# Pharmaceutical Marketing Expenditures in the District of Columbia, 2016



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

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## **Executive Summary**

## Overview

This report discusses pharmaceutical marketing expenditures in the District of Columbia in 2016. The <u>AccessRx Act of 2004</u> requires pharmaceutical manufacturers to report marketing expenditures to the District of Columbia Department of Health (DOH). The report is supplemented with data reported to the federal government through the Centers for Medicare and Medicaid's (CMS) <u>Open Payments</u> system. Open Payments collects information about gifts from pharmaceutical and medical device manufacturers to physicians and teaching hospitals. A summary of reporting requirements can be found in Appendices A and B.

Pharmaceutical marketing in 2016 totaled \$99.2 million for all gift, advertising, and aggregate employee expenses reported in the District of Columbia. One hundred and seventy-seven pharmaceutical manufacturers reported expenditures to AccessRx, and 457 pharmaceutical and medical device manufacturers reported to Open Payments; altogether, 498 individual companies reported to one or both programs. It is notable that \$81.2 million was reported to AccessRx and \$18 million was reported to Open Payments.

This report discusses pharmaceutical marketing as a whole and analyzes marketing expenditures 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 2016, pharmaceutical and device manufacturers reported a total of \$99.2 million in gift, advertising, and aggregate (detailing) expenses in the District of Columbia. *Aggregate (Detailing) Expenses* accounted for \$62.8 million (63.4%), *Gift Expenses* for \$24.7 million (24.9%), and *Advertising Expenses* for \$11.7 million (11.8%) of total expenses.

Between 2015 and 2016:

- Total expenditures increased by \$3 million (3.1%), from \$96.2 million in 2015 to \$99.2 million in 2016.
- *Aggregate (Detailing) Expenses* decreased by \$3.4 million (5.1%), from \$66.2 million in 2015 to \$62.8 million in 2016.
- *Gift Expenses* increased by \$310,588 (1.3%), from \$24.4 million in 2015 to \$24.7 million in 2016.
- *Advertising Expenses* increased by \$6 million (107%), from \$5.6 million in 2015 to \$11.7 million in 2016.

- Gifts to Individual Recipients totaled \$14.5 million.
  - *Physicians*, reported to Open Payments and AccessRx, received \$13.1 million in gifts (90% of the total value of gift expenses).
    - The 25 physicians who received the highest total gift values, received a total of \$5.7 million. This accounted for 43.4% of all gifts to physicians and 39% of total individual gifts.
  - Advanced Practice Nurses (nurse practitioners, nurse midwives, and nurse anesthetists, all of whom can prescribe drugs) received a total of \$339,254, or 2.3% of individual gifts.
  - *Physician Assistants* received \$116,293.
  - *Dentists*, analyzed separately from *Physicians* for the first time, received \$153,578.
  - *Registered Nurses* received \$151,383.
  - *Pharmacists* received \$50,085.
  - Other Healthcare Providers received \$49,036.
  - *Clinical Office Staff and Other Recipients* received \$573,042 in gifts and payments.
- Gifts to Non-individual recipients totaled \$10.2 million.
  - *Teaching Hospitals* accounted for the largest portion with \$5.4 million in gifts, \$4.9 million reported to Open Payments and \$508,392 reported to AccessRx.
    - Washington Hospital Center received the highest total value of gifts (\$3.5 million), accounting for 71.3% of all gifts to Teaching Hospitals.
    - Academic medical centers received the next largest gift totals among teaching hospitals: Georgetown University Hospital (\$915,053), George Washington University Hospital (\$152,374), and Howard University Hospital (\$144,090).
    - Children's Hospital received \$150,946. The remaining teaching hospitals each received less than \$30,000 in total gifts, which included Providence Hospital (\$25,484), National Rehabilitation Hospital (\$6,500), and Sibley Memorial Hospital (\$6,119).
  - *Professional Organizations* accounted for \$2.1 million in gifts received (21.1%).
  - Advocacy Organizations accounted for \$949,963 (9.4%). This was a 43.2% decrease from 2015, when Advocacy Organizations received \$1.7 million.
  - Professional Organizations and Advocacy Organizations had large increases in gifts reported as Other. This was primarily due to one company's reporting high- value gifts to AccessRx as Other.
  - Clinical Organizations accounted for \$691,565 (6.8%). This was a 37.9% decrease from 2015 when Clinical Organizations received \$1.1 million.
  - The remaining *Non-Individual Recipients* included *Universities* (\$772,988), *Continuing Medical Education Organizations* (\$142,774), and *Other Organizations* (\$60,258).

# I. Summary of Pharmaceutical Marketing Expenditures

In 2016, pharmaceutical and device companies reported spending \$99.2 million on marketing, including gifts, advertising, and aggregate (detailing) expenses in the District of Columbia.

This total includes data from both the DC AccessRx program and the Federal CMS Open Payments system. One hundred seventy-seven pharmaceutical manufacturers and labelers reported \$81.2 million in marketing expenditures to the DC AccessRx program in 2016. With only 140 companies reporting in 2015, there was a 26.4% increase in the number of companies reporting.

More companies reported gifts through the CMS Open Payments system. Four hundred fiftyseven pharmaceutical and device manufacturers reported spending \$18 million in DC on gifts to physicians, dentists, podiatrists, chiropractors, and teaching hospitals to the CMS Open Payments system.

After considering overlapping data of companies that reported to both AccessRx and Open Payments, 498 unique pharmaceutical companies and device manufacturers reported marketing expenses in the District of Columbia. This was a 7.6% increase in companies reporting than in 2015 when 463 companies reported to AccessRx and Open Payments.

### **Total Expenses**

In 2016, companies reported spending \$99.2 million in total marketing expenses; a 3.1% increase from 2015. This includes \$62.8 million in *Aggregate* (Detailing) expenses, \$24.7 million in *Gift* expenses, and \$11.7 million in *Advertising* expenses. The biggest jump in expenditures was *Advertising* expenses, which doubled in 2016 from 2015; the total amount, however, is far less than other categories. Table 1 displays expenses for each of these three categories from 2006 to 2016. *Gift* expenses from 2013 to 2016 includes data collected from Open Payments.

