* received \$10.2 million in about 1,000 payments. Of this amount, \$418,700 represents 12 gifts from one company to unnamed recipients that were assumed to be non-individual recipients.

Distribution of Gift Expenses by Type of Recipient						
Individual Recipients						
Individual Recipient	Total Value	Frequency	Highest Value Median Value			
Physicians	\$13,067,818	42,833	\$9,428	\$64		
Advanced Practice Nurses (APN)	\$317,118	1,297	\$4,500	\$90		
Nurses	\$122,312	883	\$7,320	\$95		
Physician Assistants (PA)s	\$68 <i>,</i> 696	772	\$2,400	\$69		
Pharmacists	\$33 <i>,</i> 348	360	\$1,250	\$98		
Other Healthcare Providers *	\$108,187	1,077	\$7,928	\$45		
Other non-Healthcare Providers +	\$40,533	454	\$5,671	\$35		
Total	\$13,758,011	47,676	576			
	Non-Individual	Recipients				
Non-Individual Recipient	Total Value	F				
Non-individual Recipient	Total Value	Frequency	Highest Value	Median Value		
Teaching Hospital	\$4,051,764	Frequency 607	Fignest Value \$375,000	Niedian Value \$8,750		
Teaching Hospital	\$4,051,764	607	\$375,000	\$8,750		
Teaching Hospital Professional	\$4,051,764 \$2,330,596	607 95	\$375,000 \$200,000	\$8,750 \$54		
Teaching Hospital Professional Advocacy	\$4,051,764 \$2,330,596 \$1,672,829	607 95 84	\$375,000 \$200,000 \$300,000	\$8,750 \$54 \$4,121		
Teaching Hospital Professional Advocacy Clinical	\$4,051,764 \$2,330,596 \$1,672,829 \$1,113,880	607 95 84 50	\$375,000 \$200,000 \$300,000 \$175,000	\$8,750 \$54 \$4,121 \$2,500		
Teaching Hospital Professional Advocacy Clinical University	\$4,051,764 \$2,330,596 \$1,672,829 \$1,113,880 \$567,141	607 95 84 50 34	\$375,000 \$200,000 \$300,000 \$175,000 \$162,000	\$8,750 \$54 \$4,121 \$2,500 \$1,750		
Teaching Hospital Professional Advocacy Clinical University CME	\$4,051,764 \$2,330,596 \$1,672,829 \$1,113,880 \$567,141 \$97,368	607 95 84 50 34 38	\$375,000 \$200,000 \$300,000 \$175,000 \$162,000 \$75,000	\$8,750 \$54 \$4,121 \$2,500 \$1,750 \$152		
Teaching Hospital Professional Advocacy Clinical University CME Other ‡	\$4,051,764 \$2,330,596 \$1,672,829 \$1,113,880 \$567,141 \$97,368 \$351,763	607 95 84 50 34 38 133	\$375,000 \$200,000 \$300,000 \$175,000 \$162,000 \$75,000 \$150,000	\$8,750 \$54 \$4,121 \$2,500 \$1,750 \$152 \$2,750		

Table 5:
Distribution of Gift Expenses by Type of Recipient

* Other Healthcare Providers include: Dentists, Dieticians, Veterinarians, Psychologists, Social Workers, Optometrists, and Physical Therapists

⁺ Other non-Healthcare Providers include: Office and Administrative Staff (e.g. Billing staff, Healthcare Administrators), Technicians, and PhDs

‡ Other includes: Meeting Event Planners, Healthcare Consultants, Accreditation Bodies, Non-profit Organizations

The bulk of payments to *Individuals*, by value (95.0%) and by number of payments (89.8%), went to *Physicians*. Of the \$13.1 million in gifts to *Physicians*, \$12.2 million was reported to Open Payments, and \$900,000 was reported to AccessRx.

The remaining gifts to individuals were split among *Nurses*, *Advanced Practice Nurses* (APNs), *Physician Assistants* (PAs), *Pharmacists*, *Other Healthcare Providers*, and *Other Recipients*.

Gifts to non-individual recipients were more spread out across categories. *Teaching Hospitals* received \$4.1 million in gifts in 607 payments, making it the largest category of non-individual gifts by value (39.8%) and frequency (58.0%). *Professional Organizations* received the next largest amount, \$2.1 million (22.8%) in 95 (0.9%) payments.

Reporting Discrepancies Regarding Physician Gifts

After Open Payments went into effect, companies were no longer required to report gifts to physicians that were covered by Open Payments to the District of Columbia.

Nonetheless, in 2015, 35 companies reported many gifts to physicians to AccessRx. Two of these companies reported physician payments correctly to AccessRx. However, the remaining 33 companies incorrectly reported physician payments to AccessRx. Errors occurred in various ways. Some companies reported physician payments to AccessRx that should have been reported to Open Payments but could not be verified in Open Payments data. In other cases, companies pooled payments to a physician and to his or her staff and reported the combined amount to AccessRx. Gifts to physicians' staff were sometimes reported as individual gifts to physicians and gifts to physicians were sometimes reported as non-individual gifts.

Although we contacted many companies individually to correct reporting errors, and some errors were corrected, it was ultimately impossible to separate out every gift to individual physicians. As a result of these discrepancies, a few instances of double counting of gifts to physicians may have occurred. AccessRx reporting instructions are currently being revised in order to reduce reporting errors by companies in the future.

III. Payments to Individual Recipients

Individual Recipients, including Physicians, Advanced Practice Nurses, Registered Nurses, Physician Assistants, Pharmacists, Other Healthcare Providers, and Other Recipients received \$13.8 million in payments in 2015 (see Table 5). Only AccessRx, not Open Payments, requires gift reporting to recipients other than physicians. The following analysis includes information on physicians and teaching hospitals from Open Payments; all other information is from AccessRx.

In 2015, reporting categories for AccessRx were changed to align as much as possible with the federal Open Payments system in order to facilitate analyses. Specifically, the categories for Nature of Payment and Form of Payment were updated to include more precise language similar to Open Payments.

Physicians (Open Payment Data)

According to Open Payments, *Physicians* received \$13.1 million in gifts in the District in 2015, a 16.7% increase over the \$11.2 million reported in 2014. Gifts to *Physicians* represent 95% of all gifts reported to individual recipients, with more than 42,000 unique payments to MDs and DOs in the District.