Table 1.1 har macculicar Marketing by Experiate Type					
Reporting Year	Gift Expenses	Advertising Expenses	Aggregate (Detailing) Expenses	Grand Total	
2016	\$24,672,754	\$11,658,176	\$62,833,677	\$99,164,608	
2015	\$24,362,166	\$5,631,108	\$66,225,062	\$96,218,336	
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 <i>,</i> 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 by Expenditure Type



Figure 1: Total Pharmaceutical Marketing by Expenditure Type

Figure 2: Breakdown of Pharmaceutical Marketing Expenditures in DC in 2016



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

## Aggregate (Detailing) Expenses

Of the 173 companies who reported to AccessRx for 2016, 158 companies reported spending a combined \$62.8 million in *Aggregate Expenses*. Aggregate or detailing expenses are the salaries and other expenses for employees and contractors engaged in marketing activities in DC (this information is not gathered by Open Payments). Detailing expenses ranged from \$325 to \$10.2 million, with a median value of \$67,693. The total of \$62.8 million in *Aggregate Expenses* in 2016 was a decrease of \$3.4 million from the \$66.2 million reported in 2015.

Total Reported Value	Number of Companies	Percent of Total Number	Total Value	Percent of Total Value
More than \$1,000,000	18	10.4%	\$44,648,200	71.1%
\$500,001 - \$1,000,000	9	5.2%	\$6,081,677	9.7%
\$250,001- \$500,000	14	8.1%	\$5,035,836	8.0%
\$100,001 - \$250,000	25	14.5%	\$4,203,880	6.7%
\$25,001 - \$100,000	39	22.5%	\$2,265,202	3.6%
\$1 - \$25,000	53	30.6%	\$598,882	1.0%
No Reported Costs	15	8.7%	-	-
Total	173	100.0%	\$62,833,677	100.0%

Table 2: Distribution of 2016 Aggregate (Detailing) Expenses in DC

It is essential to monitor detailing expenses because of the impact that detailing can have on decisions made by prescribers. Interactions between prescribers and pharmaceutical detailers have been found to contribute to irrational prescribing.<sup>1</sup>

In 2017, pharmaceutical sales representatives earned an average salary of \$128,490 (including bonuses and commissions); specialty pharmaceuticals sales representatives earned \$147,318 (including bonuses and commissions). The average base salary for a pharmaceutical sales representative was \$99,087 in 2017; for specialty sales representatives the average salary was \$108,548.<sup>2</sup> Representatives typically receive bonuses based on the volume of targeted drugs sold within their territory.

Total *Aggregate Expenses* include salaries and expenses not only for pharmaceutical representatives, but also for a variety of other positions including Clinical Nurse Educators, Territory Managers, Senior Managers, Institutional Account Managers, and Regional Sales Directors.

<sup>&</sup>lt;sup>1</sup> Fickweiler F, Fickweiler W, Urbach E. Interactions between physicians and the pharmaceutical industry generally and sales representatives specifically and their association with physicians' attitudes and prescribing habits: a systematic review. BMJ Open. 2017;7(9). doi:10.1136/bmjopen-2017-016408.

<sup>&</sup>lt;sup>2</sup> MedReps 2017 Pharmaceutical Sales Salary Report https://www.medreps.com/medical-salescareers/pharmaceutical-sales-salary-report/

#### **Gift Expenses**

In 2016, 497 pharmaceutical and medical device companies reported *Gift Expenses* to the District. Compared to 2015, when 448 companies reported to the District, this was an 11% increase. These 497 companies reported a total of \$24.7 million in gifts to both AccessRx and Open Payments. *Gift Expenses* include gifts to *Individual Recipients* (including *Physicians, Nurse Practitioners,* and *Physicians Assistances*) and *Non-Individual Recipients* (including *Teaching Hospitals, Advocacy Organizations,* and *Professional Organizations*).

One hundred seventy-seven pharmaceutical companies reported \$6.7 million in gift expenditures to AccessRx. Payments ranged from less than \$1 to \$241,240, with a median gift value of \$66.

Four hundred fifty-seven pharmaceutical and medical device companies reported \$18 million in gift expenditures to Open Payments. Gifts reported to Open Payments ranged from less than \$1 to \$647,185, with a median gift value of \$22.

Total Reported Value	Number of Companies	Percent of Total Number	Total Value	Percent of Total Value
More than \$1,000,000	3	0.6%	\$5,583,413	22.6%
\$500,000 - \$999,999	8	1.6%	\$4,765,819	19.3%
\$250,000 - \$499,999	17	3.4%	\$5,802,035	23.5%
\$100,000 - \$249,999	27	5.4%	\$4,338,606	17.6%
\$50,000 - \$99,999	23	4.6%	\$1,693,352	6.9%
\$25,000 - \$49,999	30	6.0%	\$1,083,556	4.4%
\$10,000 - \$24,999	52	10.5%	\$883,461	3.6%
\$1,000 - \$9,999	114	22.9%	\$471,693	1.9%
\$1-\$999	200	40.2%	\$50,819	0.2%
No Reported Costs	23	4.6%	_	-
Total	497	100.0%	\$24,672,754	100.0%

#### Table 3: Distribution of Gift Expenses in DC

## **Advertising Expenses**

In 2016, 83 pharmaceutical companies reported \$11.7 million dollars in *Advertising Expenses* to AccessRx. This is twice the amount reported in 2015, which was \$5.6 million. *Advertising Expenses* included only local advertising expenditures in the District, not national expenditures. These estimates provided by companies may not be reliable as there was variability among companies in methods used to calculate expenditures.

Table 4. Distribution of Advertising Expenses in DC						
Total Reported Value	Number of Companies	Percent of Total Number	Total Value	Percent of Total Value		
More than \$1,000,000	4	2.3%	\$8,278,795	71.0%		
\$250,001-\$1,000,000	2	1.2%	\$954,600	8.2%		
\$100,001-\$250,000	10	5.8%	\$1,647,476	14.1%		
\$25,001-\$100,000	8	4.6%	\$343,796	3.0%		
\$10,001-\$25,000	17	9.8%	\$310,306	2.7%		
\$1,001-\$10,000	26	15.0%	\$115,562	1.0%		
\$1-\$1,000	16	9.2%	\$7,642	0.1%		
No Reported Costs	90	52.0%	_	-		
Total	173	100.0%	\$11,658,176	100.00%		

<b>Table 4: Distribution</b>	of Advertising	Expenses in DC
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#### **Differences between AccessRx and Open Payments**

Reporting requirements for AccessRx are not duplicative of Open Payments. AccessRx requires reporting for marketing expenditures beyond payments to physicians, dentists, chiropractors, podiatrists, and teaching hospitals. Companies are required to report detailing and advertising expenditures as well as gifts to organizations and all licensed healthcare providers besides those reported to Open Payments.

AccessRx and Open Payments serve similar purposes but capture different sets of data. Open Payments only requires companies to report on gifts to physicians and teaching hospitals. The DC DOH AccessRx program is far more comprehensive, requiring reporting for all other licensed healthcare providers (e.g. nurses, nurse practitioners, physician assistants, and pharmacists), non-teaching hospitals, healthcare staff, and organizations. Only AccessRx picks up gifts received by nurse practitioners (NPs), nurse midwives, nurse anesthetists, physician assistants (PAs), and optometrists.

Data reported to Open Payments, including physician names, are publicly available. Payments to physicians and teaching hospitals are searchable online through Open Payments, allowing researchers to track patterns in gifts. Additionally, individual patients can see whether their physicians have accepted gifts from pharmaceutical companies. Although AccessRx reports are publicly available, details of individual expenditures, such as name and payment amounts, cannot be reported. According to the AccessRx Act, reported information at the individual or organizational level is confidential and available in detail only to DC DOH.

#### **Discrepancies in Reporting**

After Open Payments was implemented in 2013, there was some confusion among companies about what expenses should be reported to AccessRx. Payments to physicians, dentists, podiatrists, and teaching hospitals must be reported to Open Payments. Gifts to all other individuals and organizations must be reported to AccessRx. There are some special circumstances when companies are not required to report to Open Payments; in these cases, companies report gifts to physicians and teaching hospitals to AccessRx.

The reporting discrepancies that occurred for this reporting year were often cases where companies reported gifts to physicians to AccessRx that were not reported to Open Payments. In some cases, gifts reported to AccessRx could be matched to Open Payments by date and company. Many of these gifts (mostly reported as *Food and Beverage*), were interpreted as being gifts to the office staff of the named physician. Companies were contacted to confirm whether or not duplicative information was reported to AccessRx. Of 29 companies that were contacted for clarification, 25 responded with explanations, and amounts were adjusted accordingly. One company submitted their report to AccessRx as a PDF file that only displayed totals of *Gifts, Advertising*, and *Aggregate* expenses, with no details on individual gifts submitted. This company was omitted from analysis of gifts.

# II. Gift Expenses Analysis

Pharmaceutical and device manufacturers reported a total of \$24.7 million in gifts in DC in 2016. *Individual* recipients accepted more than 50,000 payments totaling \$14.5 million. *Non-Individual* recipients received more than 1,000 payments totaling \$10.2 million.

More than 90% of gifts to individuals, totaling \$13.1 million, went to *Physicians*. Among *Individual* recipients, *Physicians* had the highest value for a single payment and the lowest median gift value. *Pharmacists* had the highest median gift value with \$101.

More than half of the payments to *Non-Individual* recipients were given to *Teaching Hospitals*. *Professional Organizations* and *Advocacy Organizations* each had median gift value of \$10,000.

Individual Recipient	Total Value	Frequency	Highest Value	Median Value		
Physicians	\$13,087,544	38,595	\$647,185	\$22		
Advanced Practice Nurses	\$339,254	1,565	\$419	\$79		
Physician Assistants	\$116,293	1,081	\$3 <i>,</i> 674	\$70		
Dentists	\$153,578	897	\$15,000	\$49		
Nurses	\$151,383	1,138	\$2,886	\$90		
Pharmacists	\$50,085	416	\$4,100	\$101		
Other Healthcare Providers	\$49,036	419	\$2,600	\$36		
Clinical Office Staff and Other Recipients	\$573,042	6,718	\$3 <i>,</i> 950	\$56		
Total \$14,520,215 50,829						
2016 Gifts to Non	-Individual Red	cipients				
Non-Individual Recipient	Total Value	Frequency	Highest Value	Median Value		
Teaching Hospitals	\$5,391,238	677	\$555,000	\$2,260		
Professional Organizations	\$2,143,752	93	\$197,750	\$10,000		
Advocacy Organizations	\$949,963	41	\$150,000	\$10,000		
Universities	\$772,988	99	\$175,000	\$1,000		
Clinical Organizations	\$691,565	56	\$203,776	\$1,000		
Continuing Medical Education Organizations	\$142,774	40	\$38,627	\$158		
Other	\$60,258	83	\$45,000	\$49		
Total	\$10,152,538	1,089				
Gift Grand Total	\$24,672,754	51,918				

# Table 5: Distribution of Gift Expenses by Type of Recipient 2016 Gifts to Individual Recipients

#### **Categories for Individual Recipients**

In 2015, reporting categories for AccessRx were changed to align better with the Federal Open Payments database. Specifically, the categories for *Nature of Payment* and *Form of Payment* were updated to include more precise language similar to Open Payments.

Reporting categories for 2016 were updated to address issues in the previous year's reporting. Several companies reported gifts to physicians that were in fact gifts to the named physician's office staff. In order to reduce confusion and minimize duplicative reporting, guidance for how to report gifts to the office staff of clinical organizations was posted on the AccessRx website. This year, a separate category for *Clinical Office Staff and Other Recipients* was included in our analysis.