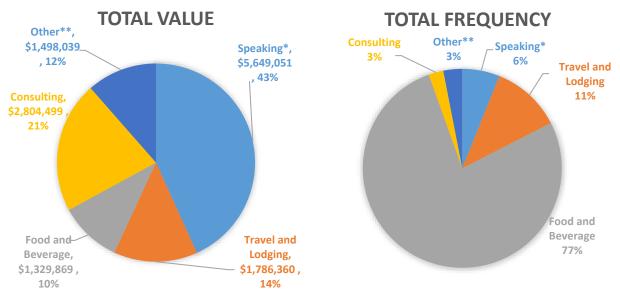
In total value, *Speaking* represented the largest percentage of gifts to physicians, accounting for \$5.6 million or 43.2%. More than \$4.8 million of gifts categorized as *Speaking* were for "services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program," usually considered to be promotional talks. Payments for speaking at a continuing medical education (CME) event totaled less than \$170,000. (In 2015, payments for CME programs that were sponsored by certain accredited organizations were exempted from Open Payments reporting. That exemption has been removed, so 2016 data will include more types of payments for CME.³)

Consulting represented one fifth of the total value of gifts to physicians with \$2.8 million. *Travel and Lodging* accounted for 13.7% with \$1.8 million, and *Food and Beverage* accounted for 10.2% with \$1.3 million. *Other* categories were 11.5% and totaled \$1.5 million, with *Royalty and License* accounting for the majority of *Other* with \$1 million.

There was a significant increase in *Royalty and License* payments to physicians in between 2014 and 2015. In 2014, \$136,627 was reported to Open Payments for *Royalty and License* payments in DC. In 2015, \$967,636 was reported for the same category.

³ https://www.cms.gov/openpayments/about/law-and-policy.html

Figure 3: Gifts to Physicians Nature of Payment



*Speaking consists of gifts reported as honoraria, compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program and compensation for serving as faculty or as a speaker for a non-accredited and non-certified continuing education program.

** "Other" includes gifts reported as Ownership or Investment Interest, Education, Entertainment, Gift, Grant, and Royalty or License.

Payments to phyicians are also classified by form of payment. *Cash and Cash Equivalent* make up the majority of gifts with \$10.5 million (80.3%) in total value. In total gift frequency, *Cash and Cash Equivalent* made up 27.4% with 10,713 unique payments. *In-Kind Items or Services* represent a minority of gifts in total value with \$2.6 million (19.6%) but are the most frequent gifts with 28,266 gifts (72.2%). In other words, there is a smaller number of large value gifts given in the form of *Cash and Cash Equivalent* and a larger number of small value gifts given in the form of *In-Kind Items or Services*.

Top 25 Physicians

The 25 physicians who received the highest gift values in the District of Columbia received a total of \$5.1 million, accounting for 39.3% of all gifts to physicians. More than half of the top-paid 25 physicians in 2015 appeared on the same list in 2014. Twelve of the 25 physicians are affiliated with academic medical centers.

Data reported to Open Payments is publicly available at <u>https://openpaymentsdata.cms.gov/</u> which allows us to report the names of the 25 physicians who received the most payments in DC in Table 6.

Ranking	Top 25 Physic	an Gift Recipients	in Washington, DC		Number
in 2015				Payments	Number of
(2014)	Name	Specialty	Affiliation	in DC	Payments
1 *	Zobair Younossi, MD, MPH	Surgery	Inova Health System	\$611,867	81
2 (2)	luce de deixe Table ve NAD	Hematology &	The GW Medical Faculty	6424 127	417
2 (2)	Imadeddine Tabbara, MD	Oncology	Associates	\$434,127	417
~ *	Maurice Nababadian MD	Plastic/Reconstructive	Georgetown University	6275 049	207
3 *	Maurice Nahabedian, MD	Surgery	Medical Center	\$375,948	387
4 (1)	Helen Barold, MD, MPH	Cardiology	Comprehensive Cardiac Care	\$368,464	1
= (0)			Georgetown University	4004 000	= 2 2
5 (8)	Laxman Bahroo, DO	Neurology	Medical Center	\$331,306	539
		Preventive	National Center for Weight	6250 644	404
6 (15)	Scott Kahan, MD, MPH	Medicine	and Wellness	\$259,644	401
7 *	Jacob O'Drian MD MDU	Orthopaedic	The Outbourgedie Courton	¢101 200	120
	Joseph O'Brien, MD, MPH	Surgery	The Orthopaedic Center	\$191,299	128
8 (20)	John Hogan, MD	Gastroenterology	Unity Health Care	\$188,071	330
e ik			MedStar Georgetown	+	
9 *	Fahd Amjad, MD	Internal Medicine	University Hospital	\$169,616	290
10 (11)			MedStar Georgetown	4469.074	0.75
10 (11)	Natasa Janicic-Kahric, MD	Endocrinology	University Hospital	\$163,974	275
11 (4)	James Simon, MD	Gynecology	Healthcare for Women	\$163,043	218
			MedStar Georgetown		
12 *	Robert Shin, MD	Neurology	University Hospital	\$160,780	182
		Hematology &	MedStar Washington	4	
13 *	Augusto Pichard, MD	Oncology	Hospital Center	\$160,779	180
			GW Center for Integrative		
14 (5)	Andrea Leonard-Segal, MD	Rheumatology	Medicine	\$154,653	79
45 (0)		N	Georgetown University	6452.450	222
15 (9)	Fernando Pagan, MD	Neurology	Medical Center	\$153,458	232
16 (10)	John L. Marshall, MD	Hematology &	MedStar Georgetown University Hospital	\$147,167	140
16 (10)		Oncology	MedStar Georgetown	\$147,107	148
17 *	Shawna Willey, MD	Surgical Oncology	University Hospital	\$139,175	146
			· ·		
18 (25)	Theo Hodge, MD	Infectious Disease	Capital Medical Associates	\$124,391	327
10 (7)	Ron Waksman, MD	Cardialagy	MedStar Washington	6124 GEG	140
19 (7)		Cardiology	Hospital Center	\$134,656	140
20 (23)	Richard Elion, MD	Family Medicine	Whitman-Walker Health	\$132,777	160
24.*		Orthopaedic	MedStar Georgetown		C0
21 *	Paul Cooper, MD	Surgery	University Hospital	\$125,184	62
22/42		Candialan	Georgetown University	6117 400	450
22 (12)	Vasilios Papademetriou, MD	Cardiology	Medical Center	\$117,169	153
23 *	Bruce Rashbaum, MD	Internal Medicine	Capital Medical Associates	\$116,416	269
			The GW Medical Faculty	444.5	
24 (18)	Allen Solomon, MD	Cardiology	Associates	\$111,105	123
२ ⊑ *			MedStar Washington	6400 700	
25 *	Andrew Shorr, MD, MPH	Pulmonary Disease	Hospital Center	\$100,700	92

Table 6:Top 25 Physician Gift Recipients in Washington, DC

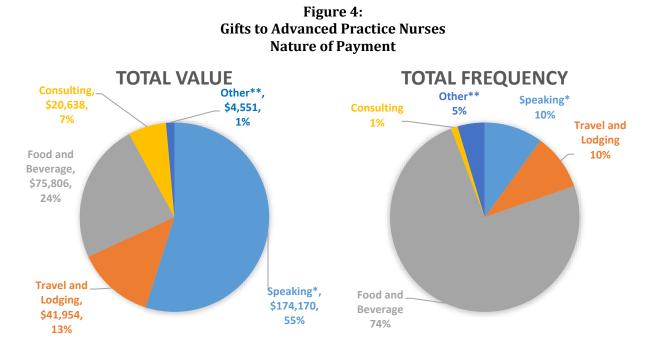
* New to the list in 2015

Advanced Practice Nurses (AccessRx Data)

Advanced Practice Nurses include nurse practitioners, nurse-midwives, and nurse-anesthetists; all have independent prescribing authority in DC. In 2015, 1,297 gifts were given to *Advanced Practice Nurses* that totaled \$317,118. This represents a slight (6.1%) increase in the total amount of gifts from 2014.