# III. Payments to Individual Recipients

Prescriber gift acceptance has been associated with an increase in irrational prescribing.<sup>3</sup> Individual Recipients, including Physicians, Advanced Practice Nurses, Registered Nurses, Physician Assistants, Pharmacists, Other Healthcare Providers, and Other Recipients, received \$14.0 million in payments in 2016. Only AccessRx, not Open Payments, requires reporting of gifts to recipients other than physicians. Information about payments to physicians and teaching hospitals was reported to Open Payments; all other data was reported to AccessRx.

## Physicians (Open Payment Data and AccessRx)

In 2016, gifts reported to *Physicians* totaled \$13,087,544, with \$12,972,002 reported to Open Payments and \$115,542 reported to AccessRx.<sup>4</sup> Gifts to *Physicians* made up 95% of all reported gifts to individual recipients. There were 38,595 unique payments to 3,480 MDs and DOs in DC.

Table 0. Distribution of difts to T hysicians in DC						
Total Reported Value	Number of Physicians	Percent of Total Number	Total Value	Percent of Total Value		
\$250,001 - \$700,000	7	0.2%	\$2,790,697	21.5%		
\$100,001 - \$250,000	24	0.7%	\$3,314,112	25.5%		
\$50,001 - \$100,000	35	1.0%	\$2,350,040	18.1%		
\$25,000 - \$50,000	49	1.4%	\$1,758,120	13.6%		
\$10,001-\$25,000	76	2.2%	\$1,191,316	9.2%		
\$1,001-\$10,000	365	10.5%	\$1,139,661	8.8%		
\$251 - \$1,000	500	14.4%	\$248,958	1.9%		
\$1 - \$250	2,424	69.7%	\$179,097	1.4%		
Total	3,480	100.0%	\$12,972,002	100.0%		

#### Table 6: Distribution of Gifts to Physicians in DC

Washington, DC has a total of 5,901 active physicians, according to the Association of American Medical Colleges' *2017 State Physician Workforce Data Report*.<sup>5</sup> This indicates that approximately 60% of physicians in the District accepted gifts from a pharmaceutical or medical device company.

<sup>&</sup>lt;sup>3</sup> Wood SF, Podrasky J, McMonagle MA, Raveendran J, Bysshe T, Hogenmiller A, Fugh-Berman A. Influence of pharmaceutical marketing on Medicare prescriptions in the District of Columbia. PLoS One. 2017;12(10):e0186060. doi: 10.1371/journal.pone.0186060.

<sup>&</sup>lt;sup>4</sup> Some companies and types of payments were exempt from reporting to Open Payments. These payments were reported to AccessRx.

<sup>&</sup>lt;sup>5</sup> 2017 State Physician Workforce Data Report. Retrieved from

https://members.aamc.org/eweb/upload/2017%20State%20Physician%20Workforce%20Data%20Report.pdf

As in years past, *Speaking* represented the largest percentage of gifts (41.2%) by value. *Physicians* accepted \$5.4 million in speaking fees, a 4.1% decrease from \$5.6 million in 2015. More than \$5.1 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 "non-accredited continuing medical education (CME) event" totaled more than \$200,000, while payments for speaking at an accredited CME event totaled only \$12,185.

*Consulting* was the second largest category of gifts to *Physicians;* \$3.1 million spent in this category constituted nearly a quarter of payments by value. *Travel and Lodging* accounted for 12.1% of the total value of gifts (\$1.6 million), a decrease from \$1.8 million in 2015. *Physicians* accepted \$1.1 million in *Food and Beverage* payments, only 8.2% of the total gift value. Two gifts were categorized as *Other Services*, the majority of which came from a single payment for \$647,185 to one physician.



#### Figure 3: Gifts to Physicians Nature of Payment

\*Speaking consists of gifts reported as consulting fees 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 noncertified continuing education program

\*\*Other includes gifts reported as Education, Charitable Contribution, Ownership or Investment Interest, Entertainment, Gift, Grant, and Royalty or License

#### **Top 25 Physicians**

The 25 physicians who accepted the highest value of gifts in the District of Columbia received a total of \$5.7 million. They are listed in Tables 7 and 8. Payments to these 25 physicians accounted for 43.4% of all gifts to physicians in DC. Nine of these physicians were not on this list in 2015.

Most payments to the 25 physicians were related to serving as a consultant or promotional speaker. Dr. Jesse Goodman accepted one gift for \$647,185 for non-executive board remuneration from GlaxoSmithKline. For a few doctors on the list, most of the value of payments was for royalty or stock payments.

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 Tables 7 and 8.

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Ranking in 2016	Physician Name	Specialty	Affiliation
1*	Jesse Goodman, MD	Infectious Disease	Walter Reed Army Medical Center
2*	Kavita K. Patel, MD	Internal Medicine	Sibley Primary Care
3 (3)	Maurice Nahabedian, MD	Plastic Surgery	Georgetown University Medical Center
4 (13)	Augusto Pichard, MD	Interventional Cardiology	MedStar Washington Hospital Center
5 (19)	Ron Waksman, MD	Interventional Cardiology	MedStar Washington Hospital Center
6 (14)	Andrea Leonard-Segal, MD	Rheumatology	GW Center for Integrative Medicine
7 (12)	Robert K. Shin, MD	Neurology	MedStar Georgetown University Hospital
8 (2)	Imadeddine Tabbara, MD	Hematology & Oncology	The GW Medical Faculty Associates
9 (11)	James A. Simon, MD	Gynecology	Sibley Memorial Hospital
10 (16)	John L. Marshall, MD	Hematology & Oncology	MedStar Georgetown University Hospital
11*	Warren Yu, MD	Orthopedic Surgery	The GW Medical Faculty Associates
12 (7)	Joseph R. O'Brien, MD, MPH	Orthopedic Surgery	Ortho Bethesda
13 (5)	Laxman Bahroo, DO	Neurology	MedStar Georgetown University Hospital
14*	Troy A. Pittman, MD	Plastic Surgery	MedStar Georgetown University Hospital
15 (9)	Fahd S. Amjad, MD	Neurology	MedStar Georgetown University Hospital
16*	Paul J. Kim, DPM	Podiatry	MedStar Georgetown University Hospital
17 (21)	Paul S. Cooper, MD	Orthopedic Surgery	MedStar Georgetown University Hospital
18*	Andrea J. Singer, MD	Internal Medicine	MedStar Georgetown University Hospital
19*	Autumn Burnette, MD	Allergy & Immunology	Howard University Hospital
20 (20)	Richard A. Elion, MD	Family Medicine	Whitmen-Walker Health
21 (8)	John W. Hogan, MD	Gastroenterology	Unity Health Care
22*	Terrence C. Keaney, MD	Dermatology	The GW Medical Faculty Associates
23*	Mehul J. Desai, MD, MPH	Pain Medicine	International Spine, Pain & Performance Center
24 (6)	Scott I. Kahan, MD, MPH	Preventive Medicine	National Center for Weight and Wellness
25*	Wayne J. Olan, MD	Neuroradiology	The GW Medical Faculty Associates
*Did not on	oper in the list of "Top 25 Dhusi		