Speaking gifts represented the largest proportion of total gift value with \$174,170 (54.9%). *Advanced Practice Nurses* accepted \$75,806 in *Food and Beverage* gifts, which represented a quarter of the total value. *Travel and Lodging* made up 13.2% with \$41,954. *Consulting* made up 6.5% with \$20,638.

Food and Beverage was the most frequent gift category with 967 gifts (74.4%). *Speaking* and *Travel and Lodging* each made up 10% of the total gift frequency with 130 gifts. *Consulting* only made up 1.2% of all gifts given to *Advanced Practice Nurses*.



*Speaking consists of gifts reported as honoraria, compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program and compensation for serving as faculty or as a speaker for an accredited or certified continuing education program.

** "Other" includes gifts reported as Education and Other.

In total value, most gifts were given in the form of *Cash or Cash Equivalent* compared to *In-Kind Items and Services*. In total frequency, most gifts were given in the form of *In-Kind Items and Services* rather than *Cash or Cash Equivalent*. Most gifts were small in value for *Food and Beverage*, but a smaller number of gifts for *Speaking* represent the majority of the total value of gifts to *Advanced Practice Nurses*.

Nurses (AccessRx Data)

In 2015, gifts to *Registered Nurses* totaled \$122,312, a 13.1% increase from 2014. There were 883 gifts to *Nurses* reported to AccessRx.

Food and Beverage gifts made up the largest proportion of gifts to *Registered Nurses* both in total value and frequency. Nurses accepted 755 gifts of *Food and Beverage* which totaled \$63,967. Twenty-four *Speaking* gifts amounted to \$29,299 and nearly a quarter of total gift value. *Travel and Lodging* represented \$14,529 (11.9%), and *Consulting* represented \$9,415 (7.7%).

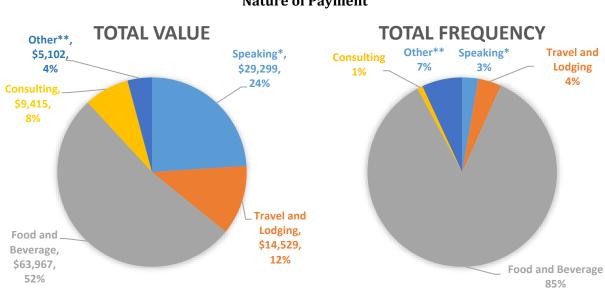


Figure 5: Gifts to Registered Nurses Nature of Payment

*Speaking consists of gifts reported as honoraria, compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program and compensation for serving as faculty or as a speaker for a non-accredited and non-certified continuing education program.

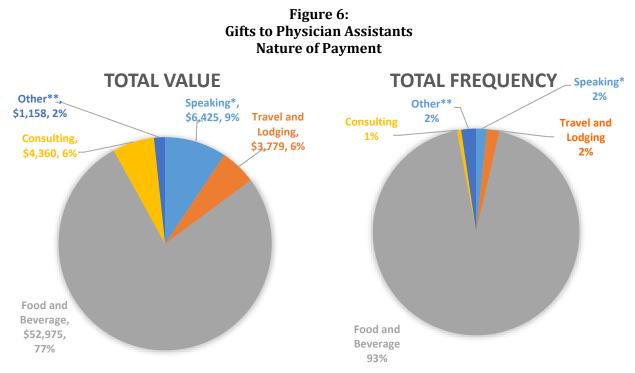
** "Other" includes gifts reported as Education, Entertainment, and Other.

Half of the value of all gift payments to *Registered Nurses* were given in the form of *In-Kind Items and Services*, and 46% of the value of gifts were given in the form of *Cash or Cash Equivalent*. In total frequency, 86% of gifts were given in the form of *In-Kind Items and Services*, compared to 14% in the form of *Cash or Cash Equivalent*.

Physician Assistants (AccessRx Data)

In 2015, gifts to *Physician Assistants* totaled \$68,696, a slight decrease from 2014.

Food and Beverage represented the majority of gifts both in total value and frequency, with 721 gifts totaling \$52,975. Payments for *Speaking* amounted to \$6,425 and 9.4% of the total value. *Travel and Lodging* (\$3,779) and *Consulting* (\$4,360) each made up 6% of the total value of payments to *Physician Assistants*.



*Speaking consists of gifts reported as honoraria, compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program and compensation for serving as faculty or as a speaker for a non-accredited and non-certified continuing education program.

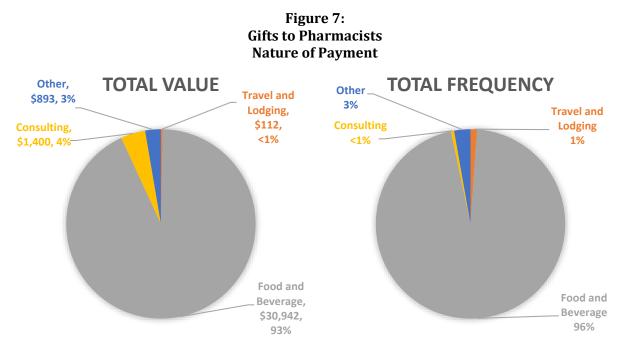
** "Other" includes gifts reported as Education, Gift, and Other.

For *Physician Assistants*, most gifts were given in the form of *In-Kind Items and Services* both in total value and total frequency. *Cash or Cash Equivalent* gifts made up \$23,537 (34.3%) in total value. The category *Cash or Cash Equivalent* made up a quarter of the total frequency of gifts.

Pharmacists (AccessRx Data)

In 2015, gifts to *Pharmacists* totaled \$33,348, a 58.4% decrease from 2014.

Most gifts (\$30,942) to *Pharmacists* were for *Food and Beverage. Consulting* made up 4.2% of total gift value with \$1,400. *Travel and Lodging* made up less than 1% with \$112. No gifts for *Speaking* were reported for *Pharmacists* in 2015.



For *Pharmacists*, the majority of gifts were given in the form of *In-Kind Items and Services* both in total value and total frequency.

Other Healthcare Providers (AccessRx Data)

In 2015, gifts to *Other Healthcare Providers* totaled \$108,187. Most of these gifts were for *Food and Beverage* for both value, \$63,951 (59%), and frequency, 1,003 gifts (93.1%). The next largest category of gift was *Travel and Lodging*, with \$16,249 (15%) and over 41 gifts (3.8%). The rest of gift payments were split between the other categories.

Payments to other healthcare providers primarily took the form of *In-Kind Items and Services* with 899 payments (83.5%) totaling \$68,253 (63.1%). In 2015, 140 payments (13%) totaling \$37,174 (34%) were made in *Cash or Cash Equivalent* form.

Other Recipients (AccessRx Data)

In 2015, gifts to *Other Recipients* totaled \$40,533. This group includes individuals reported as *Medical Staff, Front Desk, Billing Specialist, Office Manager,* and *Other.* The majority of reported gifts were for *Food and Beverage* with \$32,072 (79%) spent on 417 gifts (91.8%). The majority of payments took the form of *In-Kind Items and Services* with 388 payments (85.5%) totaling \$34,701 (85.5%).

Comparisons of Speaking Fees among Provider Types

Speaking payments made up the largest proportion of the total value of gifts for both *Physicians* and *Advanced Practice Nurses.*

Companies paid more than \$5.8 million in *Speaking* fees to individual healthcare providers in 2015. Among *Physicians*, the median value for *Speaking* payments was \$2,000. Among *Advanced Practice Nurses*, the median value for *Speaking* payments was \$1,400. Among *Registered Nurses*, the median value for *Speaking* payments was \$1,200. The majority of speaking fees were for events other than a continuing education program, which are considered to be promotional presentations.

Speaking Payments among Provider Types						
Credential	Total	Frequency	Median	Range		
Physician	\$5,626,586	2,432	\$2,000	\$200 - \$21,600		
Advanced Practice Nurse	\$174,170	130	\$1,400	\$150 - \$4,500		
Nurse	\$29,299	24	\$1,200	\$360 - \$2,340		
Total	\$5,830,055	2,586				

Table 7: Speaking Payments among Provider Types

Currently, physicians are much more likely than APNs or RNs to be compensated for speaking engagements, though this may change over time since physician payments are publicly identified through Open Payments. Changes in the amounts, frequency, and distribution of *Speaking* payments after the implementation of Open Payments are an area of interest because greater public transparency about physician payments could result in a shift in gifts and payments to APNs, nurses and physician assistants, especially for promotional or continuing education speaking engagements. Only AccessRx collects data on payments to non-physicians, thus allowing for year-to-year monitoring of changes and shifts in payments.

IV. Payments to Non-Individual Recipients

Gifts to *Non-Individual Recipients* totaled \$10.6 million in 2015 (see Table 5). This analysis includes gifts reported to recipients and organizations based in the District of Columbia. While Open Payments only collects gifts to teaching hospitals, AccessRx is unique because it collects information on payments to professional, advocacy, clinical and CME organizations. These organizations are influential because they create medical guidelines, advocate for specific policies, provide education to their members and the public, and may sponsor continuing medical education programs.

In 2015, *Teaching Hospitals* received the highest value in gifts. In 2014, *Professional Organizations* received the highest value in gifts, while *Teaching Hospitals* received the second highest value in gifts. The average value of gifts to *Professional Organizations* was \$24,533, while the average value of gifts to *Teaching Hospitals* was \$4,953.

In total frequency, *Teaching Hospitals* received 38.2% of all gifts to *Non-Individuals*, a decrease in the total proportion from 45.4% in 2014. *Professional Organizations* received 22.0% of all gifts, and *Advocacy Organizations* received 15.8%.

Teaching Hospitals (Open Payment Data)

In 2015, gifts to *Teaching Hospitals* totaled \$4.1 million, with \$3,804,100 reported to Open Payments and \$247,663 reported to AccessRx. This is an increase from 2014, in which *Teaching Hospitals* received \$3.8 million in gifts.

Washington Hospital Center received 243 gifts that totaled \$2.8 million. Although \$2.8 million accounted for 73.2% of the total value of gifts to teaching hospitals, the 243 gifts to Washington Hospital Center only made up 43.6% of the total frequency of gifts to teaching hospitals. The three academic medical centers in the District received \$927,915 in total, making up 26.5% of the gift value. Georgetown University Hospital received \$601,264 in 84 gifts. George Washington University Hospital received \$184,592 in 105 gifts. Howard University Hospital received \$142,059 in 40 gifts. Children's, Providence, National Rehabilitation, and Sibley Memorial Hospital each received less than \$50,000 in gifts. Their total gift value of \$91,387 makes up less than 3% of the total value in gifts.

Teaching Hospital	Total Value	Frequency			
Washington Hospital Center	\$2,784,796	243			
Georgetown University Hospital	\$601,2645	84			
George Washington University Hospital	\$184,592	105			
Howard University Hospital	\$142,060	40			
Children's Hospital	\$45,577	27			
Providence Hospital	\$23,165	47			
National Rehabilitation Hospital	\$16,500	3			
Sibley Memorial Hospital	\$6,146	8			
Total	\$3,804,101	557			

Table 8:Gifts to Teaching Hospitals in Washington, DC

Of the \$3.8 million in gifts, \$1.6 million (38%) was for *Grants* to hospitals. The next largest category was for *Investment Interest/Royalty/License* at \$1.3 million. This is a significant change from 2014, when <1% of gifts were for *Investment Interest/Royalty/License* with only \$9,952⁴. It is unclear why there was such a large increase in reporting of this category in 2015. There also was a significant decrease in *Education*. In 2014, gifts for *Education*⁵ made up 32% of the gift value (\$1.2 million) and 50% of the gift frequency. This year, *Education* was only 4% of the gift value (\$152,300) and 1% of the gift frequency.

⁴ In 2014, *Investment Interest/Royalty/License* was put in the category *"Other"*, which also included *Travel and Lodging*, *Food and Beverage*, and *Other*.

⁵ All expenses associated with educational or informational programs, materials, and seminars, and remuneration for promoting or participating in educational or informational sessions, regardless of whether the manufacturer or labeler provides the educational or informational sessions or materials.

These changes are also reflected in the gift frequency, with Investment Interest/Royalty/License making up the majority of gift frequency (45%). Although Grants have the largest share of gift value, it makes up 16% of the gift frequency.

Categories that stayed consistent for teaching hospitals with 2014 figures include Space Rental (\$615,392) and Speaking or Consulting Fee (\$325,347).