#### Table 7: Top 25 Physician Gift Recipients in Washington, DC

\*Did not appear in the list of "Top 25 Physician Gift Recipients" in 2015

	Table 6. Top 25 Physician dift Recipients in Washington, DC					
Ranking in 2016	Physician Name	Payment s in DC	Number of Payments	Primary Companies (Drugs) Associated with Payments		
1*	Jesse Goodman, MD	\$647,185	1	GlaxoSmithKline		
2*	Kavita K. Patel, MD	\$628,894	31	Tesaro [stock ownership]		
3 (3)	Maurice Nahabedian, MD	\$341,965	400	LifeCell (Alloderm, Strattice), Allergan (Natrelle Implants)		
4 (13)	Augusto Pichard, MD	\$334,433	311	Medtronic, Boston Scientic Corporation, St. Jude Medical		
5 (19)	Ron Waksman, MD	\$306,413	133	Biotronik (AstronPulsar)		
6 (14)	Andrea Leonard-Segal, MD	\$297,208	134	Sanofi-Aventis (Cialis), Galderma, Valeant		
7 (12)	Robert K. Shin, MD	\$267,470	282	Novartis, Biogen, Genzyme (various drugs for multiple sclerosis)		
8 (2)	Imadeddine Tabbara, MD	\$225,776	220	Celgene (Revlimid), Amgen (Krypolis), Millennium (Ninlaro)		
9 (11)	James A. Simon, MD	\$199,926	236	Shionogi (Osphena)		
10 (16)	John L. Marshall, MD	\$188,395	175	Amgen (Vectibix), Genentech (Avastin)		
11*	Warren Yu, MD	\$187,205	94	Spineart [royalty]		
12 (7)	Joseph R. O'Brien, MD, MPH	\$180,480	141	Globus Medical (spine devices)		
13 (5)	Laxman Bahroo, DO	\$179,415	321	US Worldmeds (Apokyn, Myobloc), Impax (Rytary)		
14*	Troy A. Pittman, MD	\$168,044	214	Novadaq		
15 (9)	Fahd S. Amjad, MD	\$160,799	317	AbbVie (Duopa), Lundbeck (Northera)		
16*	Paul J. Kim, DPM	\$150,640	182	KCI USA (VAC ULTA)		
17 (21)	Paul S. Cooper, MD	\$146,263	84	Smith & Nephew [royalty]		
18*	Andrea J. Singer, MD	\$144,116	197	Amgen (Prolia)		
19*	Autumn Burnette, MD	\$143,395	253	Shire (Cinryze)		
20 (20)	Richard A. Elion, MD	\$140,449	169	Gilead (Truvada)		
21 (8)	John W. Hogan, MD	\$138,017	197	Gilead (Genvoya)		
22*	Terrence C. Keaney, MD	\$133,424	226	Allergan		
23*	Mehul J. Desai, MD, MPH	\$131,144	205	Halyard (Coolief)		
24 (6)	Scott I. Kahan, MD, MPH	\$121,325	140	Orexigen (Contrave), Novo Nordisk (Saxenda)		
25*	Wayne J. Olan, MD	\$119,168	114	Stryker (spine devices)		
*Did not on	near in the list of "Ton 25 Physici	an Cift Dealer	anto" in 2015			

#### Table 8: Top 25 Physician Gift Recipients in Washington, DC

\*Did not appear in the list of "Top 25 Physician Gift Recipients" in 2015

#### Advanced Practice Nurses (AccessRx Data)

Advanced Practice Nurses (APNs) include nurse practitioners, nurse midwives, and nurse anesthetists; all have independent prescribing authority. In 2016, gifts reported to Advanced Practice Nurses totaled \$339,227. This represents a slight increase from 2015 (\$317,118).

*Speaking* gifts represented the largest portion of gifts with \$135,829 (40%). This is a decrease from 2015 where *Speaking* gifts made up 55% of the total gifts with \$174,170. APNs accepted \$96,116 worth of *Food and Beverage*, which made up 29% of gifts in 2016. The next largest category was *Consulting* with \$58,655 in gifts, comprising 17% of total gift value. This category has doubled since 2015, when APNs received \$20,638 for *Consulting*, making up 7% of total gift value and 1% of gift frequency. *Traveling and Lodging* has remained consistent since 2015; in 2016, *Traveling and Lodging* made up 13% of the total value with \$44,570 in gifts. The smallest category was *Other* with \$4,057 (1%).

*Food and Beverage* was the most frequent type of gift, comprising 77% of gifts given with 1565 gifts. The other categories were each less than 10% of the total gifts frequency: *Traveling and Lodging* (9%), *Speaking* (6%), *Consulting* (4%), and *Other* (4%).



#### Figure 4: Gifts to Advanced Practice Nurses Nature of Payment

\*Speaking consists of gifts reported as honoraria and compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program \*\*Other includes gifts reported as Education and Other

20

## Physician Assistants (AccessRx Data)

In 2016, gifts reported to Physician Assistants (PAs) totaled \$116,293. Physician Assistants have independent prescribing authority.

A majority of gifts were for Food and Beverages. This category made up 67% of the total gift value with \$77,610 in gifts. Speaking made up 14% of the total value with 14% of the gifts. Both Travel and Lodging and Consulting made up 9% of the gift value. Other made up only 1% of the gift value, with \$1,560 in gifts.