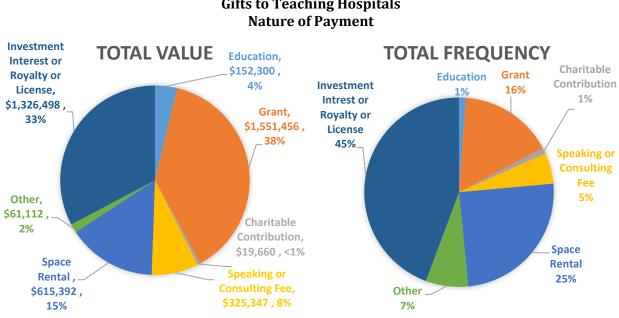


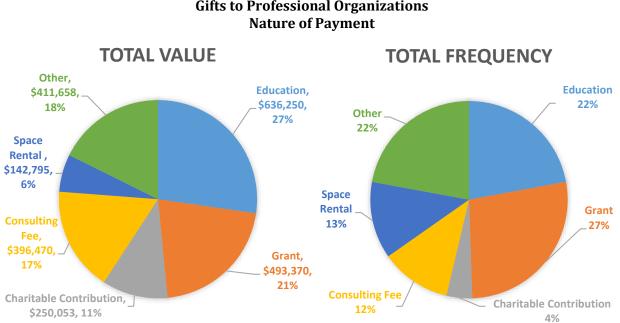
Figure 8: **Gifts to Teaching Hospitals**

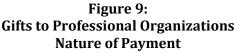
Professional Organizations (AccessRx Data)

Gifts to Professional Organizations totaled \$2.3 million in 2015, which is a decrease from the \$4.4 million received in 2014. These organizations include societies and associations.

Companies reported \$636,250 in gifts for *Education*, 27.3% of the total value of payments to Professional Organizations. Grants made up 21.2% of gift value with \$493,370 but made up a larger percentage of gift frequency at 27% of total gifts. The next highest gift value was for the category Other (\$411,658, 11%), followed by Consulting Fees (\$396,470, 17%).

Comparisons to 2014 data cannot be made as 2014 reports did not have equivalent categories to the current 2015 categories. Comparisons for this category and other AccessRx categories will be able to be made next year with 2016 reported data.





Advocacy Organizations (AccessRx Data)

Gifts to *Advocacy Organizations,* including advocacy and research organizations that focus on specific diseases, totaled \$1.7 million in 2015, an increase over 2014, when *Advocacy Organizations* received \$1.1 million.

The largest gift value was for *Consulting Fees* at \$877,057, which made up a majority of the gift value (52%). This category made up less of the gift frequency (24%), suggesting that these were gifts of larger value. *Advocacy Organizations* received \$515,981 in *Charitable Contributions*, which made up 31% of the gift value and 25% of the gift frequency. *Advocacy Organizations* received less than 10% in gift value for *Education* (\$146,250), *Other* (\$72,680), and *Space Rental* (\$17,195).

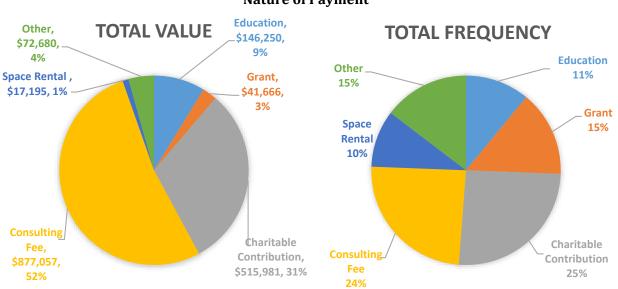


Figure 10: Gifts to Advocacy Organizations Nature of Payment

Clinical Organizations (AccessRx Data)

Gifts to *Clinical Organizations* totaled \$1.1 million in 2015. *Clinical Organizations* include community health clinics, private medical centers, and large private practices. More than a million dollars of the total reported gift value was in the form of *Cash or Cash Equivalent*. This is a significant increase from 2014, where *Clinical Organizations* received \$263,550 in gifts. Pharmaceutical companies may be focusing their gifts more towards hospitals, clinics and other *Clinical Organizations* because of their reach in the community, but the exact reason cannot be determined.

Grants were the reported Nature of Payment for 92.7% of the total value, with \$1.0 million in gifts. The next largest gift category was *Space Rental or Facilities Fees* with \$53,990 in gifts. *Education* had \$11,500 in gifts, *Charitable Contribution* had \$6,000 in gifts, *Compensation for services other than consulting* had \$4,100 in gifts, *Other* had \$4,000 in gifts, and *Food and Beverage* had \$822 in gifts.

Universities (AccessRx Data)

In 2015, companies reported 34 gifts to *Universities* that totaled \$567,141. The largest category of gifts was *Grants*, with \$485,691 in gifts. Payments for *Space Rental or Facility Fees* had the highest frequency with 23 of the 34 gifts to universities. Most gifts (91%) were given as *Cash or Cash Equivalent*.

Continuing Medical Education Organizations (AccessRx Data)

Gifts to *Continuing Medical Education Organizations* totaled \$97,368 in 2015. This is a decrease from 2014, where *CME Organizations* received \$343,164 in gifts. Most gifts in 2015 were in the category *Other*. Almost all gifts (97%) were in the form of *Cash or Cash Equivalent*.

Other Non-Individual Recipients (AccessRx Data)

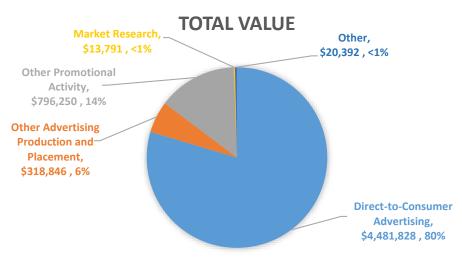
Other Non-Individual Recipients received \$351,763 in gifts in 2015. This group includes consulting companies, event planners, and others. The largest proportion of the total value of gifts was for *Education* with \$225,000. The majority of gifts were made in the form of *Cash or Cash Equivalent*.

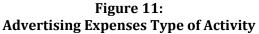
V. Advertising Expenses Analysis

In 2015, 63 companies (45% of companies that reported to AccessRx) reported a total of \$5.6 million in *Advertising Expenditures* totaling \$5.6 million. An analysis by *Activity Type* of *Advertising Expenses* found that the majority of expenditures fell into five categories: *Direct-to-Consumer Advertising, Other Advertising Production and Placement, Other Promotional Activity, Market Research,* and *Other*. These are estimates provided by companies and may not be reliable because it is unclear whether companies included only advertising limited to DC or a portion of national advertising.

Expenditures classified as *Direct-to-Consumer Advertising* accounted for the largest share of *Advertising Expenses*, with a total of \$4.5 million or 80% of total *Advertising Expenses*. Expenditures classified as *Other Promotional Activity* accounted for \$796,250 or 14% of total *Advertising Expenses; Other Advertising Production and Placement* accounted for \$318,846 or 6% of total *Advertising Expenses; Market Research* accounted for \$13,791 or <1% of total *Advertising Expenses*. The remaining expenditures were classified as *Other* which accounted for \$20,392, also <1% of total *Advertising Expenses*.

Between 2014 and 2015, there was a decrease in the total reported *Advertising Expenses* by \$2.3 million. This decrease could be, in part, due to the decrease in total number of companies that reported any advertising expenses from 68 in 2014 to 63 in 2015.





When considering *Advertising Expenses* in terms of frequency of expenditures, the outlook is slightly different. Expenditures classified as *Other Promotional Activity* account for nearly half of all reported expenditures (49.1%). *Other Advertising Production and Placement* accounted for 23.6% of the total frequency of expenditures and *Direct-to-Consumer Advertising* accounted for 18.8%. The remaining gifts went to *Market Research* (2.1%) and to *Other* (6.3%).

Media Type

Advertising Expenses were grouped into nine media categories: *Television, Internet, Medical Journal, Patient and Other Printed Materials, Direct Mail, Radio, Newspaper and Magazine, Conference and Other Event,* and *Other.* The majority of expenditures fell under *Television* and *Internet* which were responsible for \$1.5 million (27% of total expenditures) and \$1.4 million (25% of total expenditures) respectively. Other significant expenditures include *Newspaper and Magazine* (\$553,000 or 10% of total expenditures), *Patient and Other Printed Materials* (\$563,000 or 10%), and *Other* (\$787,560 or 14%). *Radio* (\$280,728 or 5%), *Conference and Other Events* (\$297,915 or 5%), *Medical Journals* (\$139,766 or 3%) and *Direct Mail* (\$77,394 or 1%) each accounted for 5% or less each of the total value.

The Advertising Expenses from Television and from Internet were the two largest changes from 2014, when Television accounted for 58% of total expenditures and Internet only 7%. The sizeable decrease in Television expenditures and increase in Internet expenditures could be in response to the large online social media based shift in culture and advertising.

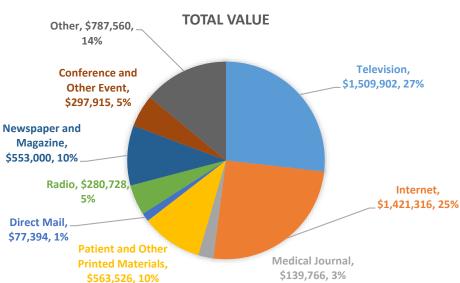


Figure 12: Advertising Expenses by Medium Type

When considering the frequency of expenditures by media type, the outlook again changes. *Internet* expenditures account for the largest share of advertising frequency (24.0%). The next highest frequencies included *Patient and Other Printed Materials* (19.3%), *Direct Mail* (14.8%), and *Other* (14.7%). Media types that each accounted for 10% or less of total frequency of expenditures were *Conference and Other Printed Materials* (9.1%), *Newspaper and Magazines* (8.6%), *Television* (4.8%), *Medical Journals* (4.5%), and *Radio* (<1%).

VI. Discussion

Public data on physician payments show that industry gifts are common among physicians in general.⁶ Even small gifts can affect prescribing practices.⁷ For example, a meal valued less than \$20 increased the prescribing of brand-named statins, cardioselective-beta-blockers, ACE inhibitors, and antidepressants.⁸ Gifts to prescribers may also increase costs to payers. One study showed that industry payments to prescribers are associated with more expensive prescriptions for Medicare Part D patients.⁹ Another study found that industry payments to physicians in Massachusetts increased prescribing of brand-name statins.¹⁰

In the 2015 *Impacts of Pharmaceutical Marketing Report*, we analyzed Medicare Part D data to examine prescribing habits of physicians and other prescribers based on whether or not prescribers accepted industry gifts. In 2013, 1,123 of 2,873 Medicare Part D prescribers (39.1%) received gifts totaling \$3.9 million. Medicare claims for healthcare providers who received any gifts from pharmaceutical companies totaled \$128 million, whereas claims for healthcare providers who received no gifts totaled \$53 million. We also found that claims for prescriptions written by gift recipients were \$56 higher on average than claims for prescriptions written by non-gift recipient claims; that gift recipients wrote about 2 more prescriptions per beneficiary than non-gift recipients; and that gift recipients wrote 8.4% more branded prescriptions than non-gift recipients.

Medicaid may be affected as well. The 2012 *Impacts of Pharmaceutical Marketing Report* analyzed gifts to Medicaid psychiatrists in the District and found that while Medicaid psychiatrists in DC accounted for about a quarter (27%) of psychiatrists who receive at least \$1,000 from major antipsychotic manufacturers, Medicaid psychiatrists received two thirds (66%) of the monetary share of gifts.

Role of Pharmaceutical Detailing Activities

Visits by pharmaceutical sales representatives (drug representatives) increases sales of the newest, most expensive drugs, which may have no advantages over older drugs. A recent study based on a nationally representative sample of 150,000 physicians found that, over 2 years, detailing increased new prescriptions for a targeted herpes drug.¹¹ A systematic review of 29 studies on pharmaceutical company promotion and prescribing also found that detailing works: 17 studies of pharmaceutical sales

⁶ Marshall DC, Jackson ME, Hattangadi-Gluth JA. Disclosure of Industry Payments to Physicians: An Epidemiologic Analysis of Early Data From the Open Payments Program. Mayo Clinic Proc. 2016;91(1):84-96. doi: 10.1016/jmayocp.2015.10.016.

⁷ Sah S. Conflicts of interest and your physician: psychological processes that cause unexpected changes in behavior. J Law Med Ethics. 2012;40(3):482-487.

⁸ DeJong C, Aguilar T, Tseng CW, Lin GA, Boscardin WJ, Dudley RA. Pharmaceutical Industry-Sponsored Meals and Physician Prescribing Patterns for Medicare Beneficiaries. JAMA Intern Med. 2016;176(8):1114-1110.

⁹ Perlis RH, Perlis CS. Physician Payments from Industry Are Associated with Greater Medicare Part D Prescribing Costs. PLoS One. 2016;11(5):e0155474.

¹⁰ Yeh JS, Franklin JM, Avorn J, Landon J, Kesselheim AS. Association of Industry Payments to Physicians With the Prescribing of Brand-name Statins in Massachusetts. JAMA Intern Med. 2016;176(6):763-768.