Food and Beverage made up the largest category in total frequency with 92% of gifts. The other categories combined comprised less than 10% of the total gift frequency: Travel and Lodging (3%), Speaking (2%), Other (2%), and Consulting (1%).



Figure 5: **Gifts 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 noncertified continuing education program \*\*Other includes gifts reported as Education and Other

## **Dentists (Open Payment and AccessRx Data)**

In 2016, gifts to Dentists totaled \$153,578, with \$136,149 reported to Open Payments and \$17,429 reported to AccessRx. There were 897 unique gifts reported to Dentists in the District. This is the first year that *Dentists* were separated from *Physicians* in the analysis.

Speaking gifts represented the largest portion (35%) of the total value of gifts with \$53,380. The next largest categories were for Food and Beverage (\$25,213), Gifts (\$24,164), Other (\$23,151) and Travel and Lodging (\$21,012) each of which accounted for 14%-16% of total value. *Consulting* accounted for \$6,658, which was 4% of total value.

Food and Beverage accounted for 61% of gifts (545 gifts). Payments reported as Gifts accounted for the next most frequent category with 22% of total frequency and 195 gifts.



Figure 6: **Gifts to Dentists** 

\*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 noncertified continuing education program \*\*Other includes gifts reported as Education, Entertainment, and Other

## Nurses (AccessRx Data)

In 2016, gifts reported to *Nurses* totaled \$151,383, a 24% increase from 2015 (\$122,312). There were 1,138 gifts given to Nurses.

Food and Beverage made up the largest portion of both gift value and frequency. Nurses accepted 928 Food and Beverage gifts (81%), totaling \$72,810. The next largest category for gift value was Speaking, making up 23% of total value with \$34,930 in gifts. Nurses accepted \$23,705 in Travel and Lodging gifts, making up 16% of the total gift value. Consulting made up 9% (\$13,087) and Other made up 4% (\$6,851) of gifts.

For gift frequency, other categories made up less than 10% of gifts given: these included Other (7%), Travel and Lodging (6%), Speaking (4%), and Consulting (2%).



Figure 7:

\*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 noncertified continuing education program \*\*Other includes gifts reported as Education, Grants, and Other

### Pharmacists (AccessRx Data)

In 2016, gifts reported to Pharmacists totaled \$50,085. Companies reported 417 gifts to Pharmacists.

A majority of gifts were for Food and Beverages. This category made up 74% of the total gift value with \$37,029 in gifts. Consulting made up 13% of the total gift value with \$6,700 in gifts. The other categories each made up less than 10% of the total value: Travel and Lodging with \$4,233 (9%), Speaking with \$2,201 (4%), and Other with \$102 (<1%) in gifts.

Food and Beverage made up the largest category in total frequency with 93% of gifts. The other categories together made up less than 10% of the total gift frequency: Travel and Lodging (4%), Speaking (1%), Consulting (1%), and Other (1%).



\*Speaking consists of gifts reported as 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 noncertified continuing education program \*\*Other includes gifts reported as Education and Other

Figure 8:

#### **Other Healthcare Providers (AccessRx Data)**

In 2016, 419 gifts, totaling \$49,036, were reported to *Other Healthcare Providers* which includes medical staff and healthcare administrators, for example. This was a 54.7% decrease from 2015 when gifts to *Other Healthcare Providers* totaled \$108,187. The largest categories of gifts reported to *Other Healthcare Providers* in 2016 were for *Speaking*, which totaled \$23,787, accounting for 48% of total value, followed by *Food and Beverage, which* totaled \$19,935, accounting for 41% of total value.

*Food and Beverage* accounted for the highest frequency of gifts reported, with 369 of 419 (88%) total gifts to *Other Healthcare Providers*.



\*Speaking consists of honoraria and compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program

## Clinical Office Staff and Other Recipients (AccessRx Data)

In 2016, 6,718 gifts were reported to *Clinical Office Staff and Other Recipients* totaling \$573,042. This was the first year that this category was included in the analysis. Changes in reporting patterns from companies showed some gifts to clinical and office staff being separated out into *Individual Gifts* for named recipients, while others were reported as *Non-Individual Gifts* to the office of a named physician. All of these gifts were combined and analyzed in this category.

The majority of gifts reported *Clinical Office Staff and Other Recipients* were for *Food and Beverage* gifts, with 6,574 gifts totaling \$544,816. Meals accounted for 95% of the total value and 98% of total frequency of gifts. *Travel and Lodging* and *Consulting* each made up 2% of the total value of gifts.

#### **Comparisons of Speaking Fees among Provider Types**

*Speaking* payments accounted for the largest proportions of the total value of gifts for both *Physicians* and *Advanced Practice Nurses.* 

Companies paid more than \$5.6 million in *Speaking* fees to individual healthcare providers in 2016. More than 90% of *Speaking* fees were paid to *Physicians*. Among *Physicians*, the total value of *Speaking* payments decreased by 4.1% from \$5.6 million in 2015 to \$5.4 million in 2016. However, the median value for *Physicians* was the same in 2015 and 2016, with \$2,000.

Tuble 7. Speaking rayments among rrovider rypes					
Credential	Total	Frequency	Median	Range	
Physicians	\$5,396,407	2,290	\$2,000	\$200 - \$135,050	
Advanced Practice Nurses	\$135,829	91	\$1,320	\$150 - \$3,500	
Physician Assistants	\$15,939	17	\$750	\$225 - \$3,674	
Dentists	\$53,380	8	\$5,000	\$500 - \$15 <i>,</i> 000	
Nurses	\$34,930	46	\$750	\$175 - \$2,500	
Total	\$5,636,485	2,459			

#### **Table 9: Speaking Payments among Provider Types**

# IV. Gifts to Non-Individual Recipients

## Teaching Hospitals (Open Payments and AccessRx Data)

In 2016, gifts to *Teaching Hospitals* totaled \$5.4 million, with \$4,882,846 reported to Open Payments and \$508,392 reported to AccessRx. This is an increase of 32% from 2015, *Teaching Hospitals* received \$4.1 million in gifts.

Washington Hospital Center received 127 gifts that totaled \$3.5 million, with a median gift value of \$7,500. Although the \$3.5 million accounted for 71.3% of the total value of gifts to *Teaching Hospitals*, the 127 gifts received by Washington Hospital Center accounted for just 21.0% of the total frequency of gifts. This was a 25% increase from 2015, when Washington Hospital Center received \$2.8 million in gifts.

The three academic medical centers in the District received a total of \$1.2 million, making up 24.8% of total gift value. Of the three academic medical centers, Georgetown University Hospital received 169 gifts, totaling \$915,053, with a median gift value of \$7,750. George Washington University Hospital received 183 gifts, totaling \$152,374, with a median gift value of \$576, and Howard University Hospital received 41 gifts, totaling \$144,090, with a median gift value of \$1,559.

Children's Hospital received 36 gifts, totaling \$150,946, with a median gift value of \$995. This was an increase of 230% from 2015, where Children's Hospital received \$45,577 in gifts. The remaining teaching hospitals received far less money. Providence Hospital received \$25,484, National Rehabilitation Hospital received \$6,500, and Sibley Memorial Hospital received \$6,119.

Teaching Hospital	Total Value	Frequency	Median Gift Value
Washington Hospital Center	\$3,482,280	127	\$7,750
Georgetown University Hospital	\$915,053	169	\$2 <i>,</i> 500
George Washington University Hospital	\$152,374	183	\$576
Children's Hospital	\$150,946	36	\$995
Howard University Hospital	\$144,090	41	\$1,559
Providence Hospital	\$25,484	32	\$580
National Rehabilitation Hospital	\$6,500	3	\$1,000
Sibley Memorial Hospital	\$6,119	14	\$278
Total	\$4,882,846	605	

#### Table 10: Gifts to Teaching Hospitals in Washington, DC

Of the \$5.4 million in gifts given to *Teaching Hospitals*, \$3.3 million (61.3%) was categorized as *Grants*. This is an increase of 113% from 2015 where \$1.6 million was given as *Grants*. The next largest category was *Education*, which accounted for \$965,023 (17.9%). *Education* showed an increase of over 500% from 2015, where *Education* accounted for \$152,300. *Space Rental* and *Speaking and Consulting* accounted for \$638,974 (11.9%) and \$339,774 (6.3%) respectively. The remaining categories, including *Gifts, Food and Beverage, Investment or Royalty or License*, and *Other* all accounted for less than 3% of total gift value when combined. *Investment or Royalty or License* decreased steeply from \$1.3 million, which was 33% of the total value in 2015, to \$7,639 (<1%) in 2016. This seems to have returned to 2014 levels, when *Investment or Royalty or License* accounted for \$9,952, also less than 1% of total gift value. These changes were also reflected in gift frequency, with *Investment or Royalty or License* accounting for less than 1% of total gift value. These changes were also reflected in gift frequency, a decrease from 45% of total frequency in 2015.

*Education, Grants,* and *Space Rental* categories each accounted for roughly a quarter (28%, 28%, and 25%) of total frequency. *Gifts* and *Speaking and Consulting* accounted for 7% each; all other categories combined accounted for the remaining 5%.



#### Figure 10: Gifts to Teaching Hospitals Nature of Payments

\*Speaking & Consulting consists of gifts reported as consulting fees 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 noncertified continuing education program

#### Professional Organizations (AccessRx Data)

Gifts to *Professional Organizations* totaled \$2.1 million in 2016, for a total of 93 gifts. Of the \$2.1 million, the largest category of gifts to *Professional Organizations* was *Education*, which accounted for \$1.1 million, 49.1% of total value of payments reported. The next largest category was classified as *Other*, accounting for \$800,500, or 37.3% of total value of payments. This was almost twice the amount (an increase of 94.5%) from 2015 when the *Other* category accounted for \$411,658. In past reports, the *Other* category combined several small categories. However, in 2016, one company reported \$791,000 in gifts to AccessRx with the nature of payments listed as *Other* and the primary purpose listed as marketing, with no other information on the gifts. A new category that was reported in 2016 was for *Corporate Sponsorship*. Five gifts, totaling \$70,100, were reported in this category, accounting for 3.3% of total value reported.

All categories reported, with the exception of *Education* and *Other,* showed decreases in value, compared to 2015. Gifts for *Grants* decreased by 80.5%, from \$493,370 in 2015 to \$96,312 in 2016. Gifts reported as *Consulting Fee* decreased 97.5% from \$396,470 in 2015 to \$10,000 in 201. *Space Rental* decreased by 79.1% from \$142,795 in 2015 to \$29,750 in 2016, and gifts reported as *Charitable Contribution* decreased 81.2% from \$250,053 in 2015 to \$47,000 in 2016. One company that reported large amounts of gifts in each of these categories in 2015 did not report any gifts to professional organizations in 2016.



#### Figure 11: Gifts to Professional Organizations Nature of Payments

\*Speaking consists of gifts reported as compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program

## Advocacy Organizations (AccessRx Data)

Gifts to *Advocacy Organizations,* including advocacy and research organizations that focus on specific diseases and health conditions, accounted for 41 gifts, totaling \$949,963 in 2016. This is more than a 40% decrease from 2015 when *Advocacy Organizations* received \$1.7 million.

There was a large increase in gifts categorized as *Other* to *Advocacy Organizations*. This category accounted for 15 gifts totaling \$297,925 (31% of total value). In 2015, the *Other* category accounted for \$72,680 and only 4% of total value. As with gifts to *Professional Organizations*, one company reported \$257,475 with the nature of payment as *Other* and the primary purpose as marketing. *Corporate Sponsorship* was associated with four gifts totaling \$58,598 and accounted for 6% of the total value.

In 2015, *Advocacy Organizations* received \$877,057 in gifts reported for *Consulting*; there were no gifts reported for *Consulting* in 2016. The amount of gifts reported as *Grants* increased dramatically from \$41,666 in 2015 to \$224,419 in 2016.