¹¹ Datta A, Dave D. Effects of Physician-directed Pharmaceutical Promotion on Prescription Behaviors: Longitudinal Evidence. Health Econ. 2016 Feb 19. doi: 10.1002/hec.3323.

representative visits found an association with increased prescribing of promoted drug. Six studies had mixed results, and five found no effect. Promotion was the most effective in increasing prescribing frequency when pharmaceutical sales representatives visited groups of physicians, when physicians had lower baseline prescribing of a targeted drug, and when physicians had larger prescribing volumes. Drug representative visits were also associated with decreased market share of competitor products. ¹²

Industry-influenced prescribing may be harmful to public health. A study of drug representatives in the US, Canada and France found that drug representatives rarely mention serious adverse effects.¹³ Restricting drug representative visits promotes rational prescribing and also may save systems money. Detailers push the most expensive drugs, and physicians do not tend to take drug costs into consideration, perhaps because they are unaware of drug costs. An analysis of 24 studies found that physicians tended to overestimate the cost of inexpensive drugs and underestimate the cost of expensive drugs.¹⁴

One study of child and adolescent psychiatrists and pediatricians found that prescriptions for on-label use of promoted antidepressants and antipsychotics fell by 34% and prescriptions for on-label use of nonpromoted drugs rose by 14% after academic medical centers restricted visits or phone calls from drug representatives to physicians. Off-label prescriptions of targeted drugs appeared to decrease.¹⁵

Role of Continuing Education

Besides physicians, other health care professionals are susceptible to industry influence that may affect therapeutic choices. A systematic review of 15 studies found that registered nurses, nurse prescribers, physician assistants (PAs), pharmacists, dieticians, and physical or occupational therapists regularly received information and education from industry and distributed industry materials to patients. Clinicians often received free samples and generally had positive views of industry interactions.¹⁶ A recent study found that pharmacists also had positive views of industry interactions.¹⁷

Most education that physicians, other health care providers, and pharmacists receive is industry-funded. The District is the only jurisdiction in the US to provide free, independent, accredited, online continuing education to its physicians, nurses, physician assistants and pharmacists through the DC Center for Rational Prescribing (<u>https://doh.dc.gov/dcrx</u>).

¹² Spurling GK1, Mansfield PR, Montgomery BD, Lexchin J, Doust J, Othman N, Vitry Al.Information from pharmaceutical companies and the quality, quantity, and cost of physicians' prescribing: a systematic review. PLoS Med. 2010 Oct 19;7(10):e1000352. doi: 10.1371/journal.pmed.1000352.

¹³Mintzes B, Lexchin J, Sutherland JM, Beaulieu MD, Wilkes MS, Durrieu G, Reynolds E. Pharmaceutical sales representatives and patient safety: a comparative prospective study of information quality in Canada, France and the United States.J Gen Intern Med. 2013 Oct;28(10):1368-75. doi: 10.1007/s11606-013-2411-7.

 ¹⁴Allan GM1, Lexchin J, Wiebe N. Physician awareness of drug cost: a systematic review. PLoS Med. 2007 Sep;4(9):e283.
 ¹⁵Larkin I, Ang D, Avorn J, Kesselheim AS. Restrictions on pharmaceutical detailing reduced off-label prescribing of antidepressants and antipsychotics in children. Health Aff(Millwood).2014 Jun;33(6):1014-23. doi:10.1377/hlthaff.2013.0939.
 ¹⁶Grundy Q, Bero L, Malone R (2013) Interactions between Non-Physician Clinicians and Industry: A Systematic Review. PLoS Med 10(11): e1001561. doi:10.1371/journal.pmed.1001561

¹⁷ Saavedra K, O'Connor B, Fugh-Berman A.Pharmacist-industry relationships. Int J Pharm Pract. 2017 Jan 18. doi: 10.1111/ijpp.12333.

VII. Recommendations for AccessRx

After analyzing 2015 pharmaceutical marketing data, we make the following recommendations. These proposed changes would strengthen the implementation of the original goals of AccessRx and would make the statute more consistent with the federal Open Payments reporting system. Some suggestions would require amending the AccessRx Act.

1. Improve instructions on data requirements in order to improve the quality of data received by AccessRx.

Manufacturers appear to be confused about some aspects of reporting to AcccessRx; gaps and inconsistencies in reporting are common and lead to limitations in data analyses. Many companies continue to report physician gifts that should only be reported to Open Payments to both AccessRx and Open Payments, resulting in double counting of some gifts. Other errors include reporting gifts to physician's offices and staff as gifts to individual physicians and gifts to individual physicians being included in non-individual gift totals to their offices.

New strategies to improve reporting accuracy should be put in place to ensure that the District receives reports that accurately reflect spending patterns. A clarification of reporting instructions is necessary to further specify when to exclude reporting gifts to physicians to AccessRx. Specifically, further guidance in needed on how to properly report gifts to physicians' offices and staff without including individual gifts to physicians in these totals.

Transitioning AccessRx to an online reporting system would make reporting to AccessRx much easier. An online system would limit responses in select columns to options detailed in the instructions, would only accept correctly reported responses, and would require companies to fill out all fields. This could also increase efficiency in reporting and make it more convenient for companies, as well for researchers collecting and organizing data.

2. Continue to collect all required AccessRx information, while utilizing Open Payments data to complement and conduct unique analyses of pharmaceutical marketing in the District of Columbia.

DC DOH maintains the most comprehensive databases on pharmaceutical marketing activity of any jurisdiction in the United States. AccessRx provides unique information to the District to explore pharmaceutical marketing practices, including millions in spending on aggregate salaries of detailing staff, advertising, and gift expenses not exposed by the federal Open Payments system. By analyzing gifts to physicians and teaching hospitals reported to Open Payments in concert with gifts to nurses, physician assistants, and other expenses reported only to AccessRx, the District's analysis of gift trends provides information that cannot currently be analyzed by any other state or federal entity. With a growing national focus on healthcare transparency, maintaining reporting requirements allows the DC DOH to continue to analyze changing trends and assess the impact on healthcare.

3. Make all reports submitted pursuant to the AccessRx Act publicly available, consistent with the Federal Open Payments system.

With data on gifts to physicians and teaching hospitals now publicly available by the Open Payments system, it would be appropriate to also make the information collected in the AccessRx system publicly available. Currently, the database containing AccessRx data is developed each year for use solely by the Department of Health, but the AccessRx Act requires that it remain confidential. In the interest of informed healthcare decision making, patients should have access to information about marketing efforts that affect their health care providers, clinical settings, and health-related organizations. This would also streamline comparative analyses of the two databases.

4. Require "product marketed" information for gift expenses, consistent with Federal Open Payments requirements.

Unlike Open Payments, the District does not require reports to specify which product is being marketed. Requesting "product marketed" information for gift expenses reported to the AccessRx system would help researchers calculate how much companies spend on marketing specific drugs, and reports of this information could also help patients make more informed decisions about their healthcare, such as selecting a generic version of a drug or asking questions of a provider who suggests a new medication. This would also allow researchers to compare how products are marked in the District and nationally.