#### Figure 12: Gifts to Professional Organizations Nature of Payments

#### **Universities (AccessRx Data)**

In 2016, companies reported 100 gifts to *Universities* that totaled \$772,988. This is an increase from 2015, when companies reported 34 gifts totaling \$567,141. The largest categories of gifts were *Grants* which accounted for 17 gifts totaling \$416,624 (54% of total value) and *Education* which accounted for seven gifts totaling \$239,274. Payments reported as *Space Rental* had the highest frequency of gifts, with 55 of the 100 gifts to *Universities*.



Figure 13: Gifts to Clinical Organizations Nature of Payments

\*Speaking consists of gifts reported as compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program

## **Clinical Organizations (AccessRx Data)**

In 2016, there were 56 gifts to *Clinical Organizations*, totaling \$691,565. *Clinical Organizations* include community health clinics, private medical centers, and large private practices. There was a 35% decrease in total value in reported gifts from 2015 to 2016, when companies reported \$1.1 million in gifts to *Clinical Organizations*.

The majority of gifts reported to *Clinical Organizations* were classified as *Grants*, which accounted for 19 gifts totaling \$612,983 (89% of total value). The next largest gift categories were *Space Rental* and *Other* which accounted for \$34,450 and \$32,401 respectively. Gifts classified as *Charitable Contributions*, *Education*, and *Food and Beverage* each accounted for 1% or less of the total value.



#### Figure 14: Gifts to Clinical Organizations Nature of Payments

## **Continuing Medical Education Organizations (AccessRx Data)**

Gifts to *Continuing Medical Education Organizations* totaled \$142,774 in 2016. This is an increase of over 45% from 2015 when *CME Organizations* received \$97,368 in gifts. Unlike 2015, when most gifts were reported as *Other*, in 2016 the majority of total value was reported as *Education*, a category that received four gifts totaling \$127,253 and had no gifts reported as *Other*. The most frequent gifts were in the form of *Grants* which accounted for 35 of 40 gifts to *CME Organizations*.



#### Other Non-Individual Recipients (AccessRx Data)

Gifts to Other Non-Individual Recipients totaled \$60,258 in 2016, with 83 gifts. This is more than an 80% decrease from 2015, when Other Non-Individual Recipients received \$351,763. In 2016, 75% of the total value of Other Non-Individual Recipients was accounted for by one gift of \$45,000, classified as a Corporate Sponsorship. The most frequent gifts went to Meeting Event Planners, which accounted for 80 of 83 gifts, totaling \$7,206, received by Other Non-Individual Recipients.

# V. Advertising Expenses Analysis

In 2016, 84 companies (49% of companies that reported to AccessRx) reported \$11.7 million in *Advertising Expenses*. This was a \$6.1 million increase from \$5.6 million in advertising expenses reported in 2015. Companies report expenses based on *Activity Type* with the majority of expenses falling into five categories: *Direct-to-consumer Advertising, Other Advertising Production & Placement, Market Research, Other Promotional Activity,* and *Other*.

Estimates provided by companied may not be reliable because companies did not describe their methodology in calculating *Advertising Expenses*. It is unclear whether companies reported the actual cost of advertising locally in DC or calculated a percentage of national advertising.



#### Figure 16: Advertising Expenses Type of Activity

The most common type of activity reported was *Direct-to-Consumer Advertising* (DTCA). DTCA advertising more than doubled from \$4.5 million in 2015 to \$10.5 million in 2016. DTCA represented more than 90% of all reported *Advertising Expenses*. The other four categories made up less than 10% of the total.

#### 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*.



#### Figure 17: Advertising Expenses by Medium Type

The majority of expenditures fell under *Television* with \$6.8 million in expenses, which made up 58% of the total value of expenses. This is a large increase from 2015, when *Television* accounted for 27% of the total with \$1.5 million in expenses.

The next largest category was *Conference and Other Events,* with 12% of the total with \$1.4 million; in 2015, companies spent less than \$300,000 on *Conference and Other Event*. The next largest category is *Newspaper and Magazine* at 10% of the total with \$1.1 million in expenses; in 2015, companies spent about half a million dollars on this category. *Internet* made up 6% of the total with about \$750,000 in expenses. This is a large decrease from 2015 when *Internet* made up 25% of the total with \$1.4 million in expenses. *Radio* also made up 6% of the total with \$672,900 in expenses. Other media types that made up less than 5% of total expenses were *Patient and Other Printed Materials* (\$479,100), *Other* (\$284,549), *Medical Journal* (\$111,240), and *Direct Mail* (\$70,315).

## VI. Recommendations for AccessRx

After analyzing 2016 pharmaceutical marketing expenditures 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 data reporting instructions and the data submission process to improve the quality of data received by AccessRx.

Last year's recommendations included improving reporting instructions. The quality of data submissions did improve between the 2015 and 2016 reporting years, but confusion about how data should be reported remains. Specifically, further guidance is needed on dhow 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 as for researchers collecting and organizing data.

# 2. 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 make the information collected through AccessRx publicly available. The AccessRx Act requires that reported data remain confidential; only the DC Department of Health and those analyzing the reports have access to the information. 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 healthrelated organizations.

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

Unlike Open Payments, the District does not require reports that 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. More information on how spending is apportioned could lead to a better understanding of future prescribing trends. Also, reporting product marketed could help patients make more informed decisions about their healthcare, including selecting a generic version of a drug, or asking questions about new medications.

# 4. 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 177 companies in 2016. Comparatively, Open Payments requires manufacturers of "drugs, devices, biologicals, or medical supplies" to report expenses, which included 457 companies in 2016. As in previous years, we recommend that AccessRx requirements should be expanded to provide a more complete picture of marketing practices in the District.

# **Appendix A: AccessRx Requirements**

Title III of the AccessRx Act of 2004<sup>6</sup> 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.

<sup>&</sup>lt;sup>6</sup> 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 1<sup>st</sup> 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 requires<sup>7</sup> "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..."

(a) General rule:

(1) Direct and indirect payments or other transfers of value provided by a 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 (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 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)

<sup>&</sup>lt;sup>7</sup>Federal 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.