5. Require reporting by device manufacturers, consistent with Federal Open Payments requirements.

AccessRx requires reporting by any "manufacturer or labeler of prescription drugs dispensed in the District that employs, directs, or utilizes marketing representatives in the District," resulting in the reporting of 153 companies in 2014. Comparatively, Open Payments requires manufacturers of "drugs, devices, biologicals, or medical supplies" to report expenses, which included 486 companies in 2014. As in previous years, we recommend that AccessRx requirements should be expanded to provide a more complete picture of marketing practices in the District and to remain consistent with the Open Payments system.

Appendix A: AccessRx Requirements

Title III of the AccessRx Act of 2004¹⁸ requires that any "manufacturer or labeler of prescription drugs dispensed in the District that employs, directs, or utilizes marketing representatives in the District" annually report marketing costs for prescription drugs in the District. §48-833.03 describes the content of the annual report:

(a) Except as provided in subsection (b) of this section, the annual report filed pursuant to §48-853.02 shall include the following information as it pertains to marketing activities conducted within the District in a form that provides the value, nature, purpose, and recipient of the expense:

(1) All expenses associated with advertising, marketing, and direct promotion of prescription drugs through radio, television, magazines, newspapers, direct mail, and telephone communications as they pertain to District residents;

(2) With regard to all persons and entities licensed to provide health care in the District, including health care professionals and persons employed by them in the District, carriers licensed under Title 31, health plans and benefits managers, pharmacies, hospitals, nursing facilities, clinics, and other entities licensed to provide health care in the District, the following information:

(A) All expenses associated with educational or informational programs, materials, and seminars, and remuneration for promoting or participating in educational or informational sessions, regardless of whether the manufacturer or labeler provides the educational or informational sessions or materials;

(B) All expenses associated with food, entertainment, gifts valued at more than \$ 25, and anything provided to a health care professional for less than market value;

(C) All expenses associated with trips and travel; and

(D) All expenses associated with product samples, except for samples that will be distributed free of charge to patients; and

(3) The aggregate cost of all employees or contractors of the manufacturer or labeler who directly or indirectly engage in the advertising or promotional activities listed in paragraphs (1) and (2) of this subsection, including all forms of payment to those employees. The cost reported under this paragraph shall reflect only that portion of payment to employees or contractors that pertains to activities within the District or to recipients of the advertising or promotional activities who are residents of or are employed in the District.

¹⁸ District of Columbia Official Code. AccessRx Act of 2004.

http://doh.dc.gov/sites/default/files/dc/sites/doh/publication/attachments/AccessRx-Act-of-2004.pdf, accessed January 27, 2016.

(b) The following marketing expenses are not subject to the requirements of this subchapter:

(1) Expenses of \$25 or less;

(2) Reasonable compensation and reimbursement for expenses in connection with a bona fide clinical trial of a new vaccine, therapy, or treatment; and

(3) Scholarships and reimbursement of expenses for attending a significant educational, scientific, or policy-making conference or seminar of a national, regional, or specialty medical or other professional association if the recipient of the scholarship is chosen by the association sponsoring the conference or seminar.

The manufacturer or labeler must file the report by July 1st of each year, in the form and manner provided by the Department of Health. §48-833.04 describes the report that the Department must then provide to the City Council:

By November 30th of each year, the Department shall provide an annual report, providing information in aggregate form, on prescription drug marketing expenses to the Council and the Corporation Counsel. By January 1, 2005, and every 2 years thereafter, the Department shall provide a report to the Council and the Corporation Counsel, providing information in aggregate form, containing an analysis of the data submitted to the Department, including the scope of prescription drug marketing activities and expenses and their effect on the cost, utilization, and delivery of health care services, and any recommendations with regard to marketing activities of prescription drug manufacturers and labelers.

§48-833.04 addresses confidentiality:

Notwithstanding any provision of law to the contrary, information submitted to the Department pursuant to this subchapter is confidential and is not a public record. Data compiled in aggregate form by the Department for the purposes of reporting required by this subchapter is a public record as long as it does not reveal trade information that is protected by District, state, or federal law.

Chapter 18 of Title 22 of the District of Columbia Municipal Regulation specifies which information must be included in annual reports in each of the three categories (advertising expenses, marketing expenses, aggregate costs).

Appendix B: Open Payments Requirements

The Patient Protection and Affordable Care Act of 2010 established the Open Payments system through the Centers for Medicare and Medicaid Services. The regulation was promulgated on February 8, 2013, requiring data collection beginning on August 1, 2013. 42 CFR Parts 402 and 403 requires¹⁹ "applicable manufacturers of drugs, devices, biologicals, or medical supplies covered by Medicare Medicaid or the Children's Health Insurance Program (CHIP) to report annually to the Secretary [of the Department of Health and Human Services] certain payments or transfers of value provided to physicians or teaching hospitals..." Specific reporting requirements outlined by §403.904 include:

(a) General rule:

(1) Direct and indirect payments or other transfers of value provided by an applicable manufacturer to a covered recipient during the preceding calendar year, and direct and indirect payments or other transfers of value provided to a third party at the request of or designated by the applicable manufacturer on behalf of a covered recipient during the preceding calendar year, must be reported by the applicable manufacturer to CMS on an annual basis.

(b) Covered Products:

(1) Any drug, device, biological, or medical supply that is eligible for payment by Medicare, Medicaid, or CHIP either individually or as a part of a bundled payment (such as the inpatient prospective payment system), and requires a prescription to be dispensed (for drugs and biologicals) or requires premarket approval by, or premarket notification to, the U.S. Food and Drug Administration (FDA) (for devices, including medical supplies that are devices).

(c) Recipients for whom gifts must be reported:

(1) Physicians, which include those with credentials of Doctor of Medicine, Doctor of Osteopathy, Doctor of Dentistry, Doctor of Dental Surgery, Doctor of Podiatry, Doctor of Optometry, or Doctor of Chiropractic Medicine.

(2) Teaching Hospitals that received payment for Medicare direct graduate medical education (GME), inpatient hospital prospective payment system (IPPS) indirect medical education (IME), or psychiatric hospitals IME programs during the last calendar year.

(c) Limitations. Certain limitations on reporting apply in the following circumstances:

- (1) \$10, indexed to inflation, provided total payments to a recipient total less than \$100 a year.
- (2) Applicable manufacturers that had less than 10 percent gross revenue during the fiscal year preceding the reporting year from covered products are only required to report payments or other transfers of value related to covered products, not all products.
- (3) Drug samples intended exclusively for distribution to patients are excluded from the reporting requirements (see rule for more)

¹⁹Federal Register. 42 CFR Parts 402 and 403. https://www.gpo.gov/fdsys/pkg/FR-2013-02-08/pdf/2013-02572.pdf, accessed January 27, 2016.